

BEFORE THE NATIONAL GREEN TRIBUNAL**PRINCIPAL BENCH, NEW DELHI****ORIGINAL APPLICATION NO. 497 OF 2024**IN THE MATTER OF: -

NEWS ITEM TITLED “IMPACT OF PHARMACEUTICAL TOXICITY ON THE ENVIRONMENT AND ITS REGULATORY ASPECTS” APPEARING IN CURRENT SCIENCE DATED 25.02.2024

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Filed by*Uthakur***(UPENDER THAKUR ADVOCATE)****FOR MOEF & CC (RESPONDENT NO.53)****Law Chambers of Upender Thakur****A-9, (LGF), South Extension – 1,****New Delhi – 110049****Email: - lawchambers.ut@gmail.com****Phone No. 011-41092152, 9711984890**

New Delhi

Dated: .09.2025

IN THE SUPREME COURT OF INDIA
CIVIL APPELLATE JURISDICTION
[UNDER SECTION 22 OF THE NATIONAL GREEN TRIBUNAL ACT 2010]
CIVIL APPEAL NO _____ OF 2022
(WITH PRAYER OF INTERIM RELIEF)

(Arising out of final impugned orders dated 06.04.2022 in O.A. No. 136 of 2020 and order dated 24.05.2022 in Review Application No. 14 of 2022 in O.A. No. 136 of 2020 passed by the Hon'ble National Green Tribunal, New Delhi)

IN THE MATTER OF:-

Union of India

...Appellant

-Versus-

Veterans Forum for Transparency in Public
Lifethrough its General Secretary&Ors. ...Respondents

WITH

I.A. No. of 2022

AN APPLICATION FOR EXEMPTION FROM FILING
CERTIFIED COPY OF IMPUGNED ORDER

AND

I.A. No. of 2022

AN APPLICATION FOR CONDONATION OF DELAY

PAPER BOOK

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ADVOCATE FOR THE APPELLANT: G.S. MAKKER

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☐	Name of Judges:	Hon'ble Mr. Justice Adarsh Kumar Goel, CP Hon'ble Mr. Justice Sudhir Agarwal, JM Hon'ble Mr. Justice Arun Kumar Tyagi, JM Hon'ble Mr. Prof. A. Senthil Vel, EM Dr.

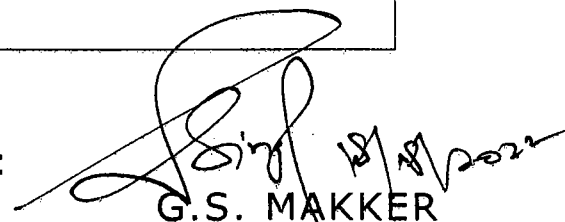
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		Vijay Kulkarni, EM Dr. Afroz Ahmad, EM
☐	Tribunal/Authority: (Name)	Hon'ble National Green Tribunal Principal Bench, New Delhi
1.	Nature of matter:	☐ Civil
2.	[a] Petitioner/Appellant No.1	Union of India
	(b) e-mail ID:	N.A.
	(c) Mobile phone No.:	N.A.
3.	(a) Respondent:	Veterans Forum for Transparency in Public Life through its General Secretary
	(b) e-mail ID:	N.A.
	(c) Mobile phone number:	N.A.
4.	(a) Main Category classification:	1503
	(b) Sub classification:	N.A.
5.	Not to be listed before:	N.A.
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	(c) Police Station	N.A.
	(d) Sentence Awarded:	N.A.
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8.	Land Acquisition Matters:	
	(a) Date of Section 4 Notification	N.A.
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10.	Special Category (first petitioner/appellant only)	N.A.
11.	Vehicle Number (in case of Motor Accident Claim matters):	N.A.

Filed by:



G.S. MAKKER

AOR for Appellant(s)
Registration No.

Dated 08.2022

SYNOPSIS AND LIST OF DATES

The present Appeal is being preferred on behalf of the Union of India, through the Ministry of Environment, Forest and Climate Change against orders dated 06.04.2022 in O.A. No. 136 of 2020 and order dated 24.05.2022 in the Review Application No. 14 of 2022 in O.A. No. 136 of 2020 passed by the Ld. National Green Tribunal, Principal Bench New Delhi.

The brief facts giving rise to the present Appeal are that the Ministry of Environment, Forest and Climate Change brought a draft notification in the public domain for seeking suggestions/objections for statutory 60 days time period for laying the standards for Bulk Drug and Formulation (Pharmaceutical) Industry including Antibiotics residue parameters were notified in the Gazette of India vide notification GSR 44(E) dated 23.01.2020. Subsequently, keeping into considerations all the facts, comments of the various expert committees of appellant, public comments and comments of various stake holders

received upon the draft notification dated 23.01.2020, the final standards were notified under Environment (Protection) Rules, 1986 vide GSR 541(E) dated 06.08.2021. However, the Hon'ble Tribunal didn't consider all these and wrongly asked the appellant ministry by issuing direction under Section 15(1) of the NGT Act that till pending finalisation by the appellant Ministry i.e., MoEF&CC, standards proposed in the draft Notification dated 23.01.2020, which are based on expert studies, be strictly followed by all concerned.

Negating the appellant issued notification dated 06.08.2021 is completely contrary to law and against the public policy. It is submitted that on respondent no 1's filed Original Application No. 136 of 2020 before the Ld. National Green Tribunal, Principal Bench, New Delhi wherein concern regarding various other issues including the remedial action against discharge of waste from CETP at Baddi and from Acme Life Sciences, Nalagarh and Helio Pharmaceuticals at

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Solan, to prevent pollution of rivers Sirsa and Satluj were raised.

According to the Respondent, the CETP is not connected to pharmaceutical units at Barotwala and Nalagarh who are discharging their effluents directly into the rivers. It is further stated by the Respondent that even after treatment in ETP/STPs, pharmaceutical ingredients may still be coming out from the industries unless ETP/STPs are specialized for the purpose. It is further stated by the Respondent that the present CETP is not designed to neutralize Active Pharmaceutical Ingredient (API).

It is most humbly submitted that the issue of standards for API, involved in the present matter, has been considered by the Committee of the Ministry and in the 17th and 18th Expert Committee meetings held on 26.04.2019 and 09.08.2019, 09.12.2019 respectively, standards had been proposed for Bulk Drug and Formulation (Pharmaceutical) Industry. Subsequently, the Ministry came out with a draft notification dated 23.01.2020 proposing

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standards for Bulk Drug and Formulation (Pharmaceutical) Industry, including Antibiotics residue parameters. The same was issued in the Gazette of India vide notification GSR 44(E). Thereafter, by keeping all the aforesaid facts and public comments received upon the draft notification dated 23.01.2020, the final standards were notified under Environment (Protection) Rules, 1986 vide GSR 541(E) dated 06.08.2021.

Hon'ble Tribunal, Principal Bench, vide its order dated 23.01.2021 directed the Ministry and state PCB to take further remedial action expeditiously. The State PCB was directed to ensure that no harmful components in the effluents are discharged into the water by the units in question or any other API unit. A joint committee was constituted comprising of Nominee of Ministry, CPCB, State PCB and District Magistrate Solan to conduct inspection of the area and give a report of the status of violations and the remedial action taken within three months. The report was supposed to give status of performance of individual

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pharmaceutical units, particularly with reference to removal of API residue by them and by the CETP, the number of pharma industries connected to the CETP and those discharging effluents directly into the drain and the river. The report was also supposed to indicate chemical and biological composition of rivers Sirsa and Satluj, including the status of residue at relevant locations. CPCB was also directed to suggest monitoring mechanism for API through a credible system so as to cover all pharma industries in the country discharging API residue directly or indirectly in river systems. CPCB was also directed to propose the timelines to undertake monitoring which may also take a note of water quality monitoring guidelines of CPCB titled "Guidelines on Water Quality Monitoring 2017".

Thereafter, Hon'ble Tribunal vide its order dated 21.01.2022, directed the respondent State to take further corrective measures to enforce the law for protecting public health and the environment. CPCB was directed to circulate

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monitoring mechanism to the State PCBs on API as directed earlier and file the action taken report before the next date. The appellant Ministry was also directed to clarify the issue of API standards. Subsequently, the appellant Ministry filed submission/clarification on the issue of residual antibiotics in Industrial effluents and API standard in view of order-dated 21.01.2022.

It is most humbly submitted that the Hon'ble Tribunal vide its order 06.04.2022, made an observation wherein Ministry's issued final notification dated 06.8.2021 has been wrongly mentioned as draft notification and has also been mentioned that the Ministry is unable to finalise the draft standards (In para 15 which is contrary to Para 8 of the impugned order dated 06.04.2022). It is worth mentioning here that earlier draft notification was released vide dated 23.01.2020 for inviting public comments and further deliberation. Accordingly, upon following all the statutory compliances, standards for bulk drugs including Antibiotics

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Residue Parameter was formulated, finalised and notified on 06.8.2021 by the Ministry.

As the Hon'ble Tribunal had committed factual error by considering the appellant issued final notification dated 06.08.2021 as draft one in its order dated 06.04.2022, the Ministry approached the Ld. National Green Tribunal by way of Review Application No. 14 of 2022 in O.A. No. 136/2020 for reviewing the order of the Ld. Tribunal dated 06.04.2022. However, the review application was also dismissed vide its order dated 24.05.2022.

Aggrieved by the orders dated 06.04.2022 in O.A. No. 136 of 2020 and O.A. No. 801 of 2018 and order-dated 24.05.2022 in Review Application No. No. 14 of 2022 in O.A. No. 136 of 2020 passed by the Hon'ble National Green Tribunal, Principal Bench New Delhi, the appellant has approached this Hon'ble Court by way of the Present Civil appeal.

List of dates

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26.04.219	As on date desirable standard parameters to measure Active Pharmaceutical Ingredient (API) and acceptable norms regarding antibiotics residues value, for the drug related industries are in a highly nascent stage worldwide. Accordingly, much deliberation and discussion are still going on in all the countries about the ideal and acceptable measuring limit about antibiotics residues for drug industries. Simultaneously, untold rivalry among large drug manufacturing countries are also going on for imposing such a measuring limit of antibiotics residues for the drug manufacturers in other competitive countries. The Expert Committee formulated by appellant Ministry i.e., MoEF&CC are constantly deliberating upon

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evolving the Environmental standard for various industrial sectors/categories. For the bulk drug and formulation industry too, various such deliberations have taken place by assimilating the views of various stakeholders. On that line, Expert Committee convened a meeting dated 26.04.2019 wherein it was observed:

“.... 5.2 Environmental Standard for Bulk Drug and Formulation Industry

The proposed revised draft Environmental Standard for Bulk Drug and Formulation Industry was presented by CPCB before the Expert Committee. It was informed that the draft notification was earlier discussed in the 16th Expert Committee Meeting held on 13/12/2018. After a detailed discussion on the proposed revised draft notification and following suggestions

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	were made by the Committee: i. The title name of Pharmaceutical Industry should be changed to Bulk Drug and Formulation Industry...."
09.08.2019	18th Expert Committee formulated by appellant Ministry again met for setting up the Environmental Standard for the bulk drug and formulation industry. It was observed: "..... 4.3. Environmental Standard for Bulk Drug and Formulation (Pharmaceutical) Industry The proposed revised draft Environmental Standard for Bulk Drug and Formulation (Pharmaceutical) Industry was presented by CPCB before the Expert Committee. It was informed that the draft notification was earlier discussed in the 17th Expert

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Committee Meeting held on 26/04/2019 and suggestions made during the meeting by the committee were incorporated. The revised standards were again discussed and the Committee suggested incorporating following:

- 1) The standard for COD in effluent may be considered as 250 mg/l in place of 200 mg/l as the 250 mg/l is already prescribed in other similar types of industries.
- 2) The CPCB should develop guidelines for State Pollution Control Boards/ Pollution Control Committees (SPCBs/PCCs) for laboratory analysis of antibiotics in the effluent for implementation of proposed standards in future.

After incorporating the above suggestions the Committee recommended the Ministry may issue the draft notification inviting

	public suggestion in accordance with EPA 1986...."
23.01.2020	The draft of the notifications was brought in the public domain for seeking suggestions/objections for statutory 60 days' time period for laying the standards for Bulk Drug and Formulation (Pharmaceutical) Industry including Antibiotics residue parameters were notified in the Gazette of India vide notification GSR 44(E) dated 23.01.2020.
20.05.2020	The expert committee of appellant Ministry in its meeting held on 20 th May, 2020 had also recommended that owing to the complexity and non-availability of any universally accepted standardized method to test Total API concentration in complex wastewater matrix; it was felt necessary to remove the proposed norms of Total API

	from the additional parameter as of now.
26.06.2020	A case was filed before Hon'ble National Green Tribunal, Principle Bench vide Original Application No. 136/2020 titled as "Veterans Forum for Transparency in Public Life Versus State of Himachal Pradesh & Ors." in which applicants had prayed various reliefs including: (i) The industries at Baddi/Barituwala/Nalagarh, Himachal Pradesh should be stopped to discharge its waste to CETP at Baddi in the circumstance as the CETP is not designed to neutralize/capture Active Pharmaceutical Ingredient's (API). (ii) All the pharmaceutical manufacturing units located at Baddi/Barotiwala/Nalagarh, who are operating in contravention of Water Act 1974 and Hon'ble Supreme



	Court direction cited above, be restrained from further industrial activity. (iii) Direct the Respondent no. 1 to 4 to conduct carrying capacity of the industrial area Baddi, Himachal Pradesh as well in future before granting any type of permission/CTE/CTO to a particular type of industries in an area/city/town, a prior study qua to carrying capacity of a particular type of industries be conducted by keeping in mind the Precautionary Principal for preventing probable damage to environment.
22.07.2020	Upon hearing the matter at admission stage, Hon'ble Tribunal passed an order stating: "...Let a joint Committee of CPCB, State PCB and District Magistrate, Solan look into

	the above issues in the light of contents of the application and take such further action as may found necessary. The State PCB will be the Nodal Agency for compliance and coordination. A factual and action taken report may be furnished to this Tribunal within three months..."
28.07.2020	A meeting on 28.07.2020 under the Chairmanship of Secretary- Environment, Forest, Climate & Change was conducted with all stakeholders, including Central Pollution Control Board (CPCB), Pharma association, Ministry of Health (MoHFW), Department of Pharma and experts. where it was unanimously observed that there is technical challenge in compliance for any static treatment option to meet the dynamic nature of the predicted no-effect Concentration (PNEC) values published by

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	a consortium of Antibiotics manufacturers.
09.12.2020	Expert Committees of appellant Ministry met for setting up the Environmental Standard for the bulk drug and formulation industry. In that meet, draft notification was deliberated point wise and based on the discussion; the Committee recommended certain modifications on additional parameters, the solvent losses, and provision of land disposal etc. for the consideration of the Ministry. The matter was re-examined in the Ministry in light of representation received from the Department of Pharma. A meeting under the chairmanship of Secretary- EFCC with various stakeholders, including CPCB, pharma association, Ministry of Health, Department of Pharma

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and experts was held. Owing to the concern on the PNEC value and its dynamic nature, it was observed that it will be a compliance challenge for any static treatment option to meet the dynamic nature of the PNEC values published by a consortium of Antibiotics Manufacturer. Considering the implementation, monitoring and compliance challenges, it was decided that CPCB may explore these challenges and also compare international practices on imposing PNEC values as regulatory provision for discharge standard to address such concerns. In view of the above, the standard was revised and placed before the expert committee for consideration on the concerns of compliance, dynamic value of PNEC and prevailing international practices on the evolving nature of PNEC understanding.

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	The committee made detailed deliberation on each aspect of the modified discharge norms in notification. Subsequent thereto, the committee recommended to drop the proposal of Antibiotics residue discharge norms and suggested that MoEF&CC may ask CPCB to issue necessary direction to Department of Pharma, Ministry of Chemicals & Fertilizers to ensure that a database be created on the AMR status in the country with the help of association of Antibiotics manufacturing units.
23.06.2021	Hon'ble NGT directed the appellant Ministry i.e., MOEF&CC to finalise the pending finalization of standards by giving an observation: "...MoEF&CC needs to expedite the process of finalizing the standards in the interest of protection of environment...." In the said order, Hon'ble Tribunal also

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	directed: "... Hon'ble NGT directed MoEF&CC and the State PCB may take further remedial action expeditiously. The State PCB may ensure that no harmful components in the effluents are discharged into the water by the units in question or any other API unit. A joint Committee of nominee of MoEF&CC, CPCB, State PCB and District Magistrate, Solan may conduct inspection of the area and give a report of the status of violations and the remedial action taken..."
06.08.2021	Keeping into considerations all the facts, comments of the various expert committees of appellant Ministry and public comments received upon the draft notification dated 23.01.2020, the final standards were notified under Environment (Protection) Rules, 1986 vide GSR 541(E)

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	dated 06.08.2021.
21.01.2022	Hon'ble Tribunal vide its order dated 21.01.2022 in Original Application No. 136/2020 "Veterans Forum for Transparency in Public Life Versus State of Himachal Pradesh & Ors.", without considering the appellant Ministry's issued final standards notified under Environment (Protection) Rules, 1986 vide GSR 541(E) dated 06.08.2021, again Observed :- 1. The MoEF&CC needs to address such vital issue and assist the State to handle the situation in the interest of environment and public health. 2. State may accordingly take further corrective measures to enforce the law for protecting public health and the environment. CPCB may circulate monitoring mechanism to the State PCBs on API, as directed earlier and file

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	the action taken report before the next date. MoEF&CC may clarify the issue of API standards..."
04.04.2022	Before the Hon'ble Green Tribunal, appellant Ministry filed a detailed submission/clarification on the issue of residual antibiotics in Industrial effluents pursuant and API standard in view of order dated 21.01.2022 passed in O.A. NO. 136 OF 2020.
06.04.2022	In O.A. NO. 136 OF 2020, Hon'ble Tribunal while passing a detailed order gave these following directions: "The draft Notification dated 23.01.2020 as well as final Notification dated 06.08.2021 and also the stand of the parties that the standards proposed in the draft notification have yet to be finalized, except and to the extent of those

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	mentioned in the Notification dated 06.08.2021. Draft standards were formulated and notified on 23.1.2020 i.e. more than two years ago, based on study by the experts. Regulatory mechanism is such important issues cannot remain in abeyance for indefinite period on the ground that the MoEF&CC is unable to finalise the draft standards even after two years. In view of serious consequences of unregulated discharge of API residue to the detriment of environment and public health, we consider it appropriate to direct under Section 15(1) of the NGT Act that pending finalisation by the MoEF&CC, standards proposed in the draft Notification dated 23.01.2020, which are based on expert studies, be strictly followed by all concerned. It is also necessary to abide by

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	the guidelines of CPCB circulated on 31.1.2022, quoted above in the matter of standards and methodology on the subject. The State PCB may take further action accordingly to prevent and remedy the situation of unregulated discharge of harmful pollutants of pharma industries in the rivers..."
10.05.2022	As the Hon'ble Tribunal while passing the order dated 06.04.2022 wrongly observed: "..we consider it appropriate to direct under Section 15(1) of the NGT Act that pending finalisation by the MoEF&CC, standards proposed in the draft Notification dated 23.01.2020, which are based on expert studies, be strictly followed by all concerned..." Appellant Ministry's draft notification had already attained finality and the same was

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	already been notified under Environment (Protection) Rules, 1986 vide GSR 541(E) dated 06.08.2021. Being aggrieved and raising the apparent error on record, appellant Ministry filed its review application under Section 19(4)(f) of the National Green Tribunal Act, 2010 on 10.05.2022.
24.05.2022	Hon'ble Tribunal by passing the impugned order in the review application of the appellant Ministry wrongly dismissed the same by observing that as the standards in the draft Notification have not been included in the final Notification, order of the Tribunal is not called for.
....08.2022	Hence the present Civil Appeal

Item Nos. 01 & 02

(Court No. 1)

**BEFORE THE NATIONAL GREEN TRIBUNAL
PRINCIPAL BENCH, NEW DELHI**

(By Video Conferencing)

Original Application No. 801/2018

Jasmeet Singh

Applicant

Versus

State of Himachal Pradesh

Respondent

WITH

Original Application No. 136/2020

Veterans Forum for Transparency
in Public Life

Applicant

Versus

State of Himachal Pradesh & Ors.

Respondent(s)

Date of hearing: 06.04.2022

**CORAM: HON'BLE MR. JUSTICE ADARSH KUMAR GOEL, CHAIRPERSON
HON'BLE MR. JUSTICE SUDHIR AGARWAL, JUDICIAL MEMBER
HON'BLE MR. JUSTICE ARUN KUMAR TYAGI, JUDICIAL MEMBER
HON'BLE PROF. A. SENTHIL VEL, EXPERT MEMBER
HON'BLE DR. VIJAY KULKARNI, EXPERT MEMBER
HON'BLE DR. AFROZ AHMAD, EXPERT MEMBER**

Applicant: Dr. Bishwanath Prasad, Wing Commander (Retd.), Applicant in
Person in OA 136/2020

Respondent(s): Mr. Balendu Shekhar, Advocate for MoEF & CC
Mr. Anuj Bhandari, Advocate for CPCB
Mr. Nalin Kohli, Advocate for HPSPCB

ORDER

1. Issue for consideration is the remedial action against failure of the authorities in the State of Himachal Pradesh in preventing pollution of rivers Balad, Sirsa and Sutlej in Baddi Industrial area in Solan District. One of the sources of pollution is on account of lack of sewerage system resulting in discharge of untreated sewage in the rivers contrary to the

mandate inter alia in judgement of the Hon'ble Supreme Court in Paryavaran Suraksha (2017) 5 SCC 326 and various orders of this Tribunal in the light thereof. Other source is discharge of toxic industrial pollution on account of leakage from the Common Effluent Treatment Plant (CETP) (as alleged in O.A. No. 801/2018). Third major and serious source of pollution is discharge of toxic waste from pharma industries which cannot be treated by CETP and even by ETPs. (as alleged in O.A. No. 136/2020). CETP is not designed to neutralize Active Pharmaceutical Ingredient (API). TSDF does not receive sludge generated from the industrial units at Nalagarh. The industries located at Baddi area are generating 20779 KLD of industrial effluent, out of which 17894 KLD is being treated at CETP and remaining 2885 KLD is being disposed of by the occupiers directly into river Sirsa. There is no existing sewerage system in BBN area and no demarcation in residential and industrial area. Presence of Ciprofloxacin in the concentration of 296.1 ug/l was found on chemical analysis. Concentration of Ciprofloxacin in the effluent discharge of M/s Acme Life Sciences work out to be 13455 times of the prescribed limit. The increasing occurrence of multi-resistant pathogens is a serious global threat to human health and it is finding its way into the water bodies and drinking water through industrial discharge and also due to heavy use of antibiotics in human and veterinary medicine.

Compliance status as noted in earlier orders

OA 801/2018 – industrial pollution due to inadequacy of CETP

2. The Tribunal noted the status in O.A. No. 801/2018 as follows:-

"2. The matter was considered on several occasions earlier. On 14.01.2020, the Tribunal considered the report dated 06.11.2019 filed by the State PCB to the effect that violation of provisions of the

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Water (Prevention and Control of Pollution) Act, 1974 was taking place by discharge of polluted effluents in the water bodies. The same is reproduced below for ready reference:-

"2.0 Inspection of CETP Baddi

- i) The CETP is designed to treat five different categories of effluent as tabulated under

Sr. No.	Category	Sector of Industry	No of Units	Consented effluent quantity (in MLD)
1.	I	Food, Paper and Textile	89	15.55
2.	II	Soap & Detergent	112	2.0
3.	III	Pharmaceutical	213	2.9
4.	IV	Dyeing	4* M/s Auro Textile Unit - I, M/s Auro Dyeing Unit - I, M/s Winsome Textile Industries	2.0
5.	V	Electroplating, Metal surface finishing	31	0.042
Total			449	22.492
				Say 23.00

- ii) It was observed that at an average of 17 mld effluent is treated by the CETP, comprising equalization tank, primary settler, aeration tank, reaction tank, secondary and tertiary clarifier. The treatment process for each stream is appended with the report (**Annexure IV**).
- iii) It was noticed that effluent of category IV is not reaching to its designated equalization tank. M/s Baddi Infrastructure Ltd., has informed that the dedicated pipe network to carry the effluent of category IV is blocked. The effluent of category IV is therefore being discharged through pipe network of Category I.
- iv) It is also observed that the CETP is designed to treat category V effluent by mixing with category IV effluent to optimize the chemical consumption and to achieve effective treatment. Since, the effluent of category IV has been mixed with category-I, in the pipe network itself before reaching CETP, which has resulted in formation of a new complex effluent for which the CETP was not designed. Therefore, it could not able to deliver the desired results w.r.t. treatment and thus, effluents was in non-conformity with the

standards, as per the monitoring results of HPPCB (Annexure-V). Besides, the effluent of category V remained effectively untreated throughout the CETP process.

v) The performance of CETP is being regularly monitored by HPPCB. The monitoring data (Annexure-V) indicate that the performance of the CETP is far from satisfactory for having not met the discharged standards. The data reveal that effluent quality does not conform the standards of Chloride (limit of 1100 mg/1 max.), Total dissolved Solids (TDS) (LIMIT OF 2100 MG/1 Mmax.) and Biochemical Oxygen Demand (BOD) (limit of 30 mg/1 max.).

vi) The CETP has provided online continuous effluent monitoring system for pH, Total Suspended Solids (TDS), Chemical Oxygen Demand (COD) and Total Organic Content (TOC) and data so recorded are linked with the server of HPPCB and CPCB.

While collecting the sample from the final outlet of tertiary clarifier and discharge point at River Sirsa, difference in colour of effluent was observed. The sample collected from the discharge point was lighter in colour than that of outlet of tertiary clarifier; giving rise to possibility of dilution. (Photograph: Plate-I)

vii) **The Committee also recorded that the Textile Units, which are generating the effluent of Category IV, were earlier operating their own effluent treatment plants prior to commencement of CETP and found it viable to operate due to their scale of production.**

viii) The designed treatment criteria of CETP are to treat effluent, stream-wise, following segregation at source, effluent of Category-I is mixed with Category-IV, resulted in alternation of criteria, hence treated effluent.

ix) For increasing the connectivity, the CETP has proposed of laying conveyance (pipeline) for a total length of 5.8 kms. The status is as under.

Sr. No.	Location	Stretch in meters	Status of permission obtained	Remarks
1.	Zydus Cadilla to Legacy Food on Baddi Barotiwala road	1655	Permission granted by HPPWD	Work has been awarded by M/s Baddi Infrastructure Ltd vide letter dated 27-09-2019. (Annexure-VI)
2.	Maplur-Baddi electrical	2250	Permission not granted	

	substation upto Bhud near Maxtar Bio Genics Company		by NHAI	
3.	Bhud to Lehi	1900	Permission granted by HPWD	
Total		5805		

To safeguard the interest of environment from being deteriorated further and having understanding of pollution problem, its cause and remedial measures, the Committee recommends following:

- i) **Textile industries (SI. No.1 to 5, Table 1) engaged in dyeing-process generating effluent of Category-IV, as mentioned above for the purpose of designing and operating CETP, should stop its operations with immediate effect, until and unless the dedicated conduits supposed to carry the said effluent, is brought to back functional.**
- ii) These units shall resume operation of their ETP to impart effective treatment on effluent of Category-IV so as to meet the standards and shall pump treated effluent to the pipe network designated to carry effluent of Category-I for further treatment at CETP.
- iii) **These units shall resume operations only upon satisfactory performance of ETP which was brought back to functional and shall be monitored once in a month by HPCB.**
- iv) M/s Baddi Infrastructure including Ltd. is to ensure proper maintenance of CETP and its infrastructure including pipe network designed to receive effluents from member industrial units. M/s Baddi Infrastructure Ltd. has to ensure operation of CETP as per the defined protocol and in accordance to standard operating practice which is in place. In case, any variation (beyond the designed criteria) of effluent quality is noticed by CETP the same shall be brought to the knowledge of SPCB, in writing. The SPCB shall acknowledge the communications and shall act to identify the cause for taking all necessary steps for taking all necessary steps to eliminate/minimize such variation.
- v) **M/s Baddi Infrastructure Ltd. has to install activated carbon, pressure sand filters and ozonizer before the treated effluent is discharged. This refers the Detailed Project Report of CETP-Baddi, which finds mentioned of the system but**

has not been provided by M/s Baddi Infrastructure Limited.

Reference is made on the observations recorded by the Committee constituted by Hon'ble Tribunal in O.A. No.916/2018 in the matter of Sobha Singh and Others v/s State of Punjab and Others, wherein the Committee recommended that Rs.1.0 crore to be levied on CETP-Baddi as Environmental Compensation for untreated effluent discharged into River Sirsa. The CETP discharged, joining the river, has failed to meet Bio-assay Test (Toxicity on fish: 0% survival with 100% effluent for 96 hours). This would have caused impact on water and land (soil) environment, plants and vegetation, aquatic life and human health all along downstream of CETP-Baddi.

Thus, Committee also recommends the following:-

- vi) Environmental compensation (EC) to be levied to CETP-Baddi (M/s Baddi Infrastructure Ltd) for not having done effluent treatment upto the standards and to those Textile Industries (dyeing units) responsible for making CETP defunct. The EC would be proportionate as under.
 - a) CETP-Baddi has to pay environmental Compensation to the tune of Rs.1.91 Crores for non-compliance of discharged standards, estimated based on violation recorded by HPPCB over last one and half year [19.10.2017 -01.11.2019] (**Annexure VII**) including compensation to the tune of Rs.87.9 Lakh imposed by HPSPCB dated 15.10.2019 over one year [20.11.2018 to 09.09.2019] (**annexure VIII**).
 - b) Textile Industries (dyeing units) are to pay establishment cost of CETP and cost of pipe network which was brought to state of irreparable.
- vii) HPPCB is to review the notification, dated 17.03.2018 wherein Total Suspended Solids (TSS), Oil & Grease and pH have been notified TDS, BOD, Chloride and Sulphide may also be considered for inclusion in the notification as these have critical bearing on operation and performance of CETP designed to impart effective treatment. HPPCB may undertake similar exercise as done in case of notification, dated 29.06.2019 for CETP Paonta Sahib, wherein eight parameters including those referred here, have been considered. Such notification may be issued in consultation with CPCB.
- viii) **For optimal performance of CETP-Baddi, HPPCB is to ensure regulating and monitoring mechanism be in place by asking all member units (falling under red category) of CETP to install online continuous effluent monitoring system. The data so recorded shall be made available on SPCB and CPCB server for effective control."**

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3. The matter was then considered on 18.06.2020 in the light of compliance report dated 11.06.2020 filed by the State PCB. It was observed:

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5. In pursuance of above, the State PCB has filed a ‘compliance report’ dated 11.06.2020 to the effect that the units gave action plans which are not satisfactory as long timeline have been prescribed.

6. We do not find the report to be as per the mandate of law. **If the pollution is continuing, the State PCB is under obligation to close the polluting activities by exercising its jurisdiction under the Water Act, 1974 and recover compensation from the polluters. Till pollution is stopped, polluting activities, which are punishable crime under the law, cannot continue. The State PCB has failed to take action merely on the ground that action plan was being prepared or had been prepared which was not satisfactory. None appears for the State PCB.**”

4. The matter was last considered on 04.01.2021 in the light of the report of the State PCB dated 01.01.2021 mentioning the steps taken for closure and recovery of compensation. The Tribunal found that the action taken was not adequate as CETP was still non-compliant. Untreated effluents were thus being discharged into the water bodies in violation of law. Discussion and direction in the said order are reproduced below:-

“1to3....xxx.....xxx.....xxx

4. Accordingly, the State PCB has filed its report on 01.01.2021. It mentions that the State PCB issued show cause notice dated 23.06.2020 to the concerned textile units for closure and recovery of compensation against which writ petitions were filed before the Himachal Pradesh High Court. The High Court, vide order dated 22.07.2020, directed that the matter be heard by the Principal Secretary, Environment and fresh order passed. The Principal Secretary, Environment passed further order on 30.12.2020 directing the State PCB to take action for enforcement of law since violation of law was established. The Principal Secretary, Environment held:

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..... **But this fact cannot be ignored that effluent discharge, FDS in particular, by these units is beyond the prescribed limits which is contributing to pollution. In the light of this discussion, I am of considered view that, keeping in view the above position, SPCB may take action strictly according to the provisions of Law and rules applicable in this case.**”

5. The State PCB accordingly issued fresh show cause notice on 28.12.2020 and passed further order dated 01.01.2021 as follows:

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Whereas, the effluent of category-IV being contributed by the unit M/s Auro Textiles, Sai Road Baddi, Distt. Solan, H.P to the CETP for final disposal and treatment by unit is not complying since 25-7-2020 till date to the discharge standards as prescribed in the schedule-1 of EP Rules, 1986 as well as the inlet quality standards notified by the State Government and thereby causing water pollution.

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Now, therefore, in consideration of the facts stated above, in view of the directions of Hon'ble High Courts orders, Hon'ble NGT and the orders passed by Principal Secretary (Env, S&T) Govt of HP and in exercise of the powers conferred under section 32 and 33-A of Water (Prevention & Control of Pollution) Act, 1974 M/s Auro Textiles, Sai Road Baddi, Distt. Solan, H.P. is hereby directed to:

1. Immediately shut down the dyeing process of the textile unit contributing towards the category- IV effluent to CETP, Baddi, till the unit becomes compliant.
2. Pay Environment Compensation to the tune of Rs. 42 lakhs (Forty Two Lakhs only) for the violation period w.e.f. 25-07-2020 to 31-12-2020 (140 days excluding the period of compliance)."

Identical orders are said to have been passed against four textile units.

6. We have heard Shri Nalin Kohli, learned Counsel appearing for the State PCB.

7. We find that though in the show cause notice the State PCB proposed disconnecting power supply, this direction has not been given in the final order. We also find that the CETP has still not complied with the environmental norms for which remedial action needs to be taken by the State PCB, by improving quality and reducing the load of inlet so as to be consistent with the designed capacity of the CETP or closing such units contributing to the waste for which the CETP is not designed till the concerned units make their own arrangement for treating the effluents. The member industries may be considered non-compliant, if they do not undertake primary treatment as per EC conditions of the CETP. The industries having effluent generation more than 200 KLD may be directed to treat the effluents and recycle/reuse to the maximum extent and also reducing the FDS. Wherever

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required, water audit of red category non-compliant units be conducted. The requisite pipeline may also be required to be constructed by the CETP to carry the waste.

8. Let further progress report be filed before the next date by e-mail at judicial-ngt@gov.in preferably in the form of searchable PDF/OCR Support PDF and not in the form of Image PDF."

5. The State PCB has filed interim report dated 06.05.2021 followed by further report dated 16.06.2021. It will suffice to refer to the last report to the effect that the samples were taken and were not found to be within the limits. The State PCB gave directions to the concerned industries. While some units have achieved the norms, further action is being taken in the matter. The status as mentioned in the report is reproduced below:-

"In compliance to afore-cited order dated 04-01-2021 it is submitted that earlier the State Board had filed an Interim Report vide letter No. PCB/OA No. 801/2018 /-1549 dated 6-5-2021 wherein it was submitted that Board has taken steps to make the CETP, Baddi compliant. The FDS level was found 2364mg/ltr as per sampling conducted at that time, though not within the prescribed limits. It is further submitted that now the latest sample taken on 21-5-2021 and 7-6-2021 has been found within the prescribed limits w.r.t. FDS as the same has been reduced to the 2019mg/ltr and 2072 mg/ltr respectively. The sampling chart of the CETP Baddi is annexed as Annexure —A which reveals that there is continuous improvement and now the analysis results of latest sample taken are meeting the norms w.r.t. FDS.

It is further submitted that as regard to the issue of industries having effluent generation of more than 200 KLD, the State Board had identified and issued directions to 16 numbers of industries to operate their treatment plants i.e. primary, secondary and tertiary treatment system for the effluent treatment as per Environment Conditions of CETP and also directed to recycle / reuse to the maximum extent and also to reduce the FDS. Now as per report received from the Regional Office Baddi, these 16 units are operating the effluent treatment plants prior to their effluent discharge to CETP. The State Board has conducted inspection and sampling of these 16 units. The earlier results of sampling conducted on 21-1-2021, 29-1-2021, 1-3-2021, 23-3-2021 and 16-4-2021, were found within limits (except of three units of M/s Vardhman and one unit of Winsome Textile) which has already been placed on record alongwith interim report dated 6-5-2021. However, the latest results of sampling conducted on 21-5-2021 the results of three units namely M/s P&G Home Products Baddi, M/s Torrent Pharmaceutical Ltd. Baddi and M/s Abbott Health care, Baddi were found above the prescribed limits for which notices dated 16-6-2021 has been issued to these units. Copy of sample results and notices issued are annexed as Annexure-B and Annexure-C (colly). The sample results of other units were found within the

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prescribed limits. It is further submitted that as reported by Regional Officer, Baddi the member industries having flow less than 200 KLD are disposing off their effluent to CETP, Baddi after primary treatment.

As regard to the compliance by the four textile units namely Auro Textile, Auro Textile unit —II, Auro Dyeing of Vardhman Textile and one unit of Winsome Textile, it is submitted that as per report received from the Regional Office, Baddi, **the work of installation of advance treatment system by M/s Vardhman textile to reduce FDS is under progress and Reverse Osmosis system of capacity of 2 MLD shall be operational by 30-6-2021.** In addition to Reverse Osmosis, M/s Vardhman Textile is also installing the Multi Effect Evaporator of capacity of 370 KLD. As regard to progress of installation of advance treatment system by M/s Winsome Textile it is submitted that as per report received from Regional Office, Baddi the unit has completed the civil construction work. **The installation of Reverse Osmosis system and other components is under progress.** Copies of progress report of these textile units received from Regional Office are annexed as Annexure D and E. **The latest sample results of these four textile units are still not meeting the norms.** Sample results are annexed as Annexure-F. As already submitted in interim progress report dated 6-5-2021, it is again submitted here that **State Board had issued directions on 1-1-2021 to these four textile units under section 33-A of Water Act, 1974 for closure and levied Environmental Compensation which were challenged by these units before the Hon'ble High Court of HP vide CWP No. 414/2021, 416/2021 417/2021 and 418/2021. The Hon'ble High Court of HP vide order dated 11-1-2021 and 15-3-2021 has stayed the operation of the directions issued by the State Board and the matter is still pending before the Hon'ble High Court of Himachal Pradesh for adjudication.** Copies of order dated 15-3-2021 are annexed as Annexure-G.

It is further submitted that due to constant efforts of all stakeholders, the two consecutive latest samples of CETP outlet are meeting the norms prescribed by the MoEF &CC vide notification dated 1-1-2016. In future, the State Board shall continue to make all efforts in form of surveillance, regular monitoring and regulation on the CETP and member industries, so that the CETP remains compliant in future as well."

6. From the above, it is clear that violations are still continuing. Stay of order of closure and assessment of compensation for the past violations does not justify inaction for failure to take action for further violations after the order of stay and to initiate prosecution of the industrial units in question, including their Owners/Directors and the CETP operators. We also find that merely keeping an eye on units discharging more than 200 KLD is not enough. Violation by those discharging less than 200 KLD is not less serious

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violation nor less harmful for the environment and public health.

7. Accordingly, let further remedial action be taken to enforce the environmental rule of law in the interest of protection of environment and public health and a report of status of compliance filed after inspection by a four Member joint Committee comprising a representative of MoEF&CC, CPCB, State PCB and District Magistrate, Solan by e-mail at judicial-ngt@gov.in preferably in the form of searchable PDF/ OCR Support PDF and not in the form of Image PDF. The State PCB will be the nodal agency for coordination and compliance."

O.A. No. 136/2020 – Pharma units:

3. In O.A. No. 136/2020, extracts from last order dated 23.06.2021 are as follows:-

"3. The matter was last considered on 04.01.2021 in the light of the report of State PCB dated 30.12.2020 noticing the violations of environmental norms. The Tribunal directed remedial action and filing of compliance report. The operative part of the discussion and order of the Tribunal are reproduced below:-

"3. Accordingly, the Himachal Pradesh State PCB has filed its report dated 30.12.2020 to the effect that the joint Committee visited the area and noticed as follows:

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i. The CETP has not installed the system to completely treat category IV effluent (High TDS/FDS Stream). Despite the fact that CETP does not have the capacity to treat this type of effluent, CETP has entered into the tripartite agreement with the Industries generating Category IV effluent has been receiving this category of effluent since 2016.

ii. As per Environmental Clearance granted to CETP Baddi by the Ministry of Environment, Forests and Climate Change (MoEF&CC), the member industries with hydraulic loading more than 200 KLD shall treat the effluent in the existing onsite ETPs and then discharge into CETP for further treatment and discharge. However, it was informed that Units with hydraulic loading of 200 KLD are not treating effluent in the onsite ETPs and supplying primary treated effluent to CETP. Therefore, CETP has not been complying with this condition of the Environmental Clearance granted by MoEF&CC for the last 04 years. Accordingly, the sampling of these units was done by HPPCB team on 10/12/2020 and the samples were sent to HPPCB Central Laboratory. The results of the analysis are expected by 10/01/2021.

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iii. The observations made by the Joint Committee during visit to the two Pharma units i.e. M/s Acme Life Sciences and M/s Helios Pharmaceuticals mentioned in the original application are as follows:

- Both the pharma units have connectivity with the CETP for supplying the primary treated effluent, for further treatment at CETP.
- No effluent was found to be discharged directly by the Units, in the drain.
- The Joint Committee collected the samples from the final outlet of the pharma units under reference, to see the concentration of residual antibiotics in the primary treated effluent which is being sent to CETP for further treatment. The results of the analysis are expected by 09/02/2021.

iv. The evaluation of the results of the analysis of the CETP samples collected by the Joint Committee on 12-13 October, 2020, indicated intended dilution by CETP so as to achieve the prescribed norms. Therefore, the Joint Committee conducted unannounced re-sampling and sent the samples for analysis from three different laboratories.

v. The results of analysis for the samples collected by the Joint Committee have been analyzed in HPPCB Regional Laboratory, Paonta Sahib and evaluation of the results indicated that CETP is not meeting the norms prescribed for COD (264 mg/l > 250 mg/l), BOD (35 mg/l > 30 mg/l), FDS (2252 mg/l > 2100 mg/l) and Chloride (1838 mg/l > 1000 mg/l). Therefore, it is concluded that CETP is discharging the effluent into the Sirsa River without complying with the prescribed norms. The results of the analysis of the samples are awaited from two other laboratories.

vi. The samples from CETP, upstream and downstream of Sirsa River and the pharma units under question, were collected by the joint committee on 09/12/2020 for analysis of 12 Nos. residual antibiotic residues from Shri Ram Institute of Industrial Research, Delhi. The results of analysis of effluent samples for residual antibiotics is expected by 09/02/2021. The issue of discharge of residual antibiotics as raised by the applicant may be concluded by the Joint Committee after receipt of the analysis results.

In view of the fact that complete analysis reports will be available by 09/02/2021, it is humbly prayed to Hon'ble National Green Tribunal that Joint Committee may kindly be permitted to file the final conclusive report by 15/02/2020."

4. Accordingly, further action taken report may be separately filed by the State PCB before the next date by e-mail at judicial-ngt@gov.in preferably in the form of searchable PDF/OCR Support PDF and not in the form of Image PDF. The directions in the connected matter being OA No. 801/2018, *Jasmeet Singh v. State of Himachal Pradesh*, dealt with by a separate order, to the extent relevant for the present matter, may also be followed."

4. The State PCB has filed its report dated 10.03.2021 giving the analysis results of samples calculated from the units as follows:-

"Supplementary Report:

The analysis results from the remaining two laboratories w.r.t samples collected by the Joint Committee have been received (Annexure-2 and Annexure-3), Further, the report of analysis w.r.t. samples collected by the Joint Committee from CETP, Pharma Units and Sirsa River for the presence of antibiotics from the approved external laboratory has also been received (Annexure-4). Accordingly, supplementary report in this matter is being filed by the Joint Committee as follows:

- i) The results of analysis as received from three different laboratories of HPPCB, indicated that CETP is not meeting the norms prescribed for BOD (41, 35 & 38 mg/l > 30 mg/l), FDS (2252 & 3190 mg/l > 2100 mg/l) and Chloride (1209, 1838 & 1209 mg/l > 1000 mg/l). Therefore, it may be concluded that CETP is discharging the effluent into the Sirsa River without complying with the prescribed norms.
- ii) The results of analysis of the samples collected from various stages of CETP and also final discharge point in River Sirsa for the presence of residual antibiotics indicate that two antibiotics viz. Ciprofloxacin and Ofloxacin are present in the final treated effluent of CETP as a concentration of 22.8 ug/l and 69.8 ug/l respectively.
- iii) **There are no standards notified by MoEF&CC for residual antibiotics in industrial effluents. However, these values are 1140 time higher for Ciprofloxacin (22.8 ug/l Vs. 0.02 ugh) and 349 times higher for Ofloxacin (69.8 ug/l Vs. 0.2 ugh) when compared with the proposed standards in the draft notification issued by MoEF&CC vide No. CG-DL-E-27012020- 215690 dated January 23, 2020 (Annexure-5), for pharmaceutical industry effluent arid CETPs with membership of Bulk drug and formulation units.**
- iv) Similarly, the samples collected by the Joint Committee from the outlets of two Pharmaceutical Industries viz. Helios Pharmaceutical and M/s Acme City Tech LLP, leading to CETP, were found be much higher than the

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standards proposed in the draft notification issued by MoEF&CC. Also, the values reported as below quantification limit (BQL), in the analysis report of the external laboratories may not be considered as conclusive and within the proposed limits as draft notified by MoEF&CC, since the BQLs of external laboratory for various antibiotics tested in the samples, as shared with the Joint Committee, are much higher than the proposed standards.

- v) As per reports and research data available in the literature, the concentration of residual antibiotics has been found to be reduced by 60-90 % in conventional biological treatment plant. In view to assess the performance of the biological treatment system installed by CETP, the samples were collected from various stages of CETP. The results of analysis indicated that the performance of biological treatment system installed by CETP is not in line with the reports and data available in the literature, w.r.t. treatment of residual antibiotics. The inefficient performance of biological treatment system is also evident from the noncompliance of CETP with regard to biochemical oxygen demand (BOD).

Conclusion and Recommendations:

In view of the fact that:

- i) **There are no standards notified by MoEF&CC w.r.t. residual antibiotics in industrial effluents;**
- ii) **Draft notified standards are yet to be decided by MoEF&CC;**
- iii) **The concentration of residual antibiotics at outlet of CETP in Sirsa River, is much higher than the draft notified standards;**
- iv) **The treatment efficiency of CETP w.r.t residual antibiotics is not at par with the reports and data available in the literature;**
- v) **The CETP is not meeting the prescribed norms of BOD, FDS and chloride and discharging effluent into Sirsa River without complying with the prescribed norms.**

It is recommended that Pharmaceutical (both bulk drug and formulation units) may be directed by Himachal Pradesh Pollution Control Board to provide primary treatment to the level of predicted no effect concentration (PNEC) as developed by members of AMR Industry Alliance (Annexure-6), as a site (Baddi) specific preventing measure, so that there is no adverse impact of residual antibiotics on the environment and

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also to prevent development of antimicrobial resistance (AMR)."

5. The report is followed by further report dated 05.05.2021 as follows:-

"It is further submitted that now the joint committee has submitted its supplementary report which is annexed as Annexure R-1/1. Based on the inspections and sampling conducted the conclusion and recommendations made by the joint committee are as under:-

- "i) There are no standards notified by MoEF & CC w.r.t. residual antibiotics in industrial effluents.
- ii) Draft notified standards are yet to be decided by MoEF & CC.
- iii) The concentration of residual antibiotics at outlet of CETP in Sirsa river is much higher than the draft notified standards.
- iv) The treatment efficiency of CETP w.r.t. residual antibiotics is not at par with the reports and data available in the literature.
- v) The CETP is not meeting the prescribed norms of BOD, FDS and chloride and discharging effluent into Sirsa River without complying with the prescribed norms....."

The copy of Supplementary Report submitted by the joint committee dated 10-03-2021 (annexed as Annexure R-1/1) may be placed on record please.

It is submitted that as of now there are no specific standards notified by the Govt. of India for residual antibiotics parameters in the existing notification of standards for pharmaceutical (Manufacturing and Formulation Industry). However, it is worthwhile to mention here that all the bulk drugs/pharmaceutical manufacturing units (if not connected with CETP) are being regulated for the compliance as per standards notified in MoEF & CC Notification dated 9-7-2009 (copy annexed as Annexure R-1/2). If the pharmaceutical (manufacturing and formulation industry) is member of CETP, then the unit is bound to comply with inlet quality standards notified by the Govt. of HP vide notification dated 17-3-2018 and 26-12-2019 (copies annexed as Annexure R-1/3 and R-1/4) The notification of specific standards for residual antibiotics (annexed as Annexure -5 with joint report) is still under proposed stage and shall be implemented for regulatory aspect as and when finalized by the MoEFF & CC."

6. The industrial units in question have also filed their Counter Affidavits. The said Counter Affidavits are of no assistance.

7. As against the above, the applicant has filed written submission on 11.06.2021 pointing out that the analysis of the samples shows presence of antibiotics in the water.

8. The conclusion drawn from the analytical results is as follows:-

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1. **Ciprofloxacin (22.8µg/L) and Ofloxacin(69.8µg/L) were detected in higher concentrations in the effluent released to Sirsa river from CETP (Sr. no 4), i.e., 1139 and 348 times higher than the prescribed MoEF& CC draft notification limits.**
2. **The higher concentrations of antibiotics in the effluent released to Sirsa river (Sr. no 4) clearly indicate that CETP is unable to completely remove or degrade these antibiotics.**
3. **Ofloxacin (960µg/L) was found in the effluent from M/S Helios Pharmaceutical (Sr. no 13) release to CETP, which is much higher than the draft notification limit (0.2 µg/L). It clearly raises doubt on the level of pre-treatment of the pharma effluent from this industry before it is released to the CETP.**
4. **The samples drawn from the effluent of M/S Acme City Tech LLP (Sr. no 14 and 15) release to CETP shows reasonably high concentrations of Ofloxacin (170 µg/L) and Azithromycin (423µg/L) even after primary treatment, indicate inefficient pre-treatment at this industry.**
5. **In the research methodology Limit of quantification (LOQ) for a compound by any method indicates the lowest concentration that can be quantified with accuracy and precision. The values below LOQ cannot be correctly quantified during the analysis and are reported as Below Quantification Limit (BQL). In the present analysis, the LOQs of the compounds fixed for the analysis by the lab are very high; namely, Ciprofloxacin (5 µg/L), Ofloxacin (5 µg/L), Piperacillin (5 µg/L), Azithromycin (10 µg/L), Tazobactam (5 µg/L), Cefprozidime (50 µg/L), Cefixime (20 µg/L), Amoxicillin (10 µg/L), Ampicillin (10 µg/L), Cefpodoxime (10 µg/L), Sulbactam (10 µg/L), Ceftriaxone (50 µg/L) and Cefoperazone (10 µg/L). The above LOQs of the compounds are much higher than even the antibiotic discharge limits set by the MoEF & CC draft notification for these compounds; except for Tazobactam.**

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6. **Incidentally Piperacillin and Amoxicillin are the antibiotics are known for the very adverse impact on the human health even in the very low concentration. In this laboratory analysis, BQL limit for these compounds are set as (5 µg/L) and (10 µg/L) which is significantly higher than the limit fixed in the draft standards. In the draft standards the limit set for these two compounds are (0.1µg/L).**
7. **This implies that the Limit of Quantification (LOQ) set up by the lab is significantly higher than the limit set by the draft notification and therefore many of the compounds are not being detected as has been marked as BQL in the analysis results.**
8. **Therefore, the samples analysis should be conducted using an analytical method to precisely and accurately quantify lower concentrations of the compounds (LOQs should be kept as close or even lower than the draft notification limits) to quantify all the compounds at lower concentrations with accuracy and precision. This raises the question mark on integrity of the overall analysis by the lab.**
9. **Further the findings also imply that the CETP is not designed to efficiently treat class IV effluents; however, operator of CETP has entered into agreement with various pharma manufacturing units who are releasing class IV effluents to the CETP since 2017."**
9. **Further submissions are reproduced below:-**
 - "14. **The migration of antimicrobials into the environment has significant impacts. They can disrupt wastewater treatment processes and adversely affect ecosystem because they are toxic to beneficial bacteria. Some antimicrobials also bio accumulates; for example, erythromycin has been found to have both a high bio accumulation factor of 45.31 and a tendency to accumulate in soil. Antimicrobials can also be persistence for extended periods of time, the environmental persistence of erythromycin for example, is longer than one year.**
 15. **Although not well studied, the presence of antimicrobials in natural waters may be exerting selective pressure leading to the development of antibiotics resistance in bacteria. The threat of growing antibiotics resistance has been recognised by, among others, the WHO, the National Academy of Science, the American Medical Association, the American Public Health Association and the US government Accountability. In fact the Centre for Disease Control and prevention (CDC) has identified antibiotics resistance as one of the most pressing public health problem facing the nation. Infections caused by**

bacteria with resistance to at least one antibiotic have been estimated to kill over 60,000 hospitalized patients each year. Methicillin resistant strains of *Staphylococcus aureus*, although previously limited primarily to hospital and health facilities, are becoming more widespread. In 2007, Consumer Reports tested over 500 whole chickens for bacterial contamination and antibiotic resistance. They found wide spread bacterial contamination in their samples and 84 percent of the salmonella and 67 percent of the campylobacter organisms that were isolated showed resistance to one or more antibiotic.

16. Antibiotic resistance is caused by a number of factors including repeated and improper use of antibiotics in both humans and animals. Half of the antibiotics used in livestock are in the same classes of drug that are used in humans and animals. The U.S. institute of Medicine and the WHO have both stated that widespread use of antibiotics in agriculture is contributing to antibiotic resistance.

17. The above study done by the HPPCB shows that from whichever place samples have been taken by HPPCB these are having antibiotics discharge which should not have been there. There is not a single sample in which the aforesaid antibiotics discharging into surface water and also seeping into the subsoil water is not there. This would lead to harmful antibiotic resistance amongst human and animal population and, thus, reducing the chances of their recovering from diseases where absence of resistance from these antibiotic would have helped. The above table and the subsequent narration would show that the antibiotics found in the discharge include some of the ultimate antibiotics developing resistance of which may be a death warrant for different life forms – human and animal – if infected with diseases where these antibiotics could have provided a cure.

18. A situation where all random samples show the same results, in technical terms, is called '100% random test positivity'. In view of the '100% random test positivity', the study conducted by HPPCB cannot be stated to be complete and conclusive. It only indicates that a whole lot of polluting antibiotics are being discharged into the surface and subsoil water which is harmful for human and animal population.

19. As per information available at internet, there are more than 270 Pharmaceutical Companies operating in Baddi-Barotiwala-Nalagarh area. List of such Pharmaceutical Companies along with their addresses, as obtained through internet sites, is placed at Annexure A.

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20. This necessarily requires a further and more detailed study as a sequel to 'the sample study' done by HPPCB to understand the entire extent of damage because of the aforesaid antibiotic discharge into the water bodies. It is being called 'sample study' because of the fact that it has '100% random test positivity' and therefore, in scientific tradition, there is an absolute need for following it up with a detailed, wide and more in depth study of the antibiotic discharge into river Sirsa."

10. We have heard the applicant in person and the Learned Counsel for State PCB.

11. We find that there is gross failure on the part of the State PCB to act as per public trust doctrine in preventing discharge of toxic effluents containing harmful residue of antibiotics in water posing threat to aquatic life (reference: "biomonitoring of Sirsa River in Baddi area of Himachal Pradesh by Bhagat S. Chauhan, et al, International Journal of Theoretical and Applied Sciences 5 (1): 183-185(2013)) which is also in violation of the Water (Prevention and Control of Pollution) Act, 1974. Such failure of statutory duties is at the cost of public health and protection of environment for which Chairman and Member Secretary of the PCB owe an explanation which may be furnished before the next date. Mere fact that standards have not been revised by MoEF&CC of the residual antibiotics in industrial effluents can be no justification for State PCB not taking steps to prevent. Pending finalization of standards by MoEF&CC, State PCB can go by earlier standards or lay down standards by itself under section 17 of the Water Act. MoEF&CC needs to expedite the process of finalizing the standards in the interest of protection of environment.

12. Accordingly, MoEF&CC and the State PCB may take further remedial action expeditiously. The State PCB may ensure that no harmful components in the effluents are discharged into the water by the units in question or any other API unit. A joint Committee of nominee of MoEF&CC, CPCB, State PCB and District Magistrate, Solan may conduct inspection of the area and give a report of the status of violations and the remedial action taken within three months by e-mail at judicial-ngt@gov.in preferably in the form of searchable PDF/ OCR Support PDF and not in the form of Image PDF. The State PCB will be the nodal agency for compliance. The Committee may interact with the concerned stake holders, including the concerned Industries. The report may inter alia give status of performance of individual pharmaceutical units, particularly with reference to removal of API residue by them and by the CETP, the number of pharma industries connected to CETP and those discharging effluents directly into the drain and the river. The report may further indicate chemical and biological water quality of rivers in question - Sirsa and Satluj, including the status of residue at relevant locations. CPCB

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may also suggest monitoring mechanism for API residue through a credible system so as to cover all pharma industries in the country discharging API residue directly or indirectly in river systems. CPCB may propose the timelines to undertake monitoring which may also take a note of water quality monitoring guidelines of CPCB titled "Guidelines on Water Quality Monitoring, 2017" and the performance audit report dated 18.09.2020 filed by CPCB in OA 95/2018, Aryavart Foundation v. M/s Vapi Green Enviro Ltd. & Ors. and the directions of the Tribunal dated 05.02.2021. Relevant direction is reproduced below:

"22. The directions on the subject are summed up as follows:

i to vi xxx.....xxx.....xxx

- vii. CPCB and State PCBs/PCCs, as directed earlier, may utilise EC funds on laboratory set up/upgradation, and on the mentioned areas in the report as well as on approved District Environment Plans. No approval of Central/State Government will be necessary in this regard in view of section 33 of the NGT Act, supra."

CPCB may file report on the above aspects before the next date of hearing by e-mail at judicial-ngt@gov.in preferably in the form of searchable PDF/ OCR Support PDF and not in the form of Image PDF."

4. The matter was last considered on 21.01.2022 in the light of reports mentioning the non-compliances by 97 industries, the CETP as well as the pharma units. The Tribunal noted the alarming situation of non-compliance and its adverse impact on public health and environment which called for immediate and regulatory action. Observations of the Tribunal are:

"6. The reports show alarming situation of serious non-compliance having continuous adverse impact on public health and environment. CETP is inefficient in its working and individual units are also non-compliant. This requires immediate effective regulatory action. Pharma units need to monitor API and take remedial steps. MoEF&CC needs to address such vital issue and assist the State to handle the situation in the interest of environment and public health.

7. Only explanation of the State is helplessness due to interim order of the High Court. Learned Counsel has stated that clarification is proposed to be sought in the matter from the High Court so that remedial action for protection of environment and public health is taken as violations are not only of prescribed inlet

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norms but also statutory provisions of the Water (Prevention and Control of Pollution) Act, 1974 and standards of water laid down under other relevant statutory provisions which are not covered by the stay order. We note that confusion pleaded is resulting in undesirable state of affairs, to the detriment of helpless public against the mandate of law which does not appear to have been properly brought to the notice of the High Court or any other higher forum. **We do not find any reason why the State PCB could not enforce law even against violators who are not covered by the interim order granted by the High Court, particularly the pharma units discharging more than 200 KLD.**

8. The State may accordingly take further corrective measures to enforce the law for protecting public health and the environment. **CPCB may circulate monitoring mechanism to the State PCBs on API, as directed earlier and file the action taken report before the next date. MoEF&CC may clarify the issue of API standards."**

Consideration of the matter in today's hearing and further orders

5. In pursuance of above, a note has been filed on behalf of the MoEF&CC on 04.04.2022. An action taken report dated 15.02.2022 has been filed by CPCB and the State PCB has filed its action taken report on 26.03.2022. We proceed to note the three reports and consider further course of action.

MoEF&CC stand about standards for API

6. The stand of the MoEF&CC is that the issue of standards for Active Pharmaceutical Ingredient (API) has been considered by the concerned Expert Committee of the MoEF&CC from time to time. In the 17th Expert Committee meeting held on 26.04.2019 and 18th meeting held on 9.8.2019 and 09.12.2020, standards were proposed for Bulk Drug and Formulation Industry. This led to draft Notification dated 23.01.2020 proposing standards for Bulk Drug and Formulation (Pharmaceutical) Industry, including Antibiotics residue parameters. This was followed by a meeting with stakeholders on 28.07.2020 and final Notification dated 06.08.2021. CPCB was to develop database and methodology for analysis

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of identified API and also the corresponding site specific PNEC values to enable a scientific rationale for deriving standards for such parameters. Methodologies have been developed and circulated but not finalized.

7. Draft Notification dated 23.01.2020 for effluent standards from Bulk Drug and Formulation (Pharmaceutical) is as follows:

Sl. No.	Industry	Parameters	Standard
1	2	3	4
73	Bulk Drug and Formulation (Pharmaceutical)	A. EFFLUENT STANDARDS	
		For final outlet of ETP	
		Limiting value for concentration (in mg/l except for pH)	
		i) Compulsory Parameters	
		pH	6.0 -8.5
		BOD (3 days 27°C)	30
		COD	250
		TSS	100
		TDS	2100
		Oil & Grease	10
		Bio - Assay Test**	90% Survival of Fish after first 96 hours in 100%
		ii) Additional Parameters	
		Ammonical Nitrogen	50
		Nitrate Nitrogen	10
		***Benzene	0.05
		***Toluene	0.05
		***Xylene	0.06
		***Methylene Chloride	0.9
		Phosphates as P	5
		Chlorides	1000
		Sulphates as SO ₄	1000
		Fluoride	2
		Sulphides as S	2
		Phenolic Compounds	1
		Total Residual Chlorine	1
		Zinc	5
		Iron	3
		Copper	3
		Total Chromium	2
		Hexavalent Chromium (Cr ⁶⁺)	0.1
		Cyanide	0.1
		Arsenic	0.2
		Mercury	0.01
		Lead	0.1
		****Active Pharmaceutical Ingredient (API)	0.05
		iii) for final outlet of Industries discharging to CETP	
		For each Common Effluent Treatment Plant(CETP), the state Board will prescribe inlet quality Standards for general parameters, Ammonical Nitrogen and Heavy Metals as per the design of the Common Effluent Treatment Plant(CETP) and local needs and conditions. As per notification S.O. 4 (E) dated 1 st January, 2016	

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Note:

ZLD = Zero Liquid Discharge system in *Bulk Drug and formulation* industry is considered when treated effluent meeting the limits prescribed for compulsory parameters shall be used in Process or Utilities (boiler/ Cooling tower etc.). The reuse of treated effluent in gardening/ horticulture shall not be considered as ZLD in Bulk Drug and formulation industries.

**** The Bio assay test** shall be conducted as per IS : 6582-1971

Parameters listed as "**Additional Parameters**" shall be prescribed depending upon the process and product.

***** Limits shall be applicable to industries those are using Benzene, Toluene, Xylene, Methylene Chloride, Chlorobenzene.**

******API limits** shall be applicable for units manufacturing API other than antibiotics.

B. EMISSION STANDARDS from Process Reactor Vents/ Tank farm Vents

Parameter	Limiting value for concentration (mg/Nm ³)
Chlorine	15
Hydrochloric acid vapour	35
Ammonia	30
Benzene	5
Toluene	100
Acetonitrile	1000
Dichloromethane	200
Xylene	100
Acetone	2000

C. The total losses of solvent should not be more than 3% of the solvent consumed.

D. Antibiotic Residues in the treated effluent of Bulk Drug and Formulation Industry and CETP with membership of Bulk Drug and formulation Units
Individual antibiotic residues will be equal to or less than the values given in the below table.

Parameter	Limiting value for concentration (µg/l)
i. Amikacin	6.40
ii. Amoxicillin	0.10
iii. Amphotericin B	0.01
iv. Ampicillin	0.10
v. Anidulafungin	0.01
vi. Avilamycin	3.20
vii. Azithromycin	0.01
viii. Aztreonam	0.20
ix. Bacitracin	3.20
x. Bedaquiline	0.03
xi. Benzylpenicillin	0.10
xii. Capreomycin	0.80
xiii. Cefaclor	0.20
xiv. Cefadroxil	0.80
xv. Cefalonium	8.40
xvi. Cefaloridine	1.60
xvii. Cefalothin	0.80
xviii. Cefazolin	0.40
xix. Cefdinir	0.10
xx. Cefepime	0.20
xxi. Cefixime	0.02
xxii. Cefoperazone	0.20
xxiii. Cefotaxime	0.04
xxiv. Cefoxitin	3.20
xxv. Cefpirome	0.02

xxvi.	Cefpodoxime	0.10
xxvii.	Cefquinome	0.64
xxviii.	Ceftaroline	0.02
xxix.	Ceftazidime	0.20
xxx.	Ceftibuten	0.10
xxxi.	Ceftiofur	0.02
xxxii.	Ceftobiprole	0.09
xxxiii.	Ceftolozane	0.76
xxxiv.	Ceftriaxone	0.01
xxxv.	Cefuroxime	0.20
xxxvi.	Cephalexin	0.03
xxxvii.	Chloramphenicol	3.20
xxxviii.	Ciprofloxacin	0.02
xxxix.	Clarithromycin	0.03
xl.	Clavulanic Acid	22.40
xli.	Clinafloxacin	0.20
xlii.	Clindamycin	0.04
xliii.	Cloxacillin	0.05
xliv.	Colistin	0.80
xlvi.	Daptomycin	0.40
xlvi.	Delamanid	0.02
xlvi.	Doripenem	0.04
xlvi.	Doxycycline	0.80
xlvi.	Enramycin	1.92
l.	Enrofloxacin	0.02
li.	Ertapenem	0.05
lii.	Erythromycin	0.20
liii.	Ethambutol	0.80
liv.	Faropenem	0.01
lv.	Fidaxomicin	0.01
lvi.	Florfenicol	0.80
lvii.	Fluconazole	0.10
lviii.	Flumequine	0.10
lix.	Fosfomycin	0.80
lx.	Fusidic acid	0.20
lxi.	Gatifloxacin	0.05
lxii.	Gemifloxacin	0.02
lxiii.	Gentamicin	0.08
lxiv.	Imipenem	0.05
lxv.	Isoniazid	0.05
lxvi.	Itraconazole	0.004
lxvii.	Kanamycin	0.44
lxviii.	Levofloxacin	0.10
lxix.	Lincomycin	0.72
lxx.	Linezolid	2.68
lxxi.	Loracarbef	0.80
lxxii.	Mecillinam	0.40
lxxiii.	Meropenem	0.02
lxxiv.	Metronidazole	0.05
lxxv.	Minocycline	0.40
lxxvi.	Moxifloxacin	0.05
lxxvii.	Mupirocin	0.10
lxxviii.	Nalidixic acid	6.40
lxxix.	Narasin	0.20
lxxx.	Neomycin	0.01
lxxxi.	Netilmicin	0.20
lxxxii.	Nitrofurantoin	25.60
lxxxiii.	Norfloxacin	0.20
lxxxiv.	Ofloxacin	0.20
lxxxv.	Oxacillin	0.40
lxxxvi.	Oxytetracycline	0.20
lxxxvii.	Pefloxacin	3.20
lxxxviii.	Phenoxyethylp enicillin	0.02
lxxxix.	Piperacillin	0.20
xc.	Polymixin	0.80

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xcv.	Retapamulin	0.02
xcvi.	Rifampicin	0.02
xcvii.	Roxithromycin	0.40
xcviii.	Secnidazole	0.40
xcix.	Sparfloxacin	0.02
c.	Spectinomycin	12.80
ci.	Spiramycin	0.20
cii.	Streptomycin	6.40
ciii.	Sulbactam	6.40
civ.	Sulfadiazine	288.00
cv.	Sulfadimethoxine	20.00
cvi.	Sulfadoxine	0.24
cvi.	Sulfamethoxazole	0.24
cvi.	Tazobactam	17.60
cvi.	Tedizolid	3.92
cvi.	Teicoplanin	0.20
cvi.	Telithromycin	0.02
cvi.	Tetracycline	0.40
cvi.	Thiamphenicol	0.40
cvi.	Tiamulin	0.40
cvi.	Ticarcillin	3.20
cvi.	Tigecycline	0.40
cvi.	Tildipirosin	0.17
cvi.	Tilmicosin	0.40
cvi.	Tobramycin	0.40
cvi.	Trimethoprim	0.20
cvi.	Trovaflaxacin	0.01
cvi.	Tylosin	0.33
cvi.	Vancomycin	3.20
cvi.	Viomycin	0.80
cvi.	Virginiamycin	0.80%.

8. Final Notification dated 06.08.2021 on the subject is as follows:

“2. In the Environment (Protection) Rules, 1986, in Schedule-I, for serial number 73 and the entries relating thereto, the following serial number and entries shall be substituted, namely:-

S. No.	Industry	Parameters	Standard
1	2	3	4
"73.	Bulk Drug and Formulation (Pharmaceutical)	A. EFFLUENT STANDARDS*	
			Limiting value for concentration (in mg/l except for pH and Bio assay)
		(i) Compulsory Parameters	
		pH	6.0 -8.5
		BOD (3 days 27°C)	30
		COD	250
		TSS	100
		Oil & Grease	10
		Ammonical Nitrogen	100

		Bio - Assay Test**	90% Survival of Fish after first 96 hours in 100% effluent
		***Benzene	0.1
		***Xylene	0.12
		***Methylene Chloride	0.9
		***Chlorobenzene	0.2
		Phosphates as P	5
		Sulphides as S	2
		Phenolic Compounds	1
		Zinc	5
		Copper	3
		Total Chromium	2
		Hexavalent Chromium (Cr ⁶⁺)	0.1
		Cyanide (as HCN)	0.1
		Arsenic	0.2
		Mercury	0.01
		Lead	0.1
		SAR	Less than 26 (applicable only for discharge on land)
		(iii) Industry connected with CETP - The discharge norms for industry connected with CETP and of CETP shall be governed by Ministry of Environment, Forest & Climate Change notification S.O. 4 (E), dated the 1st January, 2016. - State Pollution Control Board shall prescribe additional relevant parameters as given at para A (ii) of this notification as per needs and discharge potential of member industries and specify the frequency of monitoring considering the receiving environment conditions.	
		Note: The standards in para A is applicable to all discharges except to CETP. *Not applicable to industry discharging to CETP, and shall be applicable to all discharge to land and surface water bodies including use of treated wastewater for horticulture or irrigation purpose. ** The Bio assay test shall be conducted as per IS : 6582-1971 ## Parameters listed as "Additional Parameters" shall be prescribed by SPCB depending on the process and product and its monitoring frequency shall be monthly/quarterly as decided by SPCBs ***Limits shall be applicable to industries those are using Benzene, Xylene, Methylene Chloride, Chlorobenzene.	
		B. EMISSION STANDARDS (Tank farm Vents)	
		Parameter	Limiting value for concentration (mg/Nm³)
		Chlorine	15
		Hydrochloric acid vapor	35

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Ammonia	30
Benzene	5
Toluene	100
Acetonitrile	1000
Dichloromethane	200
Xylene	100
Acetone	2000
C. The total cumulative losses of solvent should not be more than 5% of the solvent on annual basis from storage inventory`	
D. Chemical and Biological sludge or any residue, reject, concentrate generated from wastewater treatment or its management facility at Industry or CETP catering to industries engaged in manufacturing of bulk drug or formulation of Pharmaceuticals, shall be classified as Hazardous Waste as per the provision of clause 17 of sub-rule (i) of rule 3 of the Hazardous and Other Wastes (Management and Trans-boundary Movement) Rules, 2016 and shall be subject to the provision made therein.	

CPCB Report

9. Report of the CPCB dated 15.02.2022 considers the problem of Antimicrobial resistance (AMR) on account of antibiotic residues discharged in waste water which requires compliance of norms by the manufacturers for which Limit of quantification (LOQ) adopted by the CPCB needs to be followed as per methodology suggested and circulated to State PCBs/PCCs. Recommendations in the report are as follows:

“Recommendations/Mitigation of AMR in the environment

40. *When a new class of antimicrobials comes on the market, it should be considered “critically important” from the outset unless strong evidence suggests otherwise. The risk assessment of new antimicrobial substances for use in food-producing species should be reinforced. One of the possible options would be to introduce an early hazard characterisation, addressing the risk to public health from antimicrobial resistance (AMR), to be assessed prior to the submission of a Marketing Authorization Application (MAA).*
41. *At the time of first approval for new antimicrobial substances/a new class of antimicrobials in veterinary medicine, marketing authorisation holders (MAHs) should have plans in place to monitor susceptibility in zoonotic and indicator bacteria through approved programmes; these data should be provided by the MAH to the regulatory*

authorities and be comparable with human AMR surveillance data.

42. Based on the outcome of antimicrobial resistance surveillance and monitoring of usage, a new risk assessment could be required for all products of a specific antimicrobial class, encompassing both generic and reference products.
43. Put in place a declaration system in order to assess the extent and evolution of off label use of human only authorised antimicrobials. Monitoring of off label use needs to be facilitated. When collecting data on consumption of off label use of antimicrobials in animals the animal species (body weight), product, indication, regimen (dose, duration, treatment interval, route of administration/formulation) are important to assess.
44. Include in future legislation flexible tools to allow banning or limitation of off label use in animals of certain antimicrobials/classes authorised only in human medicine following an unfavourable hazard characterization or benefit-risk assessment.
45. Existing drugs that are already classified as "critically important" antimicrobials but which are not currently used in food production such as carbapenems, oxazolidinones (linezolid) and lipopeptides (daptomycin) should not be used in the future in food animal production".
46. Recognising the need to preserve the effectiveness of the antimicrobial agents in human medicine, careful consideration should be given regarding their potential use (including extra-label/off label use)."

Reduce the input of antibiotics into environmental

47. Antimicrobials manufacturing industry should possess a valid authorization for discharge of treated effluent. Compliance with each condition in the authorization should be achieved.
48. Levels of antibiotic in process wastewater are quantified e.g. mass balance.
49. Wastewater sources from operations are characterized and evaluated for treatability and control.
50. Effective waste water treatment plant is equipped with primary, secondary and tertiary treatment (e.g., neutralization, clarification, settling, inactivation, biological or chemical treatment) which is efficacious to eliminate the residual Antibiotics. Industries may deploy the Antibiotic deactivation techniques like acidification, neutralization and others to degrade the active Antibiotics moiety.

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51. *The technology plays crucial part for conversion and recovery of product i.e. minimizing the product loss into mother liquor. The adoption of best practices during manufacturing process to arrest (minimize) the emission of antibiotics into water stream to reduce the influx into waste water treatment plant or environment.*
52. *The CETP, waste water treatment plant (WWTP) infrastructure, design and its effectiveness i.e. onsite, offsite and infrastructure & performance of treatment system before discharging to common effluent treatment plant, are to release the emission of residual antibiotics into environment.*
53. *Sludge from process wastewater treatment is managed in compliance with all local regulations. Assessments are conducted to determine potential risk from sludge application to land.*
54. *Setting up systems and best practice guidelines to correctly dispose of unused medicines.*
55. *Limiting the use of antimicrobials (especially critically important compounds).*
56. *Frequent sampling is important to understand the levels of API residue in the discharge.*
57. *Samples are collected, stored, and analysed with results reported in accordance with regulatory requirements.*
58. *Process areas (e.g., tanks, container storage areas, and process sewer systems) are designed, constructed and operated to prevent spills or releases antibiotic residue to the environment.*
59. *Treatment systems should be in placed to prevent soil, surface water, or groundwater contamination.*
60. *Waste classification, labelling, storage and disposal methods should be in accordance with the hazard characteristics of the waste, and in accordance with regulatory requirements. i) Waste containers are labelled with contents, hazard characteristics (e.g., flammable, biological), and closed once waste is placed in the container. ii) Disposal methods are based on waste characteristics. Records (e.g., waste classification determinations including analytical results, letters from waste contractors/facility, and certificates of destruction) are maintained.*
61. *Waste disposal contractors/facility should possess authorizations/certifications from SPCBs/PCCs to manage specific waste streams in accordance with regulations."*

10. The recommendation is preceded by discussion which to the extent relevant is reproduced below:

"Introduction

Antimicrobial resistance (AMR) is the ability of a microorganism to survive and multiply in the presence of a compound with antimicrobial properties that would normally inhibit or kill this microorganism. Several different mechanisms are involved in the development of resistance to antimicrobials. Antibiotic residues may find their way to the environment via any of the following three modes:

- i) Waste water discharge from pharmaceutical manufacturing: Although the treatment of wastewater can partly eliminate or remove pharmaceuticals, some traces are still detectable in effluents and surface/groundwater as well depending on the concentration of antibiotics at the inlet of effluent treatment process and efficiency of effluent treatment process. Process Control to minimize the release of antibiotic residues in the effluent for end of the pipe treatment is seen as a viable option.*
- ii) Human and Animal consumption and excretion: 30-90% of orally consumed dose of pharmaceutical consumed, are excreted as per reports available in the literature. Antibiotics used in aquacultures/poultry farms, animal husbandry etc are posing additional threat in this regard.*
- iii) Non-scientific disposal of expired and/or unused medicines.*

The presence of antibiotic residues in the environment cannot be attributed to a single source, direct release of antibiotic either accidental or due to lack of efficient effluent treatment technologies or process inefficiencies has made pharma industries as a starting point for addressing issue of antibiotic resistance. Besides above, other factors for antibiotic residues in effluents include:

- a) Direct emissions, if any, by pharma industries, although localized, are being considered as a source of discharge in much higher concentration when compared to other indirect sources.*
- b) Since the antibiotic residues which are released directly in the pharma effluents, are not consumed and hence not metabolized like other sources and hence reduction in concentration in that ratio may not be achievable. Further, in principle, any compound that is not readily degraded/metabolized, has the potential to reach adverse exposure concentration in environment.*
- c) It is unlikely that pharma industries will intentionally discharge their final product in the form of antibiotic residues. But at the same time, if discharged even accidentally or due to inefficient working of effluent treatment process, the concentration can always be several time more in comparison to other sources.*

In addition to their indirect discharge, antimicrobials are also used in aquaculture where they are generally used as in-feed preparations. Ultimately, antimicrobials can reach various external environmental

compartments such as rivers, lakes and soils where they can continue to exert their effects. Once in the environment, some antibiotics bind strongly to soil and sediments, which contributes to their persistence as they become inaccessible to degradation (these 'trapped' compounds can persist in soil for many years).

Resistance to antibiotics among human and veterinary pathogens increases the risks of treatment failure, increases mortality by increasing the time from an initial diagnosis to an effective therapy, and can also lead to morbidity by increasing the use of more toxic antibiotics as replacements for those rendered ineffective due to resistance. This issue also imposes an additional healthcare cost and productivity loss. Hence, it's a necessity to develop guidelines for sampling and monitoring of the Antimicrobials.

Common Antibiotic manufacturing framework should follow the rules as mentioned in the Antimicrobial Industry Alliance (AMR IA). It was found that antibiotics compounds are sold in India in the form of antibiotics either individually or different combinations of 126 antibiotics. The Predicted no-effect concentration (PNEC) data contains two values. PNEC- Environment (PNEC- ENV) values are based on eco-toxicology data generated by Alliance member companies. These values are intended to be protective of ecological species and incorporate assessment factors consistent with standard environmental risk methodologies. The PNEC- Minimum Inhibitory Concentration (PNEC-MIC) values are intended to be protective of resistance promotion. These PNEC values are updated periodically as new reliable and robust data become available. These PNEC values, in absence of national standards for antibiotic residue, may be used as reference limit for self-monitoring purpose to prevent release of high levels of antibiotic residues in the environment.

Limit of Quantification

Trace Organics Laboratory of Central Pollution Control Board, Delhi has validated method for 21 Pharmaceuticals compounds with Limit of quantifications (LOQ) as follows:

S. No.	Name of Antibiotic	Limit of Quantification (LOQ) (µg/L)
	Amoxicillin	0.08
	Cefixime	0.13
	Cefadroxile	0.12
(4)	Fluconazole	0.14
(5)	Levofloxacin	0.16
(6)	Ciprofloxacin	0.15
(7)	Metronidazole	0.12
(8)	Azithromycin	0.03
(9)	Doxycycline	0.03
(0)	Chloramphenicol	0.09

(1)	Norfloxacin	0.045
(2)	Ofloxacin	0.03
(3)	Ampicillin	0.045
(4)	Nalidixic Acid	0.045
(5)	Spiramycin	0.051
(6)	Roxithromycin	0.026
(7)	Lincomycin	0.028
(8)	Enrofloxacin	0.022
(9)	Cloxacillin	0.088
(10)	Diclofenac	0.14
(11)	Mefenamic Acid	0.14

Guidelines for Sampling:
Sample Collection and locations:

(1) The procedure for sample collection in respect of surface water shall be as under:

- a) Samples for Baseline and Trend stations shall be collected from well-mixed section of the river or main stem 30 cm below the water surface using a weighted bottle.
- b) Samples for Impact stations shall be collected 30 cm below the water surface from the point of interest, such as bathing Ghats, downstream of point discharges, water supply intakes and other sources.

(2) The procedure for sample collection in respect of reservoir water shall be as under:

- a) Reservoir water quality has temporal, spatial as well as depth variation. The water is generally not well-mixed and sampling from a single depth may inadequately represent the overall water quality. It is, therefore necessary to ensure that sampling stations are truly representative of the water body.
- b) It is necessary to conduct preliminary survey to determine whether and where differences in water quality occur before deciding on the number of stations to establish. The most important feature of water in reservoir is vertical stratification which results in water quality variation along the depth. The vertical stratification at a sampling station can be detected by taking a temperature reading at 1 m below the surface and another at 1 m above the bottom. If there is a significant difference (more than 3 °C) between the two readings, there is a "thermocline" (a layer where the temperature changes rapidly with depth) and the reservoir is stratified. In stratified reservoirs, more than one sample is necessary to describe water quality.

- c) For reservoirs of 10 m depth or more, it is essential that the position of the thermocline is first assessed by means of regularly-spaced temperature readings through the water column (e.g. metre intervals). Samples should then be taken according to the position and extent (in depth) of the thermocline. As a general guide, the minimum samples should consist of 1 m below the water surface, just above the determined depth of the thermocline, just below the determined depth of the thermocline, and 1 m above the bottom sediment (or closer if possible without disturbing the sediment). If the thermocline extends through several meters depth, additional samples are necessary from within the thermocline in order to characterise fully the water quality variations with depth.
- d) In general, if the water depth at the sampling site is less than 10 m, the minimum sampling programme should consist of a sample taken 1 m below the water surface and another sample taken at 1 m above the bottom sediment.
- e) Access to reservoir sampling stations is usually by boat and returning to precisely to the same locations for subsequent samples can be extremely difficult unless GPS is used or alternatively poles may be installed for the purpose.

(3) The procedure for sample collection in respect of ground water shall be as under:

- (a) Open dug wells, which are not in use or have been abandoned, shall not be considered as water quality monitoring station. However, such well could be considered for water level monitoring. The ground water quality monitoring agencies should close down the unused open dug wells if they are potential source of microbiological contaminations in the areas without affecting the water level monitoring programme by replacing the abandoned dug wells with piezometers.
- (b) Weighted sample bottle to collect sample from an open well about 30 cm below the surface of water may be used. The plastic bucket, which is likely to skim the surface layer only, shall not be used.
- (c) Samples from the production tube wells shall be collected after running the well for about five minutes.
- (d) Non-production piezometers shall be purged using a submersible pump. The purged water volume shall equal 4 to 5 times the standing water volume, before sample is collected.
- (e) For bacteriological samples, when collected from tube wells or hand pump, the spout or outlet of the pump shall be sterilized under flame by spirit lamp before collection of sample in container.

Sample preservation and transportation:

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- (1) Samples shall be transported (Cool to 0 - 6 °C) concerned laboratory as soon as possible, preferably within forty-eight hours of collection.
- (2) Analysis for coliforms shall be started within twenty-four hours of collection of sample. If time is exceeded, it should be recorded with the result.
- (3) Departments involved in monitoring should provide adequate training to the persons involved in water quality monitoring on collection and preservation techniques of water samples.
- (4) Departments involved should review the sample collection and analysis programme if it is not in conformity with Protocol norms. If it is not possible to adhere to transport time and analysis time due to large number of samples in one laboratory, the departments should outsource the analysis to nearby existing accredited laboratory.
- (5) Sample identification forms for the water sample analysis for surface and ground water samples shall be as per annexed Form-I and Form-II.

Quantity of samples to be collected:

The quantity of samples to be collected for analysis shall be as follows:

1. General analysis: 1 litre.
2. Bacteriological analysis: 1000 ml. in sterilized bottle.
3. Metal analysis: 250 to 500 ml.
4. Pesticide analysis: 1000 ml in amber color glass bottle with Teflon lid cap Collect samples in amber glass containers following conventional sampling practices.
5. Aqueous samples
 - 5.1 Samples that flow freely are collected as grab samples or in refrigerated bottles using automatic sampling equipment. Collect 1 L each for the acid and base fractions (2 L total). If high concentrations of the analytes of interest are expected, collect two smaller volumes (e.g., 100 mL each) in addition to the 1 L samples. Do not rinse the bottle with sample before collection.
 - 5.2 If residual chlorine is present, add 80 mg sodium thiosulfate per liter of water. Any method suitable for field use may be employed to test for residual chlorine.
 - 5.3 Maintain aqueous samples in the dark at < 6 °C from the time of collection until receipt at the laboratory. If the sample will be frozen, allow room for expansion.

Sample records:

- (1) Each laboratory shall have a bound register, which shall be used for registering samples as they are received. A format for sample receipt register is annexed as Form- III.
- (2) The Laboratory In-Charge shall maintain a register for assignment of works to specific analyst.

Analytical Techniques:

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Each agency shall follow the analytical techniques prescribed in the 'Standard Methods for analysis of Water and Wastewater' published by American Public Health Association (latest edition) or 'Methods for Testing Water and Wastewater-methods of sampling and testing (physical and chemical)' by Bureau of Indian Standards - IS:3025.

Manpower requirements in laboratories:

The manpower requirements shall be optimized by the concerned monitoring agencies in order to get the maximum utilization of man-days for timely completion of analysis.

Data Processing, Reporting and Dissemination:

Each monitoring agency shall process the analytical data and report the data after validation to the Data Centre at the Central Pollution Control Board (CPCB) or Central Water Commission (CWC). The CPCB or CWC shall store the data and disseminate through website or electronic mail to various users on demand. There should be free sharing of data among the various agencies collecting the water quality data.

Accreditation of laboratories:

The water quality laboratories shall seek recognition from the Ministry of Environment, Forests and Climate Change, Government of India and accreditation from National Accreditation Board for Testing and Calibration Laboratories (NABL) under Ministry of Science and Technology, Government of India. The water quality monitoring agencies/organizations should provide adequate financial support for strengthening of their laboratories with adequate manpower and their upgradation with advance instruments for the purpose of recognition / accreditation.

Sampling and Analysis:

1. Sampling of effluent shall be done from the inlet and outlet of the effluent treatment systems viz. Effluent Treatment Plant, Multiple Effect Evaporator, Agitated Thin Film Dryer, Reverse Osmosis etc. (wherever required) along with the point of final discharge of the treated effluent to assess effectiveness of effluent treatment.
2. Composite and 24H flow-proportional sampling may be better than single grab sampling as wastewater composition changes significantly over short time scales and individual samples may be "flooded" by homogenous solid material. Although, Grab sampling, which was the most commonly used method, is convenient and avoids significant auto sampler-associated workload and capital costs. However, sampling of influent and composite sampling optimise the chance of identifying human-wastewater AMR correlations and are most suitable for wastewater-based AMR surveillance studies.
3. Use and cleaning of sample Bottles and Caps: For Liquid Samples (waters, sludge and similar materials containing 5

percent solids or less): the sample bottle, amber glass, 1 L minimum, with screw cap must be used. For Solid samples (soil, sediment, sludge, filter cake, compost, and similar materials that contain more than 5 percent solids): Sample bottle, wide mouth, amber glass, 500-mL minimum must be used. If amber bottles are not available, samples must be protected from light, threaded Caps must be lined with fluoropolymer. Before use the bottles are washed with detergent and water, then rinsed with solvent. Similarly, Liners are washed with detergent and water and rinsed with reagent water before use.

4. The determination of pharmaceuticals and personal care products (PPCPs) in multi-media environmental samples must be done by **US EPA Method 1694** [(high performance liquid chromatography combined with tandem mass spectrometry (HPLC/MS/MS)]. This method was developed for use in Clean Water Act (CWA) programs and is based on existing EPA methods. This method is performance-based which means that it may be modified to improve performance (e.g., to overcome interferences or improve the accuracy or precision of the results) provided that all performance requirements of this method are met. The quality of the analysis is assured through reproducible calibration and testing of the extraction, clean-up, and LC/MS/MS systems.
5. For good quality of analysis proper cleaning of glassware is extremely important, because glassware may not only contaminate the samples but may also remove the analytes of interest by adsorption on the glass surface. Hence, before use Glassware should be rinsed with solvent and washed with a detergent solution. After detergent washing, glassware should be rinsed immediately, first with methanol, then with hot tap water. The tap water rinse is followed by another methanol rinse, then acetone, and then methylene chloride.
6. Safety measures taken during analysis: The toxicity or carcinogenicity of each chemical used in analysis method has not been precisely determined; however, each compound should be treated as a potential health hazard. Pure standards of the compounds should be handled only by highly trained personnel thoroughly familiar with handling and cautionary procedures and the associated risks. The laboratory is responsible for maintaining a current awareness file of OSHA regulations regarding the safe handling of the chemicals.
7. A reference file of material safety data sheets (MSDSs) should also be made available to all personnel involved in these analyses.
8. It is also suggested that the laboratory perform personal hygiene monitoring of each analyst who perform the analysis.
9. The analyst and all personnel involved in these analyses must wear Protective equipment viz. Disposable plastic gloves (Latex or non-Latex (such as nitrile)), apron or lab coat, safety glasses or mask, and a glove box or fume hood should be used. During analytical operations that may give

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rise to aerosols or dusts, personnel should wear respirators equipped with activated carbon filters. Eye protection (preferably full face shields) should be worn while working with exposed samples or pure analytical standards. Latex or non-Latex (such as nitrile) gloves are commonly used to reduce exposure of the hands.

10. Workers must be trained in the proper method of removing contaminated gloves and clothing without contacting the exterior surfaces.
11. Personal hygiene of all personnel involved in these analyses: Hands and forearms should be washed thoroughly after each operation involving high concentrations of the analytes of interest, and before breaks (coffee, lunch, and shift).
12. Waste handling or techniques for minimizing contaminated waste: Plastic bag liners should be used in waste cans. Janitors (a caretaker or doorkeeper of a building) and other personnel should be trained in the safe handling of waste.
13. Bio solids samples may contain high concentrations of biohazards, and must be handled with gloves and opened in a hood or biological safety cabinet to prevent exposure. Laboratory staff should know and observe the safety procedures required in a microbiology laboratory that handles pathogenic organisms when handling bio solids samples.
14. Sample collection from field: Liquid samples that flow freely are collected as grab samples or in refrigerated bottles using automatic sampling equipment. If residual chlorine is present in the sample, add 80 mg sodium thiosulfate per liter of water.
15. Solid, mixed-phase, and semi-solid samples, including bio solids: Collect samples as grab samples using wide-mouth jars. Collect a sufficient amount of wet material to produce a minimum of 10 g of solids. If the sample will not be extracted within 48 hours of collection, the laboratory should adjust the pH of aqueous samples to 5.0 to 9.0 with a sodium hydroxide or sulfuric acid solution. Record the volume of acid or base used. If extraction of samples within 48 hours is not practical, then samples should be frozen to increase the holding time to seven days. If aqueous samples are stored frozen, extraction should begin within 48 hours of removal from the freezer.

Requirements for The Analysis of Antibiotics

S. No.	Requirements	Quantity	Size	Remarks
Requirement of Space				
01	Room with AC and Exhaust	04	• ≈ 625.0 Square Feet (Instrument Room) • ≈ 400.0 Square Feet (Process Room) • ≈ 400.0 Square Feet (Sample Storage Room) • ≈ 400.0 Square Feet (Chemical and CRM Storage Room)	
Requirement of Instruments and Equipment				

02	LC-MS/MS (Tandem Mass)	01		For Qualitative & Quantitative Analysis
03	Solid Phase Extraction System	01	12 or 24 port	For Extraction & Cleanup
04	Ultra Sonicator	01		For sonication of mobile phase and cleaning of HPLC parts
05	MiniVap or Turbovap Concentrator	01	06-10 port	For Concentration
06	Rotatory Evaporator	01		For Concentration
07	Millipore Filtration Assembly	01		For Filtration of sample And Mobile phase
08	MQ Water Assembly	01		For MQ Water
09	Deep Freezer	01		CRM Storage
10	Vici cooler	01		Sample Storage
11	UPS 20KVA	01	20 KVA	Only for LC-MS/MS
12	UPS 10KVA	01	120 KVA	For others equipment
Miscellaneous Requirement				
Chemicals and Glassware/100 Sample (Approx.)				
13	Methanol	1.5L		LC-MS/MS Grade
14	Acetonitrile	1.5L		LC-MS/MS Grade
15	HPLC Water	3.0L		LC-MS/MS Grade
16	Formic Acid	5.0ml		LC-MS/MS Grade
17	Ammonium Acetate	5.0gm		LC-MS/MS Grade
18	Ammonia Liquid	5.0ml		LC-MS/MS Grade
19	Orthophosphoric Acid	100.0ml		AR-Grade
20	Sulphuric Acid	20.0ml		AR-Grade
21	pH paper	150 strip		
22	Filter Paper GF/A	200	0.45µm / 47mm	
23	Filter Paper GF/A	10	0.25 µm / 47mm	
24	Syringe Filter	100	0.25 µm nylon	
25	HLB Cartridge	100	60 mg / 20cc	
26	Micropipette	01	100-1000µl (Variable)	
27	Micropipette	01	10µl (Fixed)	
28	Micropipette	01	25µl (Fixed)	

29	Micropipette	01	50µl (Fixed)	
30	Micropipette tip		As per requirements	
31	Sample Storage Vial	100		
32	Reference Standards for Antibiotics		As per requirements	
(1) Others				
33	Argon Gas Cylinder with Regulator	01	Approx. one cylinder for 500 sample	For LC-MS/MS
34	Nitrogen Gas Cylinder with regulator	01	Approx. one cylinder (47L) for 06 sample	For Sample Preparation
Requirement of Manpower				
35	Manpower	01		1.For Instrument operation, calibration & Analysis.
36	Manpower	02		2.For Sampling, processing including extraction, clean up, & sample preparation.

16.

- I) *Pollution Prevention: comprises techniques that reduces or eliminates the quantity or toxicity of waste at the point of generation. Many opportunities for pollution prevention exist in laboratory operation. EPA has established a preferred hierarchy of environmental management techniques that places pollution prevention as the management option of first choice. Whenever feasible, laboratory personnel should use pollution prevention techniques to address waste generation. When wastes cannot be reduced at the source, the Agency recommends recycling as the next best option.*
- II) *Waste Management: Samples at pH<2, or pH >12 are hazardous and must be neutralized before being poured down a drain, or must be handled as hazardous waste.*
- III) *Low-level waste such as absorbent paper, tissues, animal remains, and plastic gloves may be burned in an appropriate incinerator. Gross quantities (milligrams) should be packaged securely and disposed of through commercial or governmental channels that are capable of handling toxic wastes.*

Duties of SPCBs/PCCs and frequency of monitoring

17. *The State Pollution Control Boards (SPCBs) and Pollution Control Committees (PCCs) shall conduct regular monitoring of every Technical grade pharmaceutical/ Bulk drug manufacturing /Formulation unit (hereinafter referred as pharma unit) under their jurisdiction. The monitoring of USP grade/ Laboratory grade pharmaceutical manufacturing units*

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shall be conducted at least on half yearly basis and the inspection of Formulation units shall be conducted at least on annual basis.

18. The inspections/monitoring shall be conducted as surprise inspections. Any prior information pertaining to inspection shall not be provided to the industrial units that are to be inspected.
19. On the basis of violations / shortcomings as observed during the inspection/monitoring, the action on the defaulter unit may be taken independently by SPCBs / PCCs as applicable, under the provisions of the extant laws.
20. The inspections shall involve monitoring of treated / discharged effluent w.r.t prescribed parameters including pharmaceutical parameters. The inspections have to be conducted irrespective of mode of treated effluent discharge by the pharmaceutical unit.
21. It shall essentially be verified during inspection whether the pharmaceutical unit (under inspection) is discharging treated /untreated effluent or disposing hazardous wastes in unauthorized manner. In case any unauthorized discharge of effluent/unauthorized disposal of Hazardous Waste is observed, action on the defaulter pharmaceutical unit under extant laws shall immediately be taken.
22. In case, the pharmaceutical unit (under inspection) claims Zero Liquid Discharge (ZLD) compliance, an assessment of feasibility of ZLD compliance shall be made thorough effluent monitoring and mass balance of effluent and it shall be ascertained that the unit does not practise effluent bypassing or discharge of effluent by any other means. ZLD may be defined as 'The entire quantity of effluent is treated to recover water and recovered water is reused in process and / or utilities, and only solids are discharged (or reused, if possible) in environmentally sound manner. Reuse of treated effluent for horticulture or agriculture purposes will be considered as discharge on land and not as means to achieve ZLD. Similarly, effluent from individual industries being sent to CETP for treatment will not be considered as ZLD.'
23. Excessive concentrations of Pharmaceutical ingredients may be toxic to living being. Hence, it shall essentially be verified during monitoring about any possibility of environmental pollution that may be caused by the pharmaceutical industry (under inspection) owing to mixing of the industrial effluent/any process effluent or leachate from the process / storage area containing minute concentration of Pharmaceutical ingredients with rain water / storm water.
24. In case, the pharmaceutical unit discharges its treated effluent to the inland surface water, river, stream or drain, the monitoring of the water body shall be conducted along with the monitoring of treated effluent. In case of discharge to rivers, streams, drains etc. upstream and downstream monitoring shall be conducted along with the monitoring of treated effluent.

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The monitoring of water body shall be done for prescribed parameters including pharmaceuticals and heavy metals.

25. Monitoring of the water body (to which the treated effluent is discharged) shall also be conducted w.r.t. pharmaceutical parameters. For the purpose of baseline concentration for reference / comparison, water samples from another location(s) as per discretion of the monitoring officials shall also be taken so that it may be ascertained whether the pharmaceutical unit (under inspection) is causing any water pollution.
26. Half yearly monitoring of water bodies, if any within the 500 m radius of pharmaceutical units shall be conducted to assess any pharmaceutical contamination/Anti-Microbial Resistance due to continuous discharge of industrial effluent with minor concentration of pharmaceutical ingredients in the water body. If it is observed that the monitored water body (within the 500 m radius of pharmaceutical units) is polluted with pharmaceutical ingredient (s), then further monitoring of water bodies situated beyond 500 m shall be done to assess the extent of pollution. For the purpose of baseline concentration for reference / comparison, fresh water samples from other locations as per discretion of the monitoring officials may be taken.
27. In case, the pharmaceutical unit uses its treated effluent in irrigation / gardening; groundwater monitoring w.r.t. pharmaceutical parameters shall be conducted by SPCBs / PCCs along with the monitoring of treated effluent. For the purpose of baseline concentration for reference / comparison, groundwater samples from another location(s) as per discretion of the monitoring officials shall also be taken so that it may be ascertained whether the pharmaceutical unit (under inspection) is causing any groundwater pollution.
28. In every case, irrespective of mode of discharge of the treated effluent, the inspections shall also involve ground water monitoring w.r.t. pharmaceutical parameters around 500 m of the pharmaceutical unit. If it is observed that the groundwater (within the 500 m radius of pharmaceutical units) is polluted with pharmaceuticals, then further monitoring of groundwater beyond 500 m shall be done to assess the extent of pollution. For the purpose of baseline concentration for reference / comparison, ground water samples from another location(s) as per discretion of the monitoring officials shall also be collected so that it may be ascertained whether the pharmaceutical unit (under inspection) is responsible for ground water pollution (if any).
29. In every case, irrespective of mode of discharge of the treated effluent, the inspections shall also involve water monitoring w.r.t. pharmaceutical parameters around 500m of the pharmaceutical unit. If it is observed that the water (within the 500 m radius of pharmaceutical units) is polluted with pharmaceutical, then further monitoring of soil beyond 500 m shall be done to assess the extent of pollution. For the purpose of baseline concentration for reference/ comparison, water samples from another location(s) as per discretion of the

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monitoring officials shall also be taken so that it may be ascertained whether the pharmaceutical unit (under inspection) is causing any water pollution.

30. In case the pharmaceutical industry is situated within a notified industrial cluster, the monitoring officials may at their discretion decide the distance from where water, and ground water have to be taken for the purpose of baseline concentration for reference / comparison.
31. SPCBs and PCCs shall conduct effluent monitoring of Common Effluent Treatment Plants and Sewage Treatment Plants under their jurisdiction w.r.t. pharmaceutical parameters. The treated effluent from Common Effluent Treatment Plants and Sewage Treatment Plants shall not contain any pharmaceutical ingredients so that to resist from Anti-microbial resistance in environment. The monitoring has to be done regularly at least on half yearly basis.
32. SPCBs and PCCs shall conduct regular inspections of Hazardous Waste Disposal / Treatment facilities as well as Municipal Waste dumping sites within their jurisdiction. The inspections have to be done at least on half yearly basis. The monitoring shall involve ground water as well as soil sampling around 500m of Hazardous waste disposal facility and Municipal Waste dumping sites w.r.t. pharmaceutical parameters. If it is observed that the groundwater and / or soil (within the 500 m radius of pharmaceutical/Bulk drug manufacturing units) is polluted with pharmaceutical ingredients (s), then further monitoring of groundwater and / or soil beyond 500 m shall be done to assess the extent of pollution. For the purpose of baseline concentration for reference and comparison, ground water samples and soil samples from another location(s) as per discretion of the monitoring officials shall be taken.
33. In case, SPCBs / PCCs observe that any Pharmaceutical/Bulk drug Manufacturing Industry, Common Effluent Treatment Plant, Sewage Treatment Plant, Municipal Waste dumping site or Hazardous Waste Disposal/Treatment facility has caused grave injury to the environment because of discharge of effluent / leachate contaminated with pharmaceutical ingredients or improper disposal of hazardous / other wastes containing pharmaceutical ingredients, action on the defaulter under extant laws shall immediately be taken.
34. The decision whether the pollution of environment and development of anti-microbial resistant in the water bodies has been caused by the pharmaceutical industries or bulk drug manufacturing units run off or by Common Effluent Treatment Plant, Sewage Treatment Plant, Municipal Waste dumping site or Hazardous Waste Disposal/Treatment shall be taken based upon the observed facts, evidences and scientific rationale.
35. SPCBs / PCCs may direct the pharmaceutical industries in their jurisdiction to recycle and reuse the treated effluent to the maximum possible extent.

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36. SPCBs / PCCs shall ensure that no pharmaceutical unit shall manufacture or formulate the pharmaceutical products other than the consented products.
 37. SPCBs / PCCs jointly with CPCB shall carry out monitoring of water bodies during pre and post monsoon seasons so as to assess the impact of the Anti-microbial resistance/pharmaceutical run off into the water bodies because of industrial discharge.
 38. For conducting the above stated inspections / monitoring; SPCBs, PCCs at their discretion may engage any Government organization or Government approved organization having adequate expertise in monitoring of Anti-microbial resistance in water bodies.
 39. The analysis of effluent / ground water / soil samples for the pharmaceutical parameters and other than pharmaceuticals parameters shall be carried out in the laboratories of SPCBs / PCCs or in the laboratories recognised by Ministry of Environment, Forests and Climate Change and accredited by National Accreditation Board for Testing and Calibration Laboratories (NABL)."
11. The said guidelines have been circulated by CPCB to all the State PCBs/PCCs vide letter dated 31.01.2022.

Action taken report of the State PCB

12. The State PCB in its action taken report filed on 26.03.2022 has stated that the Notification dated 06.08.2021 issued by the MoEF&CC does not cover antibiotic residue standards. Regulatory action has also been taken against CETP against which proceedings are pending in the High Court. Monitoring has been intensified.

Surviving issue for resolution, Finding and directions

13. Thus, the question which survives for consideration by this Tribunal is the remedial action against discharge of toxic pollution from the antibiotic residue by the pharmaceutical units, apart from other pollution.

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OA 801/2018

14. As regards pollution other than that generated by the pharma units, we reiterate our earlier direction of taking remedial action as per law by closure of polluting units till compliance and fixing accountability for past violations, following due process. OA 801/2018 will stand disposed of accordingly with liberty to the aggrieved party to take remedy in accordance with law, if any grievance survives.

OA 136/2020

15. As regards the issue of pharma industries, we have noted the draft Notification dated 23.01.2020 as well as final Notification dated 06.08.2021 and also the stand of the parties that the standards proposed in the draft notification have yet to be finalized, except and to the extent of those mentioned in the Notification dated 06.08.2021. Draft standards were formulated and notified on 23.1.2020 i.e. more than two years ago, based on study by the experts. Regulatory mechanism is such important issues cannot remain in abeyance for indefinite period on the ground that the MoEF&CC is unable to finalise the draft standards even after two years. In view of serious consequences of unregulated discharge of API residue to the detriment of environment and public health, we consider it appropriate to direct under Section 15(1) of the NGT Act that pending finalisation by the MoEF&CC, standards proposed in the draft Notification dated 23.01.2020, which are based on expert studies, be strictly followed by all concerned. It is also necessary to abide by the guidelines of CPCB circulated on 31.1.2022, quoted above in the matter of standards and methodology on the subject. The State PCB may take further action accordingly to prevent and remedy the situation of unregulated discharge of harmful pollutants of pharma industries in the rivers.

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16. CPCB may coordinate with the State PCBs to strengthen monitoring of API and assess Predicted No-Effect Concentration (PNEC) values. ETPs and CETPs may be upgraded to control the discharge of active ingredient. Ambient monitoring of recipient aquatic resources like rivers, lakes, ground water and other environmental entities be monitored, if necessary, with the assistance of institutions of repute. CPCB and PCBs may intensify monitoring of micro pollutants by regular vigilance.

OA 136/2020 will stand disposed of accordingly, with liberty to the aggrieved parties to take remedies against any surviving grievance as per law.

Adarsh Kumar Goel, CP

Sudhir Agarwal, JM

Arun Kumar Tyagi, JM

Prof. A. Senthil Vel, EM

Dr. Vijay Kulkarni, EM

Dr. Afroz Ahmad, EM

April 06, 2022
Original Application No. 801/2018
Original Application No. 136/2020
DV

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Item No. 01

(Court No. 1)

**BEFORE THE NATIONAL GREEN TRIBUNAL
PRINCIPAL BENCH, NEW DELHI**

(By Video Conferencing)

Review Application No. 14/2022
In
Original Application No. 136/2020

Veterans Forum for Transparency in Public Life

Applicant

Versus

State of Himachal Pradesh & Ors.

Respondent(s)

MoEF&CC

Review Applicant

Date of hearing: 24.05.2022

CORAM: HON'BLE MR. JUSTICE ADARSH KUMAR GOEL, CHAIRPERSON
HON'BLE MR. JUSTICE SUDHIR AGARWAL, JUDICIAL MEMBER
HON'BLE MR. JUSTICE ARUN KUMAR TYAGI, JUDICIAL MEMBER
HON'BLE PROF. A. SENTHIL VEL, EXPERT MEMBER
HON'BLE DR. VIJAY KULKARNI, EXPERT MEMBER
HON'BLE DR. AFROZ AHMAD, EXPERT MEMBER

IN CHAMBER BY CIRCULATION

ORDER

1. This application has been filed by the MoEF&CC for review of order of this Tribunal dated 06.04.2022 in O.A. No. 136/2020, *Veterans Forum for Transparency in Public Life v. State of Himachal Pradesh & Ors.* Thereby, the Tribunal dealt with the grievance of damage to the environment due to discharge of API residues by pharma companies. Reason for not preventing such damage according to the State PCB was that proposed standards had not been finalised. The Tribunal directed

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that proposed standards be acted upon in the interest of environment.

Direction of the Tribunal inter-alia is as follows:-

"1 to 14....xxx.....xxx.....xxx"

15. As regards the issue of pharma industries, we have noted the draft Notification dated 23.01.2020 as well as final Notification dated 06.08.2021 and also the stand of the parties that the standards proposed in the draft notification have yet to be finalized, except and to the extent of those mentioned in the Notification dated 06.08.2021. Draft standards were formulated and notified on 23.1.2020 i.e. more than two years ago, based on study by the experts. Regulatory mechanism is such important issues cannot remain in abeyance for indefinite period on the ground that the MoEF&CC is unable to finalise the draft standards even after two years. In view of serious consequences of unregulated discharge of API residue to the detriment of environment and public health, we consider it appropriate to direct under Section 15(1) of the NGT Act that pending finalisation by the MoEF&CC, standards proposed in the draft Notification dated 23.01.2020, which are based on expert studies, be strictly followed by all concerned. It is also necessary to abide by the guidelines of CPCB circulated on 31.1.2022, quoted above in the matter of standards and methodology on the subject. The State PCB may take further action accordingly to prevent and remedy the situation of unregulated discharge of harmful pollutants of pharma industries in the rivers.

16. CPCB may coordinate with the State PCBs to strengthen monitoring of API and assess Predicted No-Effect Concentration (PNEC) values. ETPs and CETPs may be upgraded to control the discharge of active ingredient. Ambient monitoring of recipient aquatic resources like rivers, lakes, ground water and other environmental entities be monitored, if necessary, with the assistance of institutions of repute. CPCB and PCBs may intensify monitoring of micro pollutants by regular vigilance."

2. The above order was found necessary to address the grievance of discharge of toxic waste by the pharmaceutical industries which could not be treated by CETP and, thus, posed serious damage to the environment and public health. The MoEF&CC proposed standards but did not mention anything about them in the final Notification. The Tribunal accordingly directed under Section 15(1) of the National Green Tribunal Act, 2010 that standards laid down in the draft Notification be followed, which was necessary for protection of the environment.

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3. In the review application stand of the MoEF&CC is that since the standards in the draft Notification have not been included in the final Notification, order of this Tribunal is not called for. We do not find any merit in the review application. The issue in question was duly considered and rehearing cannot be allowed in the guise of a review application. Jurisdiction of this Tribunal is not dependent on MoEF&CC's decision alone. To enforce sustainable development under section 20 of the NGT Act, direction under section 15 can be issued even beyond the decision of the MoEF&CC, as held inter alia in Mantri Techzone, (2019) 18 SCC 494, prs 41-42.

The application is dismissed.

Adarsh Kumar Goel, CP

Sudhir Agarwal, JM

Arun Kumar Tyagi, JM

Prof. A. Senthil Vel, EM

Dr. Vijay Kulkarni, EM

Dr. Afroz Ahmad, EM

May 24, 2022
R.A. No. 14/2022 in O.A. No. 136/2020
A

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IN THE SUPREME COURT OF INDIA
CIVIL APPELLATE JURISDICTION
 [UNDER SECTION 22 OF THE NATIONAL GREEN TRIBUNAL ACT 2010]
CIVIL APPEAL NO _____ OF 2022

(Arising out of final impugned orders dated 06.04.2022 in O.A. No. 136 of 2020 and order dated 24.05.2022 in Review Application No. 14 of 2022 in O.A. No. 136 of 2020 passed by the Hon'ble National Green Tribunal, New Delhi)

IN THE MATTER OF:-

Union of India ...Appellant

-Versus-

Veterans Forum for Transparency in Public
 Lifethrough its General Secretary&Ors. ...Respondents

(WITH PRAYER FOR INTERIM RELIEF)

POSITION OF PARTIES

	Before the National Green Tribunal	Before this Hon'ble Court
1. Union of India Through Secretary Ministry of Environment, Forest and Climate Change through Director (MoEF & CC), Indira Paryavaran Bhawan, Jor Bagh, New Delhi - 110003	Respondent/ Review Applicant	Appellant

VERSUS

1. Veterans Forum for	Original	Contesting

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Transparency in Public
Life, B – 124, Swarn
Nagri, Greater Noida,
DIST – G.B. Nagar (U.P) –
201306.

Through its General
Secretary, Wing
Commander (Retd.)
Dr. Bishwanath Prasad
Singh, Email:
2bnpsingh@gmail.com.
Mob: 9999383602

Applicant/Review Respondent
w Respondent t No. 1
No. 1

2. State of Himachal Pradesh, Office at:
Government Secretariat,
Shimla, Himachal Pradesh
– 171002.
Through its Chief
Secretary
0177-2621022

Respondent No. Contesting
1 Respondent
t No. 2

3. Himachal Pradesh
Pollution Control Board,
HIM PARIVESH, Phase –
III, New Shimla, Himachal
Pradesh – 171009.
Through its Member
Secretary. Email: [mspcb-
hp@nic.in](mailto:mspcb-hp@nic.in), 0177 2673766

Respondent No. Contesting
2 Respondent
t No. 3

4. State Drug Controller, Respondent No. Contesting
Government of Himachal, 3 Respondent
t No. 4

Dist - Solan, Baddi,
Himachal Pradesh -
173205
94183-26111
sdc4hp@gmail.com

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5. ACME Life Sciences, Nalagarh, Dist-Solan, Himachal Pradesh-173205 info@acmeformulation.co m, 01795-228501-03 Through its Managing Director/Director/CS	Respondent No. 5	Contesting Responden t No. 5
6. Helios Pharmaceuticals, Vill-Malpurp.O-Bhud, Dist-Solan, Himachal Pradesh-173205 ho@heliospharma.com. 079 -4023 2000 through its Managing Director/Director/CS Central Pollution Control	Respondent No. 6	Contesting Responden t No. 6
7. Board Prarivesh Bhawan, East Vinod Nagar, Delhi-110032 Through its Chairman	Respondent No. 4	Performa Responden tNo. 7

TO

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THE HONOURABLE CHIEF JUSTICE OF INDIA AND OTHER
HONOURABLE JUDGES OF THE HON'BLE SUPREME COURT
OF INDIA;

THE HUMBLE APPEAL OF THE
APPELLANT ABOVENAMED

MOST RESPECTFULLY SHOWETH:

1. The instant Appeal under section 22 of the National Green Tribunal Act, 2010 ('the NGT Act') arises against two orders i.e., the Order dated 06.04.2022 passed in O.A. No. 136 of 2020 and O.A. No. 801 of 2018 whereby the Hon'ble National Green Tribunal ('the Hon'ble Tribunal') has disposed of the said Original Applications *inter alia* directing under Section 15 (1) of the National Green Tribunal Act, that till pending finalization of the draft notification by the Ministry of Environment, Forest and Climate Change ("MoEF & CC"), standards proposed in the draft notification dated 23.01.2020 which are based on expert studies, be strictly followed by all concerned. The instant Appeal also lies against the Order dated 24.05.2022 in Review Application No. 14 of 2022 in O.A. No. 136 of 2020, passed by the Hon'ble Tribunal wherein

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the Hon'ble Tribunal dismissed the Review Application of the Appellant Ministry with the direction that the stand of Appellant Ministry that the order of the Hon'ble Tribunal is uncalled for since the standards in the Draft Notification dated 23.01.2020 have not been included in the final Notification and the issue in question was duly considered.

2. That the appellant states that no other appeal seeking leave to appeal has been filed by them against the orders dated 06.04.2012 in O.A. No. 136 of 2020 and O.A. No. 801 of 2018 and order dated 24.05.2022 in Review Application No. 14 of 2022 in O.A. No. 136 of 2020 passed by the Hon'ble National Green Tribunal.
3. That the main issue involved in the instant appeal is that notification dated 06.08.2021 finalized by the appellant upon following due process of law and on the constructive deliberations of various expert committees formed by the appellant as well as upon hearing all the stake holders. However, the impugned orders grossly over looked all

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those facts and passed the impugned orders on completely wrong premises.

4. The main question of law which germane from the present appeal are as follows:

- i. Whether the Hon'ble Tribunal has not committed wrong while exercising its jurisdiction under Section 15(1) of the National Green Tribunal Act, 2010 while negating the Appellant Ministry's notification dated 6th August, 2021 which was formulated by following all due process of law in exercise of powers under Section 6 and Section 25 of the Environment Protection Act, 1986 read with sub – rule (3), Rule 5 of the Environment Protection Rules, 1986?
- ii. Whether the Hon'ble Tribunal while passing the impugned orders has erred by not considering the mammoth consultations carried out by the appellant through various expert committees of appellant and other stake holders while deciding the desirable standard parameters to

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measure Active Pharmaceutical Ingredient (API) and acceptable norms regarding antibiotics residues value which all resulted in bringing the notification vide GSR 541(E) dated 06.08.2021?

iii. Whether the Notification dated 06.08.2021 notified in the Official Gazette vide GSR 541(E) under Environment (Pollution) Rules has not been duly notified after following the due process of bringing in a draft notification in the public domain for seeking suggestions/objections for statutory 60 days time period for laying the standards for Bulk Drug and Formulation (Pharmaceutical) Industry including Antibiotics residue parameters, where draft notification GSR 44(E) dated 23.01.2020 was already in public domain?

iv. Whether the Hon'ble Tribunal's orders are not contrary to law laid down in various cases by Hon'ble Court such as:

(a) "Federation of Railway Officers Association & Ors. Vs. Union of India" reported in (2003) 4 SCC 289, wherein it has been held:

"...12. In examining a question of this nature where a policy is evolved by the Government judicial review thereof is limited. When policy according to which or the purpose for which discretion is to be exercised is clearly expressed in the statute, it cannot be said to be an unrestricted discretion. On matters affecting policy and requiring technical expertise the Court would leave the matter for decision of those who are qualified to address the issues. Unless the policy or action is inconsistent with the Constitution and the laws or arbitrary or irrational or abuse of power, the Court will not interfere with such matters..."?

(b) Directorate of Film Festivals & Ors. Vs. Gaurav Ashwin Jain & Ors., reported in (2007) 4 SCC 737, wherein it has been held:

"....16. The scope of judicial review of governmental policy is now well defined. Courts do not and cannot act as Appellate Authorities examining the correctness, suitability and appropriateness of a policy nor are courts. Advisors to

the executive on matters of policy, which the executive is entitled to formulate.

The scope of judicial review when examining a policy of the government is to check whether it violates the fundamental rights of the citizens or is opposed to the provisions of the Constitution, or opposed to any statutory provision or manifestly arbitrary. Courts cannot interfere with policy either on the ground that it is erroneous or on the ground that a better, fairer or wiser alternative is available. Legality of the policy, and not the wisdom or soundness of the policy, is the subject of judicial review.

It is settled law that the Court would not ordinarily interfere with the policy decision of the executive unless the same can be faulted on the grounds of malafides, unreasonableness, arbitrariness or unfairness, in which case the policy would render itself to be declared unconstitutional...."?

(c) "Balco Employees Union (Regd.) Vs Union of India & Ors; reported in (2002) 2 SCC 333, wherein it has been held:

".....In a democracy, it is the prerogative of each elected Government to follow its own policy. Often a change in Government may result in the shift in focus or change in economic policies. Any such change may result in adversely affecting some vested interests. Unless any illegality is committed in the execution of the policy or the same is contrary to law or mala fide, a decision bringing about change cannot per se be interfered with by the Court.

98. In the case of a policy decision on economic matters, the Courts should be very circumspect in conducting any enquiry or investigation and must be most reluctant to impugn the judgment of the experts who may have arrived at a conclusion unless the Court is satisfied that there is illegality in the decision itself...."?

(d) "Parisons Agrotech Private Limited & Anr Vs Union of India & Ors; reported in (2015) 9 SCC 657, wherein this Hon'ble Court has held:

"....14. No doubt, the Writ Court has adequate power of judicial review in respect of such decisions. However, once it is found that there is sufficient material for taking

a particular policy decision, bringing it within the four corners of Article 14 of the Constitution of India, power of Judicial Review would not extend to determine the correctness of such a policy decision or to indulge into the exercise of finding out whether there could be more appropriate or better alternatives.

Once we find that parameters of Article 14 are satisfied; there was due application of mind in arriving at the decision which is backed by cogent material; the decision is not arbitrary or irrational and; it is taken in public interest, the Court has to respect such a decision of the Executive as the policy making is the domain of the Executive and the decision in question has passed the test of the Judicial Review...."?

(e) "Vasavi Engineering College Parents Association Vs State of Telangana & Ors., reported in (2019) 7 SCC, 172 wherein this Hon'ble Court has held:

"....17. Judicial review, as is well known, lies against the decision-making process and not the merits of the decision itself. If the decision-making process is flawed inter alia by violation of the basic principles of natural

justice, is ultra-vires the powers of the decision maker, takes into consideration irrelevant materials or excludes relevant materials, admits materials behind the back of the person to be affected or is such that no reasonable person would have taken such a decision in the circumstances, the court may step in to correct the error by setting aside such decision and requiring the decision maker to take a fresh decision in accordance with the law.

The Court in the garb of Judicial Review, cannot usurp the jurisdiction of the decision maker and make the decision itself. Neither can it act as an Appellate Authority of the Telangana Admission & Fee Regulatory Committee....."?

(f) "Fertilizer Corporation Kamgar Union (Regd.), Sindri v Union of India, reported in (1981) 1 SCC 568, wherein it was observed:

"35. We certainly agree that judicial interference with the administration cannot be meticulous in our Montesquien system of separation of powers. The court

cannot usurp or abdicate, and the parameters of judicial review must be clearly defined and never exceeded....".

v. Any other relevant question of law

5. That the facts of the present appeal briefly stated as under:

(1) That the Appellant, Ministry of Environment Forest and Climate Change, is a Ministry of the Government of India. The Appellant is the nodal agency in the administrative structure of the Central Government for the planning, promotion, co-ordination and overseeing the implementation of India's environmental and forestry policies and programs.

(2) That as on date desirable standard parameters to measure Active Pharmaceutical Ingredient (API) and acceptable norms regarding antibiotics residues value, for the drug related industries are in a highly nascent stage worldwide. Accordingly,

much deliberation and discussion are still going on in all the countries about the ideal and acceptable measuring limit about antibiotics residues for drug industries. Simultaneously, untold rivalry among large drug manufacturing countries are also going on for imposing such a measuring limit of antibiotics residues for the drug manufacturers in other competitive countries. The Expert Committee formulated by MoEF&CC are constantly deliberating upon evolving the Environmental standard for various industrial sectors/categories. For the bulk drug and formulation industry too, various such deliberations have taken place by assimilating the views of various stakeholders. 17th Expert Committee formulated by MoEF&CC convened a meeting dated 26.04.2019 wherein it was observed:

".... 5.2 Environmental Standard for Bulk Drug and Formulation Industry

The proposed revised draft Environmental Standard for Bulk Drug and Formulation Industry was presented by CPCB before the Expert Committee. It was informed that the draft notification was earlier discussed in the 16th Expert Committee Meeting held on 13/12/2018."

A true typed copy of Minutes of the 17th Expert Committee meeting on Environmental Standards dated 26.04.2019 is annexed herewith and marked as **Annexure A-1 [From Page no to]**.

(3) That 18th Expert Committee formulated by MoEF&CC again met for setting up the Environmental Standard for the bulk drug and formulation industry. It was observed:

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"..... 4.3. Environmental Standard for Bulk Drug
and Formulation (Pharmaceutical) Industry

The proposed revised draft Environmental Standard for Bulk Drug and Formulation (Pharmaceutical) Industry was presented by CPCB before the Expert Committee. It was informed that the draft notification was earlier discussed in the 17th Expert Committee Meeting held on 26/04/2019 and suggestions made during the meeting by the committee were incorporated. The revised standards were again discussed and the Committee suggested incorporating following:

1) The standard for COD in effluent may be considered as 250 mg/l in place of 200 mg/l as the 250 mg/l is already prescribed in other similar types of industries.

2) The CPCB should develop guidelines for State Pollution Control Boards/ Pollution Control

Committees (SPCBs/PCCs) for laboratory analysis of antibiotics in the effluent for implementation of proposed standards in future.

After incorporating the above suggestions the Committee recommended the Ministry may issue the draft notification inviting public suggestion in accordance with EPA 1986...."

A true typed copy of Minutes of the 18th Expert Committee meeting on Environmental Standards dated 09.08.2019 is annexed herewith and marked as **Annexure A-2 [From Page no to]**.

- (4) That the appellant brought a draft notification in the public domain for seeking suggestions/objections for statutory 60 days time period for laying the standards for Bulk Drug and Formulation (Pharmaceutical) Industry including Antibiotics residue parameters. The same were notified in the Gazette of India vide notification

GSR 44(E) dated 23.01.2020 in exercise of the powers conferred by Section 6 and 25 of the Environment (Protection) Act, 1986 read with sub - rule (3) of Rule 5 of the Environment (Protection) Rules, 1986.

A true typed copy of notification GSR 44(E) dated 23.01.2020 is annexed herewith and marked as **AnnexureA-3 [From Page no to]**.

(5) That expert committee of appellant in its meeting held on 20th May, 2020 had recommended that owing to the complexity and non-availability of any universally accepted standardized method to test total API concentration in complex wastewater matrix, it was felt necessary to remove the proposed norms of total API from the additional parameter.

A fresh meeting was convened on 28.07.2020 by appellant under the chairmanship of Secretary- Environment, Forest, Climate & Change was

conducted with all stakeholders, including Central Pollution Control Board (CPCB), Pharma association, Ministry of Health (MoHFW), Department of Pharma and experts where it was unanimously observed that there is technical challenge in compliance for any static treatment option to meet the dynamic nature of the predicted no-effect Concentration (PNEC) values published by a consortium of Antibiotics manufacturers.

- (6) A case was filed before Hon'ble National Green Tribunal, Principle Bench vide Original Application No. 136/2020 titled as "Veterans Forum for Transparency in Public Life Versus State of Himachal Pradesh & Ors." praying for various reliefs including for remedial action against discharge of waste from CETP at Baddi and from Acme Life Sciences, Nalagarh and Helio

Pharmaceuticals at Solan, to prevent pollution of rivers Sirsa and Satluj.

- (7) On 22.07.2020, upon hearing the matter at admission stage, Hon'ble Tribunal passed an order stating:

"...Let a joint Committee of CPCB, State PCB and District Magistrate, Solan look into the above issues in the light of contents of the application and take such further action as may found necessary. The State PCB will be the Nodal Agency for compliance and coordination. A factual and action taken report may be furnished to this Tribunal within three months..."

A true typed copy of order dated 22.07.2020 in O.A. No. 136 Of 2020 and O.A. No. 801 of 2018 passed by the Hon'ble National Green Tribunal Principal Bench, New Delhi is annexed herewith

and marked as **Annexure A-4 [From Page no to]**.

- (8) That the expert Committee of the appellant again met on 09.12.2020. In that meet, draft notification was deliberated point wise and based on the discussion; the Committee recommended certain modifications on additional parameters, the solvent losses, and provision of land disposal etc. for the consideration of the Ministry.

The matter was re-examined in the Ministry in light of representation received from the Department of Pharma. A meeting under the chairmanship of Secretary- EFCC with various stakeholders, including CPCB, pharma association, Ministry of Health, Department of Pharma and experts was held. Owing to the concern on the PNEC value and its dynamic nature, it was observed that it will be a compliance challenge for any static treatment option to meet the dynamic nature of the PNEC values published by a consortium of Antibiotics Manufacturer.

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Considering the implementation, monitoring and compliance challenges, it was decided that CPCB may explore these challenges and also compare international practices on imposing PNEC values as regulatory provision for discharge standard to address such concerns. In view of the above, the standard was revised and placed before the expert committee for consideration on the concerns of compliance, dynamic value of PNEC and prevailing international practices on the evolving nature of PNEC understanding.

The committee made detailed deliberation on each aspect of the modified discharge norms in notification. Subsequent thereto, the committee recommended to drop the proposal of Antibiotics residue discharge norms and suggested that MoEF&CC may ask CPCB to issue necessary direction to Department of Pharma, Ministry of Chemicals & Fertilizers to ensure that a database be created on the AMR status in the country with

the help of association of Antibiotics manufacturing units.

A true typed copy of Minutes of the First Expert Committee Meeting to Environmental Standards (through video conferencing) dated 09.12.2020 Delhi is annexed herewith and marked as **Annexure A-5 [From Page no to]**.

- (9) That the Hon'ble Tribunal, Principal Bench, New Delhi vide its order dated 23.06.2021 directed the Ministry and state PCB to take further remedial action expeditiously. The State PCB was directed to ensure that no harmful components in the effluents are discharged into the water by the units in question or any other API unit. A joint committee was constituted comprising of nominee of Ministry, CPCB, State PCB and District Magistrate Solan to conduct inspection of the area and give a status report on the violations and the remedial action taken within three months. The report was supposed to give status of performance of individual pharmaceutical units, particularly with

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reference to removal of API residue by them and by the CETP, the number of pharma industries connected to the CETP and those discharging effluents directly into the drain and the river. The report was also supposed to indicate chemical and biological composition of rivers Sirsa and Satluj, including the status of residue at relevant locations. CPCB was also directed to suggest monitoring mechanism for API through a credible system so as to cover all pharma industries in the country discharging API residue directly or indirectly in river systems. CPCB was also directed to propose the timelines to undertake monitoring which may also take a note of water quality monitoring guidelines of CPCB titled "Guidelines on Water Quality Monitoring 2017".

A true typed copy of order dated 23.06.2021 in O.A. No. 136 Of 2020 and O.A. No. 801 of 2018 passed by the Hon'ble National Green Tribunal Principal Bench, New Delhi is annexed herewith

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and is marked as **Annexure A-6 [From Page no to]**.

(10) That keeping into considerations all the facts, comments of the various expert committees of appellant, and public comments received upon the draft notification dated 23.01.2020, the final standards were notified under Environment (Protection) Rules, 1986 vide GSR 541(E) dated 06.08.2021.

A true typed copy of the final standards duly notified under Environment (Protection) Rules, 1986 vide GSR 541(E) dated 06.08.2021 is annexed herewith and is marked as **Annexure A-7 [From Page no to]**.

That Hon'ble Tribunal vide its order-dated 21.01.2022, directed the State to take further corrective measures to enforce the law for protecting public health and the environment. CPCB was directed to circulate monitoring mechanism to the State PCBs on API as directed earlier and file the action taken report before the

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next date. In addition, Appellant Ministry was directed to clarify the issue of API standards. Subsequently, the Ministry filed submission/clarification on the issue of residual antibiotics in Industrial effluents and API standard in view of order-dated 21.01.2022.

A true typed copy of order dated 21.01.2022 in O.A. No. 136 Of 2020 and O.A. No. 801 of 2018 passed by the Hon'ble National Green Tribunal Principal Bench is annexed herewith and is marked as **Annexure A-8 [From Page no to]**.

That the Appellant Ministry filed submission/clarifications on the issue of residual antibiotics in Industrial effluents pursuant and API standard in view of order dated 21.01.2022.

A true typed copy of submission/clarifications on the issue of residual antibiotics in Industrial effluents pursuant and API standard in view of order dated 21.01.2022 filed by the Appellant

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Ministry is annexed herewith and marked as **Annexure A-9 [From Page no to]**.

That the Hon'ble Tribunal vide its order 06.04.2022 (Impugned order), made an observation wherein Ministry's issued final notification dated 06.8.2021 has been mentioned as draft notification and has also been mentioned that the Ministry is unable to finalise the draft standards (In para 15 which is contrary to Para 8 of the impugned order dated 06.04.2022). It is most humbly submitted that in the instant case, earlier draft notification was released vide notification dated 23.01.2020 for inviting public comments and further deliberation. Accordingly, upon following all the statutory compliances, standards for bulk drugs including Antibiotics Residue Parameter was formulated, finalised and notified on 06.8.2021 by the Ministry.

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(11) That as the final notification dated 06.08.2021 was not duly considered by the Hon'ble Tribunal vide its order dated 06.04.2022, the appellant approached the Hon'ble National Green Tribunal by way of Review Application No. 14 of 2022 in O.A. No. 136 of 2020 for reviewing the order of the Hon'ble Tribunal dated 06.04.2022.

A true typed copy of Review Application No. 14 of 2022 in O.A. No. 136 of 2020 filed before the Hon'ble National Green Tribunal Principal Bench, New Delhi is annexed herewith and marked **Annexure A-10 [From Page no to]**.

That Hon'ble Tribunal dismissed the Review Application filed by the appellant Ministry vide its order dated 24.05.2022 while holding that the Review Application was bereft of merit as the issue had already been dealt in detail and duly considered. The Ministry's stand in the review application was that since the Appellant ministry has notified the final Notification after following

the due process subsequent to notification of draft notification dated 23.01.2018, the order of the Hon'ble Tribunal was uncalled for.

(12) That as the Appellant Ministry is the nodal agency regarding all Environmental issues coupled with their responsibility to adhere to all the International commitments related with the environment. Accordingly all its policies, guidelines and formulated yardsticks are expected to be evolved upon constructive and effective deliberation as per the prescribed norms with keeping fine balance among all the stakeholders.

(13) That it is worth mention that the issues involved in the instant case i.e. regarding desirable standard parameters to measure Active Pharmaceutical Ingredient (API) and acceptable norms regarding antibiotics residues value, for the drug related industries are in a highly nascent stage worldwide. Accordingly, much deliberation

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and discussion are still going on in all countries about the ideal and acceptable measuring limit about antibiotics residues for drug industries. Simultaneously, untold rivalry among large drug manufacturing countries are also going on for imposing such a measuring limit of antibiotics residues for the drug manufacturers in other competitive countries.

(14) That the Ministry being conscious about the facts that in the field of drug manufacturing activities due to higher cost, India is facing stiff competition from other countries, especially from China and has in recent times become no. 2 in API manufacturing. It is most humbly submitted that the Appellant Ministry, is equally obligated that any norms should not compromise with the environmental requirements, but should be prescribed in such a proposition that there is no excess financial burden to the industry as well to retain their international competitiveness.

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(15) That discussion also included that scientific rationale and the present derivation of PNEC for use in environmental risk lacks some scientific validity because the assessment factors are derived empirically. Accordingly, Expert Committee suggested creating appropriate data before determining any value for PNEC or API.

(16) That views during discussion of Expert committee also included that ecosystem are as sensitive as the most sensitive species and that the ecosystem function is dependent on the ecosystem structure. Therefore, PNECS derived from single species toxicity data may not represent the sensitivity of site-specific ecosystem and its toxicology.

(17) That Central Pollution Control Board (CPCB) has been entrusted to develop database as well as methodology for analysis of identified API and also

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the corresponding site-specific PNEC values to enable a scientific rationale for deriving standards for such parameters. It is submitted that CPCB has made some progress on development of methodology for sampling and analysis of certain APIs, which is based on in house competency and is broadly based on US-EPA guidelines. These methodologies have been circulated to all SPCBs/PCCs. The proposed methodologies are yet to be validated by laboratory of SPCBs or other scientific laboratories by carrying an inter-laboratory competency comparison. These methodology needs to be further improvised to have its acceptability by undertaking inter-laboratory comparison, Standardization of the process to be made acceptable to the provisions of NABL accreditation, which is minimum requirement for qualifying the methodology and process to be acceptable under the provisions of Environment (Protection) Act, 1986 for acceptance

of analytical results to be used for regulatory purpose.

(18) That in the UN- UNEP/IPCS Training Module No.

3- Section B - Environmental Risk Assessment
Chapter 3,- Effect Assessment (para 3.1) has suggested some methodology, including the limitation, to be adopted for development of PNEC values to have environmental risk assessment arising out of API and other chemicals. These PNAC values are site specific and eco-system based. A detailed study on toxicology vis-à-vis the expected chemical needs to be done, in order to standardize PNEC values. However, these values may also have risk of being dynamic over a period of time and therefore, more research is required to standardized the criteria for legal regulation purpose.

(19) That Appellant Ministry as on date has already formulated the necessary provisions for dealing

the "API" issue for drug industries in India. Though, CPCB has also been enshrined the responsibilities to explore more on this issue which would eventually lead to a better handling of such effluents while enhancing the current structure to bear the current level of such discharge.

(20) That, it is most humbly submitted that, apart from the above mentioned facts and details, as per Section 17 of the Water (Prevention and Control of Pollution) Act, 1974, it is evident that the State Pollution Control Board equally possesses the power to evolve efficient methods of disposal of sewage and trade effluents on land.

(21) That Aggrieved by the orders dated 06.04.2022 in O.A. No. 136 of 2020 and O.A. No. 801 of 2018 and order-dated 24.05.2022 in Review Application No. No. 14 of 2022 in O.A. No. 136 of 2020 passed by the Hon'ble National Green Tribunal, Principal Bench New Delhi, the Appellant has approached

this Hon'ble Court by way of the Present Civil Appeal.

6. **GROUND:**

The Impugned Orders dated 06.04.2022 in O.A. No. 136 of 2020 and O.A. No. 801 of 2018 and 23.05.2022 in Review Application No. 14 of 2022 in O.A. No. 136 of 2020, passed by the Hon'ble Tribunal is bad in law and liable to be set aside/modify inter-alia amongst others on the following grounds:-

- A. **BECAUSE** while passing the Impugned Orders, the Hon'ble Tribunal has miserably failed to appreciate that in the instant case i.e., regarding desirable standard parameters to measure Active Pharmaceutical Ingredient (API) and acceptable norms regarding antibiotics residues value, final standard under Environment (Protection) Rules, 1986 vide GSR 541(E) dated 06.08.2021 has already been issued. Accordingly, no such draft notification is pending with the answering Ministry which is needed to be finalized.

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- B. **BECAUSE** the Hon'ble Tribunal while passing the Impugned Orders ought to have appreciated that there is no such draft notification in the instant issue which is pending for its finalization, and the Appellant Ministry is not in a position to issue any other or further final notification. Ministry in its filed submission has duly appraised the said facts before the Hon'ble Tribunal.
- C. **BECAUSE** the Hon'ble Tribunal has ignored the fact that the draft notification was brought in the public domain for seeking suggestions/objections for statutory 60 days time period for laying the standards for Bulk Drug and Formulation (Pharmaceutical) Industry including antibiotics residue parameters.
- D. **BECAUSE** the Hon'ble Tribunal completely failed to consider and appreciate that the Central Pollution Control Board (CPCB) have been entrusted to develop database as well as methodology for analysis of identified API and also the corresponding site specific PNEC values to enable a

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scientific rationale for deriving standards for such parameters. It is submitted that CPCB has made some progression development of methodology for sampling and analysis of certain APIs, which is based on in-house competency and is broadly based on US-EPA guidelines. These methodologies have been circulated to all SPCBs/PCCs. The proposed methodologies are yet to be validated by laboratory of SPCBs or other scientific laboratories by carrying an inter-laboratory competency comparison. These methodology needs to be further improvised to have its acceptability by undertaking inter-laboratory comparison, Standardization of the process to be made acceptable to the provisions of NABL accreditation, which is minimum requirement for qualifying the methodology and process to be acceptable under the provisions of Environment (Protection) Act, 1986 for acceptance of analytical results to be used for regulatory purpose.

- E. **BECAUSE** the Hon'ble Tribunal has failed to consider that in the UN-UNEP/IPCS Training Module No. 3 - Section B -

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Environmental Risk Assessment - Chapter 3, -
EffectAssessment (para 3.1) has also suggested
somemethodology, including the limitation, to be
adoptedfor development of PNEC values to
haveenvironmental risk assessment arising out of APIand
other chemicals. These PNAC values are sitespecific and
eco-system based. A detailed study ontoxicology vis-à-vis
the expected chemical needs to be conducted to
standardize PNEC values. However, these values may also
have risk of beingdynamic over a period of time and
therefore, more research is required to standardize the
criteria forlegal regulation purpose.

- F. **BECAUSE** the Hon'ble Tribunal failed to appreciate that a
meeting under the chairmanship of Secretary Ministry of
Environment Forest& Climate Change was convened on
28.07.2020 with all stake holders including Central
Pollution Control Board, Pharma Association, Ministry of
Health and Family Welfare, Department of Pharma and
experts, wherein it was unanimously observed that there

is a technical challenge in compliance for any static treatment option to meet the dynamic nature of the PNEC values published by a consortium of Antibiotics manufacturers.

- G. **BECAUSE** the Hon'ble Tribunal failed to appreciate that considering the implementation, monitoring and compliance challenges, it was decided that CPCB may explore these challenges and also compare international practices on imposing PNEC values as regulatory provision for discharge standard to address such concerns.
- H. **BECAUSE** the Hon'ble Tribunal failed to appreciate that expert committee of MOEF&CC in its meeting held on 20th May, 2020 had also recommended that owing to the complexity and non-availability of any universally accepted standardized method to test total API concentration in complex wastewater matrix; it was felt necessary to remove the proposed norms of total API from

the additional parameter as of now. Accordingly, the parameter for total API concentration was also removed.

- I. **BECAUSE** the Hon'ble Tribunal failed to consider that the Appellant Ministry has duly considered the views of experts, stake holders and public comments received upon the draft notification dated 23.01.2020, and after due deliberation upon them went ahead with the final standards which were notified under Environment (Protection) Rules, 1986 vide GSR 541(E) dated 06.08.2021.
- J. **BECAUSE** the Hon'ble Tribunal has committed a grave error in not appreciating the fact that the Appellant Ministry as on date has already formulated the necessary provisions for dealing the "API" issue for drug industries in India. Though, CPCB has also been enshrined the responsibilities to explore more on this issue which would eventually lead to a better handling of such effluents while enhancing the current structure to bear the current level of such discharge.

- ✓K. **BECAUSE** the Hon'ble Tribunal further failed to appreciate that apart from the above mentioned facts and details, as per Section 17 of the Water (Prevention and Control of Pollution) Act, 1974; it is evident that the State Pollution Control Board equally possesses the power to evolve efficient methods of disposal of sewage and trade effluents on land.
- L. **BECAUSE** the Hon'ble Tribunal also did not appreciate that the Appellant Ministry had placed the actual facts and developments upon the instant issues. However, as the issue regarding evolution of API and PNEC standard is at a nascent stage worldwide, the Appellant Ministry would keep tuning its standards and yardsticks as per requirement.
- M. **BECAUSE** the impugned order passed by the Hon'ble Tribunal failed to consider that in the field of drug manufacturing activities due to higher cost, India is facing stiff competition from other countries, especially from China and has in recent times become no. 2 in API manufacturing.

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N. **BECAUSE** the Hon'ble Tribunal has not taken into consideration that the Appellant Ministry, is equally obligated that any norms should not compromise with the environmental requirements, but should be prescribed in such a proposition that there is no excess financial burden to the industry as well to retain their international competitiveness.

O. **BECAUSE that impugned** orders are contrary to law laid down in various cases by Hon'ble Court such as:

(a) "Federation of Railway Officers Association & Ors. Vs. Union of India" reported in (2003) 4 SCC 289, wherein it has been held:

"...12. In examining a question of this nature where a policy is evolved by the Government judicial review thereof is limited. When policy according to which or the purpose for which discretion is to be exercised is clearly expressed in the statute, it cannot be said to be an unrestricted discretion. On matters affecting policy and

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requiring technical expertise the Court would leave the matter for decision of those who are qualified to address the issues. Unless the policy or action is inconsistent with the Constitution and the laws or arbitrary or irrational or abuse of power, the Court will not interfere with such matters..."?

(b) Directorate of Film Festivals & Ors. Vs. Gaurav Ashwin Jain & Ors., reported in (2007) 4 SCC 737, wherein it has been held:

"....16. The scope of judicial review of governmental policy is now well defined. Courts do not and cannot act as Appellate Authorities examining the correctness, suitability and appropriateness of a policy nor are courts. Advisors to the executive on matters of policy, which the executive is entitled to formulate.

The scope of judicial review when examining a policy of the government is to check whether it violates the fundamental rights of the citizens or is opposed to the provisions of the Constitution, or opposed to any statutory provision or manifestly arbitrary. Courts cannot interfere

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with policy either on the ground that it is erroneous or on the ground that a better, fairer or wiser alternative is available. Legality of the policy, and not the wisdom or soundness of the policy, is the subject of judicial review.

It is settled law that the Court would not ordinarily interfere with the policy decision of the executive unless the same can be faulted on the grounds of malafides, unreasonableness, arbitrariness or unfairness, in which case the policy would render itself to be declared unconstitutional...."?

(c) "Balco Employees Union (Regd.) Vs Union of India & Ors; reported in (2002) 2 SCC 333, wherein it has been held:

".....In a democracy, it is the prerogative of each elected Government to follow its own policy. Often a change in Government may result in the shift in focus or change in economic policies. Any such change may result in adversely affecting some vested interests. Unless any illegality is committed in the execution of the policy or the same is contrary to law or mala fide, a decision bringing

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about change cannot per se be interfered with by the Court.

98. In the case of a policy decision on economic matters, the Courts should be very circumspect in conducting any enquiry or investigation and must be most reluctant to impugn the judgment of the experts who may have arrived at a conclusion unless the Court is satisfied that there is illegality in the decision itself...."?

(d) "Parisons Agrotech Private Limited &Anr Vs Union of India & Ors; reported in (2015) 9 SCC 657, wherein this Hon'ble Court has held:

"....14. No doubt, the Writ Court has adequate power of judicial review in respect of such decisions. However, once it is found that there is sufficient material for taking a particular policy decision, bringing it within the four corners of Article 14 of the Constitution of India, power of Judicial Review would not extend to determine the correctness of such a policy decision or to indulge into the exercise of finding out whether there could be more appropriate or better alternatives.

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Once we find that parameters of Article 14 are satisfied; there was due application of mind in arriving at the decision which is backed by cogent material; the decision is not arbitrary or irrational and; it is taken in public interest, the Court has to respect such a decision of the Executive as the policy making is the domain of the Executive and the decision in question has passed the test of the Judicial Review...."?

(e) "Vasavi Engineering College Parents Association Vs State of Telangana & Ors., reported in (2019) 7 SCC, 172 wherein this Hon'ble Court has held:

"....17. 'Judicial review, as is well known, lies against the decision-making process and not the merits of the decision itself. If the decision-making process is flawed inter alia by violation of the basic principles of natural justice, is ultra-vires the powers of the decision maker, takes into consideration irrelevant materials or excludes relevant materials, admits materials behind the back of the person to be affected or is such that no reasonable person would have taken such a decision in the circumstances, the court may step in to correct the error

by setting aside such decision and requiring the decision maker to take a fresh decision in accordance with the law.

The Court in the garb of Judicial Review, cannot usurp the jurisdiction of the decision maker and make the decision itself. Neither can it act as an Appellate Authority of the Telangana Admission & Fee Regulatory Committee....."?

(f) "Fertilizer Corporation Kamgar Union (Regd.), Sindri v Union of India, reported in (1981) 1 SCC 568, wherein it was observed:

"35. We certainly agree that judicial interference with the administration cannot be meticulous in our Montesquieu system of separation of powers. The court cannot usurp or abdicate, and the parameters of judicial review must be clearly defined and never exceeded....".

P. **BECAUSE** that Hon'ble Tribunal has in fact misread the documents and has not properly appreciated the material

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placed on record and thereby reached to a wrong conclusion.

Q. **BECAUSE** of any other and further grounds, if any, shall be urged at the time of hearing.

7. The Appellant craves leave to add to, amend, alter or modify the grounds of appeal, if necessary.

8. The Appellant states that no other civil appeal or other proceeding has been filed by it against the Impugned Orders dated 06.04.2022 in O.A. No. 136 of 2020 and O.A. No. 801 of 2018 and 23.05.2022 in Review Application No. 14 of 2022 in O.A. No. 136 of 2020, passed by the Hon'ble Tribunal either before this Hon'ble Court or before any other Court.

9. This appeal is being filed bonafide and in the interest of justice. The appellant respectfully submits that this is a fit case for interference by this Hon'ble Court.

10. **MAIN PRAYER**

It is, therefore, most respectfully prayed that this Hon'ble Court may graciously be pleased to:-

- a) Admit and allow the present Civil Appeal and set aside the Impugned Orders dated 06.04.2022 in O.A. No. 136 of 2020 and 23.05.2022 in Review Application No. 14 of 2022 in O.A. No. 136 of 2020, passed by the Hon'ble National Green Tribunal, New Delhi; and
- b) Pass such other and further orders as this Hon'ble Court may deem fit and proper in the facts and circumstances of the case.

11. **PRAYER FOR INTERIM RELIEF:**

It is, therefore, most respectfully prayed that this Hon'ble Court may graciously be pleased to:-

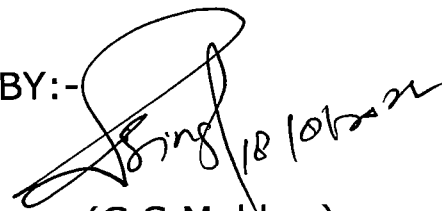
- a) Grant ex-parte ad-interim stay on the operation of the impugned Orders dated 06.04.2022 in O.A. No. 136 of 2020 and 23.05.2022 in Review Application No. 14 of 2022 in O.A. No. 136 of 2020, passed by the Hon'ble National Green Tribunal, New Delhi; and

- b) Pass such other and further orders as this Hon'ble Court may deem fit and proper in the facts and circumstances of the case.

AND FOR THIS ACT OF KINDNESS, THE APPELLANT SHALL EVER PRAY.

Drafted By:-
(Balendu Shekhar)
Advocate

Filed BY:-



(G S Makker)
Advocate for the Appellant

NEW DELHI
DRAWN ON: _____.08.2022
FILED ON: _____.08.2022

IN THE SUPREME COURT OF INDIA
CIVIL APPELLATE JURISDICTION
CIVIL APPEAL NO _____ OF 2022

IN THE MATTER OF:-

Union of India

...Appellant

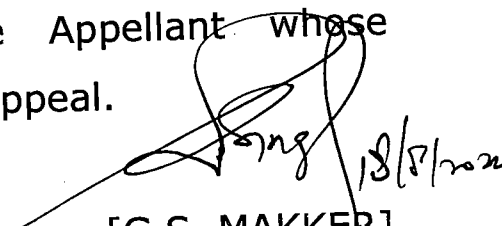
-Versus-

Veterans Forum for Transparency in Public
Life through its General Secretary & Ors.

...Respondents

CERTIFICATE

Certified that the Civil Appeal is confined only to the pleadings before the Hon'ble National Green Tribunal whose Orders is challenged and the other documents relied upon in those proceedings. No Additional facts, documents or grounds have been taken therein or relied upon in the Civil Appeal. It is further certified that the copies of the documents/annexures attached to the Civil Appeal are necessary to answer the question of law raised in the petition or to make out grounds urged in the Civil Appeal for consideration of this Hon'ble Court. This Certificate is given on the basis of the instructions given by the Appellant/person authorized by the Appellant whose Affidavit is filed in support of the Civil Appeal.


[G.S. MAKKER]

ADVOCATE FOR THE APPELLANT

FILED ON:
NEW DELHI.

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IN THE SUPREME COURT OF INDIA
CIVIL APPELLATE JURISDICTION
CIVIL APPEAL NO _____ OF 2022

IN THE MATTER OF:-

Union of India

...Appellant

-Versus-

Veterans Forum for Transparency in Public
Lifethrough its General Secretary & Ors.

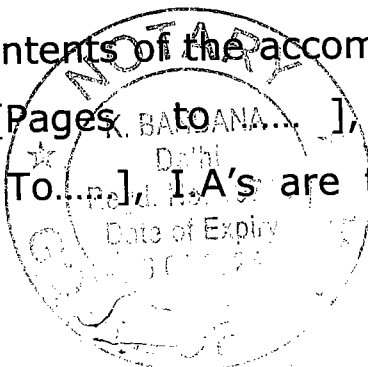
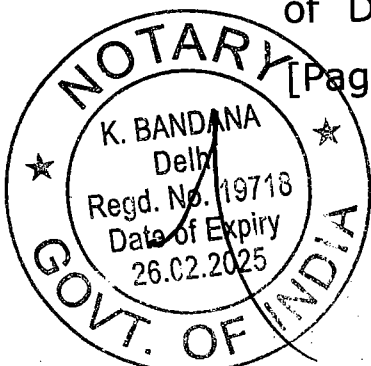
..Respondents

AFFIDAVIT

I, Ved Prakash Mishra, S/o Shri Ram Shidh Mishra, aged about 48 years Working as Director, Office at Ministry of Environment, Forest and Climate Change, Govt. of India, Indira Paryavarān Bhawan, Ali Ganj, Jor Bagh, New Delhi hereby solemnly affirm and state as under:

1. That, I am authorized person on behalf of petitioner in the abovementioned matter and am well conversant with the facts and circumstances of the case and am competent to swear to this affidavit.

2. That the contents of the accompanying Synopsis & List of Dates [Pages to ...], Special Leave Petition [Pages To ...], I.A's are true and correct to the

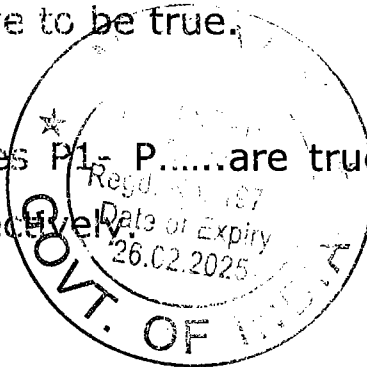


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best of my knowledge based on the records of the case which I believe to be true.

3. That the Annexures P1- P.....are true Type copies of their original respectively.



[Signature]

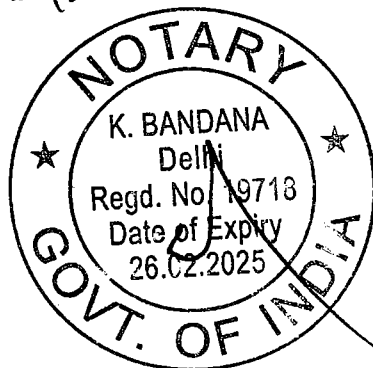
DEPONENT

वेद प्रकाश मिश्रा
VED PRAKASH MISHRA
निदेशक/Director
पर्यावरण, वन एवं जलवायु परिवर्तन मंत्रालय
Min. of Environment, Forest and Climate Change
भारत सरकार, नई दिल्ली
Govt. of India, New Delhi

VERIFICATION:

18 AUG 2022 I, the above named deponent do hereby verify on 08.2022, at New Delhi, that the contents of my above affidavit are true and correct which I belief to be true.

IDENTIFIED
UP.02559/01-03/2014
[Signature]
18/08/22



[Signature]

DEPONENT

वेद प्रकाश मिश्रा
VED PRAKASH MISHRA
निदेशक/Director
पर्यावरण, वन एवं जलवायु परिवर्तन मंत्रालय
Min. of Environment, Forest and Climate Change
भारत सरकार, नई दिल्ली
Govt. of India, New Delhi

18 AUG 2022

ATTESTED

NOTARY PUBLIC, DELHI
GOVT. OF INDIA

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F. No. 15017/42/2007-CPW
GOVERNMENT OF INDIA

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ANNEXURE A1

MINISTRY OF ENVIRONMENT, FOREST & CLIMATE CHANGE
(CP DIVISION)

Indira Paryavaran Bhawan
Level-II, Prithvi Wing, Jorbagh Road
New Delhi-110003

Dated: 10th May, 2019

To

As per list enclosed

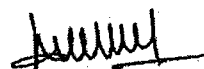
Subject: Minutes of the 17th Expert Committee Meeting on Environmental Standards held on 26/04/2019 at Indira Paryavaran Bhawan, MoEF&CC, New Delhi- regarding.

Sir,

Please find herewith a copy of minutes of the 17th Expert Committee Meeting on Environmental Standards held on 26/04/2019 under the Chairmanship of Shri Arvind Kumar Nautiyal, Joint Secretary, Ministry of Environment Forest & Climate Change, New Delhi on the mentioned subject for your perusal and necessary action.

Yours faithfully,

Encl: as above


(Dr. H. Kharkwal)
Additional Director/
Scientist 'E'

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List of Members

1. Joint Secretary/Adviser (CP Division) : Chairman
2. Representative of Ministry of Heavy Industries, Udyog Bhawan, Rafi Marg, New Delhi- 110001 : Member
3. Director & Head (Chemical), BIS, 9, Bahadur Shah Zafar Marg New Delhi : Member
4. Executive Director, (R&D) IOCL, Faridabad, Sector-13, Faridabad, Haryana : Member
5. Director, Department of Health & Family Welfare, M/o Health, Family & Welfare, Udyog Bhawan, New Delhi : Member
6. Advisor (Tech), Ministry of Coal, Shashtri Bhawan New Delhi-110001 : Member
7. Controller General, Indian Bureau of Mines, Civil lines-440001 Nagpur : Member
8. Director, National Institute of Occupational Health (NIOH), ICMR, Ahmadabad-380016 : Member
9. Director/Addl. Director (CPDiv), MoEF&CC : Member Convener
10. Head (Env Division), CII, ITC Centre of Excellence for sustainable, 2nd Floor, Thapar House, 124, Janpath New Delhi : Member
11. Head (Env. Division), PHD Chamber of Commerce and Industries Kranti Marg, Siri Institutional Area, Block-a, Nipccd Campus, Hauz Khas, New Delhi-110016: Member
12. Chief Engineer (EMO), Central Water Commission, Sewa Bhawan, R.K. Puram, Delhi : Member
13. Secretary, Central Electricity Authority, Sewa Bhawan, Sector-5, R.K. Puram, Delhi : Member
14. Sh. K.P. Nyati, Environment Professor, D-1-C/56, A, Janakpuri New Delhi-110058 : Member
15. Dr. S. P. Chakraborty, Ex-Member Secretary/Director, CPCB, A-601, Mansara Apartment, C-line Calcutta- Vasundhara Enclave, Delhi : Member
16. Member Secretary, Central Pollution Control Board, Delhi : Member

21044 **106** Res of the 17th Expert Committee Meeting held on 26th April, 2019 at Indira Paryavaran Bhawan, MoEF&CC, New Delhi for finalization of the Environmental Standards for different industries.

The 17th Meeting of the Expert Committee was held on 26th April, 2019 at Indira Paryavaran Bhawan, MoEF&CC, New Delhi under the Chairmanship of Shri A.K. Nautiyal, Joint Secretary, MoEF&CC for finalization of Two Amendment, Five Final and Two draft environmental standards in respect of Nine Industrial Sector / Categories, which are as follows:

(A) Proposed for issue of the Amendment notification under EPA 1986:-

- i. Water Quality Standard for Coastal Water Marine Outfalls in respect of Primary Water Quality Criteria for Class SW-III Waters and Class SW-V Water
- ii. Standards for Boilers using Industries for SO₂ and NO_x

(B) Proposed for issue of the Final notification under EPA 1986:-

- i. Automobile Service Stations, Bus Depots or Workshop
- ii. Fermentation Industry,
- iii. Coffee Industry,
- iv. Tannery Industry,
- v. Revised Discharge Standards for STP vide NGT order dated 21/12/2018

(C) Proposed for issue of the Draft notification under EPA 1986:-

- i. Diesel Locomotives Standards
- ii. Bulk Drug and Formulation Industry Standards

1.1. At the outset, the Chairman welcomed the Members of the Expert Committee and the stakeholders representing the above sectors/categories. In his opening remarks he appraised the background of the standards for emission or discharge of environmental pollutants viz. Air pollutants, water pollutants and noise limits from industries, operations or processes with an aim to protect and improve the quality of the environment and abate environmental pollution. He requested Dr. H. Kharkwal, Member Secretary / Scientist 'E', MoEF&CC to brief about the meeting.

1.2 Dr. Kharkwal has appraised the background of the meeting and also gave brief background for finalization of the Environmental Standards for different industries / categories. Afterwards, he requested CPCB to present the details of each proposed Amendment standards for (A) above, public comments received with regards to i to iv draft notification at (B) above and the proposed draft standards for (C) above. The list of participants is at **Annexure-A**.

1.3. The Expert Committee took up amendment/final/draft notifications as indicated above. The stakeholders from each of the above sectors were invited for discussions when the sectors/categories were taken.

2. Confirmation of Minutes of the 16th Expert Committee Meeting

The Comments sought on draft minutes of the 16th Expert Committee Meeting held on dated 13th December, 2018. Since, there is no comment, this minute were confirmed.

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3. Proposed for issue of the Amendment Notification under EPA 1986:-

3.1. Consideration of Amendment regarding Water Quality Standard for Coastal Water Marine Outfalls in respect of Primary Water Quality Criteria for Class SW-III Waters and Class SW-V Water.

The proposed amendment draft notification for Water Quality Standard for Coastal Water Marine Outfalls in respect of Primary Water Quality Criteria for Class SW-III Waters and Class SW-V Water under Environment (Protection) Rules, 1986 was presented by Dr. S. R. Marigoudar, Scientist 'D', National Centre for Coastal Research (NCCR), Ministry of Earth Science (MoES). It was informed that the draft notification was earlier discussed in the 16th Expert Committee Meeting held on 13/12/2018 and also explained the background, purpose, comments provided by the coastal SPCBs, PCCs, concerned Government Departments and Institutions as well as the proposed criteria.

After detailed deliberations, Expert Committee suggested for CPCB and MoES to check the values of proposed standards vis-à-vis existing BIS standards. The CPCB and MoES shall consult each other on the aforesaid and CPCB shall propose the draft notification to be issued under EP Act, 1986. (Action: CPCB)

3.2. Environmental Standards for Boilers using Industries for SO₂ and NO_x

The proposed amendment notification for Boilers using Industries for SO₂ and NO_x was presented by Dr. Nazimuddin, Scientist 'E', CPCB. It was informed that the final notification was issued on 29/01/2018. In the draft notification for the same pet coke boilers was mentioned as a separate category about which there was a foot note regarding continuous monitoring requirement whereas in the final notification, the 'pet coke' boilers had been merged along with 'other fuels' boiler as a result of which the continuous monitoring requirement proposed for pet coke boilers have been inadvertently applied to all boilers. The CPCB requested amendment after table in para 2 shall be substituted as:

***** "The emission from industrial boilers using Petcoke of Fuel/Furnace oil (FO) as fuel would be required to install online monitoring system as per online monitoring mechanism put in place by Central Pollution Control Board from time to time".***

After detailed discussion on the notification, Committee recommended the amendment and suggested to notify under Environment (Protection) Rules, 1986. (Action: MoEF&CC)

4. Proposed for issue of the Final Notification under EPA 1986:-

4.1 Environmental Standard for Automobile Service Stations, Bus Depots or Workshop

The proposed final notification for environmental standard Automobile Service Stations, Bus Depots or Workshop was presented by CPCB before the Expert Committee. The proposed draft notification was placed on website of MoEF&CC for public consultation on 05/12/2018. On the draft notification only one comment /suggestion was received from Society of Indian Automobile Manufacturers (SIAM) and CPCBs response was noted by the Committee.

After detailed discussion on the notification, Committee recommended to notify the final notification by adding a foot note 'Solid Wastes/ Hazardous Waste, if any shall be

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disposed off as per the Solid Waste Management Rules 2016 and Hazardous and Other Waste (Management & Trans-boundary Movement) Rules, 2016, under Environment (Protection) Rules, 1986 as at Annexure B. (Action: CPCB)

4.2 Environmental Standard for Fermentation Industry 106

The final notification for Environmental Standard for Fermentation Industry was presented by CPCB before the Expert Committee. It was informed that the draft notification was placed on website of MoEF&CC for public consultation on 06/07/2018. On the draft notification comments / suggestions were received from different Stakeholders and same were forwarded to CPCB. Based on the comments / suggestions, CPCB proposed the final notification. On which Committee made following observations:

I. Molasses and grain based distillery- The Committee agreed to the proposal of imposing Zero Liquid Discharge standards in these sectors. However the Expert Committee observed that specifying technologies in the notification for environmental standards should be avoid as far as possible. It was clarified by CPCB representatives that available and established technologies for achieving ZLD based on the experience and monitoring data available with CPCB was included in the proposed revised standard notification and option for alternate technologies which achieves the desired output has been kept open, with the approval of SPCB. It was informed by CPCB representatives that all operating units in Ganga Basin have implemented ZLD through proposed routes and requirements. CPCB representatives further clarified that the output limits in terms of volume reduction with solid concentration of concentrated spent wash has been specified to ensure that substantial volume reduction and recovery & reuse of water is achieved and possibility of dilution is avoided. The Committee concluded that indicative technologies and options for achieving ZLD can be part of foot notes or separate directions to install the required systems and achieve ZLD, as per the specified technical routes, shall be issued by CPCB and there may not be part of the main standard.

II. Breweries & Malteries – The Committee generally agreed to the proposed standards as notified and also to correct the anomaly of BOD standard for land discharge as 100 mg/l maximum against the published standard of 20 mg/l maximum. The Committee, after discussion agreed to the effluent discharge standards of pH-6.5-8.5, BOD-20 mg/l & 100 mg/l respectively for surface water and land discharge, SS-50 mg/l & Colour-350 PCU for Malteries & Breweries.

III. Emission standards for Spent wash incineration boilers: After discussion, it was decided by the Committee that an emission standard of P.M-100mg/Nm³ shall be made applicable for both new and existing Spent Wash incineration boilers. The existing incineration boilers, presently few in number, may be phased out or retrofitted in the stipulated time line for achieving the proposed standard. CPCB representatives and the representatives from the industries also agreed to this decision of the committee.

IV. Time lines for achieving the standard: As decided in the previous meeting, the Committee agreed that a timeline of 2 years from the date of publication shall be given to the industries for achieving the above proposed standards.

The Committee advised CPCB to submit the revised notification based on the aforesaid observations to MoEF&CC to take a final view in the matter.

(Action: CPCB)

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4.3 Environmental Standard for Coffee Industry

The final notification for Environmental Standard for Coffee Industry was presented by CPCB before the Expert Committee. It was informed that the draft notification was placed on website of MoEF&CC for public consultation on 24/10/2018. On the draft notification comments /suggestions were received from different Stakeholders and same forwarded to CPCB. Based on the comments / suggestions, CPCB proposed the final notification. CPCB proposed revision of the existing notified standards as:

- The revised standard for instant & dry processing and wet/parchment processing for land application.
- Options for discharge on surface water bodies and proposed standards for the same.
- Revised Liner system specification for solar evaporation.
- Options for alternative lining material.

After detailed discussions, the Committee recommended that:

- The standards for land application for instant / dry processing and wet / parchment processing should be in uniformity with other sector.
- The representative from Coffee Board and Coffee Planter Association requested that option for discharge on surface water body should not be given. The Committee discussed the issues and recommended that as desired by the Coffee Board and Planter Association, Coffee Estates should not be allowed to discharge on surface water body/stream/river and accordingly this option and corresponding standard are now removed with appropriate foot note in this regard.

The Committee advised CPCB to submit the revised notification based on the aforesaid observations to MoEF&CC to take a final view in the matter. **(Action: CPCB)**

4.4 Environmental Standard for Tannery Industry

The proposed final notification for Environmental Standard Tannery Industry was presented by CPCB before the Expert Committee. The draft notification was placed on website of MoEF&CC for public consultation on 01/08/2018. On the draft notification comments /suggestions were received from different Stakeholders and same forwarded to CPCB. Based on the comments / suggestions, CPCB proposed the final notification. After detailed discussions, the following decisions were taken:

- BOD and TSS limits to be kept as 20 mg/l and 50 mg/l. Industry should make necessary improvements in ETPs to comply with these stringent limits.
- TDS parameter to be introduced with its limits as 2100 mg/l to provide level playing field for standalone units and units in clusters.
- In view of inadequate information about total nitrogen content in raw effluent and thus cost implications of the new parameters and keeping in view that introducing NH₃-N parameter will have impact not only on standalone tanneries for which the revision in standards is proposed but also on CETPs which cover 90% tanneries, the Members agreed to defer introduction of this parameter.

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Cr⁺⁶ parameter to be introduced with its limits as 0.1 mg/l as proposed and Industry should take necessary precautions in chemical handling to comply with the prescribed limit.

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- In view of the difficulties expressed by the industry representatives in complying the proposed limits for Maximum Specific Water Consumption (SWC) for different raw materials / sets of processes, the Committee agreed to accept following changes in Maximum SWC limits:

- Raw to Wet blue / Wet white / Vegetable tanning - 20 m³ per ton hide/skin
- Post tanning processes - 20 m³ per ton hide/skin
- Raw to Finished - 40 m³ per ton hide/skin

The Committee advised CPCB to submit the revised notification based on the aforesaid observations to MoEF&CC to take a final view in the matter. (Action: CPCB)

4.5. Revised Discharge Standards for STP vide NGT order dated 21/12/2018

It was informed by Dr. H. Kharkwal, Scientist 'E', MoEF&CC that in the matter O.A No. 1069/2018 (M.A.Nos. 1792/2018 & 1793/2018), Nitin Shankar Deshpande Vs. UOI & Ors, the Hon'ble NGT was constituted an Expert Committee comprising of the Director or his nominee (Senior Professor of Environment Engineering) IIT Kanpur and IIT Roorkee, Senior representative of NEERI and Senior Scientist nominated by CPCB to review the matter of formulation of Discharge Standards for Sewage Treatment Plant and suggested to submit a report. The relevant para of the NGT Order is reproduced here-below:

"19. The report may be furnished by the CPCB to the MoEF&CC as well as to this Tribunal by email at ngt.filing@gmail.com on or before 31.03.2019. It will be open to MoEF&CC to take a fresh view in the light of the report and furnish its comments by email before the next date. The registry may forward the report to the applicant also who may file his comments, if any, before the next date."

In compliance of above NGT Order, the CPCB had forwarded a report of the Expert Committee constituted by Hon'ble NGT and same was discussed with concerned CPCB Officers on 18/04/2019 and suggested it should be placed in the next meeting of the Expert Committee on Environmental Standard for consideration. The Report was placed before the Expert Committee on 26/04/2019.

After detailed discussion the Expert Committee noted that the matter of Environmental Standards for STP a Sub-judice before Hon'ble NGT. The matter shall be taken in next meeting of the Expert Committee accordingly. (Action: MoEF&CC)

5. Proposed for issue of the Draft Notification under EPA 1986:-

5.1 Environmental Standard for Diesel Locomotives

The proposed draft notification for environmental standard Diesel Locomotives was presented by CPCB before the Expert Committee and intimated that the proposed standard formulated by the CPCB constituted a Standing Committee. Before presentation, Dr. H.Kharkwal, Scientist 'E', MoEF&CC informed the Expert Committee that in compliance of Hon'ble NGT vide order dated 23rd December, 2016 in the matter O.A.No.356 of 2013, S.K. Goyal Vs Chairperson, CPCB and Ors, emission norms need to be framed for diesel locomotives was earlier discussed in the 13th Expert Committee

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Meeting held on 8th & 9th November, 2017. In this connection meetings have been held on 02/02/2017 with the Ministry of Railway (MoR), RITES, RDSO, CPCB and MoEF&CC. In the meeting, it was decided for that the emission data of total 59 (38 ALCO + 21 EMD) locomotives are required to be considered as representative sample for the study to achieve confidence level of 95% and margin of error of 10% and issued by March 2019. CPCB in consultation of MoR, so far was examined only 23 representative's diesel locomotives. In view of the above the committee was of the opinion that CPCB shall complete the examination of the balance locomotives and formulate the standards at the earliest within a period of three months. Thereafter, the Ministry shall issue the draft notification inviting public comments under EPA 1986. The Report from CPCB was received end of March, 2019.

The Ministry of Railway representative intimated that Railway is going for 100% electrification and hence development of Standards for Railway Loco engines is uncalled for. The Expert Committee wanted to know from the Railway representatives about the time line for conversion to electric loco engines, which was not responded to in clear terms. Moreover, the Hon'ble NGT's directives need to be complied with, irrespective of the no's of Diesel Locomotives.

After detailed deliberations, the Expert Committee noted that the proposed standard by CPCB had not been shared with Ministry of Railway and suggested that Ministry of Railway advise their observations to CPCB / MoEF&CC by 17/05/2019 for further consideration. Thereafter CPCB shall propose the revised draft notification to MoEF&CC and Ministry shall issue the draft notification inviting public comments under EP Act, 1986. **(Action: CPCB)**

5.2 Environmental Standard for Bulk Drug and Formulation Industry

The proposed revised draft Environmental Standard for Bulk Drug and Formulation Industry was presented by CPCB before the Expert Committee. It was informed that the draft notification was earlier discussed in the 16th Expert Committee Meeting held on 13/12/2018. After detailed discussion on the proposed revised draft notification and following suggestions were made by the Committee:

- i. The title name of Pharmaceutical Industry should be changed to Bulk Drug and Formulation Industry.
- ii. In Additional Parameters, the limits shall be applicable to industries those are using Benzene, Toluene, Xylene, Methylene Chloride, Chlorobenzene in the effluent discharged.
- iii. API limits shall be applicable for units manufacturing API other than antibiotics in the effluent standard.
- iv. In order to control VOC emission, the condition of solvent recovery should be imposed, accordingly the standard was introduced i.e. the total losses of solvent should not be more than 3% of the solvent consumed.

The Committee advised the CPCB to submit the revised notification based on the aforesaid observations to MoEF&CC to take a final view in the matter. **(Action: CPCB)**

6. The meeting ended with vote of thanks to the Chair.

List of the Participants who attended the 17th meeting of the Expert Committee to finalize the Environment Standards held on 26th April, 2019 at Indira Paryavaran Bhawan, Jor Bagh Road, New Delhi.

S. No.	Name	Designation & Name of Organisation
1.	Shri A. K. Nautiyal	Chairman & Joint Secretary, MoEF&CC
2.	Dr. K. P. Nyati	Expert Member
3.	Shri S.P. Chakrabarti	Expert Member, Ex-MS, CPCB,
4.	Shri A.K. Diwakar	Expert Member (Representative), Sr. Manager, Ministry of Coal / CIL
5.	Ms. B. Sandhya	Expert Member (Representative), Scientist 'D', BIS, New Delhi
6.	Shri R. K. Jaiswal	Expert Member (Representative), Development Officer, D/o Heavy Industry
7.	Shri Makarand Phadke	Special Invitee, Director (Sugar & Veg. Oil), Department of Food & Public Distribution, New Delhi
8.	Shri S. Anil Kumar	Special Invitee, JTO, Department of Food & Public Distribution
9.	Ms. Supriya Devasthali	Special Invitee, Director, DIPP
10.	Ms. Remya Prabha	Special Invitee, Deputy Director (Policy)
11.	Dr. D.S. Kharat	Invitee, Scientist 'E', CPCB
12.	Shri P.K. Mishra	Invitee, Scientist 'E' CPCB
13.	Shri Gurnam Singh	Invitee, Scientist 'E' CPCB
14.	Shri Dinbandhu Gouda	Invitee, Scientist 'E' CPCB
15.	Shri Nazimuddin	Invitee, Scientist 'E' CPCB
16.	Shri J.Chandra Babu	Invitee, Scientist 'D' CPCB
17.	Ms. Smriti Upadhyay	Invitee, Scientist 'D' CPCB
18.	Shri Vivek K.	Invitee, Scientist 'D' CPCB
19.	Shri Mukesh Balodhi	Invitee, Scientist 'D' CPCB
20.	Shri Kamlesh Singh	Invitee, Scientist 'D' CPCB
21.	Shri Y. N. Mishra	Invitee, Scientist 'C' CPCB
22.	Shri Kedarnath Das	Invitee, Scientist 'C' CPCB
23.	Ms. Alka Srivastava	Invitee, SSA, CPCB
24.	Dr. H. Kharkwal	Member Convener, Scientist 'E', MoEF&CC
Environmental Standards for Sea Water Criteria for Metal & Pesticides:		
25.	Dr. S.R. Marigoudar	Scientist 'D', National Centre for Coastal Research (NCCR), Ministry of Earth Science (MoES).
Automobile Service Station and Bus Depot:		
26.	Dr. Rashid Hasan	Advisor, SIAM
Environmental Standards for Fermentation Industry:		
27.	Shri G.K.Thakur	Director, Indian Sugar Mills Association
28.	Shri V.N. Raina	AIDA
29.	Shri K.P. Singh	AIDA

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30.	Shri Narendra Kumar Jain	AIDA
31.	Shri Sandeep Kumar Misra	AIDA (Mawana Sugar)
32.	Shri Ashish Awasthi	Triveni Engg. & Ind. Ltd
Environmental Standards for Coffee Industry		
33.	Dr. J. S. Nagaraja	Coffee Board, CCRI, CRS
34.	Dr. M. M. Chersgappa	Karnataka Planters Association
35.	Shri Vijay Karnad	Karnataka Planters Association
Tannery Industry		
36.	Shri Anil Kumar Mishra	Regional Director, CLE
37.	Shri Vinay Singh	Calcutta Leather Complex Tanners Association
38.	Shri Arshad Jamal	Leather Industries Welfare Association
39.	Shri Ghular	Gujarat Tanners
40.	Shri C.M. Zaffarullah	Secretary, South India Tanners & Dealers Association
41.	Shri Adeel Arshad	All India Skin & Hide Tanners & Merchants Association (AISHTMA)
42.	Shri Faiyaz Ahmed	All India Skin & Hide Tanners & Merchants Association (AISHTMA)
43.	Shri R. Ramesh Prasad	All India Skin & Hide Tanners & Merchants Association AISHTMA)
44.	Shri C. Ramesh D.	All India Skin & Hide Tanners & Merchants Association AISHTMA)
Diesel Locomotives		
45.	Shri S.K. Tanti	DME(Tr) Railway Board
46.	Shri Sanjeev Wadehre	SSE, Railway Board
47.	Shri Vineet Singhal	Director, RDSO

Environmental Standard for Automobile Service Stations, Bus Depots or Workshop:

S.No.	Industry	Parameter	Standard
(1)	(2)	(3)	(4)
	Automobile Service Station, Bus Depot or Workshop	Effluent Standard	
		(Concentration not to exceed, in mg/l except for pH)	
		Inland Surface water/land for irrigation/Public Sewer	
		pH	6.5-8.5
		Total Suspended Solids	50
		Chemical Oxygen Demand	150
		Oil & Grease	10

Note:

- For Service Stations, Bus Depots and Workshops with metal pre-treatment facilities, limit of 5 mg/l of dissolved phosphates (as P) and 5 mg/l of zinc shall also apply
- Solid Wastes/ Hazardous Waste, if any shall be disposed off as per the Solid Waste Management Rules 2016 and Hazardous and Other Waste (Management & Trans-boundary Movement) Rules, 2016.

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ANNEXURE A 2

F. No. 15017/42/2007-CPW
GOVERNMENT OF INDIA
MINISTRY OF ENVIRONMENT, FOREST & CLIMATE CHANGE
(CP DIVISION)

Indira Paryavaran Bhawan
Level-II, Prithvi Wing, Jorbagh Road
New Delhi-110003

Dated: 25th September, 2019

To

As per list enclosed

Subject: Minutes of the 18th Expert Committee Meeting on Environmental Standards held on 09/08/2019 at Indira Paryavaran Bhawan, MoEF&CC, New Delhi- regarding.

Sir,

I am directed to forward herewith a copy of minutes of the 18th Expert Committee Meeting on Environmental Standards held on 09/08/2019 under the Chairmanship of Shri A.K. Nautiyal, Joint Secretary, Ministry of Environment Forest & Climate Change, New Delhi on the mentioned subject for your perusal and necessary action.

Yours faithfully,

Encl: as above

Vinod Kumar
25/9/19
(Vinod Kumar Kushwaha)
Section Officer

List of Members

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1. Joint Secretary/Adviser (CP Division) : Chairman
2. Representative of Ministry of Heavy Industries, Udyog Bhawan, Rafi Marg, New Delhi- 110001 : Member
3. Director & Head (Chemical), BIS, 9, Bahadur Shah Zafar Marg New Delhi : Member
4. Executive Director, (R&D) IOCL, Faridabad, Sector-13, Faridabad, Haryana : Member
5. Director, Department of Health & Family Welfare, M/o Health, Family & Welfare, Udyog Bhawan, New Delhi : Member
6. Advisor (Tech), Ministry of Coal, Shashtri Bhawan New Delhi-110001 : Member
7. Controller General, Indian Bureau of Mines, Civil lines-440001 Nagpur : Member
8. Director, National Institute of Occupational Health (NIOH), ICMR, Ahmadabad-380016 : Member
9. Director/Addl. Director (CPDiv), MoEF&CC : Member-Convener
10. Head (Env. Division), CII, ITC Centre of Excellence for sustainable, 2nd Floor, Thapar House, 124, Janpathn New Delhi : Member
11. Head (Env. Division), PHD Chamber of Commerce and Industries Kranti Marg, Siri Institutional Area, Block-a, Nipccd Campus, Hauz Khas, New Delhi-110016: Member
12. Chief Engineer (EMO), Central Water Commission, Sewa Bhawan, R.K. Puram, Delhi : Member
13. Secretary, Central Electricity Authority, Sewa Bhawan, Sector-5, R.K. Puram, Delhi : Member
14. Sh. K.P. Nyati, Environment Professor, D-1-C/56, A, Janakpuri New Delhi-110058 : Member
15. Dr. S. P. Chakraborty, Ex-Member Secretary/Director, CPCB : Member
16. Member Secretary, Central Pollution Control Board, Delhi : Member

Minutes of the 18th Expert Committee Meeting held on 9th August, 2019 at Indira Paryavaran Bhawan, MoEF&CC, New Delhi for finalization of the Environmental Standards for different industries.

The 18th Meeting of the Expert Committee was held on 9th August, 2019 at Indira Paryavaran Bhawan, MoEF&CC, New Delhi under the Chairmanship of Shri A.K. Nautiyal, Joint Secretary, MoEF&CC for finalization of Four Final, Three Draft and One New Draft proposed environmental standards in respect of Eight(8) Industrial Sector / Categories, which are as follows:

(A) Proposed for issue of the Final Notification under EPA 1986: -

- i. Fermentation Industry,
- ii. Coffee Industry,
- iii. Tannery Industry,
- iv. Discharge Standards for Sewage Treatment Plants (STP) - Revised

(B) Proposed for issue of the Draft Notification under EPA 1986:-

- i. Water Quality Standard for Coastal Water Marine Outfalls in respect of Primary Water Quality Criteria for Class SW-III Waters and Class SW-V Water-Amendment,
- ii. Diesel Locomotives Standards
- iii. Bulk Drug and Formulation (Pharmaceutical) Industry Standards

(C) New Proposed Draft Notification under EPA 1986:-

- i. Environmental Standards for Hot Mix Plants

1.1. At the outset, the Chairman welcomed the Members of the Expert Committee and the Stakeholders representing the above sectors / categories. In his opening remarks he appraised the background of the proposed Final, Draft and New Notifications for different Eight (8) sectors. He requested CPCB to present the details of each of the notifications at (A), (B) and (C) above. The list of participants is at **Annexure-A**.

1.2. The Expert Committee took up final / draft / new notifications as indicated above. The CPCB concerned officers from each of the above sectors were invited for brief presentation when the sectors / categories were taken.

2. Confirmation of Minutes of the 17th Expert Committee Meeting

The Comments sought on draft minutes of the 17th Expert Committee Meeting held on dated 26th April, 2019. Since, there is no comment, this minute were confirmed.

3. Proposed for issue of the Final Notification under EPA 1986: -

3.1 Environmental Standard for Tannery Industry

The final revised notification for Environmental Standard Tannery Industry was presented by CPCB after incorporating the suggestions / recommendations of the 17th Expert Committee meeting held on 26/04/2019. After detailed discussions

on the revised notification, Committee recommended a footnote should be added that: 'Standards for TDS shall not be applicable in case of marine disposal through proper marine outfall' and notify the final notification under Environment (Protection) Rules, 1986 as at **Annexure B**.

3.2 Environmental Standard for Coffee Industry

The final revised notification for Environmental Standard Coffee Industry was presented by CPCB after incorporating the suggestions / recommendations of the 17th Expert Committee meeting held on 26/04/2019. After detailed discussions on the proposed final revised notification, Committee recommended to notify the final notification under Environment (Protection) Rules, 1986 as at **Annexure C**.

3.3. Standard for Fermentation Industry

The final revised notification for Environmental Standard Fermentation Industry was presented by CPCB after incorporating the suggestions / recommendations of the 17th Expert Committee meeting held on 26/04/2019. After detailed discussions the Committee suggested / incorporate the following:

1. In footnote a) may be change as: "Molasses based distilleries shall achieve minimum volume reduction of 60% for raw spent wash through evaporation-concentration before utilizing in bio composting with press mud/incineration/dryer for achieving ZLD. The distilleries practicing incineration/drying or equivalent routes shall additionally achieve a minimum of 45 % solids in the concentrated spent wash."
2. Additionally, the following shall be inserted at footnote point no.d):
"Any proposal for alternate technology for achieving ZLD by molasses and grain based distilleries shall be evaluated by SPCBs/ MoEF&CC while issuing CTE/CTO/EC"
3. The maximum limit for Colour shall be read as 150 PCU instead of 350 PCU, which was a typographical error, in the draft notification. The same value of 150 PCU has been stipulated in the notified standards for Textile Industry vide G.S.R. (E) 978, dated 10/10/2016.

After incorporating the above suggestions, the Committee recommended to notify the final notification under Environment (Protection) Rules, 1986 as at **Annexure D**.

3.4. Environmental Standard for Sewage Treatment Plants (Revised)

The final notification for Environmental Standard for Sewage Treatment Plants (STP) - revised was presented by CPCB and informed that the MoEF&CC standards for STP vide G.S.R. No. 1265(E), dated 13/10/2017 was challenged in O.A No. 1069/2018 (M.A.Nos. 1792/2018 & 1793/2018), filed by Shri Nitin Shankar Deshpande before Hon'ble NGT. The Hon'ble NGT vide order dated 21/12/2018 stayed notified standards and constituted an Expert Committee comprising of the Director or his nominee (Senior Professor of Environment Engineering) IIT Kanpur and IIT Roorkee, Senior representative of NEERI and Senior Scientist nominated by CPCB to review the matter of formulation of Discharge Standards for Sewage Treatment Plant and suggested to submit a report. The Expert Committee

recommended standards for 07 parameters viz pH, BOD, COD, Total Nitrogen, Phosphorus, Fecal Coliform. The Expert Committee have been recommended more stringent for Mega and Metropolitan Cities than Class 1 cities followed by Others Towns and Deep Marine Outfall in that order. Hon'ble Tribunal vide its order dated 30/04/2019 accepted the report of the Expert Committee with the modification that the standards recommended for Mega and Metropolitan Cities will also apply to rest of the country.

Being aggrieved by the order dated 30/04/2019 pronounced by the NGT the Municipal Corporation of Greater Mumbai filed the instant appeal under section 22 of the National Green Tribunal, 2010. Municipal Corporation of Greater Mumbai filed Civil Appeal before Supreme Court. MCGM prayed that Impugned order passed by Hon'ble NGT in OA No. 1069 of 2018 dated 30/04/2019 may be set aside and the standards prescribed by the expert committee constituted by Hon'ble NGT vide order dated 21/12/2018 may be implemented.

Meeting convened with concerned organizations on July 12, 2019 at MoEF & CC and following points were observed. Current standards notified by MoEF & CC comparable with STP discharge standards applicable in other countries. Standards suggested by Expert Committee for Mega / Metropolitan Cities, as mandated by NGT will not be practical to implement uniformly across the country and majority of STPs would become non-compliant. 46 metropolitan cities contribute 33099 MLD of sewage which is about 51 % of the total sewage generation across India and hence there is need for stringent standards for metropolitan cities so as to reduce pollution load on recipient river / water bodies in metropolitan cities. During the meeting it was decided the CPCB shall propose draft environmental standard for effluent discharge from STP.

After detailed discussions on the submitted revised notification by CPCB, Committee recommended the proposed standards for adoption as at Annexure E. However, since the matter is sub-judice, further decision will take out after the direction of Hon'ble Court.

4. Proposed for issue of the Draft Notification under EPA 1986: -

4.1 Water Quality Standard for Coastal Water Marine Outfalls in respect of Primary Water Quality Criteria for Class SW-III Waters and Class SW-V Water-Amendment

The revised amendment draft notification for Water Quality Standard for Coastal Water Marine Outfalls in respect of Primary Water Quality Criteria for Class SW-III Waters and Class SW-V Water was presented by CPCB. The CPCB informed that as per recommendations of 17th MoEF & CC Experts Committee, an expert committee meeting was held on 24/05/2019 at NCCR (MoES), Chennai in consultation with CPCB and suggestions of the Experts Consultation Meeting were presented i.e. proposed standards for seven metals and one Pesticide in addition to the existing Primary Water Quality Criteria for Class SW-III Waters [for Industrial Cooling, Recreation (non-contact) and Aesthetics] and Primary Water Quality Criteria for Class SW-V Waters [for Navigation and Controlled Waste Disposal].

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CPCB representative also informed the Committee that in order to impart knowledge on assessing criterion continuous concentration of the proposed additional parameters (seven heavy metals and pesticides), a hands-on training on measurement of such heavy metals and pesticide at marine outfall is also being organised to the coastal States/UTs, during 21-23 August, 2019 at NCCR, Chennai.

During the discussion, Committee suggested to carry out such studies by NCCR, Chennai in association with CPCB to derive such standards for Primary Water Quality Criteria for Class SW-I, Class SW-II and Class SW-IV waters by including heavy metals as well as predominantly used pesticides in the coastal States/UTs in India and also to propose such amendments in second phase.

After deliberations, the Committee recommended inclusion of proposed additional parameters (seven metals and one pesticide) to the existing Primary Water Quality Criteria for Class SW-III Waters [for Industrial Cooling, Recreation (non-contact) and Aesthetics] and Class SW-V Waters [for Navigation and Controlled Waste Disposal] and to notify the draft notification inviting public suggestion in accordance with EPA 1986 is at Annexure F.

4.2. Environmental Standard for Diesel Locomotives

The background of environmental standard for Diesel Locomotives was presented by CPCB before the Expert Committee. The CPCB informed that as suggested by Experts Committee in its 17th meeting held on 26/04/2019, the senior officials from Railways had met Chairman CPCB in July 2019 and informed that the RITES Report shall be submitted in September 2019. The Report was to be submitted in June 2019. CPCB further informed that Railways had been asked to incorporate the financial and technical requirement for the proposed emission standards proposed for Diesel Locomotives as well the detailed phase-out plan for Diesel Locomotives as informed by the Railways. After detailed discussions, the Chair directed the Railways to submit the complete report as per CPCB requirements to CPCB at the earliest. The CPCB may also pursue the same with Ministry of Railway.

4.3. Environmental Standard for Bulk Drug and Formulation (Pharmaceutical) Industry

The proposed revised draft Environmental Standard for Bulk Drug and Formulation (Pharmaceutical) Industry was presented by CPCB before the Expert Committee. It was informed that the draft notification was earlier discussed in the 17th Expert Committee Meeting held on 26/04/2019 and suggestions made during meeting by the committee were incorporated. The revised standards were again discussed and the Committee suggested incorporating following:

- 1) The standard for COD in effluent may be considered as 250 mg/l in place of 200 mg/l as the 250 mg/l is already prescribed in other similar type of industries.
- 2) The CPCB should develop guidelines for State Pollution Control Boards/ Pollution Control Committees (SPCBs/PCCs) for laboratory analysis of antibiotics in the effluent for implementation of proposed standards in future.

After incorporating the above suggestions the Committee recommended Ministry may issue the draft notification inviting public suggestion in accordance with EPA 1986 is at Annexure G.

5. New Proposed Draft Notification under EPA 1986: -

5.1 Environmental Emission Standards for Hot Mix Plants

The proposed revised draft Environmental Emission Standard for Hot Mix Plants (HMPs) was presented by CPCB before the Expert Committee covering aspects related to classification/type of HMPs, manufacturing process, sources of pollution, main pollutants, and comments from stakeholders, formulation of standards, etc. CPCB also informed that the emission standards for Hot Mix Plants were earlier considered in the 16th Expert Committee meeting held on 13/12/2018 and recommended to consult the proposed standards with stakeholders. Accordingly, the proposed standards were forwarded to the stakeholders and the comments/views received from the 14 stakeholders were considered. During the meeting, Committee was of the view that the normalization of particulate matter (PM) results at 5% CO₂ is too low and goes against the fuel / energy economy.

After detailed discussions, the Committee agreed for draft notification of the proposed emission standards for HMPs delete the footnote on CO₂ correction and recommended Ministry may issue the draft notification inviting public suggestion in accordance with EPA 1986 is at **Annexure H**.

6. The meeting ended with vote of thanks to the Chair.

List of the Participants who attended the 18th meeting of the Expert Committee to finalize the Environment Standards held on 9th August, 2019 at Indira Paryavaran Bhawan, Jor Bagh Road, New Delhi.

S. No.	Name	Designation & Name of Organisation
1.	Shri A. K. Nautiyal	Chairman & Joint Secretary, MoEF&CC
2.	Dr. K. P. Nyati	Expert Member
3.	Shri Gyan Prakash	Scientist 'B', BIS, New Delhi
4.	Mohd. Zakir Hussain	Director, D/o Heavy Industry
5.	Shri Sushil hakra	Consultant, D/o Heavy Industry
6.	Ms. Anita Gahlot	Director, CEA
7.	Shri Chetan Sharma	Assistant Director, CEA
8.	Shri P.K. Mishra	Invitee, Scientist 'E' CPCB
9.	Shri Ajay Aggarwal	Invitee, Scientist 'E' CPCB
10.	Ms. Divya Sinha	Invitee, Scientist 'E' CPCB
11.	Ms. Smriti K. Upadhyay	Invitee, Scientist 'E' CPCB
12.	Shri J.Chandra Babu	Invitee, Scientist 'E' CPCB
13.	Shri Vishal Gandhi	Invitee, Scientist 'D' CPCB
14.	Shri Vivek K.	Invitee, Scientist 'D' CPCB
15.	Shri Mukesh Balodhi	Invitee, Scientist 'D' CPCB
16.	Shri Kamlesh Singh	Invitee, Scientist 'D' CPCB
17.	Shri Y. N. Mishra	Invitee, Scientist 'C' CPCB
18.	Shri K.N.Dash	Invitee, Scientist 'C' CPCB
19.	Ms. Deepa Chaudhary	Invitee, SRF, CPCB
Water Quality Standard for Coastal Water Marine Outfalls- Amendment		
20.	Dr. S.R. Marigoudar	Scientist 'D', National Centre for Coastal Research (NCCR), Ministry of Earth Science (MoES).
21.	Shri K. Venkatarama Sharma	NCCR
Tannery Industry		
22.	Shri Shahid Parnez	Jt. Secretary, CLC Tanners Association
23.	Shri Anshuman Mishra	Jt. Convenor, CLC Tanners Association
Diesel Locomotives		
24.	Shri S.K. Tanti	DME(Tr) Railway Board
25.	Shri Sanjeev Wadehre	SSE, Railway Board

Environmental Standards for Discharge of Effluent from Tannery Industry

S. No.	Industry	Parameter	Standards (applicable for all modes of disposal*)
1	2	3	4
57	Tanneries	Treated Effluent	Max. permissible values (in mg/l, except for pH)
		pH	6 to 9
		Biochemical Oxygen Demand (BOD ₅ at 27 °C)	20
		Chemical Oxygen Demand (COD)	250
		Total Suspended Solids (TSS)	50
		Total Dissolved Solids (TDS)	2100**
		Sulphides (as S)	2
		Total Chromium (as Cr)	2
		Hexavalent Chromium (as Cr ⁺⁶)	0.1
		Oils and Grease	10
		Notes:	
		1. **TDS limit with respect to treated effluent shall be 2100 milligram per litre; however, in case where TDS in intake water is above 1100 milligram per litre, a maximum contribution up to 1000 milligram per litre shall be permitted provided the maximum limit of 3100 milligrams per litre is not exceeded in the treated effluent. 2. Standards for TDS shall not be applicable in case of marine disposal through proper marine outfall. 3. Standards are equally applicable to all types of stand-alone tanneries irrespective of their scale of production. 4. Chrome tanning units shall ensure installation of 'Chrome Recovery Plant' for treatment of spent chrome liquor so as to recover chromium sulphate. 5. The tannery shall ensure salt recovery through soak liquor segregation. 6. The standalone units shall meet prescribed discharge norms; however, SPCB / PCC shall mandate recycle / reuse of the treated water in water scarce / environmentally sensitive / critical areas. 7. In case of discharge of treated effluent on land for irrigation, the impact on soil and groundwater quality shall be monitored twice a year (pre- and post- monsoon) by the tannery unit.	
		Maximum specific water consumption for processing hides/ skins: (monthly average values)	
		Raw to Wet blue/Wet white/Vegetable tanning	20 m ³ per ton of hides /skins
		Post tanning processes	20 m ³ per ton of hides /skins
		Raw to finished	40 m ³ per ton of hides /skins

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		Maximum wastewater discharge= 85% of maximum water consumption.
		Factors to re-calculate Finished leather into Wet blue/white and Hide: Shoe upper leather: 15 ton of Raw hides /skins = 7.84 ton of Wet blue = 2.94 ton of finished leather Upholstery leather: 15 ton of Raw hides/skins = 5.08 ton of Wet blue = 1.48 ton of finished leather

Environmental Standards Fermentation Industry (Distilleries, Malteries and Breweries)

(A) Effluent Standards

Sl. No.	Category	Standard		
1.	Molasses based distilleries including yeast manufacturing, grain based distilleries and any other process / industry producing alcohol by distillation	Zero Liquid Discharge (ZLD) All effluent streams including spent wash/stillage, spent lees, condensate/permeate, washings, etc shall be suitably treated** and disposed/recycled/reused and shall not be discharged within or outside the industrial premises		
2.	Breweries, Malteries and Standalone bottling units	Sl. No.	Parameter	Limiting Standard (Concentration not to exceed mg/l except for pH and colour)
		1.	pH	6.5-8.5
		2.	Colour	150 PCU
		3.	Suspended solids	50
		4.	BOD (3 days at 27°C)	
			Disposal to inland surface water or river / streams	20
			Disposal on land or for irrigation	100
	Note: ** a) Molasses based distilleries shall achieve minimum volume reduction of 60% for raw spent wash through evaporation-concentration before utilizing in bio composting with press mud/incineration/dryer for achieving ZLD. The distilleries practicing incineration/drying or equivalent routes shall additionally achieve a minimum of 45 % solids in the concentrated spent wash. b) Grain based distillery shall achieve ZLD through DDGS production (max. 10 % moisture) or equivalent route. c) All other effluent streams shall be suitably treated and reused/recycled. Discharge/Land application of treated/partially treated effluent is not permitted. d) Any proposal for alternate route in achieving ZLD by molasses and grain based distilleries shall be evaluated by SPCBs/MoEF&CC while issuing CTE/CTO/EC.			

(B) Emission Standard:

Sl. No.	Category	Standard	
1.	Spent wash incineration boilers	Parameter	Limiting Standard (Concentration not to exceed mg/Nm ³)
		Particulate Matter	100

Environmental Standard for Sewage Treatment Plants (Revised)

Sl. No.	Industry	Parameters	Standards		
1	2	3	4		
		Effluent discharge standards(applicable to all mode of disposal)			
			Metropolitan Cities (>10 Lakhs)	Class 1 Cities (>1 Lakhs)	Others
"105	Sewage Treatment Plants (STPs)	pH	5.5-9.0	5.5-9.0	5.5-9.0
		Bio-Chemical Oxygen Demand (BOD)	10	20	30
		Total Suspended Solids (TSS)	20	50	100
		Chemical Oxygen Demand (COD)	100	150	250
		Fecal Coliform (FC) (Most Probable Number per 100 milliliter, MPN/100ml)	1000	1000	1000
Note:					
i. Metropolitan Cities- Population More than 10 Lakhs and Class-I-Population more than 1 Lakh					
ii. All values in mg/l except for pH and Fecal Coliform.					
iii. These standards shall be applicable for discharge into water bodies as well as for land disposal/applications.					
iv. The standards for Fecal Coliform shall not apply in respect of use of treated effluent for industrial purposes.					
v. Old/existing STPs shall achieve these standards within a period of three years from date of publication of this notification in the Official Gazette.					
vi. In case of discharge of treated effluent into sea, it shall be through proper marine outfall and the existing shore discharge shall be converted to marine outfalls, and in cases where the marine outfall provides a minimum initial dilution of 150 times at the point of discharge and a minimum dilution of 1500 times at a point 100 meters away from discharge point, then, the existing norms shall apply as specified in the general discharge standards vide G.S.R. 422(E) dated 19/05/1993.					
vii. Reuse/Recycling of treated effluent shall be encouraged and in cases where part of the treated effluent is reused and recycled involving possibility of human contact, standards as specified above shall apply.					
viii. Central Pollution Control Board / State Government /Union Territory may issue more stringent norms taking account to local condition and identified polluted river stretches under section 5 of the Environment (Protection) Act, 1986".					

Water Quality Standard for Coastal Water Marine Outfalls in respect of Primary Water Quality Criteria for Class SW-III Waters and Class SW-V Water-Amendment

In the Environment (Protection) Rules, 1986, in Schedule-I, for serial number 86 relating to water quality standards for coastal waters marine outfalls, the following entries shall be inserted namely:-

(a) under Table 1.3- Primary Water Quality Criteria for Class SW-III Waters [For Industrial Cooling, Recreation (non-contact) and Aesthetics], serial number 9 to 16, the standards for the additional parameters shall be inserted after Sl.No.8, as follows: -

S. No.	Parameter	Standards	Rationale /Remarks
9.	Cadmium (as Cd)	3.03 µg/1 or less	Based on Criterion Continuous Concentration (CCC)**
10.	Copper (as Cu)	4.1µg/1 or less	
11.	Mercury (as Hg)	0.38µg/1 or less	
12.	Zinc (as Zc)	10.6µg/1 or less	
13.	Lead (as Pb)	4.6µg/1 or less	
14.	Arsenic (as As)	3.5 µg/1 or less	
15.	Chromium (as Cr)	8.0µg/1 or less	
16.	Monocrotophos	89 ng/1 or less	

** Criterion Continuous Concentration (CCC)- an estimate of the highest concentration of the material in ambient water (based on bio-assay toxicity) to which an aquatic community can be exposed indefinitely without resulting in an unacceptable adverse effect.

(b) under Table 1.5-Primary Water Quality Criteria for Class SW-V Waters [For Navigation and Controlled Waste Disposal], serial number 6 to 13 and the parameters shall be inserted after S1.No. 5 as follows: -

S No.	Parameter	Standards	Rationale /Remarks
6.	Cadmium (as Cd)	3.03 µg/1 or less	*Based on Criterion Continuous Concentration (CCC)
7.	Copper (as Cu)	4.1µg/1 or less	
8.	Mercury (as Hg)	0.38µg/1 or less	
9.	Zinc (as Zc)	10.6 µg/1 or less	
10.	Lead (as Pb)	4.6µg/1 or less	
11.	Arsenic (as As)	3.5µg/1 or less	
12.	Chromium (as Cr)	8.0µg/1 or less	
13.	Monocrotophos	89 ng/1 or less	

* Criterion Continuous Concentration (CCC) - an estimate of the highest concentration of the material in ambient water (based on bio-assay toxicity) to which an aquatic community can be exposed indefinitely without resulting in an unacceptable adverse effect.

Bulk Drug and Formulation (Pharmaceutical) Industry Standards (Draft)

Sl. No.	Industry	Parameters	Standard
1	2	3	4
73	Bulk Drug and Formulation (Pharmaceutical)	A. EFFLUENT STANDARDS	
		For final outlet of ETP Limiting value for concentration (in mg/l except for pH and Bio assay)	
		i) Compulsory Parameters	
		pH	6.0 -8.5
		BOD (3 days 27°C)	30
		COD	250
		TSS	100
		TDS	2100
		Oil & Grease	10
		Bio - Assay Test**	90% Survival of Fish after first 96 hours in 100% effluent
		ii) Additional Parameters	
		Ammonical Nitrogen	50
		Nitrate Nitrogen	10
		***Benzene	0.05
		***Toluene	0.05
		***Xylene	0.06
		***Methylene Chloride	0.9
		Phosphates as P	5
		Chlorides	1000
		Sulphates as SO ₄	1000
		Fluoride	2
		Sulphides as S	2
		Phenolic Compounds	1
		Total Residual Chlorine	1
		Zinc	5
		Iron	3
		Copper	3
		Total Chromium	2
		Hexavalent Chromium (Cr ⁶⁺)	0.1
		Cyanide	0.1
		Arsenic	0.2
		Mercury	0.01
		Lead	0.1

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		****Active Pharmaceutical Ingredient (API)	0.05
		iii) for final outlet of Industries discharging to CETP	
		For each Common Effluent Treatment Plant(CETP), the state Board will prescribe inlet quality Standards for general parameters, Ammonical Nitrogen and Heavy Metals as per the design of the Common Effluent Treatment Plant(CETP) and local needs & conditions. As per notification S.O. 4 (E) dated 1 st January, 2016	
		Note:	
		ZLD = Zero Liquid Discharge system in <i>Bulk Drug and formulation</i> industry is considered when treated effluent meeting the limits prescribed for compulsory parameters shall be used in Process or Utilities (boiler/ Cooling tower etc.). The reuse of treated effluent in gardening/ horticulture shall not be considered as ZLD in Bulk Drug and formulation industries.	
		** The Bio assay test shall be conducted as per IS : 6582-1971	
		i) Parameters listed as "Additional Parameters" shall be prescribed depending upon the process and product.	

		ii) Limits shall be applicable to industries those are using Benzene, Toluene, Xylene, Methylene Chloride, Chlorobenzene.	

		(iii) API limits shall be applicable for units manufacturing API other than antibiotics.	
		B. EMISSION STANDARDS from Process Reactor Vents/ Tank farm Vents	
		Parameter	Limiting value for concentration (mg/Nm ³)
		Chlorine	15
		Hydrochloric acid vapour	35
		Ammonia	30
		Benzene	5
		Toluene	100
		Acetonitrile	1000
		Dichloromethane	200
		Xylene	100
		Acetone	2000
		C. The total losses of solvent should not be more than 3% of the solvent consumed.	

D. Antibiotic Residues in the treated effluent of Bulk Drug and Formulation Industry and CETP with membership of Bulk Drug and formulation Units
Individual antibiotic residues will be equal to or less than the values given in the below table.

Parameter	Limiting value for concentration (µg/l)
i. Amikacin	6.40
ii. Amoxicillin	0.10
iii. Amphotericin B	0.01
iv. Ampicillin	0.10
v. Anidulafungin	0.01
vi. Avilamycin	3.20
vii. Azithromycin	0.01
viii. Aztreonam	0.20
ix. Bacitracin	3.20
x. Bedaquiline	0.03
xi. Benzylpenicillin	0.10
xii. Capreomycin	0.80
xiii. Cefaclor	0.20
xiv. Cefadroxil	0.80
xv. Cefalonium	8.40
xvi. Cefaloridine	1.60
xvii. Cefalothin	0.80
xviii. Cefazolin	0.40
xix. Cefdinir	0.10
xx. Cefepime	0.20
xxi. Cefixime	0.02
xxii. Cefoperazone	0.20
xxiii. Cefotaxime	0.04
xxiv. Cefoxitin	3.20
xxv. Cefpirome	0.02
xxvi. Cefpodoxime	0.10
xxvii. Cefquinome	0.64
xxviii. Ceftaroline	0.02
xxix. Ceftazidime	0.20
xxx. Ceftributen	0.10
xxxi. Ceftiofur	0.02
xxxii. Ceftobiprole	0.09
xxxiii. Cefotolozane	0.76
xxxiv. Ceftriaxone	0.01
xxxv. Cefuroxime	0.20
xxxvi. Cephalixin	0.03
xxxvii. Chloramphenicol	3.20
xxxviii. Ciprofloxacin	0.02
xxxix. Clarithromycin	0.03
xl. Clavulanic Acid	22.40
xli. Clinafloxacin	0.20
xlif. Clindamycin	0.04
xlili. Cloxacillin	0.05
xliv. Colistin	0.80
xlvi. Daptomycin	0.40
xlvi. Delamanid	0.02
xlvi. Doripenem	0.04

	xlvi. Doxycycline	0.80
	xlix. Enramycin	1.92
	i. Enrofloxacin	0.02
	ii. Ertapenem	0.05
	iii. Erythromycin	0.20
	iiii. Ethambutol	0.80
	liv. Faropenem	0.01
	lv. Fidaxomicin	0.01
	lvi. Florfenicol	0.80
	lvii. Fluconazole	0.10
	lviii. Flumequine	0.10
	lix. Fosfomycin	0.80
	lx. Fusidic acid	0.20
	lxi. Gatifloxacin	0.05
	lxii. Gemifloxacin	0.02
	lxiii. Gentamicin	0.08
	lxiv. Imipenem	0.05
	lxv. Isoniazid	0.05
	lxvi. Itraconazole	0.004
	lxvii. Kanamycin	0.44
	lxviii. Levofloxacin	0.10
	lxix. Lincomycin	0.72
	lxx. Linezolid	2.68
	lxxi. Loracarbef	0.80
	lxxii. Mecillinam	0.40
	lxxiii. Meropenem	0.02
	lxxiv. Metronidazole	0.05
	lxxv. Minocycline	0.40
	lxxvi. Moxifloxacin	0.05
	lxxvii. Mupirocin	0.10
	lxxviii. Nalidixic acid	6.40
	lxxix. Narasin	0.20
	lxxx. Neomycin	0.01
	lxxxi. Netilmicin	0.20
	lxxxii. Nitrofurantoin	25.60
	lxxxiii. Norfloxacin	0.20
	lxxxiv. Ofloxacin	0.20
	lxxxv. Oxacillin	0.40
	lxxxvi. Oxytetracycline	0.20
	lxxxvii. Pefloxacin	3.20
	lxxxviii. Phenoxymethylpenicillin	0.02
	lxxxix. Piperacillin	0.20
	xc. Polymixin	0.80
	xc. Retapamulin	0.02
	xcii. Rifampicin	0.02
	xciii. Roxithromycin	0.40
	xciv. Secnidazole	0.40
	xcv. Sparfloxacin	0.02
	xcvi. Spectinomycin	12.80
	xcvii. Spiramycin	0.20
	xcviii. Streptomycin	6.40
	xcix. Sulbactam	6.40
	c. Sulfadiazine	288.00
	ci. Sulfadimethoxine	20.00
	cii. Sulfadoxine	0.24

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	ciii.	Sulfamethoxazole	0.24
	civ.	Tazobactam	17.60
	cv.	Tedizolid	3.92
	cvi.	Teicoplanin	0.20
	cvi.	Telithromycin	0.02
	cviii.	Tetracycline	0.40
	cix.	Thiamphenicol	0.40
	cx.	Tiamulin	0.40
	cxii.	Ticarcillin	3.20
	cxii.	Tigecycline	0.40
	cxiii.	Tildipirosin	0.17
	cxiv.	Tilmicosin	0.40
	cxv.	Tobramycin	0.40
	cxvi.	Trimethoprim	0.20
	cxvii.	Trovafloxacin	0.01
	cxviii.	Tylosin	0.33
	cxix.	Vancomycin	3.20
	cxx.	Viomycin	0.80
	cxxi.	Virginiamycin	0.80

13)

Note:- The sludge containing antibiotic residues shall be incinerated and the standard of incinerator notified for common hazardous waste incinerator or industry specific incinerator shall be applicable.

Environmental Standards for Hot Mix Plants (Draft)

Sl. No.	Type of hot mix plant	Concentration of particulate matter (mg/Nm ³) in stack emission shall not exceed
1.	Batch hot mix plant	150
2.	Drum hot mix plant	300

Note:

1. The stack height shall be calculated as (a) Stack height (H_s) = $14(Q)^{0.3}$ where, Q is the SO₂ emission rate in kg/h; and (b) Stack height (H_{pm}) = $74(Q)^{0.27}$ where, Q is the PM emission rate in ton/h. The stack height whichever is higher shall apply.
2. Use of furnace oil and rubber process oil shall be avoided.
3. Dust emission from material handling shall be contained with water sprinkling or covering of the points of dust emission.
4. The internal roads, working platform, loading and unloading areas in premises should be paved and kept clean all times.
5. Use of recycled asphalt pavement (RSP) shall be allowed.
6. Any process rejects or left over of the hot mix should be recycled in the process.
7. The site shall be reinstated at the end of operation phase i.e. after dismantling the plant.

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ANNEXURE A3
REGD. NO. D. L.-33004/99

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पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय

अधिसूचना

नई दिल्ली, 23 जनवरी, 2020

सा. का. नि. 44(अ).—अधिसूचना, जिसे केन्द्रीय सरकार, पर्यावरण (संरक्षण) अधिनियम, 1986 (1986 का 29) की धारा 6 और धारा 25 में प्रदत्त शक्तियों का प्रयोग करते हुए जारी करने का प्रस्ताव करती है, का निम्नलिखित प्रारूप पर्यावरण (संरक्षण) नियम, 1986 के नियम 5 के उपनियम (3) की अपेक्षानुसार, जनसाधारण जिनके उसके द्वारा प्रभावित होने की संभावना है, की जानकारी के लिए, एतद्वारा प्रकाशित किया जाता है; और एतद्वारा सूचना दी जाती है कि उक्त प्रारूप अधिसूचना पर उस तारीख से, जिसको भारत के राजपत्र की प्रतियां, जिसमें यह अधिसूचना अंतर्विष्ट है, जनसाधारण को उपलब्ध करा दी जाती है, साठ दिन की अवधि की समाप्ति पर या उसके पश्चात विचार किया जाएगा।

ऐसा कोई व्यक्ति, जो प्रारूप अधिसूचना में अंतर्विष्ट प्रस्तावों पर कोई आपत्ति या सुझाव देने में हितबद्ध है, इस प्रकार ऊपर विनिर्दिष्ट की गई अवधि के भीतर, केन्द्रीय सरकार द्वारा विचार किए जाने के लिए, आपत्ति या सुझाव सचिव, पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय, इंदिरा पर्यावरण भवन, जोर बाग रोड, नई दिल्ली - 110003 को या ई-मेल पते अर्थात् mscb.cpcb@nic.in और h.kharkwal@nic.in पर सदस्य सचिव, केन्द्रीय प्रदूषण नियंत्रण बोर्ड और मंत्रालय के वैज्ञानिक 'ई' को लिखित रूप में भेज सकेगा।

प्रारूप अधिसूचना

केन्द्रीय सरकार, पर्यावरण (संरक्षण) अधिनियम, 1986 में और अधिक संशोधन करने के लिए एतद्वारा निम्नलिखित नियम बनाती है, अर्थात्-

- 1 संक्षिप्त शीर्षक और प्रारम्भ—(1) इन नियमों को पर्यावरण (संरक्षण) संशोधन नियम, 2019 कहा जाएगा।
(2) ये आधिकारिक राजपत्र में उनके अंतिम प्रकाशन की तारीख से लागू होंगे।
2. पर्यावरण (संरक्षण) अधिनियम, 1986 में, अनुसूची-1 में क्रम संख्या 73 और उससे संबंधित प्रविष्टियों के लिए निम्नलिखित क्रम संख्या और प्रविष्टियां प्रतिस्थापित की जाएगी अर्थात:-

क्रम सं.	उद्योग	पैरामीटर	मानक
1	2	3	4
73	थोक दवा और निर्माण (फार्मास्युटिकल)	क. बहिस्त्राव मानक	
			ईटीपी का अंतिम आउटलेट सांद्रण के लिए सीमित मान) पीएच और जैव परख को छोड़कर मिलीग्राम / एल में)
		i) अनिवार्य पैरामीटर	
		पीएच	6.0 -8.5
		बीओडी) 3 दिन 27 डिग्री सेल्सियस(	30
		सीओडी	250
		टीएसएस	100
		टीडीएस	2100
		तेल और चिकनाई (ग्रीज)	10
		जैव - परख परीक्षण**	100% बहिस्त्राव में पहले 96 घंटों के बाद मछली की 90% उत्तरजीविता
		ii) अतिरिक्त पैरामीटर	
		अमोनिकल नाइट्रोजन	50
		नाइट्रेट नाइट्रोजन	10
		*** बेंजीन	0.05
		*** टॉल्विन	0.05
		*** ज़ाइलीन	0.06
		***मीथाइलीन क्लोराइड	0.9
		फॉस्फेट पी के रूप में	5
		क्लोराइड	1000
		सल्फेट SO ₄ के रूप में	1000
		फ्लोराइड	2
		एस के रूप में सल्फाइड	2
		फेनोलिक यौगिक	1
		कुल अवशिष्ट क्लोरीन	1
		जस्ता	5
		लोहा	3
		तांबा	3
		कुल क्रोमियम	2
		हेक्सावैलेंट क्रोमियम) Cr 6+)	0.1

		साइनाइड	0.1
		आर्सेनिक	0.2
		पारा	0.01
		लेड	0.1
		**** सक्रिय दवा संघटक) एपीआई(	0.05
		iii) साझा बहिष्काव शोधन संयंत्र में निस्सारित कर रहे उद्योगों के अंतिम आउटलेट के लिए	
		दिनांक 1 जनवरी, 2016 की अधिसूचना का के अनुसार प्रत्येक (अ) 4 .आ.साझा बहिष्काव शोधन संयंत्र) सीईटीपी) के लिए, राज्य बोर्ड साझा बहिष्काव शोधन संयंत्र) सीईटीपी) के डिजाइन और स्थानीय जरूरतों और स्थितियों के अनुसार सामान्य मापदंडों, अमोनियम नाइट्रोजन और हैवी मेटल्स के लिए इनलेट क्वालिटी स्टैंडर्ड्स निर्धारित करेगा।	
		टिप्पणी:	
		जेडएलडी= थोक दवा और निर्माण उद्योग में शून्य तरल निस्सारण प्रणाली पर विचार किया जाता है, जब अनिवार्य पैरामीटरों के लिए निर्धारित की गई सीमाओं को पूरा करते हैं। शोधित बहिष्कावों को प्रक्रिया अथवा उपयोगिताओं के प्रयोग में लाया जाएगा। (क्लिंग टॉवरो आदि/बॉयलर) बागवानी / बागवानी में शोधित अपशिष्ट के पुनः उपयोग को थोक दवा और निर्माण उद्योगों में जेडएलडी नहीं माना जाएगा।	
		** जैव परख परीक्षण आईएस :6582-1971 के अनुसार आयोजित किया जाएगा	
		"अतिरिक्त पैरामीटर" के रूप में सूचीबद्ध पैरामीटर प्रक्रिया और उत्पाद के आधार पर निर्धारित किए जाएंगे।	
		*** ये सीमाएं उन उद्योगों पर लागू होंगी जो बेंजीन, टाल्विन, ज़ाइलीन, मिथाइलीन क्लोराइड, क्लोरोबेंजीन का उपयोग कर रहे हैं।	
		**** * एपीआई सीमाएं एंटीबायोटिक दवाओं के अलावा एपीआई बनाने वाली इकाइयों के लिए लागू होगी।	
		ख प्रक्रिया .रिएक्टर वेंटस / टैंक फार्म वेंटस से उत्सर्जन मानक	
		पैरामीटर	सांद्रण के लिए सीमित मान)मिलीग्राम/एनएम ³)
		क्लोरीन	15
		हाइड्रोक्लोरिक एसिड वाष्प	35
		अमोनिया	30
		बेंजीन	5
		टाल्विन	100
		ऐसिटोनाईट्राईल	1000
		डिक्लोरोमीथेन	200
		ज़ाइलीन	100
		ऐसीटोन	2000
		ग विलायक का कुल नुकसान, उपभोग किए गए विलायक के 3% से अधिक नहीं होना चाहिए।	
		घ. थोक दवा और निर्माण उद्योग में शोधित बहिष्काव में एंटीबायोटिक अवशिष्ट और थोक दवा और निर्माण इकाइयों की सदस्यता सहित सीईटीपी।	
		पृथक एंटीबायोटिक अवशिष्ट नीचे तालिका में दिए गए मानों के बराबर या उससे कम होंगे।	
		पैरामीटर	सांद्रण के लिए सीमित मान) u/g / l)
		i. एमिकासिन	6.40

	ii. एमोक्सिसिलिन	0.10
	iii. एम्फोटेरिसिन बी	0.01
	iv. एम्पीसिलीन	0.10
	v. एनीड्युलाफगिन	0.01
	vi. एबिलामाईसिन	3.20
	vii. एजिथ्रोमाईसिन	0.01
	viii. एजट्रियोनाम	0.20
	ix. बेसिट्रेसिन	3.20
	x. बेडाक्विलिन	0.03
	xi. बेन्ज़ाइलपेन्सिलीन	0.10
	xii. केप्रियोमाईसिन	0.80
	xiii. सेफेक्लोर	0.20
	xiv. सेफाड्रोक्सिल	0.80
	xv. सेफालोनियम	8.40
	xvi. सेफालोरिडीन	1.60
	xvii. सेफालोथिन	0.80
	xviii. सेफाजोलिन	0.40
	xix. सेफडिनिर	0.10
	xx. सेफेपाईम	0.20
	xxi. सेफीजाईम	0.02
	xxii. सेफोपेराजोन	0.20
	xxiii. सेफोटैक्सिम	0.04
	xxiv. सेफोएक्सिटिन	3.20
	xxv. सेफपिरोम	0.02
	xxvi. सेफपोडोक्सिन	0.10
	xxvii. सेफक्विनोम	0.64
	xxviii. सेफटेरोलिन	0.02
	xxix. सेफटाजिडिम	0.20
	xxx. सेफटीब्यूटेन	0.10
	xxxi. सेफटीओफर	0.02
	xxxii. सेफटोबिप्रोल	0.09
	xxxiii. सेफटोलोजेन	0.76
	xxxiv. सेफाट्रियोक्सन	0.01
	xxxv. सेफुरोक्सिम	0.20
	xxxvi. सेफालेक्सिन	0.03
	xxxvii. क्लोरामफेनिकोल	3.20
	xxxviii. सिपरोफ्लोक्सासिन	0.02
	xxxix. क्लेरिथ्रोमाईसिन	0.03
	xl. क्लेब्युलेनिक एसिड	22.40

	xli. क्लिनाफ्लोक्सासिन	0.20
	xlii. क्लिन्डामाईसिन	0.04
	xliii. क्लोक्सासिलीन	0.05
	xliv. कोलिस्टिन	0.80
	xlv. डेपटोमाईसिन	0.40
	xlvi. डेलमानिड	0.02
	xlvi. डोरीपेनेम	0.04
	xlvi. डॉक्सीसाइक्लिन	0.80
	xlix. एनरामाईसिन	1.92
	i. एनरोफ्लोक्ससिन	0.02
	ii. एरटापेनेम	0.05
	iii. एरिथ्रोमाईसिन	0.20
	liii. एथामब्युटोल	0.80
	liv. फेरोपेनेम	0.01
	iv. फिडाएक्सोमाईसिन	0.01
	lvi. फ्लोरफेनिकोल	0.80
	lvii. फ्लूकोनेज़ोल	0.10
	lviii. फ्लुमेक्विन	0.10
	lix. फॉस्फोमाईसिन	0.80
	lx. फ्यूसीडिक एसिड	0.20
	lxi. सेटीफ्लोक्सासिन	0.05
	lxii. जेमीफ्लोक्सासिन	0.02
	lxiii. जेंटामाईसिन	0.08
	lxiv. इनीपेनेम	0.05
	lxv. आइसोनियाजिड	0.05
	lxvi. इट्राकोनेज़ोल	0.004
	lxvii. कानामाईसिन	0.44
	lxviii. लेवोफ्लोक्सासिन	0.10
	lxix. लिकोमाईसिन	0.72
	lxx. लाईनज़ोलिड	2.68
	lxxi. लोराकार्बेफ	0.80
	lxxii. मेसिलिनेम	0.40
	lxxiii. मेरोपेनेम	0.02
	lxxiv. मेट्रोनिडेज़ोल	0.05
	lxxv. माइनोसाइक्लिन	0.40
	lxxvi. मॉक्सीफ्लोक्सिन	0.05
	lxxvii. म्युरीरोसिन	0.10
	lxxviii. नेलीडिक्सिक एसिड	6.40
	lxxix. नारासिन	0.20

	lxxx. नियोमाईसिन	0.01
	lxxxi. नेटीलमिसिन	0.20
	lxxxii. निट्रोफ्यूरेनटोएन	25.60
	lxxxiii. नॉरफ्लोक्सिन	0.20
	lxxxiv. ऑफ्लोक्सिन	0.20
	lxxxv. ऑक्सासिलिन	0.40
	lxxxvi. ऑक्सीटेट्रासाइक्लिन	0.20
	lxxxvii. पेफक्लोसिन	3.20
	lxxxviii. फेनक्सीमेथिलपेनसिलिन	0.02
	lxxxix. पिपेरासिलिन	0.20
	xc. पॉलीमिक्सिन	0.80
	xc. रेटापाम्युलिन	0.02
	xcii. रिफाम्पसिन	0.02
	xciii. रॉक्सीथ्रोमाईसिन	0.40
	xciv. सेक्नीडेजोल	0.40
	xcv. स्पाराफ्लोक्सिन	0.02
	xcvi. स्पेक्टिनोमाईसिन	12.80
	xcvii. स्पिरामाईसिन	0.20
	xcviii. स्ट्रेप्टोमाइसिन	6.40
	xcix. सल्बेक्टम	6.40
	c. सल्फाडियाजिन	288.00
	ci. सल्फाडिमिथियोजिन	20.00
	cii. सल्फाडॉक्सिन	0.24
	ciii. सल्फामेथोक्साजोल	0.24
	civ. टेजोबेक्टम	17.60
	cv. टेडीजोलिड	3.92
	cvi. टेईकोप्लानिन	0.20
	cvii. टेलीथ्रोमाईसिन	0.02
	cviii. टेट्रासाइक्लिन	0.40
	cix. थियाम्फेनीकोल	0.40
	cx. टियाम्युलिन	0.40
	cx. टिकार्सिलिन	3.20
	cxii. टिगेसाइक्लिन	0.40
	cxiii. टिल्डीपीरोसिन	0.17
	cxiv. टिल्मीकोसिन	0.40
	cxv. टोबरामाईसिन	0.40
	cxvi. ट्रिमेथोप्रिम	0.20
	cxvii. ट्रोवाफ्लोक्सासिन	0.01
	cxviii. टाइलोसिन	0.33

		cxix. बेंकोमाईसिन	3.20
		cxx. वियोमाईसिन	0.80
		cxxi. विजिनियामाईसिन	0.80. "

टिप्पणी: - एंटीबायोटिक अवशिष्ट युक्त गाद को जलाकर राख किया जाएगा और साझा खतरनाक अपशिष्ट भस्मक अथवा उद्योग विशिष्ट भस्मक के लिए अधिसूचित किए गए भस्मक का मानक लागू होगा।

[फा.सं.क्यू.-15017/12/2018-सीपीडब्ल्यू]

जिगमेट टक्पा, संयुक्त सचिव

टिप्पणी: मूल नियम भारत के राजपत्र असाधारण, भाग- II, खंड 3, उप-खंड (i) में दिनांक 19 नवम्बर, 1986 को संख्या का.आ. 844 (अ) द्वारा प्रकाशित किए गए थे और उन्हें अंतिम बार दिनांक 26 दिसम्बर, 2019 को सा.का.नि. 952 (अ) की अधिसूचना द्वारा संशोधित किया गया था।

MINISTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE

NOTIFICATION

New Delhi, the 23rd January, 2020

G.S.R. 44(E).— The following draft of the notification, which the Central Government proposes to issue in exercise of the powers conferred by sections 6 and 25 of the Environment (Protection) Act, 1986 (29 of 1986) is hereby published, as required under sub-rule (3) of rule 5 of the Environment (Protection) Rules, 1986, for the information of the public likely to be affected thereby; and notice is hereby given that the said draft notification shall be taken into consideration on or after the expiry of a period of sixty days from the date on which copies of the Gazette containing this notification are made available to the public.

Any person interested in making any objections or suggestions on the proposals contained in the draft notification may forward the same in writing, for consideration of the Central Government within the period specified above to the Secretary, Ministry of Environment, Forest and Climate Change, Indira Paryavaran Bhawan, Jor Bagh Road, New Delhi-110003, or send it to Member Secretary, CPCB and Scientist 'E' Ministry at the e-mail address i.e. mscb.cpcb@nic.in and h.kharkwal@nic.in.

Draft Notification

The Central Government hereby makes the following rules further to amend the Environment (Protection) Rules, 1986, namely:-

- Short title and commencement-** (1) These rules may be called the Environment (Protection) Amendment Rules, 2019.
(2) They shall come into force on the date of their final publication in the Official Gazette.
- In the Environment (Protection) Rules, 1986, in Schedule-I, for serial number 73 and the entries relating thereto, the following serial number and entries shall be substituted, namely:-

Sl. No.	Industry	Parameters	Standard
1	2	3	4
“73	Bulk Drug and Formulation (Pharmaceutical)	A. EFFLUENT STANDARDS	
		For final outlet of ETP Limiting value for concentration (in mg/l except for pH and Bio assay)	
		i) Compulsory Parameters	
		pH	6.0 -8.5

BOD (3 days 27°C)	30
COD	250
TSS	100
TDS	2100
Oil & Grease	10
Bio - Assay Test**	90% Survival of Fish after first 96 hours in 100% effluent
ii) Additional Parameters	
Ammonical Nitrogen	50
Nitrate Nitrogen	10
***Benzene	0.05
***Toluene	0.05
***Xylene	0.06
***Methylene Chloride	0.9
Phosphates as P	5
Chlorides	1000
Sulphates as SO ₄	1000
Fluoride	2
Sulphides as S	2
Phenolic Compounds	1
Total Residual Chlorine	1
Zinc	5
Iron	3
Copper	3
Total Chromium	2
Hexavalent Chromium (Cr ⁶⁺)	0.1
Cyanide	0.1
Arsenic	0.2
Mercury	0.01
Lead	0.1
****Active Pharmaceutical Ingredient (API)	0.05
iii) for final outlet of Industries discharging to CETP	
For each Common Effluent Treatment Plant(CETP), the state Board will prescribe inlet quality Standards for general parameters, Ammonical Nitrogen and Heavy Metals as per the design of the Common Effluent Treatment Plant(CETP) and local needs and conditions. As per notification S.O. 4 (E) dated 1 st January, 2016	
Note:	
ZLD = Zero Liquid Discharge system in <i>Bulk Drug and formulation</i> industry is considered when treated effluent meeting the limits prescribed for compulsory parameters shall be used in Process or Utilities (boiler/ Cooling tower etc.). The reuse of treated effluent in gardening/ horticulture shall not be considered as ZLD in Bulk Drug and formulation industries.	
** The Bio assay test shall be conducted as per IS : 6582-1971	
Parameters listed as " Additional Parameters " shall be prescribed depending upon the process and product.	
*** Limits shall be applicable to industries those are using Benzene, Toluene, Xylene, Methylene Chloride, Chlorobenzene.	
****API limits shall be applicable for units manufacturing API other than antibiotics.	
B. EMISSION STANDARDS from Process Reactor Vents/ Tank farm Vents	
Parameter	Limiting value for concentration (mg/Nm³)
Chlorine	15
Hydrochloric acid vapour	35
Ammonia	30
Benzene	5
Toluene	100
Acetonitrile	1000
Dichloromethane	200

	Xylene	100
	Acetone	2000
C. The total losses of solvent should not be more than 3% of the solvent consumed.		
D. Antibiotic Residues in the treated effluent of Bulk Drug and Formulation Industry and CETP with membership of Bulk Drug and formulation Units		
Individual antibiotic residues will be equal to or less than the values given in the below table.		
Parameter	Limiting value for concentration (µg/l)	
i. Amikacin	6.40	
ii. Amoxicillin	0.10	
iii. Amphotericin B	0.01	
iv. Ampicillin	0.10	
v. Anidulafungin	0.01	
vi. Avilamycin	3.20	
vii. Azithromycin	0.01	
viii. Aztreonam	0.20	
ix. Bacitracin	3.20	
x. Bedaquiline	0.03	
xi. Benzylpenicillin	0.10	
xii. Capreomycin	0.80	
xiii. Cefaclor	0.20	
xiv. Cefadroxil	0.80	
xv. Cefalonium	8.40	
xvi. Cefaloridine	1.60	
xvii. Cefalothin	0.80	
xviii. Cefazolin	0.40	
xix. Cefdinir	0.10	
xx. Cefepime	0.20	
xxi. Cefixime	0.02	
xxii. Cefoperazone	0.20	
xxiii. Cefotaxime	0.04	
xxiv. Cefoxitin	3.20	
xxv. Cefpirome	0.02	
xxvi. Cefpodoxime	0.10	
xxvii. Cefquinome	0.64	
xxviii. Ceftaroline	0.02	
xxix. Ceftazidime	0.20	
xxx. Ceftibuten	0.10	
xxxi. Ceftiofur	0.02	
xxxii. Ceftobiprole	0.09	
xxxiii. Cestolozane	0.76	
xxxiv. Ceftriaxone	0.01	
xxxv. Cefuroxime	0.20	
xxxvi. Cephalixin	0.03	
xxxvii. Chloramphenicol	3.20	
xxxviii. Ciprofloxacin	0.02	
xxxix. Clarithromycin	0.03	
xl. Clavulanic Acid	22.40	
xli. Clinafloxacin	0.20	
xlii. Clindamycin	0.04	
xliii. Cloxacillin	0.05	
xliv. Colistin	0.80	
xlvi. Daptomycin	0.40	
xlvi. Delamanid	0.02	
xlvi. Doripenem	0.04	
xlvi. Doxycycline	0.80	
xlvi. Enramycin	1.92	
l. Enrofloxacin	0.02	

	li.	Ertapenem	0.05
	lii.	Erythromycin	0.20
	liii.	Ethambutol	0.80
	liv.	Faropenem	0.01
	lv.	Fidaxomicin	0.01
	lvi.	Florfenicol	0.80
	lvii.	Fluconazole	0.10
	lviii.	Flumequine	0.10
	lix.	Fosfomycin	0.80
	lx.	Fusidic acid	0.20
	lxi.	Gatifloxacin	0.05
	lxii.	Gemifloxacin	0.02
	lxiii.	Gentamicin	0.08
	lxiv.	Imipenem	0.05
	lxv.	Isoniazid	0.05
	lxvi.	Itraconazole	0.004
	lxvii.	Kanamycin	0.44
	lxviii.	Levofloxacin	0.10
	lix.	Lincomycin	0.72
	lxx.	Linezolid	2.68
	lxxi.	Loracarbef	0.80
	lxxii.	Mecillinam	0.40
	lxxiii.	Meropenem	0.02
	lxxiv.	Metronidazole	0.05
	lxxv.	Minocycline	0.40
	lxxvi.	Moxifloxacin	0.05
	lxxvii.	Mupirocin	0.10
	lxxviii.	Nalidixic acid	6.40
	lxxix.	Narasin	0.20
	lxxx.	Neomycin	0.01
	lxxxi.	Netilmicin	0.20
	lxxxii.	Nitrofurantoin	25.60
	lxxxiii.	Norfloxacin	0.20
	lxxxiv.	Ofloxacin	0.20
	lxxxv.	Oxacillin	0.40
	lxxxvi.	Oxytetracycline	0.20
	lxxxvii.	Pefloxacin	3.20
	lxxxviii.	Phenoxymethylp enicillin	0.02
	lxxxix.	Piperacillin	0.20
	xc.	Polymixin	0.80
	xc.	Retapamulin	0.02
	xcii.	Rifampicin	0.02
	xciii.	Roxithromycin	0.40
	xciv.	Secnidazole	0.40
	xcv.	Sparfloxacin	0.02
	xcvi.	Spectinomycin	12.80
	xcvii.	Spiramycin	0.20
	xcviii.	Streptomycin	6.40
	xcix.	Sulbactam	6.40
	c.	Sulfadiazine	288.00
	ci.	Sulfadimethoxin e	20.00
	cii.	Sulfadoxine	0.24
	ciii.	Sulfamethoxazol e	0.24
	civ.	Tazobactam	17.60
	cv.	Tedizolid	3.92
	cvi.	Teicoplanin	0.20
	cvi.	Telithromycin	0.02

	cvi. Tetracycline	0.40
	cix. Thiamphenicol	0.40
	cx. Tiamulin	0.40
	cx. Ticarcillin	3.20
	cxii. Tigecycline	0.40
	cxiii. Tildipirosin	0.17
	cxiv. Tilmicosin	0.40
	cxv. Tobramycin	0.40
	cxvi. Trimethoprim	0.20
	cxvii. Trovafloxacin	0.01
	cxviii. Tylosin	0.33
	cxix. Vancomycin	3.20
	cxx. Viomycin	0.80
	cxxi. Virginiamycin	0.80."

Note:- The sludge containing antibiotic residues shall be incinerated and the standard of incinerator notified for common hazardous waste incinerator or industry specific incinerator shall be applicable.

[F.No. Q-15017/12/2018-CPW]

JIGMET TAKPA, Jt. Secy.

Note: The principal rules were published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number S.O. 844 (E), dated the 19th November, 1986 and last amended vide notification number G.S.R. 952(E), dated the 26th December, 2019.

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ANNEXURE A4
 Court No. 1

Item No. 02

**BEFORE THE NATIONAL GREEN TRIBUNAL
 PRINCIPAL BENCH, NEW DELHI**

(By Video Conferencing)

Original Application No. 136/2020

Veterans Forum for Transparency
 in Public Life

Applicant(s)

Versus

State of Himachal Pradesh & Ors.

Respondent(s)

Date of hearing: 22.07.2020

**CORAM: HON'BLE MR. JUSTICE ADARSH KUMAR GOEL, CHAIRPERSON
 HON'BLE MR. JUSTICE S. P. WANGDI, JUDICIAL MEMBER
 HON'BLE DR. NAGIN NANDA, EXPERT MEMBER**

ORDER

1. Prayer in this application is to direct remedial action against discharge of waste in CETP at Baddi by Acme Life Sciences, Nalagarh and Helio Pharmaceuticals at Solan to prevent pollution of rivers Sirsa and Satluj. According to the applicant, the CETP is not connected to pharmaceutical units at Barotiwala and Nalagarh who are discharging their effluents directly into the rivers. It is further stated that even after treatment in ETP/STPs, pharmaceutical ingredients may still be coming out from the industries unless ETP/STPs are specialized for the purpose. It is further stated that present CETP is not designed to neutralize API. The TSDF does not receive sludge generated from the industrial units at Nalagarh. The industries located at Baddi area are generating 20779 KLD of industrial effluent, out of which 17894 KLD is being treated at CETP and remaining 2885 KLD is being disposed of by the occupiers directly

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into river Sirsa. There is no existing sewerage system in BBN area and no demarcation in residential and industrial area. Presence of Ciprofloxacin in the concentration of 296.1 ug/l was found on chemical analysis. Concentration of Ciprofloxacin in the effluent discharge of M/s Acme Life Sciences work out to be 13455 times of the prescribed limit. The increasing occurrence of multi-resistant pathogens is a serious global threat to human health and it is finding its way into the water bodies and drinking water through industrial discharge and also due to heavy use of antibiotics in human and veterinary medicine.

2. The above issue may need to be looked into and action taken to prevent discharge of untreated chemical waste in water bodies in the interest of environment and public health.

3. Let a joint Committee of CPCB, State PCB and District Magistrate, Solan look into the above issues in the light of contents of the application and take such further action as may found necessary. The State PCB will be the Nodal Agency for compliance and coordination. A factual and action taken report may be furnished to this Tribunal within three months by e-mail at judicial-ngt@gov.in preferably in the form of searchable PDF/ OCR Support PDF and not in the form of Image PDF.

A copy of this order be forwarded to the CPCB, State PCB and District Magistrate, Solan by e-mail.

The applicant may serve a set of papers on CPCB, State PCB and District Magistrate, Solan and file affidavit of service within ten days.

List for further consideration on 04.01.2021.

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O.A. No. 801/2018, Jasmeet Singh v. State of Himachal Pradesh
which relates to the same area and is now listed for hearing on
25.08.2020, may also now be listed on 04.01.2021.

Adarsh Kumar Goel, CP

S. P. Wangdi, JM

Dr. Nagin Nanda, EM

July 22, 2020
Original Application No. 136/2020
A

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No. Q-15017/04/2020-CPW
GOVERNMENT OF INDIAMINISTRY OF ENVIRONMENT, FOREST & CLIMATE CHANGE
(CP Division)Indira Paryavaran Bhawan
Level -II, Prithvi Wing, Jorbagh Road
New Delhi-110003Dated: 4th January, 2021**Subject: Minutes of the First Expert Committee Meeting to Environmental Standards (through Video Conference) on 09th December, 2020 -reg.**

Sir,

I am directed to forward herewith a copy of minutes of the First Expert Committee Meeting to Environmental Standards (through Video Conference) was held on 09/12/2020 at 11.00 AM under the Chairmanship of Shri Jigmet Takpa, Joint Secretary, Indira Paryavaran Bhawan, Jor Bagh Road, New Delhi for perusal and necessary action.

Yours faithfully,

Encl: As above

V.K. Kushwaha
4/01/2021
(V.K. Kushwaha)
Section Officer (CPW)

To,

1. Shri Navdeep Rinwa, Joint Secretary, Ministry of Chemical and Fertilizers, Department of Pharmaceuticals Shastri Bhawan, New Delhi-110001-Special Invitee in respect of agenda item no. A (ii).
2. Shri Subodh Yadav, Joint Secretary, Ministry of Jal Shakti, Department of Water Resources, River Development & Ganga Rejuvenation, Shram Shakti Bhawan, Rafi Marg, New Delhi -110001-Special Invitee in respect of agenda item no. A (iv).
3. Prof. (Dr.) S. K. Nayak, Director General – CIPET, CIPET Head Office, T.V.K. Industrial Estate, Guindy, Chennai - 600 032-Special Invitee in respect of agenda item no. A (v).
4. Dr. S.R. Marigoudar, Scientist 'D', National Centre for Coastal Research (NCCR), Ministry of Earth Sciences, NIOT Campus, Pallikaranai, Chennai-600100- Special Invitee in respect of agenda item no. A (i).
5. Shri Manish Jain, Executive Director, Mechanical Engineer (Traction), Ministry of Railways, New Delhi-110001-Special Invitee in respect of agenda item no. A (iii).

All Members of Expert Committee
(As per list enclosed)
AD (RJ)
JD (Ak)

Copy to:

1. PPS to JS (JT)/PPS to JS(NPG)
2. PS to Director (CPW)

List of Members

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Sl. No.	Name & Organization	Role
Permanent Members		
1.	Joint Secretary / Adviser (CP Division)	Chairman
2.	Scientist & Head, Chemical Department, Bureau of Indian Standards (BIS), 9, Bahadur Shah Zafar Marg, New Delhi-110002	Member
3.	Director / Head (Env. Division), PHD Chamber of Commerce, PHD House, 4/2, August Kranti Marg, Siri Institutional Area, Block A, Nipccd Campus, Hauz Khas, New Delhi- 110016 Dr. J.P. Gupta, Chairman E-mail- ipglobalconsultinggroup@gmail.com , president@phdcci.in Tel. No. 011-49545454, 49545400 Dr. Ranjeet Mehta, Director E-mail- ranjeetmehta@phdcci.in Tel. No. 011-26863801-4, 49545514	Member
4.	Head, Environment Division, PHD Chamber of Commerce and Industry (CII), The Mantosh Sondhi Centre, 23, Lodhi Rd, Institutional Area, New Delhi-110003 Sh. Shikhar Jain, Principal Counsellor, CII-ITC CESD E-mail – shikhar.jain@cii.in , cb@cii.in Tel. No. - +91-124-4346372	Member
5.	Sh. K.P. Nyati, D-1-C/56-A, Janakpuri, New Delhi-110058 E-mail- kponyati@hotmail.com	Member (Non-Official)
6.	Dr. Rashid Hasan, Former Advisor & MoEFCC, 428 Satyam, Sector-19, Vasundhara, Gaziabad -201012 (U.P.) E-mail- hasan@slam.in , hasan.mef@gmail.com	Member (Non-Official)
7.	Dr. Ajay A. Deshpande, Flat A-26, Flat 403, Happy Valley Homes, Manpada, Near Tikujini Wadi, Ghodbunder Road, Thane (West)-400610, Maharashtra E-mail- ajaydeshpande1@rediffmail.com	Member (Non-Official)
8.	Sh. Sundeep, Scientist 'F', MoEF&CC New Delhi	Member
9.	Dr. Sonu Singh, Scientist 'E', MoEFCC New Delhi / or Officer dealing the Programme	Member Secretary
Special Invitee		
10.	Joint Secretary or his Representatives of Concerned Ministry / Department related to Environmental Standards of Industrial sectors schedule to be considered	Member
11.	Experts co-opted / independent (specific subject) in the field of related to Environmental Standards of Industrial sectors schedule to be considered	Member (Non-Official / Official)

**Minutes of First Meeting (through Video Conference) of Expert Committee for
Environmental Standards on 09th December, 2020**

1. The first meeting of Expert Committee for Environmental Standard was held on 09th December, 2020 at Indira Paryavaran Bhawan, MoEF&CC, New Delhi under the Chairmanship of Shri Jigmet Takpa, Joint Secretary, MoEF&CC for consideration of proposed New norms and amendment in existing standards in respect of Industrial Sector / Categories as given below. The list of participants who attended the VC is at **Annexure-I**.

(A) Notifications for finalization after public consultation:

- i. Water Quality Standard for Coastal Water Marine Outfalls in respect of Primary Water Quality Criteria for Class SW-III Waters and Class SW-V Water
- ii. Bulk Drug and Formulation (Pharmaceutical) Industry
- iii. Membrane based water purification system (MWPS).
- iv. Use of Lead Stabilizer in Polyvinyl Chloride (PVC) Pipes and Fittings

(B) Notifications at draft Stage for public consultation:

- i. Diesel Locomotive
- ii. Emission norms for 'Genset engines (CPCB stage IV+)

2. At the outset, the Chairman welcomed all Members of the Expert Committee and the representatives from concerned Department and line Ministries and other special invitees. In his opening remarks he appraised the background of the proposed final and draft notifications for different Six (6) sectors. It was highlighted that minutes of the 19th Meeting of Expert Committee held on dated 20th May, 2020 was circulated to the members and comments were sought and no comments were received, consequently the minutes were confirmed and necessary follow-up action was initiated.

The CPCB was thereafter requested to present the details of each of the notifications agenda wise at Para 1 (A) and 1 (B) above except agenda item A (ii) which was presented by Shri Sundeep, Scientist F, MoEFCC and A(iv), which was presented by Dr. Ritesh Joshi. Scientist 'E'- MoEF&CC.

3. Standards for finalization after public consultation: -

3.1 Agenda No. A(i): Water Quality Standard for Coastal Water Marine Outfalls in respect of Primary Water Quality Criteria for Class SW-III Waters and Class SW-V Water- Amendment

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The proposal is for amendment in notification for Water Quality Standard for Coastal Water in respect of Primary Water Quality Criteria for Class SW-III Waters and Class SW-V Water. The draft notification was put on Ministry's website for public consultation on 17.02.2020. It was informed that no suggestion/comment has been received from Public. The proposal was presented before the committee in its 19th meeting held on 20th May 2020 by CPCB / National Centre for Coastal Research (NCCR), Ministry of Earth Sciences. After detailed discussions the Committee suggested to incorporate the following:

1. The concentration values proposed shall be rounded to nearest whole number.
2. The proposed amendment is in sea water usability quality based on its best designated use. Therefore, it was felt by the committee that the water quality shall be consistent / in-agreement with the best designated use of other water quality (River/ in-land surface water bodies) for the same purpose. CPCB may examine the consistency in reference to designated purpose of use and resubmit the proposal for further perusal.

The revised proposal was placed before the committee and detailed presentation was made by the CPCB. The Committee was of the view that these standards will have very wide ramifications, and suggested that reports and data related to the study for formulation of standards may be shared to the members and a separate one-day presentation on the topic should be scheduled.

(Action: CPCB & MoES (ICMAM))

3.2 Agenda A(ii): Environmental Standard for Bulk Drug and Formulation (Pharmaceutical) Industry

The draft notification for Environmental Standard for Bulk Drug and Formulation (Pharmaceutical) Industry was presented by CPCB in the 19th meeting of the Expert Committee held on 20.05.2020. It was informed that the draft notification was placed on website of Ministry for public consultation on 23.01.2020 and more than 35 numbers of suggestions were received which includes association, NGOs, Individual experts and industry. The comment(s)/suggestion(s) received have been assessed for their acceptability based on the concern raised vis-a-vis their feasibility, viability and relevance to the objective of prescribing norms. The committee deliberated on each para of the proposed standard.

The Joint Secretary, Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals as a special invitee highlighted the present status of the pharma industry and the challenges arising due to COVID-19 demand. It was highlighted that due to higher cost, India is facing stiff competition from other countries, specially China and has in recent times become no. 2 in API manufacturing. He stressed that the norms should not compromise with the environmental requirements, but should be prescribed in such proposition that there is no excess financial burden to the industry to retain their international competitiveness. He also highlighted the concern raised by association of Bulk drug and pharmaceutical manufacturing units specially on monitoring location proposed in the draft. He requested that in present situation, prescribing

standard on AMR may be a challenge for the industry to meet and it was expressed that the committee may take appropriate consideration of the concern raised by the associations.

The draft was deliberated point wise and based on the discussion; the Committee recommended certain modification on additional parameters, the solvent losses, and provision of land disposal etc. for consideration of Ministry.

Further the matter was re-examined in the Ministry in light of representation received from Department of Pharma. A meeting under the chairmanship of Secretary- EFCC with various stakeholders, including CPCB, pharma association, Ministry of Health, Department of Pharma and experts was held. Owing to the concern on the PNEC value and its dynamic nature, it was observed that it will be compliance challenge for any static treatment option to meet the dynamic nature of the PNEC values published by a consortium of AMR manufacturer. Considering the implementation, monitoring and compliance challenges, it was decided that CPCB may explore these challenges and also compare international practices on imposing PNEC values as regulatory provision for discharge standard to address such concerns. In view of above, standard was revised and placed before the expert committee for consideration on the concerns of compliance, dynamic value of PNEC and prevailing international practices on the evolving nature of PNEC understanding.

Shri Sundeep, Scientist F, MoEFCC made a detailed presentation before the committee and clarified the apprehensions of Industry Associations and Department of Pharma that the standards are applicable on the units involved in discharge and emissions, since April 1996. The present proposal are aligned with the emission norms stipulated for similar process and applicable to other industries. A time line relief of one year for meeting the newly introduced emission and discharge norms is also proposed for consideration by the committee owing to COVID-19 impact.

The committee after details deliberation on each aspect of the modified discharge norms in notification recommended to modified/incorporated the followings:

1. Ammonia and Nitrate was considered to be an important parameter in light of concern of polluted river stretches, and therefore it may be removed from additional parameter and made as compulsory parameter applicable to all units and CETP at discharge point.
2. Industry permitted to discharge/dispose their effluent to CETP shall be governed by the provision of notified CETP norms dated 01/01/2016.
3. Additional Parameters of Chlorides and Sulphate may be removed and concern of impact on land disposal may be addressed by introducing Sodium Adsorption Ratio (SAR) with upper limit of 26. CPCB may provide appropriate norms of SAR.
4. Owing to the complexity and non-availability of any universally accepted standardized method to test Total API concentration in wastewater matrix, the committee

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felt necessary to remove the proposed norms of Total API from the additional parameter as of now.

5. Any discharge to inland water bodies or for horticulture or irrigation or land disposal of treated process wastewater from any industry and or to CETP shall not be considered as Zero Liquid Discharge (ZLD) and the stipulated norms in the notification shall be applicable to all such discharges.

6. The total loss from annual inventory of solvents from storage area shall not be more than 5% of cumulative on annual basis.

7. CPCB shall prepared a standard protocol for determining the loss and relevant record maintenance practices for verification purpose in consultation with industry association and other organization. Provision of One year time may be allowed to the industry for compliance of this norms considering the time required to make necessary abatement cum control arrangement.

8. AMR concentration in ambient environment is rising and its consequences are far reaching. Predicted No-Effect Concentrations (PNECs) value of AMR are the probable values at the mixing point in receiving environment, which reflects the critical level of any adverse impact on the receiving ecology or its component.

The proposed values of various AMR (PNEC) in draft notification was for its applicability at the inlet of treatment facility (applicable on raw influent). It was felt that the purpose was to avoid any adverse impact on the receiving environment and also to promote comprehensive and efficient performance of treatment facility. CPCB has observed that there is significant reduction in monitored AMR concentration in efficient operating treatment facilities. The present notification proposal is for discharge norms and therefore, any stipulation of norms before treatment facility doesn't serve the purpose or objective, as the outcome will be depend on the efficacy of the treatment facility.

It was also observed that the PNEC value considered were based on the studies carried out by an international Alliance of AMR manufacturer and presently it is yet to be accepted as a discharge regulatory provision anywhere. The rationale of the proposed values were not scientifically derived based on field performance studies for all proposed parameter.

Further, the PNEC values are dynamic and is in process of evolving. The parameter and its values both keep on changing based on the API under use and imposing all parameter will lead to uncalled challenges of standardization of monitoring protocol in dynamic environment. The challenge associated with meeting a dynamic values with static infrastructure or through regular retrofitting may lead to more non-compliance of other parameters as well.

Considering the evolving nature of PENC values and associated challenges of infrastructural implementation, monitoring constraints and absences of acceptable standardized testing of samples in complex metrics of pollutants, the committee felt that the

discharge norms based on dynamic PNEC values for AMR may be dropped from the proposed standard for discharge.

The present ecosystem for monitoring and implementation of AMR concentration in complex wastewater matrix at low concentration with dynamic PNEC values based standard will lead to challenges of monitoring and compliance. However, it was felt that infrastructure and capacity development and readiness of the regulatory bodies, stability in PNEC values in varying Indian condition are some of the essentials for adopting any regulatory provision on AMR.

It was decided that association of AMR manufacturing industries in India shall undertake comprehensive study on AMR impact at all major critical locations identified by CPCB. The study shall be obligatory on the AMR manufacturer and protocol for the study may be prepared in consultation with CPCB and Department of Pharma, Ministry of Chemicals & Fertilizers.

Accordingly, the committee recommended to drop the proposal of AMR discharge norms and suggested that MoEF&CC may ask CPCB to issue necessary direction to Department of Pharma, Ministry of Chemicals & Fertilizers to ensure a database is created on the AMR status in the country with the help of association of AMR manufacturing units. CPCB shall provide the monitoring protocol for the purpose.

9. To contain any adverse impact arising from the disposal of contaminated sludge and or concentrate or reject or residue generated from wastewater treatment and management facility of industry or CETP, it is felt necessary to have their management and disposal with utmost care. Therefore, all sludge (chemical or biological) or any residue, reject, concentrate generated from wastewater treatment or its management facility at Industry engaged in manufacturing of bulk drug or formulation of Pharmaceuticals or CETP catering such industries shall be classified as Hazardous Waste within the provision of sub-section 17 of section 3 of Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016 and shall be managed within the applicable provisions thereof.

10. All new norms / parametrs introduced in this notification shall be applicable after after one year from the date of this notification in due consideration of COVID-19 Impact.

Based on above deliberations and recommendation of the committee the draft notification was modified as attached at Annexure II. The committee recommend for considering the notification under Environment (Protection) Rules, 1986 with appropriate legal modification.

(Action: MoEFCC)

3.3 Agenda A(iii): Environmental Standard Membrane based water purification system (MWPS).

Hon'ble NGT in the matter O.A. No. 134 OF 2015 (MA No. 757 of 2015 & 477 of 2016) titled "Friends through its General Secretary Vs. Ministry of Water Resources & Ors. directed

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MoEFCC to issue appropriate notification prohibiting use of RO where TDS in water is less than 500 mg/l and wherever RO is permitted, a requirement is laid down for recovery of water be more than 60%. Further, provision be laid down for recovery of water upto 75% and use of such RO reject water for purposes such as utensil washing, flushing, gardening, cleaning of vehicles and floor mopping. These directions were based on the Expert Committee report "Appropriate use of Reverse Osmosis (RO) plant and disposal of RO Reject" submitted by CPCB in this matter to Hon'ble NGT.

Based on above report and direction the notification was drafted and stakeholder consultations were held and subsequently the draft Notification on was uploaded on 04.02.2020 on the Website of the Ministry inviting suggestions and comments from public.

It was informed that more than 4000 suggestions has been received and the analysis of such suggestion has been completed. A draft notification has been made. However, in compliance to the order of Hon'ble Supreme Court, Secretary- EF&CC has called a meeting of major Stakeholders representing Manufacture, BIS, Element manufacturers, NEERI, CPCB, Bulk Water Suppliers and users, to have their input before it is finalised. The stakeholders were again requested to provide their inputs based on draft notification for consideration by ministry. The finalisation of draft after consideration of input was made and is due for consideration of Secretary. Due to some urgency, the draft could not get placed before by Secretary and therefore the proposal could not be placed before the committee.

The committee agreed to the proposal of taking as an agenda item in its next meeting.

(Action: MoEFCC)

3.4 Agenda A(iv): Regulation on Lead Stabilizers in Manufacturing of PVC Pipes and Fittings Rules, 2018

The draft 'Regulation on Lead Stabilizers in Manufacturing of PVC Pipes and Fittings Rules, 2018' was evolved by MoEF&CC in compliance of the judgement dated 25th May, 2017 of Hon'ble NGT in the matter O.A. No. 477/ 2015 titled 'Jan Sahyog Manch Vs. Union of India & Ors.' in which Ministry was directed by Hon'ble Tribunal to lay down standards for eliminating lead from PVC pipes. The draft notification was placed on website of MoEF&CC for public consultation on 12.12.2019. The concern raised by the petitioners was that the lead compounds used as stabilizers in manufacture of PVC pipes and fittings impose health hazard due to the lead leaching out of such products, thereby contaminating water. Ministry was directed to notify, with concerned agencies the quality standards of lead to be used for PVC pipes and to lay down the standards for presence of lead in PVC pipes, in consultation with BIS; and to draw up a programme for phasing out of lead as stabilizer in PVC pipes.

Accordingly, the draft rules were formulated on the basis of several rounds of consultations held with various Ministries/ Departments. These rules cover 3 categories of PVC pipes and fittings used for (A) potable water supply, (B) suction and delivery lines of agricultural pumps and rain water systems and (C) drainage and sewerage. The Public objections and suggestions received on the draft rules were examined in consultation with BIS. Proposed final rules were placed before

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the Expert Committee for Environment Standards in its 19th meeting held on 20th May 2020. The Committee suggested certain modifications and it was decided that the draft may be modified in consultation with BIS and thereafter submit before the Expert Committee in the next meeting for its final consideration.

Thereafter, in the month of September 2020, a presentation was made before the Secretary (EFCC) on draft rules, wherein Secretary (EFCC) directed to cross-check the cost implications for replacing the use of lead with Ca-Zn (Calcium zinc)/Tin in manufacturing and preparedness of the industries/stakeholders for better compliance of the rules. Secretary (EFCC) also suggested for regulating the sale within the country, except export. Subsequently views of CIPET, CPCB, members of AIPMA and other manufacturers were taken.

Further, a meeting was also organized with concerned stakeholders on 5th November 2020 under the chairmanship of the Joint Secretary, CPW Division, MoEFCC to discuss about the percentage increase in the cost for replacing lead stabilizer with other non-toxic material in PVC pipes and fittings. The meeting was attended by the representatives of AIPMA, CIPET, Ministry of Housing and Urban Affairs, BIS, CPCB, and some other manufacturers. In the meeting, it was agreed that for technological and other associated changes and its compliance, at least one-year time is needed.

After detailed deliberations, the Committee recommended the notification, subject to verification by BIS on referred codes in the notification.

The committee highlighted that the published notification shall be shared with the line ministries (users) for incorporating in the required specification of the materials in their schemes/projects/programs.

The notification was recommended by the committee for publication under Environment (Protection) Rules, 1986.

(Action: MoEFCC)

3.5 Agenda B (i): Environmental Standard for Diesel Locomotives

The background of environmental standard for Diesel Locomotives was presented by CPCB before the Expert Committee meeting held on 09.08.2019. The CPCB informed that as suggested by Experts Committee in its 17th meeting held on 26.04.2019, the senior officials from Railways had met Chairman CPCB in July 2019 and informed that the RITES Report shall be submitted in September 2019. The Report was to be submitted in June 2019. CPCB further informed that Railways had been asked to incorporate the financial and technical requirement for the proposed emission standards proposed for Diesel Locomotives as well the detailed phase-out plan for Diesel Locomotives as informed by the Railways. After detailed discussions, the Chair directed the Railways to submit the complete report as per CPCB requirements to CPCB at the earliest. The CPCB may also pursue the same with Ministry of Railway.

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The proposal was placed in the present meeting and CPCB made a presentation. Further, representative of Railways mentioned the railways is proposing to phase-out 2695 out of 5780 loco engines by the year 2026. Railway reiterated its stand that it consumes only 4% of the total Diesel consumption, Life of Diesel Loco engines is around 36 years and hence no Loco standard for Diesel Loco engines are required considering phase-out plan. It was also discussed that existing Diesel Loco engines need to be retrofitted to comply the proposed one stage below emission norms. During the discussions it also noted that total phase-out of Diesel Locomotives is not possible due to land diversity and emergency issues.

The committee recommended that CPCB should organize a meeting with all stakeholders after sharing all documents/reports with railways and members of this Committee. The proposal shall be work out in consultation with Railways with clarity on the implementing agency, monitoring protocol, and reporting mechanism on compliance etc.

(Action: CPCB & Railways)

3.6 Agenda B (ii): Environmental Standard for emission norms for Genset engines

Emission norms for Petrol/Kerosene, Diesel and dedicated Gas based and dual/ bi fuel Genset engines were revised/ developed vide GSR 353(E) ; dated 07.08.2013 for Kerosene and Petrol, GSR 771(E) ; dated 11.12.13 for Diesel and GSR 281(E) ; dated 07.03.2016 for dedicated Gas based and dual/ bi fuel Genset engines. Considering availability of better fuel quality, advancement in technology and present achievability of more stringent norms by different manufacturer; it was proposed by CPCB to revise the present emission norms of Genset engines.

The present emission standards are as follows:

Power Category	Emission Limits (g/kW-hr)			Smoke Limit (m ⁻¹)
	NO _x +HC	CO	PM	
Upto 19 kW	≤ 7.5	≤ 3.5	≤ 0.3	≤ 0.7
19 to 75 kW	≤ 4.7	≤ 3.5	≤ 0.3	≤ 0.7
More than 75 to 800 kW	≤ 4.0	≤ 3.5	≤ 0.2	≤ 0.7

The proposed emission norms are as follows:

Power Category	HC*+ NO _x	NO _x	HC *	CO	PM	Smoke m ⁻¹
	g/kW-h					
≤ 8 kW	≤ 7.5	NA	NA	≤ 3.5	≤ 0.3	≤ 0.7

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$<8 \text{ kW} \leq 19 \text{ kW}$	≤ 4.7	NA	NA	≤ 3.5	≤ 0.3	≤ 0.7
$<19 \text{ kW} \leq 56 \text{ kW}$	≤ 4.7	NA	NA	≤ 3.5	≤ 0.03	≤ 0.7
$<56 \text{ kW} \leq 560 \text{ kW}$	NA	≤ 0.40	≤ 0.19	≤ 3.5	≤ 0.02	≤ 0.7
$<560 \text{ kW} \leq 800 \text{ kW}$	NA	≤ 0.67	≤ 0.19	≤ 3.5	≤ 0.03	≤ 0.7

The CPCB made a presentation. After detailed deliberated committee recommended following:

1. The monitoring mechanism (post installation) for emission compliance verification shall be incorporated in the proposal.
2. The effective implementation date should be finalized in consultation with industry.
3. Phasing plan for the existing DG sets shall also be proposed in due consideration of an effective service life.
4. Justification and need of enforcing such a standard should be provided by CPCB.
5. The stack height or necessary installation guidelines for the DG sets may also be considered to meet the objective of stipulating norms
6. Why BSIV genset engine emission standard are proposed when the vehicles have to comply with the BSVI norms.

(Action: CPCB)

4. The meeting ended with vote of thanks to the Chair.

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Annexure- I

List of the Participants who attended the Video Conference First meeting of the Expert Committee to finalize the Environment Standards held on 09th December, 2020.

S. No.	Name	Designation/ Department/ Organisation	e-mail address
1.	Shri Jigmet Takpa (Chairman)	Joint Secretary, MoEF&CC	takpa.jigmet@gov.in
2.	Shri Navdeep Rinwa	Joint Secretary, Ministry of Chemical & Fertilizers, Depatt. of Pharmaceutical -Invitee	Js.pharma@nic.in
3.	Shri Ajay Deshpande	Expert Member	ajaydeshpandel@rediffmail.com
4.	Dr. Rashid Hasan	Expert Member	hasan@siam.in, hasan.mef@gmail.com
5.	Dr. J.P. Gupta	Representative PHD Chamber of Commerce	jglobalconsultinggroup@gmail.com,
6.	Dr. Ranjeet Mehta	Representative PHD Chamber of Commerce	ranjeetmehta@phdcci.in
7.	Dr. J.S. Sharma	Representative PHD Chamber of Commerce	sharmajswarup@hotmail.com
8.	Shri Shikhar Jain	Representative CII	shikhar.jain@cii.in
9.	Ms. Madhurima Madhav	Sci 'D' Expert Member Representative BIS	madhurima@bis.gov.in
10.	Shri Mohit Janoiya	Sci. C/CMD-1, Representative BIS	cmd1@bis.gov.in
11.	Shri Ashish Kumar	Sci. C/CMD-3, Representative BIS	cmd3@bis.gov.in
12.	Shri Gyan Prakash	Sci 'B', BIS, Representative BIS	chd@bis.gov.in
13.	Shri Manish Kumar	Sci. 'B' HLPPD, Representative BIS	hrd@bis.org.in
14.	Shri Dinbandhu Gouda	Sci. 'E', CPCB	Dinabandhu.cpcb@nic.in
15.	Ms. Divya Sinha	Sci. 'E', CPCB	divyasinha.cpcb@nic.in

16.	Shri J.C. Babu	Sci. 'E', CPCB	Jcb.cpcb@nic.in
17.	Dr. Kedarnath Das	Sci. 'D', CPCB	kndin@yahoo.com ; knd.cpcb@nic.in
18.	Shri Mukesh Balodhi	Sci. 'D', CPCB	Mbalodhi.cpcb@nic.in
19.	Shri Vishal Gandhi	Sci. 'D', CPCB	vishalcpb@gmail.com
20.	Shri Sundeep	Expert Member, Director, MoEF&CC	sundeep.cpcb@nic.in
21.	Dr. Ritesh Joshi	Sci. 'E', MoEF&CC	ritesh.joshi@nic.in
22.	Dr. Sonu Singh	Member Convener, Sci. 'E', MoEF&CC	sonu.singh@gov.in
Diesel Locomotives and Emission norms for Genset engines			
23.	Shri Kishore Kumar, PEDEE RS	Executive Director/EE(RS) Railway Board	dycmmg@cr.railnet.gov.in
24.	Shri Anivash K. Agrawal	Professor, IIT, Kanpur	akag@iitk.ac.in
25.	Shri Neelkanth Marathe	Representative ARAI	nvmarathe.edl@araiindia.com
26.	Dr. Prashanth Ravi	Representative IDEMA	prashanth_ravi@cat.com
27.	Shri Ankit Trivedi	Representative ICAT	ankit.trivedi@icat.in
28.	Dr M N Kumar, ,	IDEMA	m.kumar@kirloskar.com
Primary Water Quality Criteria for Class SW-III Waters and Class SW-V Water and RO standards			
29.	Shri Ramana Murthy	Director, MoES-NCCR	mvr@nccr.gov.in
30.	K. Venkatarama Sharma	Scientist-F, MoES-NCCR	venkat@nccr.gov.in
31.	Dr.S.R.Marigoudar	Scientist-D, MoES-NCCR	srmarigoudar@nccr.gov.in
32.	Dr. Sudhir Srivastava	Scientist-D (Sr. Chemist), CGWB	sksrivastava-cgwb@gov.in
33.	Shri Sanjay Marwaha	Regional Director CGWB	smarwaha-cgwb@nic.in; mhq-cgwb@gov.in
Bulk Drug and Formulation (Pharmaceutical) Industry			
34.	Shri R.K. Agrawal	Senior Vice President - Bulk Drugs Manufacturers Association	agrawal@nakodachemical.com / info@bdmai.org

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35.	Shri Yogin Majmudar	Representative IDMA	ym@bakulpharma.com
36.	Shri Harish Verma,	Representative IDMA	harish.verma@piramal.com
37.	Shri Kaushik	Representative IDMA	kaushiksamanta@lupin.com

Proposed Notification Bulk Drug

[To be published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i)]
GOVERNMENT OF INDIA
MINISTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE
NOTIFICATION

New Delhi, the, 2020

G.S.R.(E) Whereas, certain draft rules, namely the Environment (Protection) Amendment Rules, 2020 were published in the Gazette of India, Extraordinary, as required under sub-rule (3) of rule 5 of the Environment (Protection) Rules, 1986, *vide* notification of the Government of India in the Ministry of Environment, Forest and Climate Change *vide* number G.S.R. 44 (E), dated the 23rd January, 2020, inviting objections and suggestions from all persons likely to be affected thereby within a period of sixty days from the dated on which copies of the Gazette containing the said notification were made available to the public;

And Whereas, copies of the Gazette containing the aforesaid notification were made available to the public on the 23rd January, 2020;

And Whereas, objections and suggestions received from all persons and stakeholders in response to the aforesaid notification have been duly considered by the Central Government;

Now, therefore, in exercise of the powers conferred by sections 6 and 25 of the Environment (Protection) Act, 1986 (29 of 1986) read with sub-rule (3) of rule 5 of the Environment (Protection) Rules, 1986, the Central Government hereby makes the following rules further to amend the Environment (Protection) Rules, 1986, namely: -

1. **Short title and commencement.** - (1) These rules may be called the Environment (Protection) Amendment Rules, 2020.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Environment (Protection) Rules, 1986, in Schedule-I, for serial number 73 and the entries relating thereto, the following serial number and entries shall be substituted, namely:

S.No.	Industry	Parameters	Standard
1	2	3	4

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“73	Bulk Drug and Formulation (Pharmaceutical)	A. EFFLUENT STANDARDS*	
			Limiting value for concentration (in mg/l except for pH and Bio assay)
		i) Compulsory Parameters	
		pH	6.0 -8.5
		BOD (3 days 27°C)	30
		COD	250
		TSS	100
		Oil & Grease	10
		Ammonical Nitrogen	50
		Nitrate Nitrogen	10
		Bio - Assay Test**	90% Survival of Fish after first 96 hours in 100% effluent
		ii) Additional Parameters ^{##}	
		***Benzene	0.05
		***Toluene	0.05
		***Xylene	0.06
		***Methylene Chloride	0.9
		***Chlorobenzene	0.15
		Phosphates as P	5
		Fluoride	2
		Sulphides as S	2
		Phenolic Compounds	1
		Zinc	5
		Iron	3
		Copper	3
		Total Chromium	2
		Hexavalent Chromium (Cr ⁶⁺)	0.1
		Cyanide (as HCN)	0.1
		Arsenic	0.2
		Mercury	0.01
		Lead	0.1
		Sodium Absorption Ratio	Less than 26
		iii) Industry connected with CETP	

	• The discharge norms for industry connected with CETP and of CETP shall be governed by MoEF&CC notification S.O. 4 (E) dated 1st January, 2016. • State Pollution Control Board shall prescribe additional relevant parameters as given at para A (ii) of this notification as per needs and discharge potential of member industries and specify the frequency of monitoring considering the receiving environment conditions.																				
	Note: The standards in para A is applicable to all discharges except to CETP. *Not applicable to industry discharging to CETP, and shall be applicable to all discharge to land and surface water bodies including use of treated wastewater for horticulture or irrigation purpose ** The Bio assay test shall be conducted as per IS : 6582-1971 ## Parameters listed as “Additional Parameters” shall be prescribed by SPCB depending on the process and product and its monitoring frequency shall be monthly/quarterly as decided by SPCBs ***<i>Limits shall be applicable to industries those are using Benzene, Toluene, Xylene, Methylene Chloride, Chlorobenzene.</i>																				
	B. EMISSION STANDARDS (Tank farm Vents) <table><tr><th>Parameter</th><th>Limiting value for concentration (mg/Nm³)</th></tr><tr><td>Chlorine</td><td>15</td></tr><tr><td>Hydrochloric acid vapor</td><td>35</td></tr><tr><td>Ammonia</td><td>30</td></tr><tr><td>Benzene</td><td>5</td></tr><tr><td>Toluene</td><td>100</td></tr><tr><td>Acetonitrile</td><td>1000</td></tr><tr><td>Dichloromethane</td><td>200</td></tr><tr><td>Xylene</td><td>100</td></tr><tr><td>Acetone</td><td>2000</td></tr></table>	Parameter	Limiting value for concentration (mg/Nm ³)	Chlorine	15	Hydrochloric acid vapor	35	Ammonia	30	Benzene	5	Toluene	100	Acetonitrile	1000	Dichloromethane	200	Xylene	100	Acetone	2000
Parameter	Limiting value for concentration (mg/Nm ³)																				
Chlorine	15																				
Hydrochloric acid vapor	35																				
Ammonia	30																				
Benzene	5																				
Toluene	100																				
Acetonitrile	1000																				
Dichloromethane	200																				
Xylene	100																				
Acetone	2000																				
	C. <i>The total cumulative losses of solvent should not be more than 5% of the solvent on annual basis from storage inventory</i>																				

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		D. Chemical and Biological sludge or any residue, reject, concentrate generated from wastewater treatment or its management facility at Industry or CETP catering to industries engaged in manufacturing of bulk drug or formulation of Pharmaceuticals, shall be classified as Hazardous Waste as per the provision of sub-section 17 of section 3 of Hazardous and Other Wastes (Management and Trans-boundary Movement) Rules, 2016 and shall be subjected to the provision made therein.
	Note:	Newly introduced norms in comparison with prevailing norms shall be effective after one year from the date of this notification

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ANNEXURE A6
(Court No. 1)

Item No. 03

**BEFORE THE NATIONAL GREEN TRIBUNAL
PRINCIPAL BENCH, NEW DELHI**

(By Video Conferencing)

Original Application No. 136/2020

(With reports dated 10.03.2021 & 05.05.2021)

Veterans Forum for Transparency in Public Life

Applicant

Versus

State of Himachal Pradesh & Ors.

Respondent(s)

Date of hearing: 23.06.2021

CORAM: HON'BLE MR. JUSTICE ADARSH KUMAR GOEL, CHAIRPERSON
HON'BLE MR. JUSTICE SUDHIR AGARWAL, JUDICIAL MEMBER
HON'BLE MR. JUSTICE M. SATHYANARAYANAN, JUDICIAL MEMBER
HON'BLE MR. JUSTICE BRIJESH SETHI, JUDICIAL MEMBER
HON'BLE DR. NAGIN NANDA, EXPERT MEMBER

Applicant: Dr. Bishwanath Prasad Singh, Wing Commander (Retd.), in
Person

Respondent: Mr. Nalin Kohli, Advocate for HPSPCB

ORDER

1. Prayer in this application is for remedial action against discharge of waste from CETP at Baddi and from Acme Life Sciences, Nalagarh and Helio Pharmaceuticals at Solan, to prevent pollution of rivers Sirsa and Satluj. According to the applicant, the CETP is not connected to pharmaceutical units at Barotiwala and Nalagarh who are discharging their effluents directly into the rivers. It is further stated that even after treatment in ETP/STPs, pharmaceutical ingredients may still be coming out from the industries unless ETP/STPs are specialized for the purpose. It is further stated that present CETP is not designed to neutralize Active Pharmaceutical Ingredient (API). The TSDF does not receive sludge generated from the industrial units at Nalagarh. The industries located at

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Baddi area are generating 20779 KLD of industrial effluent, out of which 17894 KLD is being treated at CETP and remaining 2885 KLD is being disposed of by the occupiers directly into river Sirsa. There is no existing sewerage system in BBN area and no demarcation in residential and industrial area. Presence of Ciprofloxacin in the concentration of 296.1 ug/l was found on chemical analysis. Concentration of Ciprofloxacin in the effluent discharge of M/s Acme Life Sciences work out to be 13455 times of the prescribed limit. The increasing occurrence of multi-resistant pathogens is a serious global threat to human health and it is finding its way into the water bodies and drinking water through industrial discharge and also due to heavy use of antibiotics in human and veterinary medicine.

2. The matter was considered on 22.07.2020. The Tribunal constituted a joint Committee of CPCB, State PCB and District Magistrate, Solan to furnish a factual and action taken report in the matter.

3. The matter was last considered on 04.01.2021 in the light of the report of State PCB dated 30.12.2020 noticing the violations of environmental norms. The Tribunal directed remedial action and filing of compliance report. The operative part of the discussion and order of the Tribunal are reproduced below:-

"3. Accordingly, the Himachal Pradesh State PCB has filed its report dated 30.12.2020 to the effect that the joint Committee visited the area and noticed as follows:

"xxx

xxx

xxx

i. The CETP has not installed the system to completely treat category IV effluent (High TDS/FDS Stream). Despite the fact that CETP does not have the capacity to treat this type of effluent, CETP has entered into the tripartite agreement with the Industries generating Category IV effluent has been receiving this category of effluent since 2016.

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ii. **As per Environmental Clearance granted to CETP Baddi by the Ministry of Environment, Forests and Climate Change (MoEF&CC), the member industries with hydraulic loading more than 200 KLD shall treat the effluent in the existing onsite ETPs and then discharge into CETP for further treatment and discharge. However, it was informed that Units with hydraulic loading of 200 KLD are not treating effluent in the onsite ETPs and supplying primary treated effluent to CETP. Therefore, CETP has not been complying with this condition of the Environmental Clearance granted by MoEF&CC for the last 04 years.** Accordingly, the sampling of these units was done by HPPCB team on 10/12/2020 and the samples were sent to HPPCB Central Laboratory. The results of the analysis are expected by 10/01/2021.

iii. The observations made by the Joint Committee during visit to the two Pharma units i.e. M/s Acme Life Sciences and M/s Helios Pharmaceuticals mentioned in the original application are as follows:

- Both the pharma units have connectivity with the CETP for supplying the primary treated effluent, for further treatment at CETP.
- No effluent was found to be discharged directly by the Units, in the drain.
- The Joint Committee collected the samples from the final outlet of the pharma units under reference, to see the concentration of residual antibiotics in the primary treated effluent which is being sent to CETP for further treatment. The results of the analysis are expected by 09/02/2021.

iv. The evaluation of the results of the analysis of the CETP samples collected by the Joint Committee on 12-13 October, 2020, indicated intended dilution by CETP so as to achieve the prescribed norms. Therefore, the Joint Committee conducted unannounced re-sampling and sent the samples for analysis from three different laboratories.

v. **The results of analysis for the samples collected by the Joint Committee have been analyzed in HPPCB Regional Laboratory, Paonta Sahib and evaluation of the results indicated that CETP is not meeting the norms prescribed for COD (264 mg/l > 250 mg/l), BOD (35 mg/l > 30 mg/l), FDS (2252 mg/l > 2100 mg/l) and Chloride (1838 mg/l > 1000 mg/l). Therefore, it is concluded that CETP is discharging the effluent into the Sirsa River without complying with the prescribed norms.** The results of the analysis of the samples are awaited from two other laboratories.

vi. The samples from CETP, upstream and downstream of Sirsa River and the pharma units under question, were

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collected by the joint committee on 09/12/2020 for analysis of 12 Nos. residual antibiotic residues from Shri Ram Institute of Industrial Research, Delhi. The results of analysis of effluent samples for residual antibiotics is expected by 09/02/2021. The issue of discharge of residual antibiotics as raised by the applicant may be concluded by the Joint Committee after receipt of the analysis results.

In view of the fact that complete analysis reports will be available by 09/02/2021, it is humbly prayed to Hon'ble National Green Tribunal that Joint Committee may kindly be permitted to file the final conclusive report by 15/02/2020."

4. Accordingly, further action taken report may be separately filed by the State PCB before the next date by e-mail at judicial-ngt@gov.in preferably in the form of searchable PDF/OCR Support PDF and not in the form of Image PDF. The directions in the connected matter being OA No. 801/2018, Jasmeet Singh v. State of Himachal Pradesh, dealt with by a separate order, to the extent relevant for the present matter, may also be followed."

4. The State PCB has filed its report dated 10.03.2021 giving the analysis results of samples calculated from the units as follows:-

"Supplementary Report:

The analysis results from the remaining two laboratories w.r.t samples collected by the Joint Committee have been received (Annexure-2 and Annexure-3). Further, the report of analysis w.r.t samples collected by the Joint Committee from CETP, Pharma Units and Sirsa River for the presence of antibiotics from the approved external laboratory has also been received (Annexure-4). Accordingly, supplementary report in this matter is being filed by the Joint Committee as follows:

- i) The results of analysis as received from three different laboratories of HPPCB, indicated that CETP is not meeting the norms prescribed for BOD (41, 35 & 38 mg/l > 30 mg/l), FDS (2252 & 3190 mg/l > 2100 mg/l) and Chloride (1209, 1838 & 1209 mg/l > 1000 mg/l). Therefore, it may be concluded that CETP is discharging the effluent into the Sirsa River without complying with the prescribed norms.
- ii) The results of analysis of the samples collected from various stages of CETP and also final discharge point in River Sirsa for the presence of residual antibiotics indicate that two antibiotics viz. Ciprofloxacin and Ofloxacin are present in the final treated effluent of CETP as a concentration of 22.8 ug/l and 69.8 ug/l respectively.
- iii) There are no standards notified by MoEF&CC for residual antibiotics in industrial effluents. However, these values are

1140 time higher for Ciprofloxacin (22.8 ug/l Vs. 0.02 ugh) and 349 times higher for Ofloxacin (69.8 ug/l Vs. 0.2 ugh) when compared with the proposed standards in the draft notification issued by MoEF&CC vide No. CG-DL-E-27012020- 215690 dated January 23, 2020 (Annexure-5), for pharmaceutical industry effluent and CETPs with membership of Bulk drug and formulation units.

- iv) Similarly, the samples collected by the Joint Committee from the outlets of two Pharmaceutical Industries viz. Helios Pharmaceutical and M/s Acme City Tech LLP, leading to CETP, were found to be much higher than the standards proposed in the draft notification issued by MoEF&CC. Also, the values reported as below quantification limit (BQL), in the analysis report of the external laboratories may not be considered as conclusive and within the proposed limits as draft notified by MoEF&CC, since the BQLs of external laboratory for various antibiotics tested in the samples, as shared with the Joint Committee, are much higher than the proposed standards.
- v) As per reports and research data available in the literature, the concentration of residual antibiotics has been found to be reduced by 60-90 % in conventional biological treatment plant. In view to assess the performance of the biological treatment system installed by CETP, the samples were collected from various stages of CETP. The results of analysis indicated that the performance of biological treatment system installed by CETP is not in line with the reports and data available in the literature, w.r.t. treatment of residual antibiotics. The inefficient performance of biological treatment system is also evident from the noncompliance of CETP with regard to biochemical oxygen demand (BOD).

Conclusion and Recommendations:

In view of the fact that:

- i) There are no standards notified by MoEF&CC w.r.t. residual antibiotics in industrial effluents;
- ii) Draft notified standards are yet to be decided by MoEF&CC;
- iii) The concentration of residual antibiotics at outlet of CETP in Sirsa River, is much higher than the draft notified standards;
- iv) The treatment efficiency of CETP w.r.t residual antibiotics is not at par with the reports and data available in the literature;
- v) The CETP is not meeting the prescribed norms of BOD, FDS and chloride and discharging effluent into Sirsa River without complying with the prescribed norms.

It is recommended that Pharmaceutical (both bulk drug and formulation units) may be directed by Himachal Pradesh Pollution Control Board to provide primary treatment to the level of predicted no effect concentration (PNEC) as developed by members of AMR

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Industry Alliance (Annexure-6), as a site (Baddi) specific preventing measure, so that there is no adverse impact of residual antibiotics on the environment and also to prevent development of antimicrobial resistance (AMR)."

5. The report is followed by further report dated 05.05.2021 as follows:-

"It is further submitted that now the joint committee has submitted its supplementary report which is annexed as Annexure R-1/1. Based on the inspections and sampling conducted the conclusion and recommendations made by the joint committee are as under:-

- "i) There are no standards notified by MoEF & CC w.r.t. residual antibiotics in industrial effluents.*
- ii) Draft notified standards are yet to be decided by MoEF & CC.*
- iii) The concentration of residual antibiotics at outlet of CETP in Sirsa river is much higher than the draft notified standards.*
- iv) The treatment efficiency of CETP w.r.t. residual antibiotics is not at par with the reports and data available in the literature.*
- v) The CETP is not meeting the prescribed norms of BOD, FDS and chloride and discharging effluent into Sirsa River without complying with the prescribed norms....."*

The copy of Supplementary Report submitted by the joint committee dated 10-03-2021 (annexed as Annexure R-1/1) may be placed on record please.

It is submitted that as of now there are no specific standards notified by the Govt. of India for residual antibiotics parameters in the existing notification of standards for pharmaceutical (Manufacturing and Formulation Industry). However, it is worthwhile to mention here that all the bulk drugs/pharmaceutical manufacturing units (if not connected with CETP) are being regulated for the compliance as per standards notified in MoEF & CC Notification dated 9-7-2009 (copy annexed as Annexure R-1/2). If the pharmaceutical (manufacturing and formulation industry) is member of CETP, then the unit is bound to comply with inlet quality standards notified by the Govt. of HP vide notification dated 17-3-2018 and 26-12-2019 (copies annexed as Annexure R-1/3 and R-1/4) The notification of specific standards for residual antibiotics (annexed as Annexure -5 with joint report) is still under proposed stage and shall be implemented for regulatory aspect as and when finalized by the MoEFF & CC."

6. The industrial units in question have also filed their Counter Affidavits. The said Counter Affidavits are of no assistance.

7. As against the above, the applicant has filed written submission on 11.06.2021 pointing out that the analysis of the samples shows presence of antibiotics in the water.

8. The conclusion drawn from the analytical results is as follows:-

“

1. *Ciprofloxacin (22.8µg/L) and Ofloxacin(69.8µg/L) were detected in higher concentrations in the effluent released to Sirsa river from CETP (Sr. no 4), i.e., 1139 and 348 times higher than the prescribed MoEF& CC draft notification limits.*
2. *The higher concentrations of antibiotics in the effluent released to Sirsa river (Sr. no 4) clearly indicate that CETP is unable to completely remove or degrade these antibiotics.*
3. *Ofloxacin (960µg/L) was found in the effluent from M/S Helios Pharmaceutical (Sr. no 13) release to CETP, which is much higher than the draft notification limit (0.2 µg/L). It clearly raises doubt on the level of pre-treatment of the pharma effluent from this industry before it is released to the CETP.*
4. *The samples drawn from the effluent of M/S Acme City Tech LLP (Sr. no 14 and 15) release to CETP shows reasonably high concentrations of Ofloxacin (170 µg/L) and Azithromycin (423µg/L) even after primary treatment, indicate inefficient pre-treatment at this industry.*
5. *In the research methodology Limit of quantification (LOQ) for a compound by any method indicates the lowest concentration that can be quantified with accuracy and precision. The values below LOQ cannot be correctly quantified during the analysis and are reported as Below Quantification Limit (BQL). In the present analysis, the LOQs of the compounds fixed for the analysis by the lab are very high; namely, Ciprofloxacin (5 µg/L), Ofloxacin (5 µg/L), Piperacillin (5 µg/L), Azithromycin (10 µg/L), Tazobactam (5 µg/L), Ceftazidime (50 µg/L), Cefixime (20 µg/L), Amoxicillin (10 µg/L), Ampicillin (10 µg/L), Cefpodoxime (10 µg/L), Sulbactam (10 µg/L), Ceftriaxone (50 µg/L) and Cefoperazone (10 µg/L). The above LOQs of the compounds are much higher than even the antibiotic discharge limits set by the MoEF & CC draft notification for these compounds; except for Tazobactam.*
6. *Incidentally Piperacillin and Amoxicillin are the antibiotics are known for the very adverse impact on the human health even in the very low concentration. In this laboratory analysis, BQL limit for these compounds are set as (5 µg/L) and (10 µg/L) which is significantly higher than the limit fixed in the draft standards. In the draft standards the limit set for these two compounds are (0.1µg/L).*

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7. This implies that the Limit of Quantification (LOQ) set up by the lab is significantly higher than the limit set by the draft notification and therefore many of the compounds are not being detected as has been marked as BQL in the analysis results.
8. Therefore, the samples analysis should be conducted using an analytical method to precisely and accurately quantify lower concentrations of the compounds (LOQs should be kept as close or even lower than the draft notification limits) to quantify all the compounds at lower concentrations with accuracy and precision. This raises the question mark on integrity of the overall analysis by the lab.
9. Further the findings also imply that the CETP is not designed to efficiently treat class IV effluents; however, operator of CETP has entered into agreement with various pharma manufacturing units who are releasing class IV effluents to the CETP since 2017."

9. Further submissions are reproduced below:-

"14. The migration of antimicrobials into the environment has significant impacts. They can disrupt wastewater treatment processes and adversely affect ecosystem because they are toxic to beneficial bacteria. Some antimicrobials also bio accumulates; for example, erythromycin has been found to have both a high bio accumulation factor of 45.31 and a tendency to accumulate in soil. Antimicrobials can also be persistence for extended periods of time, the environmental persistence of erythromycin for example, is longer than one year.

15. Although not well studied, the presence of antimicrobials in natural waters may be exerting selective pressure leading to the development of antibiotics resistance in bacteria. The threat of growing antibiotics resistance has been recognised by, among others, the WHO, the National Academy of Science, the American Medical Association, the American Public Health Association and the US government Accountability. In fact the Centre for Disease Control and prevention (CDC) has identified antibiotics resistance as one of the most pressing public health problem facing the nation. Infections caused by bacteria with resistance to at least one antibiotic have been estimated to kill over 60,000 hospitalized patients each year. Methicillin resistant strains of *Staphylococcus aureus*, although previously limited primarily to hospital and health facilities, are becoming more widespread. In 2007, Consumer Reports tested over 500 whole chickens for bacterial contamination and antibiotic resistance. They found wide spread bacterial contamination in their samples and 84 percent of the salmonella and 67 percent of the campylobacter organisms that were isolated showed resistance to one or more antibiotic.

16. Antibiotic resistance is caused by a number of factors including repeated and improper use of antibiotics in both humans and animals.

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Half of the antibiotics used in livestock are in the same classes of drug that are used in humans and animals. The U.S. institute of Medicine and the WHO have both stated that widespread use of antibiotics in agriculture is contributing to antibiotic resistance.

17. The above study done by the HPPCB shows that from whichever place samples have been taken by HPPCB these are having antibiotics discharge which should not have been there. There is not a single sample in which the aforesaid antibiotics discharging into surface water and also seeping into the subsoil water is not there. This would lead to harmful antibiotic resistance amongst human and animal population and, thus, reducing the chances of their recovering from diseases where absence of resistance from these antibiotic would have helped. The above table and the subsequent narration would show that the antibiotics found in the discharge include some of the ultimate antibiotics developing resistance of which may be a death warrant for different life forms – human and animal – if infected with diseases where these antibiotics could have provided a cure.

18. A situation where all random samples show the same results, in technical terms, is called '100% random test positivity'. In view of the '100% random test positivity', the study conducted by HPPCB cannot be stated to be complete and conclusive. It only indicates that a whole lot of polluting antibiotics are being discharged into the surface and subsoil water which is harmful for human and animal population.

19. As per information available at internet, there are more than 270 Pharmaceutical Companies operating in Baddi-Barotiwal-Nalagarh area. List of such Pharmaceutical Companies along with their addresses, as obtained through internet sites, is placed at Annexure A.

20. This necessarily requires a further and more detailed study as a sequel to 'the sample study' done by HPPCB to understand the entire extent of damage because of the aforesaid antibiotic discharge into the water bodies. It is being called 'sample study' because of the fact that it has '100% random test positivity' and therefore, in scientific tradition, there is an absolute need for following it up with a detailed, wide and more in depth study of the antibiotic discharge into river sirsa."

10. We have heard the applicant in person and the Learned Counsel for State PCB.

11. We find that there is gross failure on the part of the State PCB to act as per public trust doctrine in preventing discharge of toxic effluents containing harmful residue of antibiotics in water posing threat to aquatic life (reference: "biomonitoring of Sirsa River in Baddi area of Himachal

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Pradesh by Bhagat S. Chauhan, *et al*, *International Journal of Theoretical and Applied Sciences* 5 (1): 183-185(2013)) which is also in violation of the Water (Prevention and Control of Pollution) Act, 1974. Such failure of statutory duties is at the cost of public health and protection of environment for which Chairman and Member Secretary of the PCB owe an explanation which may be furnished before the next date. Mere fact that standards have not been revised by MoEF&CC of the residual antibiotics in industrial effluents can be no justification for State PCB not taking steps to prevent. Pending finalization of standards by MoEF&CC, State PCB can go by earlier standards or lay down standards by itself under section 17 of the Water Act. MoEF&CC needs to expedite the process of finalizing the standards in the interest of protection of environment.

12. Accordingly, MoEF&CC and the State PCB may take further remedial action expeditiously. The State PCB may ensure that no harmful components in the effluents are discharged into the water by the units in question or any other API unit. A joint Committee of nominee of MoEF&CC, CPCB, State PCB and District Magistrate, Solan may conduct inspection of the area and give a report of the status of violations and the remedial action taken within three months by e-mail at judicial-ngt@gov.in preferably in the form of searchable PDF/ OCR Support PDF and not in the form of Image PDF. The State PCB will be the nodal agency for compliance. The Committee may interact with the concerned stake holders, including the concerned Industries. The report may inter alia give status of performance of individual pharmaceutical units, particularly with reference to removal of API residue by them and by the CETP, the number of pharma industries connected to CETP and those discharging effluents directly into the drain and the river. The report may further indicate chemical and biological water quality of rivers in

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question - Sirsa and Satluj, including the status of residue at relevant locations. CPCB may also suggest monitoring mechanism for API residue through a credible system so as to cover all pharma industries in the country discharging API residue directly or indirectly in river systems. CPCB may propose the timelines to undertake monitoring which may also take a note of water quality monitoring guidelines of CPCB titled "Guidelines on Water Quality Monitoring, 2017" and the performance audit report dated 18.09.2020 filed by CPCB in OA 95/2018, *Argavart Foundation v. M/s Vapi Green Enviro Ltd. & Ors.* and the directions of the Tribunal dated 05.02.2021. Relevant direction is reproduced below:

"22. The directions on the subject are summed up as follows:

i to vi xxx.....xxx.....xxx

vii. CPCB and State PCBs/PCCs, as directed earlier, may utilise EC funds on laboratory set up/upgradation, and on the mentioned areas in the report as well as on approved District Environment Plans. No approval of Central/State Government will be necessary in this regard in view of section 33 of the NGT Act, supra."

CPCB may file report on the above aspects before the next date of hearing by e-mail at judicial-ngt@gov.in preferably in the form of searchable PDF/ OCR Support PDF and not in the form of Image PDF.

List for further consideration on 05.10.2021.

A copy of this order be forwarded to MoEF&CC, State PCB District Magistrate Solan and CPCB by e-mail for compliance.

Adarsh Kumar Goel, CP

Sudhir Agarwal, JM

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M. Sathyanarayanan, JM

Brijesh Sethi, JM

Dr. Nagin Nanda, EM

June 23, 2021
Original Application No. 136/2020
SN

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Item Nos. 09&10

(Court No. 1)

**BEFORE THE NATIONAL GREEN TRIBUNAL
PRINCIPAL BENCH, NEW DELHI**

(By Video Conferencing)

Original Application No. 801/2018

With

Original Application No. 136/2020

(With reports dated 18.01.2022 & 20.01.2022)

Jasmeet Singh

Applicant

Versus

State of Himachal Pradesh

Respondent

With

Veterans Forum for Transparency in Public Life

Applicant

Versus

State of Himachal Pradesh & Ors.

Respondent(s)

Date of hearing: 21.01.2022

**CORAM: HON'BLE MR. JUSTICE ADARSH KUMAR GOEL, CHAIRPERSON
HON'BLE MR. JUSTICE SUDHIR AGARWAL, JUDICIAL MEMBER
HON'BLE MR. JUSTICE BRIJESH SETHI, JUDICIAL MEMBER
HON'BLE PROF. A. SENTHIL VEL, EXPERT MEMBER
HON'BLE DR. AFROZ AHMAD, EXPERT MEMBER**

Applicant: Dr. Bishwanath Prasad Singh, Wing Commander (Retd.), Applicant
in Person in OA 136/2020

Respondent: Mr. Nalin Kohli, Adv. for HPSPCB

ORDER

1. Both the above matters are being taken up together as the issue involved is of discharge of toxic industrial pollution in river Balad in Baddi industrial area in District Solan and rivers Sirsa and Satluj. Vide order dated 23.06.2021, scope of O.A. No. 801/2018 was noted to be "the remedial action against pollution of River Balad in Baddi industrial area in

District Solan, on account of leakage from the Common Effluent Treatment Plant (CETP)" while scope of O.A. No. 136/20220 was noted to be, "remedial action against discharge of waste from CETP at Baddi and from Acme Life Sciences, Nalagarh and Helio Pharmaceuticals at Solan, to prevent pollution of rivers Sirsa and Satluj. According to the applicant, the CETP is not connected to pharmaceutical units at Barotiwala and Nalagarh who are discharging their effluents directly into the rivers. It is further stated that even after treatment in ETP/STPs, pharmaceutical ingredients may still be coming out from the industries unless ETP/STPs are specialized for the purpose. It is further stated that present CETP is not designed to neutralize Active Pharmaceutical Ingredient (API). The TSDF does not receive sludge generated from the industrial units at Nalagarh. The industries located at Baddi area are generating 20779 KLD of industrial effluent, out of which 17894 KLD is being treated at CETP and remaining 2885 KLD is being disposed of by the occupiers directly into river Sirsa. There is no existing sewerage system in BBN area and no demarcation in residential and industrial area. Presence of Ciprofloxacin in the concentration of 296.1 ug/l was found on chemical analysis. Concentration of Ciprofloxacin in the effluent discharge of M/s Acme Life Sciences work out to be 13455 times of the prescribed limit. The increasing occurrence of multi-resistant pathogens is a serious global threat to human health and it is finding its way into the water bodies and drinking water through industrial discharge and also due to heavy use of antibiotics in human and veterinary medicine."

2. The Tribunal noted the status in O.A. No. 801/2018 as follows:-

"2. The matter was considered on several occasions earlier. On 14.01.2020, the Tribunal considered the report dated 06.11.2019 filed by the State PCB to the effect that violation of provisions of the Water (Prevention and Control of Pollution) Act, 1974 was taking place by

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discharge of polluted effluents in the water bodies. The same is reproduced below for ready reference:-

"2.0 Inspection of CETP Baddi

- i) The CETP is designed to treat five different categories of effluent as tabulated under

Sr. No.	Category	Sector of Industry	No of Units	Consented effluent quantity (in MLD)
1.	I	Food, Paper and Textile	89	15.55
2.	II	Soap & Detergent	112	2.0
3.	III	Pharmaceutical	213	2.9
4.	IV	Dyeing	4* M/s Auro Textile Unit - I, M/s Auro Dyeing Unit - I, M/s Winsome Textile Industries	2.0
5.	V	Electroplating, Metal surface finishing	31	0.042
Total			449	22.492
				Say 23.00

- ii) It was observed that at an average of 17 mld effluent is treated by the CETP, comprising equalization tank, primary settler, aeration tank, reaction tank, secondary and tertiary clarifier. The treatment process for each stream is appended with the report (**Annexure IV**).
- iii) It was noticed that effluent of category IV is not reaching to its designated equalization tank. M/s Baddi Infrastructure Ltd., has informed that the dedicated pipe network to carry the effluent of category IV is blocked. The effluent of category IV is therefore being discharged through pipe network of Category I.
- iv) It is also observed that the CETP is designed to treat category V effluent by mixing with category IV effluent to optimize the chemical consumption and to achieve effective treatment. Since, the effluent of category IV has been mixed with category-I, in the pipe network itself before reaching CETP, which has resulted in formation of a new complex effluent for which the CETP was not designed. Therefore, it could not able to deliver the desired results w.r.t. treatment and thus, effluents was in non-conformity with the standards, as per the

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monitoring results of HPPCB (Annexure-V). Besides, the effluent of category V remained effectively untreated throughout the CETP process.

- v) The performance of CETP is being regularly monitored by HPPCB. The monitoring data (Annexure-V) indicate that the performance of the CETP is far from satisfactory for having not met the discharged standards. The data reveal that effluent quality does not conform the standards of Chloride (limit of 1100 mg/1 max.), Total dissolved Solids (TDS) (LIMIT OF 2100 MG/1 Mmax.) and Biochemical Oxygen Demand (BOD) (limit of 30 mg/1 max.).
- vi) The CETP has provided online continuous effluent monitoring system for pH, Total Suspended Solids (TDS), Chemical Oxygen Demand (COD) and Total Organic Content (TOC) and data so recorded are linked with the server of HPPCB and CPCB.
- While collecting the sample from the final outlet of tertiary clarifier and discharge point at River Sirsa, difference in colour of effluent was observed. The sample collected from the discharge point was lighter in colour than that of outlet of tertiary clarifier; giving rise to possibility of dilution. (Photograph: Plate-I)
- vii) **The Committee also recorded that the Textile Units, which are generating the effluent of Category IV, were earlier operating their own effluent treatment plants prior to commencement of CETP and found it viable to operate due to their scale of production.**
- viii) The designed treatment criteria of CETP are to treat effluent, stream-wise, following segregation at source, effluent of Category-I is mixed with Category-IV, resulted in alternation of criteria, hence treated effluent.
- ix) For increasing the connectivity, the CETP has proposed of laying conveyance (pipeline) for a total length of 5.8 kms. The status is as under.

Sr. No.	Location	Stretch in meters	Status of permission obtained	Remarks
1.	Zydus Cadilla to Legacy Food on Baddi Barotiwala road	1655	Permission granted by HPPWD	Work has been awarded by M/s Baddi Infrastructure Ltd vide letter dated 27-09-2019. (Annexure-VI)
2.	Maplur-Baddi electrical substation upto Bhud	2250	Permission not granted by NHAI	

	near Maxtar Bio Genics Company			
3.	Bhud to Lehi	1900	Permission granted by HPWD	
Total		5805		

To safeguard the interest of environment from being deteriorated further and having understanding of pollution problem, its cause and remedial measures, the Committee recommends following:

- i) **Textile industries (SI. No.1 to 5, Table 1) engaged in dyeing-process generating effluent of Category-IV, as mentioned above for the purpose of designing and operating CETP, should stop its operations with immediate effect, until and unless the dedicated conduits supposed to carry the said effluent, is brought to back functional.**
- ii) These units shall resume operation of their ETP to impart effective treatment on effluent of Category-IV so as to meet the standards and shall pump treated effluent to the pipe network designated to carry effluent of Category-I for further treatment at CETP.
- iii) **These units shall resume operations only upon satisfactory performance of ETP which was brought back to functional and shall be monitored once in a month by HPCB.**
- iv) M/s Baddi Infrastructure including Ltd. is to ensure proper maintenance of CETP and its infrastructure including pipe network designed to receive effluents from member industrial units. M/s Baddi Infrastructure Ltd. has to ensure operation of CETP as per the defined protocol and in accordance to standard operating practice which is in place. In case, any variation (beyond the designed criteria) of effluent quality is noticed by CETP the same shall be brought to the knowledge of SPCB, in writing. The SPCB shall acknowledge the communications and shall act to identify the cause for taking all necessary steps for taking all necessary steps to eliminate/minimize such variation.
- v) **M/s Baddi Infrastructure Ltd. has to install activated carbon, pressure sand filters and ozonizer before the treated effluent is discharged. This refers the Detailed Project Report of CETP-Baddi, which finds mentioned of the system but has not been provided by M/s Baddi Infrastructure Limited.**

Reference is made on the observations recorded by the Committee constituted by Hon'ble Tribunal in O.A.

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No.916/2018 in the matter of Sobha Singh and Others v/s State of Punjab and Others, wherein the Committee recommended that Rs.1.0 crore to be levied on CETP-Baddi as Environmental Compensation for untreated effluent discharged into River Sirsa. The CETP discharged, joining the river, has failed to meet Bio-assay Test (Toxicity on fish: 0% survival with 100% effluent for 96 hours). This would have caused impact on water and land (soil) environment, plants and vegetation, aquatic life and human health all along downstream of CETP-Baddi.

Thus, Committee also recommends the following:-

- vi) Environmental compensation (EC) to be levied to CETP-Baddi (M/s Baddi Infrastructure Ltd) for not having done effluent treatment upto the standards and to those Textile Industries (dyeing units) responsible for making CETP defunct. The EC would be proportionate as under.
 - a) CETP-Baddi has to pay environmental Compensation to the tune of Rs.1.91 Crores for non-compliance of discharged standards, estimated based on violation recorded by HPPCB over last one and half year [19.10.2017 -01.11.2019] (**Annexure VII**) including compensation to the tune of Rs.87.9 Lakh imposed by HPSPCB dated 15.10.2019 over one year [20.11.2018 to 09.09.2019] (**annexure VIII**).
 - b) Textile Industries (dyeing units) are to pay establishment cost of CETP and cost of pipe network which was brought to state of irreparable.
- vii) HPPCB is to review the notification, dated 17.03.2018 wherein Total Suspended Solids (TSS), Oil & Grease and pH have been notified TDS, BOD, Chloride and Sulphide may also be considered for inclusion in the notification as these have critical bearing on operation and performance of CETP designed to impart effective treatment. HPPCB may undertake similar exercise as done in case of notification, dated 29.06.2019 for CETP Paonta Sahib, wherein eight parameters including those referred here, have been considered. Such notification may be issued in consultation with CPCB.
- viii) **For optimal performance of CETP-Baddi, HPPCB is to ensure regulating and monitoring mechanism be in place by asking all member units (falling under red category) of CETP to install online continuous effluent monitoring system. The data so recorded shall be made available on SPCB and CPCB server for effective control."**

3. The matter was then considered on 18.06.2020 in the light of compliance report dated 11.06.2020 filed by the State PCB. It was observed:

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5. In pursuance of above, the State PCB has filed a 'compliance report' dated 11.06.2020 to the effect that the units gave action plans which are not satisfactory as long timeline have been prescribed.

6. We do not find the report to be as per the mandate of law. **If the pollution is continuing, the State PCB is under obligation to close the polluting activities by exercising its jurisdiction under the Water Act, 1974 and recover compensation from the polluters. Till pollution is stopped, polluting activities, which are punishable crime under the law, cannot continue. The State PCB has failed to take action merely on the ground that action plan was being prepared or had been prepared which was not satisfactory. None appears for the State PCB.**

4. The matter was last considered on 04.01.2021 in the light of the report of the State PCB dated 01.01.2021 mentioning the steps taken for closure and recovery of compensation. The Tribunal found that the action taken was not adequate as CETP was still non-compliant. Untreated effluents were thus being discharged into the water bodies in violation of law. Discussion and direction in the said order are reproduced below:-

"1 to 3....xxx.....xxx.....xxx"

4. Accordingly, the State PCB has filed its report on 01.01.2021. It mentions that the State PCB issued show cause notice dated 23.06.2020 to the concerned textile units for closure and recovery of compensation against which writ petitions were filed before the Himachal Pradesh High Court. The High Court, vide order dated 22.07.2020, directed that the matter be heard by the Principal Secretary, Environment and fresh order passed. The Principal Secretary, Environment passed further order on 30.12.2020 directing the State PCB to take action for enforcement of law since violation of law was established. The Principal Secretary, Environment held:

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..... **But this fact cannot be ignored that effluent discharge, FDS in particular, by these units is beyond the prescribed limits which is contributing to pollution. In the light of this discussion, I am of considered view that, keeping in view the above position, SPCB may take action strictly according to the provisions of Law and rules applicable in this case.**
....."

5. The State PCB accordingly issued fresh show cause notice on 28.12.2020 and passed further order dated 01.01.2021 as follows:

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Whereas, the effluent of category-IV being contributed by the unit M/s Auro Textiles, Sai Road Baddi, Distt. Solan, H.P to the CETP for final disposal and treatment by unit is not complying since 25-7-2020 till date to the discharge standards as prescribed in the schedule-1 of EP Rules, 1986 as well as the inlet quality standards notified by the State Government and thereby causing water pollution.

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Now, therefore, in consideration of the facts stated above, in view of the directions of Hon'ble High Courts orders, Hon'ble NGT and the orders passed by Principal Secretary (Env, S&T) Govt of HP and in exercise of the powers conferred under section 32 and 33-A of Water (Prevention & Control of Pollution) Act, 1974 M/s Auro Textiles, Sai Road Baddi, Distt. Solan, H.P. is hereby directed to:

1. Immediately shut down the dyeing process of the textile unit contributing towards the category- IV effluent to CETP, Baddi, till the unit becomes compliant.
2. Pay Environment Compensation to the tune of Rs. 42 lakhs (Forty Two Lakhs only) for the violation period w.e.f. 25-07-2020 to 31-12-2020 (140 days excluding the period of compliance)."

Identical orders are said to have been passed against four textile units.

6. We have heard Shri Nalin Kohli, learned Counsel appearing for the State PCB.

7. We find that though in the show cause notice the State PCB proposed disconnecting power supply, this direction has not been given in the final order. We also find that the CETP has still not complied with the environmental norms for which remedial action needs to be taken by the State PCB, by improving quality and reducing the load of inlet so as to be consistent with the designed capacity of the CETP or closing such units contributing to the waste for which the CETP is not designed till the concerned units make their own arrangement for treating the effluents. The member industries may be considered non-compliant, if they do not undertake primary treatment as per EC conditions of the CETP. The industries having effluent generation more than 200 KLD may be directed to treat the effluents and recycle/reuse to the maximum extent and also reducing the FDS. Wherever required, water audit of red category non-compliant units be conducted. The requisite pipeline may also be required to be constructed by the CETP to carry the waste.

8. Let further progress report be filed before the next date by e-mail at judicial-ngt@gov.in preferably in the form of

searchable PDF/OCR Support PDF and not in the form of Image PDF."

5. The State PCB has filed interim report dated 06.05.2021 followed by further report dated 16.06.2021. It will suffice to refer to the last report to the effect that the samples were taken and were not found to be within the limits. The State PCB gave directions to the concerned industries. While some units have achieved the norms, further action is being taken in the matter. The status as mentioned in the report is reproduced below:-

"In compliance to afore-cited order dated 04-01-2021 it is submitted that earlier the State Board had filed an Interim Report vide letter No. PCB/OA No. 801/2018 /-1549 dated 6-5-2021 wherein it was submitted that Board has taken steps to make the CETP, Baddi compliant. The FDS level was found 2364mg/Itr as per sampling conducted at that time, though not within the prescribed limits. It is further submitted that now the latest sample taken on 21-5-2021 and 7- 6-2021 has been found within the prescribed limits w.r.t. FDS as the same has been reduced to the 2019mg/Itr and 2072 mg/ltr respectively. The sampling chart of the CETP Baddi is annexed as Annexure —A which reveals that there is continuous improvement and now the analysis results of latest sample taken are meeting the norms w.r.t. FDS.

It is further submitted that as regard to the issue of industries having effluent generation of more than 200 KLD, the State Board had identified and issued directions to 16 numbers of industries to operate their treatment plants i.e. primary, secondary and tertiary treatment system for the effluent treatment as per Environment Conditions of CETP and also directed to recycle / reuse to the maximum extent and also to reduce the FDS. Now as per report received from the Regional Office Baddi, these 16 units are operating the effluent treatment plants prior to their effluent discharge to CETP. The State Board has conducted inspection and sampling of these 16 units. The earlier results of sampling conducted on 21-1-2021, 29-1-2021, 1- 3-2021, 23-3-2021 and 16-4-2021, were found within limits (except of three units of M/s Vardhman and one unit of Winsome Textile) which has already been placed on record alongwith interim report dated 6-5-2021. However, the latest results of sampling conducted on 21-5-2021 the results of three units namely M/s P&G Home Products Baddi, M/s Torrent Pharmaceutical Ltd. Baddi and M/s Abbott Health care, Baddi were found above the prescribed limits for which notices dated 16-6-2021 has been issued to these units. Copy of sample results and notices issued are annexed as Annexure-B and Annexure-C (colly). The sample results of other units were found within the prescribed limits. It is further submitted that as reported by Regional Officer, Baddi the member industries having flow less than 200 KLD are disposing off their effluent to CETP, Baddi after primary treatment.

As regard to the compliance by the four textile units namely Auro Textile, Auro Textile unit —II, Auro Dyeing of

Vardhman Textile and one unit of Winsome Textile, it is submitted that as per report received from the Regional Office, Baddi, **the work of installation of advance treatment system by M/s Vardhman textile to reduce FDS is under progress and Reverse Osmosis system of capacity of 2 MLD shall be operational by 30-6-2021.** In addition to Reverse Osmosis, M/s Vardhman Textile is also installing the Multi Effect Evaporator of capacity of 370 KLD. As regard to progress of installation of advance treatment system by M/s Winsome Textile it is submitted that as per report received from Regional Office, Baddi the unit has completed the civil construction work. **The installation of Reverse Osmosis system and other components is under progress.** Copies of progress report of these textile units received from Regional Office are annexed as Annexure D and E. **The latest sample results of these four textile units are still not meeting the norms.** Sample results are annexed as Annexure-F. As already submitted in interim progress report dated 6-5-2021, it is again submitted here that **State Board had issued directions on 1-1-2021 to these four textile units under section 33-A of Water Act, 1974 for closure and levied Environmental Compensation which were challenged by these units before the Hon'ble High Court of HP vide CWP No. 414/2021, 416/2021 417/2021 and 418/2021. The Hon'ble High Court of HP vide order dated 11-1-2021 and 15-3-2021 has stayed the operation of the directions issued by the State Board and the matter is still pending before the Hon'ble High Court of Himachal Pradesh for adjudication.** Copies of order dated 15-3-2021 are annexed as Annexure-G.

It is further submitted that due to constant efforts of all stakeholders, the two consecutive latest samples of CETP outlet are meeting the norms prescribed by the MoEF &CC vide notification dated 1-1-2016. In future, the State Board shall continue to make all efforts in form of surveillance, regular monitoring and regulation on the CETP and member industries, so that the CETP remains compliant in future as well."

6. From the above, it is clear that violations are still continuing. Stay of order of closure and assessment of compensation for the past violations does not justify inaction for failure to take action for further violations after the order of stay and to initiate prosecution of the industrial units in question, including their Owners/Directors and the CETP operators. We also find that merely keeping an eye on units discharging more than 200 KLD is not enough. Violation by those discharging less than 200 KLD is not less serious violation nor less harmful for the environment and public health.

7. Accordingly, let further remedial action be taken to enforce the environmental rule of law in the interest of protection of environment and public health and a report of status of compliance filed after inspection by a four Member joint Committee comprising a representative of MoEF&CC,

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CPCB, State PCB and District Magistrate, Solan by e-mail at judicial-ngt@gov.in preferably in the form of searchable PDF/ OCR Support PDF and not in the form of Image PDF. The State PCB will be the nodal agency for coordination and compliance."

3. In O.A. No. 136/2020, extracts from last order dated 23.06.2021 are as follows:-

"3. The matter was last considered on 04.01.2021 in the light of the report of State PCB dated 30.12.2020 noticing the violations of environmental norms. The Tribunal directed remedial action and filing of compliance report. The operative part of the discussion and order of the Tribunal are reproduced below:-

"3. Accordingly, the Himachal Pradesh State PCB has filed its report dated 30.12.2020 to the effect that the joint Committee visited the area and noticed as follows:

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i. The CETP has not installed the system to completely treat category IV effluent (High TDS/FDS Stream). Despite the fact that CETP does not have the capacity to treat this type of effluent, CETP has entered into the tripartite agreement with the Industries generating Category IV effluent has been receiving this category of effluent since 2016.

ii. As per Environmental Clearance granted to CETP Baddi by the Ministry of Environment, Forests and Climate Change (MoEF&CC), the member industries with hydraulic loading more than 200 KLD shall treat the effluent in the existing onsite ETPs and then discharge into CETP for further treatment and discharge. However, it was informed that Units with hydraulic loading of 200 KLD are not treating effluent in the onsite ETPs and supplying primary treated effluent to CETP. Therefore, CETP has not been complying with this condition of the Environmental Clearance granted by MoEF&CC for the last 04 years. Accordingly, the sampling of these units was done by HPPCB team on 10/12/2020 and the samples were sent to HPPCB Central Laboratory. The results of the analysis are expected by 10/01/2021.

iii. The observations made by the Joint Committee during visit to the two Pharma units i.e. M/s Acme Life Sciences and M/s Helios Pharmaceuticals mentioned in the original application are as follows:

- Both the pharma units have connectivity with the CETP for supplying the primary treated effluent, for further treatment at CETP.

- No effluent was found to be discharged directly by the Units, in the drain.
- The Joint Committee collected the samples from the final outlet of the pharma units under reference, to see the concentration of residual antibiotics in the primary treated effluent which is being sent to CETP for further treatment. The results of the analysis are expected by 09/02/2021.

iv. The evaluation of the results of the analysis of the CETP samples collected by the Joint Committee on 12-13 October, 2020, indicated intended dilution by CETP so as to achieve the prescribed norms. Therefore, the Joint Committee conducted unannounced re-sampling and sent the samples for analysis from three different laboratories.

v. **The results of analysis for the samples collected by the Joint Committee have been analyzed in HPPCB Regional Laboratory, Paonta Sahib and evaluation of the results indicated that CETP is not meeting the norms prescribed for COD (264 mg/l > 250 mg/l), BOD (35 mg/l > 30 mg/l), FDS (2252 mg/l > 2100 mg/l) and Chloride (1838 mg/l > 1000 mg/l). Therefore, it is concluded that CETP is discharging the effluent into the Sirsa River without complying with the prescribed norms.** The results of the analysis of the samples are awaited from two other laboratories.

vi. The samples from CETP, upstream and downstream of Sirsa River and the pharma units under question, were collected by the joint committee on 09/12/2020 for analysis of 12 Nos. residual antibiotic residues from Shri Ram Institute of Industrial Research, Delhi. The results of analysis of effluent samples for residual antibiotics is expected by 09/02/2021. The issue of discharge of residual antibiotics as raised by the applicant may be concluded by the Joint Committee after receipt of the analysis results.

In view of the fact that complete analysis reports will be available by 09/02/2021, it is humbly prayed to Hon'ble National Green Tribunal that Joint Committee may kindly be permitted to file the final conclusive report by 15/02/2020."

4. Accordingly, further action taken report may be separately filed by the State PCB before the next date by e-mail at judicial-ngt@gov.in preferably in the form of searchable PDF/OCR Support PDF and not in the form of Image PDF. The directions in the connected matter being OA No. 801/2018, Jasmeet Singh v. State of Himachal Pradesh, dealt with by a separate order, to the extent relevant for the present matter, may also be followed."

4. The State PCB has filed its report dated 10.03.2021 giving the analysis results of samples calculated from the units as follows:-

"Supplementary Report:

The analysis results from the remaining two laboratories w.r.t samples collected by the Joint Committee have been received (Annexure-2 and Annexure-3). Further, the report of analysis w.r.t. samples collected by the Joint Committee from CETP, Pharma Units and Sirsa River for the presence of antibiotics from the approved external laboratory has also been received (Annexure-4). Accordingly, supplementary report in this matter is being filed by the Joint Committee as follows:

- i) The results of analysis as received from three different laboratories of HPPCB, indicated that CETP is not meeting the norms prescribed for BOD (41, 35 & 38 mg/l > 30 mg/l), FDS (2252 & 3190 mg/l > 2100 mg/l) and Chloride (1209, 1838 & 1209 mg/l > 1000 mg/l). Therefore, it may be concluded that CETP is discharging the effluent into the Sirsa River without complying with the prescribed norms.
- ii) The results of analysis of the samples collected from various stages of CETP and also final discharge point in River Sirsa for the presence of residual antibiotics indicate that two antibiotics viz. Ciprofloxacin and Ofloxacin are present in the final treated effluent of CETP as a concentration of 22.8 ug/l and 69.8 ug/l respectively.
- iii) There are no standards notified by MoEF&CC for residual antibiotics in industrial effluents. However, these values are 1140 times higher for Ciprofloxacin (22.8 ug/l Vs. 0.02 ugh) and 349 times higher for Ofloxacin (69.8 ug/l Vs. 0.2 ugh) when compared with the proposed standards in the draft notification issued by MoEF&CC vide No. CG-DL-E-27012020- 215690 dated January 23, 2020 (Annexure-5), for pharmaceutical industry effluent and CETPs with membership of Bulk drug and formulation units.
- iv) Similarly, the samples collected by the Joint Committee from the outlets of two Pharmaceutical Industries viz. Helios Pharmaceutical and M/s Acme City Tech LLP, leading to CETP, were found to be much higher than the standards proposed in the draft notification issued by MoEF&CC. Also, the values reported as below quantification limit (BQL), in the analysis report of the external laboratories may not be considered as conclusive and within the proposed limits as draft notified by MoEF&CC, since the BQLs of external laboratory for various antibiotics tested in the samples, as shared with the Joint Committee, are much higher than the proposed standards.
- v) As per reports and research data available in the literature, the concentration of residual antibiotics has been found to be reduced by 60-90 % in conventional biological treatment plant. In view to assess the

performance of the biological treatment system installed by CETP, the samples were collected from various stages of CETP. The results of analysis indicated that the performance of biological treatment system installed by CETP is not in line with the reports and data available in the literature, w.r.t. treatment of residual antibiotics. The inefficient performance of biological treatment system is also evident from the noncompliance of CETP with regard to biochemical oxygen demand (BOD).

Conclusion and Recommendations:

In view of the fact that:

- i) There are no standards notified by MoEF&CC w.r.t. residual antibiotics in industrial effluents;
- ii) Draft notified standards are yet to be decided by MoEF&CC;
- iii) The concentration of residual antibiotics at outlet of CETP in Sirsa River, is much higher than the draft notified standards;
- iv) The treatment efficiency of CETP w.r.t residual antibiotics is not at par with the reports and data available in the literature;
- v) The CETP is not meeting the prescribed norms of BOD, FDS and chloride and discharging effluent into Sirsa River without complying with the prescribed norms.

It is recommended that Pharmaceutical (both bulk drug and formulation units) may be directed by Himachal Pradesh Pollution Control Board to provide primary treatment to the level of predicted no effect concentration (PNEC) as developed by members of AMR Industry Alliance (Annexure-6), as a site (Baddi) specific preventing measure, so that there is no adverse impact of residual antibiotics on the environment and also to prevent development of antimicrobial resistance (AMR)."

5. The report is followed by further report dated 05.05.2021 as follows:-

"It is further submitted that now the joint committee has submitted its supplementary report which is annexed as Annexure R-1/1. Based on the inspections and sampling conducted the conclusion and recommendations made by the joint committee are as under:-

- i) There are no standards notified by MoEF & CC w.r.t. residual antibiotics in industrial effluents.
- ii) Draft notified standards are yet to be decided by MoEF & CC.

- iii) *The concentration of residual antibiotics at outlet of CETP in Sirsa river is much higher than the draft notified standards.*
- iv) *The treatment efficiency of CETP w.r.t. residual antibiotics is not at par with the reports and data available in the literature.*
- v) *The CETP is not meeting the prescribed norms of BOD, FDS and chloride and discharging effluent into Sirsa River without complying with the prescribed norms....."*

The copy of Supplementary Report submitted by the joint committee dated 10-03-2021 (annexed as Annexure R-1/1) may be placed on record please.

It is submitted that as of now there are no specific standards notified by the Govt. of India for residual antibiotics parameters in the existing notification of standards for pharmaceutical (Manufacturing and Formulation Industry). However, it is worthwhile to mention here that all the bulk drugs/pharmaceutical manufacturing units (if not connected with CETP) are being regulated for the compliance as per standards notified in MoEF & CC Notification dated 9-7-2009 (copy annexed as Annexure R-1/2). If the pharmaceutical (manufacturing and formulation industry) is member of CETP, then the unit is bound to comply with inlet quality standards notified by the Govt. of HP vide notification dated 17-3-2018 and 26-12-2019 (copies annexed as Annexure R-1/3 and R-1/4) The notification of specific standards for residual antibiotics (annexed as Annexure -5 with joint report) is still under proposed stage and shall be implemented for regulatory aspect as and when finalized by the MoEFF & CC."

6. *The industrial units in question have also filed their Counter Affidavits. The said Counter Affidavits are of no assistance.*

7. *As against the above, the applicant has filed written submission on 11.06.2021 pointing out that the analysis of the samples shows presence of antibiotics in the water.*

8. *The conclusion drawn from the analytical results is as follows:-*

1. *Ciprofloxacin (22.8µg/L) and Ofloxacin(69.8µg/L) were detected in higher concentrations in the effluent released to Sirsa river from CETP (Sr. no 4), i.e., 1139 and 348 times higher than the prescribed MoEF& CC draft notification limits.*
2. *The higher concentrations of antibiotics in the effluent released to Sirsa river (Sr. no 4) clearly indicate that CETP is unable to completely remove or degrade these antibiotics.*

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3. Ofloxacin (960µg/L) was found in the effluent from M/S Helios Pharmaceutical (Sr. no 13) release to CETP, which is much higher than the draft notification limit (0.2 µg/L). It clearly raises doubt on the level of pre-treatment of the pharma effluent from this industry before it is released to the CETP.
4. The samples drawn from the effluent of M/S Acme City Tech LLP (Sr. no 14 and 15) release to CETP shows reasonably high concentrations of Ofloxacin (170 µg/L) and Azithromycin (423µg/L) even after primary treatment, indicate inefficient pre-treatment at this industry.
5. In the research methodology Limit of quantification (LOQ) for a compound by any method indicates the lowest concentration that can be quantified with accuracy and precision. The values below LOQ cannot be correctly quantified during the analysis and are reported as Below Quantification Limit (BQL). In the present analysis, the LOQs of the compounds fixed for the analysis by the lab are very high; namely, Ciprofloxacin (5 µg/L), Ofloxacin (5 µg/L), Piperacillin (5 µg/L), Azithromycin (10 µg/L), Tazobactam (5 µg/L), Ceftazidime (50 µg/L), Cefixime (20 µg/L), Amoxicillin (10 µg/L), Ampicillin (10 µg/L), Cefpodoxime (10 µg/L), Sulbactam (10 µg/L), Ceftriaxone (50 µg/L) and Cefoperazone (10 µg/L). The above LOQs of the compounds are much higher than even the antibiotic discharge limits set by the MoEF & CC draft notification for these compounds; except for Tazobactam.
6. Incidentally Piperacillin and Amoxicillin are the antibiotics are known for the very adverse impact on the human health even in the very low concentration. In this laboratory analysis, BQL limit for these compounds are set as (5 µg/L) and (10 µg/L) which is significantly higher than the limit fixed in the draft standards. In the draft standards the limit set for these two compounds are (0.1µg/L).
7. This implies that the Limit of Quantification (LOQ) set up by the lab is significantly higher than the limit set by the draft notification and therefore many of the compounds are not being detected as has been marked as BQL in the analysis results.
8. Therefore, the samples analysis should be conducted using an analytical method to precisely and accurately quantify lower concentrations of the compounds (LOQs should be kept as close or even lower than the draft notification limits) to quantify all the compounds at lower concentrations with accuracy and precision. This raises the question mark on integrity of the overall analysis by the lab.
9. Further the findings also imply that the CETP is not designed to efficiently treat class IV effluents; however, operator of CETP has entered into agreement with various pharma manufacturing units who are releasing class IV effluents to the CETP since 2017."

9. Further submissions are reproduced below:-

"14. The migration of antimicrobials into the environment has significant impacts. They can disrupt wastewater treatment processes and adversely affect ecosystem because they are toxic to beneficial bacteria. Some antimicrobials also bio accumulates; for example, erythromycin has been found to have both a high bio accumulation factor of 45.31 and a tendency to accumulate in soil. Antimicrobials can also be persistence for extended periods of time, the environmental persistence of erythromycin for example, is longer than one year.

15. Although not well studied, the presence of antimicrobials in natural waters may be exerting selective pressure leading to the development of antibiotics resistance in bacteria. The threat of growing antibiotics resistance has been recognised by, among others, the WHO, the National Academy of Science, the American Medical Association, the American Public Health Association and the US government Accountability. In fact the Centre for Disease Control and prevention (CDC) has identified antibiotics resistance as one of the most pressing public health problem facing the nation. Infections caused by bacteria with resistance to at least one antibiotic have been estimated to kill over 60,000 hospitalized patients each year. Methicillin resistant strains of *Staphylococcus aureus*, although previously limited primarily to hospital and health facilities, are becoming more widespread. In 2007, Consumer Reports tested over 500 whole chickens for bacterial contamination and antibiotic resistance. They found wide spread bacterial contamination in their samples and 84 percent of the salmonella and 67 percent of the campylobacter organisms that were isolated showed resistance to one or more antibiotic.

16. Antibiotic resistance is caused by a number of factors including repeated and improper use of antibiotics in both humans and animals. Half of the antibiotics used in livestock are in the same classes of drug that are used in humans and animals. The U.S. institute of Medicine and the WHO have both stated that widespread use of antibiotics in agriculture is contributing to antibiotic resistance.

17. The above study done by the HPPCB shows that from whichever place samples have been taken by HPPCB these are having antibiotics discharge which should not have been there. There is not a single sample in which the aforesaid antibiotics discharging into surface water and also seeping into the subsoil water is not there. This would lead to harmful antibiotic resistance amongst human and animal population and, thus, reducing the chances of their recovering from diseases where absence of resistance from these antibiotic would have helped. The above table and the subsequent narration would show that the antibiotics found in the discharge include some of the ultimate antibiotics developing resistance of which may be a death warrant for different life forms – human and animal – if

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infected with diseases where these antibiotics could have provided a cure.

18. A situation where all random samples show the same results, in technical terms, is called '100% random test positivity'. In view of the '100% random test positivity', the study conducted by HPPCB cannot be stated to be complete and conclusive. It only indicates that a whole lot of polluting antibiotics are being discharged into the surface and subsoil water which is harmful for human and animal population.

19. As per information available at internet, there are more than 270 Pharmaceutical Companies operating in Baddi-Barotiwala-Nalagarh area. List of such Pharmaceutical Companies along with their addresses, as obtained through internet sites, is placed at Annexure A.

20. This necessarily requires a further and more detailed study as a sequel to 'the sample study' done by HPPCB to understand the entire extent of damage because of the aforesaid antibiotic discharge into the water bodies. It is being called 'sample study' because of the fact that it has '100% random test positivity' and therefore, in scientific tradition, there is an absolute need for following it up with a detailed, wide and more in depth study of the antibiotic discharge into river sirsa."

10. We have heard the applicant in person and the Learned Counsel for State PCB.

11. **We find that there is gross failure on the part of the State PCB to act as per public trust doctrine in preventing discharge of toxic effluents containing harmful residue of antibiotics in water posing threat to aquatic life (reference: "biomonitoring of Sirsa River in Baddi area of Himachal Pradesh by Bhagat S. Chauhan, et al, International Journal of Theoretical and Applied Sciences 5 (1): 183-185(2013)) which is also in violation of the Water (Prevention and Control of Pollution) Act, 1974. Such failure of statutory duties is at the cost of public health and protection of environment for which Chairman and Member Secretary of the PCB owe an explanation which may be furnished before the next date. Mere fact that standards have not been revised by MoEF&CC of the residual antibiotics in industrial effluents can be no justification for State PCB not taking steps to prevent. Pending finalization of standards by MoEF&CC, State PCB can go by earlier standards or lay down standards by itself under section 17 of the Water Act. MoEF&CC needs to expedite the process of finalizing the standards in the interest of protection of environment.**

12. **Accordingly, MoEF&CC and the State PCB may take further remedial action expeditiously. The State PCB may ensure that no harmful components in the effluents are discharged into the water by the units in question or any other API unit. A joint Committee of nominee of MoEF&CC, CPCB, State PCB and District Magistrate, Solan may conduct**

inspection of the area and give a report of the status of violations and the remedial action taken within three months by e-mail at judicial-ngt@gov.in preferably in the form of searchable PDF/ OCR Support PDF and not in the form of Image PDF. The State PCB will be the nodal agency for compliance. The Committee may interact with the concerned stake holders, including the concerned Industries. The report may inter alia give status of performance of individual pharmaceutical units, particularly with reference to removal of API residue by them and by the CETP, the number of pharma industries connected to CETP and those discharging effluents directly into the drain and the river. The report may further indicate chemical and biological water quality of rivers in question - Sirsa and Satluj, including the status of residue at relevant locations. CPCB may also suggest monitoring mechanism for API residue through a credible system so as to cover all pharma industries in the country discharging API residue directly or indirectly in river systems. CPCB may propose the timelines to undertake monitoring which may also take a note of water quality monitoring guidelines of CPCB titled "Guidelines on Water Quality Monitoring, 2017" and the performance audit report dated 18.09.2020 filed by CPCB in OA 95/2018, Aryavart Foundation v. M/s Vapi Green Enviro Ltd. & Ors. and the directions of the Tribunal dated 05.02.2021. Relevant direction is reproduced below:

"22. The directions on the subject are summed up as follows:

i to vi xxx.....xxx.....xxx

- vii. CPCB and State PCBs/PCCs, as directed earlier, may utilise EC funds on laboratory set up/upgradation, and on the mentioned areas in the report as well as on approved District Environment Plans. No approval of Central/State Government will be necessary in this regard in view of section 33 of the NGT Act, supra."

CPCB may file report on the above aspects before the next date of hearing by e-mail at judicial-ngt@gov.in preferably in the form of searchable PDF/ OCR Support PDF and not in the form of Image PDF."

4. In pursuance of above, reports have been filed by the State PCB. In O.A. No. 801/2018, report filed on 18.01.2022 mentions the visit to the site on 01.10.2021 and 23.11.2021 and non-compliances found. The report mentions that 97 industries were found to be non-compliant. In view of the fact that there is an interim order granted by the Himachal Pradesh High Court on 01.09.2021 and 10.11.2021 against industries having less than 200 KLD discharge, applicable to action in pursuance of Notification

dated 26.12.2019 issued by the HP Government laying down inlet norms of the CETP. CETP itself was found to be non-compliant due to toxicity of the waste received. CETP is now to be upgraded by the funds received from the Central Government. The report also mentions compliance status of the industrial units covered in O.A 136/2020 and it is found that in post-monsoon sampling, there is deterioration of water quality, downstream of CETP. The relevant extracts from the report are:-

"2.0. Findings of the Joint Committee and Status of Compliance:

In compliance of the directions of the Hon'ble NGT, HPPCB submitted report of the Joint Committee on 30/9/2021, followed by supplementary report on 23/11/2021. In continuation of the above reports, the final report/findings of the Joint Committee are submitted as follows:

- i. ***Total Number of Industrial units in BBN (Baddi, Barotiwala, Nalagarh) Area covered under Consent Mechanism are 2444 (Red Category 219, Orange 900 and Green category 1325)***
- ii. ***Out of 2444 industrial units in BBN Area, 1703 units are located in Baddi Barotiwala area and remaining 741 units are located in Nalagarh region.***
- iii. ***Total number of water polluting industries in BBN Area is 576.***
- iv. ***Out of total 576 water polluting industries, 456 industries are located in Baddi area and 120 industries are located in Nalagarh area. All these 456 industries located in Baddi Barotiwala area, are connected to CETP either through pipe line or tankers. Further, out of these 456 Industries located in Baddi Barotiwala area, 376 industries are operational and remaining 80 are temporarily closed.***
- v. ***Out of 120 water polluting industries located in Nalagarh area, 24 industries are connected to CETP, Baddi through tankers and remaining 96 water polluting industries have installed their own ETP to treat the industrial effluent. As per information provided by HPPCB, none of these units are discharging treated effluent into the water bodies.***
- vi. ***All 456 industries of Baddi Barotiwala area were monitored by HPPCB, during July to October, 2021 in this matter. Joint Committee also monitored randomly selected 13 No. Industries out of these 456 industries, during 1-2***

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November, 2021, for cross verification of the compliance **(Annexure-I)**.

- vii. Out of these 456 industries monitored by the HPPCB and Joint Committee, **97 industries were found to be non-compliant w.r.t norms prescribed by HPPCB** for discharge at the inlet of CETP for further treatment. The list of **97** industries not complying with the prescribed norms is attached as **Annexure-II**.
- viii. MoEF&CC has prescribed limits for the discharge parameters of CETP vide notification dated January 1, 2016, wherein, it is also mentioned that **"For each Common Effluent Treatment Plant (CETP), the State Board will prescribe Inlet Quality Standards for General Parameters, Ammonical Nitrogen and Heavy metals as per design of the Common Effluent Treatment Plant (CETP) and local needs & conditions" (Annexure-III)**. Accordingly, in compliance of the MoEF&CC notification, **CETP inlet norms have been prescribed vide notification dated 26/12/2019 issued by Govt. of HP (Department of Environment Science & Technology)**.
- ix. No action was taken by HPPCB against **97 Nos.** industries having hydraulic loading less than 200 KLD, which were found to be not complying with the CETP inlet norms, since, the Baddi Barotiwala Nalagarh Industrial Association(BBHIA) has filed a petition in the High Court of Shimla (CWP No. 4961 of 2021), wherein the CETP inlet norms as per notification dated 26/12/2019 issued by Govt. of HP (Department of Environment Science & Technology) in compliance of MoEF&CC Notification dated January 1, 2016, have been challenged, taking a plea that the environmental clearance has specified condition of treatment and inlet norms which may be specified by State Pollution Board for units discharging more than 200 KLD and direction has been issued to the State Pollution Control Board. Hon'ble High Court vide orders dated 01/09/2021 and 10/11/2021, had directed not to take coercive action against them. The copies of petition filed by the industries, Hon'ble High Court Order dated 1/09/2021, order dated 10/11/2021 and order dated 29/12/2021 and the reply filed by HPPCB before the Hon'ble High Court are enclosed as **Annexure IV**. The orders passed by Hon'ble High Court is as under:

"...In the meanwhile, respondents are restrained from taking any coercive action against petitioners.... order dated 01-09-2021"

"... The order dated 01-09-2021 is clarified to the extent that the same shall only be applicable to those industries having less than 200 KLD hydraulic discharge....order dated 10-11-2021"

Now, the above matter is listed for hearing before the Hon'ble High Court on 12-04-2022"

- x. The analysis results of primary treated Category-I effluent (Discharged to CETP for further treatment) from M/s Vardhman Textiles Limited (Auro Textile-I, Auro Textile-II & Auro Dyeing-I) is complying with CETP inlet norms w.r.t Category-I effluent. However, as per Environmental Clearance granted to CETP vide F. No. 1053/2011-IA-III Dated 8.01.2013 (copy attached as **Annexure-V**), the member industries with hydraulic loading more than 200 KLD shall treat in the existing onsite ETPs (as these industries have already provided on site ETP consisting of Primary/Secondary and Tertiary Treatment System) to the level of treatment and standards prescribed in the consent orders issued by the State PCB before discharging into the CETP for further treatment.
- xi. M/s Vardhman Textiles Limited and M/s Winsome textiles Limited, have installed the tertiary treatment system only for treatment of Category-IV and it was verified by the Joint Committee. M/s Vardhman Textiles Limited and Winsome Textile Limited have discontinued discharging CAT-IV effluent to CETP Treatment in the RO and MEE seemed to help the CETP meet the discharge norms of FDS/TDS as indicated in the analysis results of the samples collected by HPPCB from the discharge point located at River Sirsa, since May 2021.
- xii. The Hon'ble High Court vide CWP No. 414 of 2021, 416 of 2021, 417 of 2021 and 418 of 2021 have stayed the action taken by the State Board under section 33 A of Water Act, 1974 against the above two units, for previous violations (**Annexure-VI**). Further, vide order dated 22/12/2021. Hon'ble High court has directed that "no coercive action shall be taken against the petitioner pursuant to the notification dated 26/12/2019" (whereby Govt. of HP, Deptt. of Env't., Sci, and Technology notified inlet quality standards in respect of CETP, Baddi). The Matter is now listed before the Hon'ble High Court of HP on 21/03/2022 (**Annexure-VII**).
- xiii. Baddi CETP was also monitored by the Joint Committee for compliance of prescribed norms. **CETP was found to be non-compliant w.r.t. Bio-assay Test (Zero % survival of fish in 100% sample after 96 hours against the standard of 90% survival of fish in 100% sample after 96 hours).** Bio-assay test is an important parameter for determining the toxicity of waste water. **All other parameters including FDS were found to be within the prescribed limits and CETP was found to be compliant in this regard.** (Report annexed as **Annexure-VIII**)

Further, the joint committee was informed by the CETP Baddi that a funding support to the tune of Rs. 28 Crores from the Ministry of Commerce and Industry, Government of India, under "Trade Infrastructure for Export Scheme" has been sanctioned for their proposal on "3 MLD Effluent Refractory Management and TDS reduction in CETP". The Govt. of Himachal Pradesh has already sanctioned and partially released the funds, for this proposal. Further, CETP Baddi has invited tenders for design, supply, construction, installation, commissioning, testing and trial run of 3 MLD capacity for

effluent refractory management and TDS/FDS Reduction at their existing 25 MLD capacity CETP & MLD STP located at Baddi, Distt. Solan (HP) and this project shall be completed within one year i.e. upto 31.10.2022, as informed to the Joint Committee by CETP, Baddi (**Annexure-IX**).

- xiv. The same Joint Committee has been constituted in the matter of OA No. 136 of 2020; Veteran form, has also conducted the monitoring of River Sirsa during Monsoon and post monsoon seasons. The Joint Monitoring conducted sampling of River Sirsa from following locations:

Sr. No.	Sampling Location	Pre-monsoon	Post-monsoon
		Class as be Designated Best Use	
1.	Point Upstream of CETP	B	B
2.	Point Downstream Of CETP	B	D
3.	River Sirsa D/s Nalagarh Bridge	B	B

The analysis data shows that the water quality of river Sirsa before CETP and when it is leaving Himachal Pradesh Boundary at D/s Nalagarh Bridge falls under Class B in both samplings i.e. pre-monsoon and post-monsoon. However in the post-monsoon sampling there is deterioration in the water quality at location downstream of CETP. The analysis reports are annexed as **Annexure-X**.

- xv. **An email dated 8/11/2021 from. Mr. R.N. Jindal, Executive Director, TSDF Facility, Nimbua Greenfield (Punjab) Limited was also received, giving comments on the HPPCB w.r.t inlet norms, compliance by CETP and the member industries (Annexure-XI). However, Joint Committee didn't find it appropriate to influence its report with his comments, since no such request was made by the Joint Committee for his comments and forwarded his mail to HPPCB, for reference and taking any action HPPCB deemed necessary."**

5. There is a separate report in O.A. No. 136/2020 with following conclusions and recommendations:-

"3.7. Conclusion and Recommendations:

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Based on the outcome of the study conducted by the Joint Committee in this matter, it is concluded and recommended as follows:

- i. **Out of 111 antibiotic manufacturing industries** monitored by Himachal Pradesh Pollution Control Board in this matter, **37 industries were found to be non-complying w.r.t. limits prescribed for discharging into the CETP.**
- ii. **No action could be taken by HPPCB against the above 37 pharmaceutical formulation industries (engaged in the manufacturing of antibiotics), which were found to be not complying with the CETP inlet norms, due to stay by Hon'ble High Court of Himachal Pradesh.** Now, the matter is listed for hearing before the Hon'ble High Court on 12-04-2022.
- iii. **Some of the antibiotics viz. Azithromycin, Ciprofloxacin, Ofloxacin, Levofloxacin etc. were found to be significantly present (no comparison could be made as MOEF&CC has not prescribed any standards for residual antibiotic) at the outlet of the industry's leading to CETP for further treatment.** The removal efficiency in the primary treatment plants installed by the industries before discharging into the CETP, was found to be **0-74% for Azithromycin, 90% for Ciprofloxacin, 67-73% for Ofloxacin, 0% for Levofloxacin and Cefpodoxime.**
- iv. **Similarly, the antibiotics viz. Ofloxacin (63 ug/l) and levofloxacin (8 ug/l) were found to be in significantly present at the final discharge of CETP into the Sirsa River.** With regard to removal efficiency of antibiotic residues in the Category-III (Pharma) effluent treatment section of CETP, it was observed that **Ofloxacin was found to be reduced by 31%, Azithromycin by 9%, Levofloxacin by 31% and Roxithroycin by 71%.** This concentration was found be further reduced to lower limits after mixing with treated effluent of other categories' effluent, before discharging into the Sirsa River.
- v. **Antibiotic residue viz. Azithromycin was found to be significantly present in River Sirsa both at the Up-stream (2.5 ug/l) and Down-stream of CETP (2.1 ug/l), which was further increased to 2.9 ug/l in the Nalagarh area.** Further, during the post-monsoon sampling, deterioration in the water quality downstream of CETP was observed during monitoring by the Joint Committee.
- vi. **Other antibiotics were found to be present at below quantification limits (BQL) in the study conducted by the Joint Committee in this matter. However, it may not be considered as absence of antibiotic residues in view of the fact the quantification limit of analysis in the Lab engaged for analysis of antibiotic residues, was 2-300 times more than the Predicted No effect Concentration (PNEC) of different antibiotics. PNEC is the concentration of antibiotic, which mark the limit, below which no adverse impact on the ecosystem is measured.**

- vii. ***It is pertinent to apprise the Hon'ble National Green Tribunal that though MOEF&CC has notified the standards for pharma industry vide Notification dated 06.08.2021 but the limit of Antibiotic residues (as mentioned in the draft Notification) has been withdrawn/dropped. Hence there is no parameter for residual antibiotic which Joint Committee could compare with.***
- viii. ***Ail. Representative of BBN Industries Association informed during stakeholders' consultation that the association has received the funding support to the tune of Rs. 28 Crores from the Ministry of Commerce and Industry, Government of India, under "Trade Infrastructure for Export Scheme" for their proposal on "3 MILD Effluent Refractory Management and TDS reduction in CETP". The 3 MLD effluent proposed to be treated under this proposal includes pharmaceutical industrial effluent for treatment of API and Antibiotic residues and the content of antibiotic residue and API in the final outlet after treatment in this proposed add on facility in CETP, Baddi will be Nil. It was also informed that the implementation of the above proposal will be completed within one year.***

In view of the fact that i) antibiotic residues were found to be present significantly at the outlet of industries leading to CETP, outlet of CETP and River Sirsa, ii) MoEF&CC has dropped the limits of antibiotics in the final standards for Pharmaceutical Industries notified vide notification vide 6/8/2021 and iii) As informed by BBN Industries Association regarding funding of Rs. 28 Crores for upgrading the CETP/add on facility, including treatment of antibiotic residues with claim of achieving the concentration of antibiotic residues as nil, It is recommended that all the Pharmaceutical Industries of BBN area (located outside the catchment area of CETP) may be connected to CETP Baddi, and the "limit of antibiotic residues as BDL/<PNEC" may be incorporated by HP State Pollution Control Board (HPSPCB) as one of the terms of Consent to Operate (CTO) granted to CETP Baddi, after commissioning of the proposed "add on facility" in CETP, Baddi."

6. The reports show alarming situation of serious non-compliance having continuous adverse impact on public health and environment. CETP is inefficient in its working and individual units are also non-compliant. This requires immediate effective regulatory action. Pharma units need to monitor API and take remedial steps. MoEF&CC needs to

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address such vital issue and assist the State to handle the situation in the interest of environment and public health.

7. Only explanation of the State is helplessness due to interim order of the High Court. Learned Counsel has stated that clarification is proposed to be sought in the matter from the High Court so that remedial action for protection of environment and public health is taken as violations are not only of prescribed inlet norms but also statutory provisions of the Water (Prevention and Control of Pollution) Act, 1974 and standards of water laid down under other relevant statutory provisions which are not covered by the stay order. We note that confusion pleaded is resulting in undesirable state of affairs, to the detriment of helpless public against the mandate of law which does not appear to have been properly brought to the notice of the High Court or any other higher forum. We do not find any reason why the State PCB could not enforce law even against violators who are not covered by the interim order granted by the High Court, particularly the pharma units discharging more than 200 KLD.

8. The State may accordingly take further corrective measures to enforce the law for protecting public health and the environment. CPCB may circulate monitoring mechanism to the State PCBs on API, as directed earlier and file the action taken report before the next date. MoEF&CC may clarify the issue of API standards.

List again on 29.03.2022.

A copy of this order be forwarded to CPCB and MoEF&CC by e-mail for compliance.

Adarsh Kumar Goel, CP

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Sudhir Agarwal, JM

Brijesh Sethi, JM

Prof. A. Senthil Vel, EM

Dr. Afroz Ahmad, EM

January 21, 2022
Original Application No. 801/2018 &
Original Application No. 136/2020
SN

Sudhir
True Copy



भारत का राजपत्र The Gazette of India

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असाधारण
EXTRAORDINARY

भाग II—खण्ड 3—उप-खण्ड (i)
PART II—Section 3—Sub-section (i)

प्राधिकार से प्रकाशित
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पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय

अधिसूचना

नई दिल्ली, 6 अगस्त, 2021

सा.का.नि. 541(अ).—जहां, कतिपय प्रारूप नियम अर्थात् पर्यावरण (संरक्षण) संशोधन नियम, 2020 भारत सरकार के पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय में अधिसूचना संख्या सा.का.नि. 44(अ), तारीख 23 जनवरी, 2020 की अधिसूचना द्वारा पर्यावरण (संरक्षण) नियम, 1986, के नियम 5 के उपनियम (3) के अधीन यथा अपेक्षानुसार भारत के राजपत्र, असाधारण में प्रकाशित किए गए थे, जिसमें सभी व्यक्तियों से जिनके उसके द्वारा प्रभावित होने की संभावना है उस तारीख से जिसको उक्त अधिसूचना में अंतर्विष्ट राजपत्र की प्रतियां जनता को उपलब्ध करा दी गई थी, साठ दिन की अवधि के भीतर आक्षेप और सुझाव आमंत्रित किए गए थे;

और पूर्वोक्त अधिसूचना में अंतर्विष्ट राजपत्र की प्रतियां 23 जनवरी, 2020 को जनता को उपलब्ध करा दी गई थीं;

और, पूर्वोक्त अधिसूचना के प्रतिउत्तर में सभी व्यक्तियों और पणधारियों से प्राप्त आक्षेपों और सुझावों को केंद्रीय सरकार द्वारा सम्यक रूप से विचार किया गया;

अतः, अब, केंद्रीय सरकार, पर्यावरण (संरक्षण) नियम, 1986 के नियम 5 के उपनियम (3) के साथ पठित पर्यावरण (संरक्षण) अधिनियम, 1986 का 29 की धारा 6 और धारा 25 द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए पर्यावरण (संरक्षण) नियम, 1986 का और संशोधन करने के लिए निम्नलिखित नियम बनाती है, अर्थात्: -

1. संक्षिप्त नाम और प्रारंभ- (1) इन नियमों का संक्षिप्त नाम पर्यावरण (संरक्षण) दूसरा संशोधन नियम, 2021 है।

(2) ये राजपत्र में उनके प्रकाशन की तारीख से एक वर्ष के पश्चात् प्रवृत्त होंगे।

4359 GI/2021

(1)

2. पर्यावरण (संरक्षण) नियम, 1986 की अनुसूची-I में क्रमांक 73 और उससे संबंधित प्रविष्टियों के स्थान पर निम्नलिखित क्रमांक और प्रविष्टियां रखी जाएंगी, अर्थात्:-

क्र. सं.	उद्योग	पैरामीटर	मानक
1	2	3	4
73।	थोक दवा और निर्माण (फार्मास्युटिकल)	क. बहिःस्त्राव मानक*	
			एकाग्रता के लिए सीमित मूल्य (पीएच और जैव परख को छोड़कर मिलीग्राम / एल में)
		(i) अनिवार्य पैरामीटर	
		पीएच	6.0 -8.5
		बीओडी (3 दिन 27 डिग्री सेल्सियस)	30
		सीओडी	250
		टीएसएस	100
		तेल और ग्रीस	10
		अमोनिकल नाइट्रोजन	100
		जैव - परख परीक्षण**	100% में पहले 96 घंटों के बाद 90% मछली की उत्तरजीविता
		(ii) अतिरिक्त पैरामीटर###	
		***बेन्जीन	0.1
		***जाइलीन	0.12
		***मीथाइलीन क्लोराइड	0.9
		***क्लोरोबेन्जीन	0.2
		पी . के रूप में फॉस्फेट	5
		एस . के रूप में सल्फाइड	2
		फेनोलिक यौगिक	1
		जस्ता	5
		लोहा	3
		कुल क्रोमियम	2
		हेक्सावैलेंट क्रोमियम (क्रो6+)	0.1
		साइनाइड (एचसीएन के रूप में)	0.1
		आर्सेनिक	0.2
		मर्करी	0.01
		लेड	0.1
		एसएआर	26 से कम (भूमि पर केवल वाहन के लिए लागू)
		(iii) सीईटीपी के साथ उद्योग	
		सीईटीपी के साथ और सीईटीपी के लिए उद्योग हेतु निर्वहन किए गए मानक पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय की अधिसूचना का.आ. 4(अ), तारीख 1 जनवरी, 2016 द्वारा शासित होंगे।	

	राज्य प्रदूषण नियंत्रण बोर्ड अतिरिक्त सुसंगत पैरामीटर को विहित करेगा जैसा कि उद्योगों के सदस्य के आवश्यकता और निर्वहन के अनुसार इस अधिसूचना के पैरा क (ii) में दिया गया है और पर्यावरण शर्तों को प्राप्त करने के विचार की निगरानी को तत्परता से विनिर्दिष्ट करता हो। टिप्पण :- पैरा क में मानक सीईटीपी के सिवाय सभी निर्वहन के लिए लागू हैं *सीईटीपी के लिए उद्योग निर्वहन को लागू नहीं किया जाता है और भूमि तथा सतह जल निकाय के सभी निर्वहन को लागू होगा जिसके अंतर्गत उद्यान और सिंचाई प्रयोजन के लिए जल निस्तारण का प्रयोग किया जाना सम्मिलित है। ** जैव परख परीक्षण आई एस: 6582-1971 के अनुसार आयोजित किया जाएगा। “अतिरिक्त पैरा मीटर”के रूप में सूचिबद्ध पैरामीटर प्रक्रिया और उत्पाद पर निर्भर रहते हुए एसपीसीवी द्वारा विहित किए जाएंगे और एसपीसीवी एस द्वारा निर्णय के अनुसार उसकी तत्परता से मानीटरी मासिक/तिमाही रूप से की जाएगी। ***ये सीमाएं उन उद्योगों पर लागू होंगी जो बेन्जीन, जाइलीन मिथाइलीन क्लोराइड, क्लोरोबेन्जीन का उपयोग कर रहे हैं।																				
	ख. उत्सर्जन मानक (टैंक फार्म वेंट) <table border="1"> <thead> <tr> <th>पैरामीटर</th><th>एकाग्रता के लिए सीमित मूल्य (मिलीग्राम / एनएम 3)</th></tr> </thead> <tbody> <tr> <td>क्लोरीन</td><td>15</td></tr> <tr> <td>हाइड्रोक्लोरिक एसिड वाष्प</td><td>35</td></tr> <tr> <td>अमोनिया</td><td>30</td></tr> <tr> <td>बेंजीन</td><td>5</td></tr> <tr> <td>टोल्यूनि</td><td>100</td></tr> <tr> <td>एसीटोनिट्राइल</td><td>1000</td></tr> <tr> <td>डाइक्लोरोमेथेन</td><td>200</td></tr> <tr> <td>जाइलीन</td><td>100</td></tr> <tr> <td>एसीटोन</td><td>2000</td></tr> </tbody> </table> ग. विलायक का कुल संचयी नुकसान भंडारण सूची से वार्षिक आधार पर विलायक 5% से अधिक नहीं होना चाहिए घ. थोक दवा के विनिर्माण या फार्मास्युटिकल के प्रतिपादन में लगे उद्योग के लिए उद्योग या सीईटीपी कैटरिंग पर बेकार जल या उसके प्रबंध सुविधा से उत्पन्न होने वाले केमिकल और बायोलोजिकल गाढ़ा कीचड़ या किसी अवशेष, हटाए जाने, खतरनाक और अन्य अपशिष्ट (मैनेजमेंट एंड ट्रांस-बाउंडरी मूवमेंट) नियम 2016 के नियम 3 के उपनियम (1) के खंड 17 के उपबंध के अनुसार खतरनाक अपशिष्ट के रूप में वर्गीकृत किया जाएगा और उसमें किए गए उपबंध के अधीन होगा।	पैरामीटर	एकाग्रता के लिए सीमित मूल्य (मिलीग्राम / एनएम 3)	क्लोरीन	15	हाइड्रोक्लोरिक एसिड वाष्प	35	अमोनिया	30	बेंजीन	5	टोल्यूनि	100	एसीटोनिट्राइल	1000	डाइक्लोरोमेथेन	200	जाइलीन	100	एसीटोन	2000
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जाइलीन	100																				
एसीटोन	2000																				

[फा. सं. क्यू-15017/12/2018-सीपीडब्ल्यू]

नरेश पाल गंगवार, संयुक्त सचिव

टिप्पण : मूल नियम भारत के राजपत्र, असाधारण, भाग II, खंड 3, उप-खंड (i) में संख्यांक का. आ. 844(अ) तारीख 19 नवंबर, 1986 में प्रकाशित किए गए थे और अंतिम बार अधिसूचना संख्यांक सा.का.नि. 243(अ) तारीख 31 मार्च, 2021 द्वारा अंतिम रूप से संशोधित किया गया था।

MINISTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE NOTIFICATION

New Delhi, the 6th August, 2021

G.S.R. 541(E).—Whereas, certain draft rules, namely the Environment (Protection) Amendment Rules, 2020 were published in the Gazette of India, Extraordinary, as required under sub-rule (3) of rule 5 of the Environment (Protection) Rules, 1986, *vide* notification of the Government of India in the Ministry of Environment, Forest and Climate Change *vide* number G.S.R. 44 (E), dated the 23rd January, 2020, inviting objections and suggestions from all persons likely to be affected thereby within a period of sixty days from the date on which copies of the Gazette containing the said notification were made available to the public;

And Whereas, copies of the Gazette containing the aforesaid notification were made available to the public on the 23rd January, 2020;

And Whereas, objections and suggestions received from all persons and stakeholders in response to the aforesaid notification have been duly considered by the Central Government;

Now, therefore, in exercise of the powers conferred by sections 6 and 25 of the Environment (Protection) Act, 1986 (29 of 1986) read with sub-rule (3) of rule 5 of the Environment (Protection) Rules, 1986, the Central Government hereby makes the following rules further to amend the Environment (Protection) Rules, 1986, namely: -

1. **Short title and commencement.** - (1) These rules may be called the Environment (Protection) Second Amendment Rules, 2021.

(2) They shall come into force after one year from the date of publication of this notification in the Official Gazette.

2. In the Environment (Protection) Rules, 1986, in Schedule-1, for serial number 73 and the entries relating thereto, the following serial number and entries shall be substituted, namely:-

S.No.	Industry	Parameters	Standard
1	2	3	4
“73.	Bulk Drug and Formulation (Pharmaceutical)	A. EFFLUENT STANDARDS*	
			Limiting value for concentration (in mg/l except for pH and Bio assay)
		(i) Compulsory Parameters	
		pH	6.0 -8.5
		BOD (3 days 27°C)	30
		COD	250
		TSS	100
		Oil & Grease	10
		Ammonical Nitrogen	100
		Bio - Assay Test**	90% Survival of Fish after first 96 hours in 100% effluent

(ii) Additional Parameters^{##}	
***Benzene	0.1
***Xylene	0.12
***Methylene Chloride	0.9
***Chlorobenzene	0.2
Phosphates as P	5
Sulphides as S	2
Phenolic Compounds	1
Zinc	5
Copper	3
Total Chromium	2
Hexavalent Chromium (Cr ⁶⁺)	0.1
Cyanide (as HCN)	0.1
Arsenic	0.2
Mercury	0.01
Lead	0.1
SAR	Less than 26 (applicable only for discharge on land)
(iii) Industry connected with CETP	
- The discharge norms for industry connected with CETP and of CETP shall be governed by Ministry of Environment, Forest & Climate Change notification S.O. 4 (E), dated the 1st January, 2016. - State Pollution Control Board shall prescribe additional relevant parameters as given at para A (ii) of this notification as per needs and discharge potential of member industries and specify the frequency of monitoring considering the receiving environment conditions.	
Note: The standards in para A is applicable to all discharges except to CETP. *Not applicable to industry discharging to CETP, and shall be applicable to all discharge to land and surface water bodies including use of treated wastewater for horticulture or irrigation purpose. ** The Bio assay test shall be conducted as per IS : 6582-1971 ^{##} Parameters listed as “Additional Parameters” shall be prescribed by SPCB depending on the process and product and its monitoring frequency shall be monthly/quarterly as decided by SPCBs ***Limits shall be applicable to industries those are using Benzene, Xylene, Methylene Chloride, Chlorobenzene.	

B. EMISSION STANDARDS	
(Tank farm Vents)	
Parameter	Limiting value for concentration (mg/Nm ³)
Chlorine	15
Hydrochloric acid vapor	35
Ammonia	30
Benzene	5
Toluene	100
Acetonitrile	1000
Dichloromethane	200
Xylene	100
Acetone	2000
C. The total cumulative losses of solvent should not be more than 5% of the solvent on annual basis from storage inventory	
D. Chemical and Biological sludge or any residue, reject, concentrate generated from wastewater treatment or its management facility at Industry or CETP catering to industries engaged in manufacturing of bulk drug or formulation of Pharmaceuticals, shall be classified as Hazardous Waste as per the provision of clause 17 of sub-rule (i) of rule 3 of the Hazardous and Other Wastes (Management and Trans-boundary Movement) Rules, 2016 and shall be subject to the provision made therein.	

[F. No. Q-15017/12/2018-CPW]

NARESH PAL GANGWAR, Jt. Secy.

Note : The principle rules were published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number S.O. 844(E), dated the 19th November, 1986 and lastly amended vide notification G.S.R. 243(E), dated the 31st March, 2021.

Prakash
True Copy

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ANNEXURE A-8

Item Nos. 09&10

(Court No. 1)

**BEFORE THE NATIONAL GREEN TRIBUNAL
PRINCIPAL BENCH, NEW DELHI**

(By Video Conferencing)

Original Application No. 801/2018

With

Original Application No. 136/2020

(With reports dated 18.01.2022 & 20.01.2022)

Jasmeet Singh

Applicant

Versus

State of Himachal Pradesh

Respondent

With

Veterans Forum for Transparency in Public Life

Applicant

Versus

State of Himachal Pradesh & Ors.

Respondent(s)

Date of hearing: 21.01.2022

**CORAM: HON'BLE MR. JUSTICE ADARSH KUMAR GOEL, CHAIRPERSON
HON'BLE MR. JUSTICE SUDHIR AGARWAL, JUDICIAL MEMBER
HON'BLE MR. JUSTICE BRIJESH SETHI, JUDICIAL MEMBER
HON'BLE PROF. A. SENTHIL VEL, EXPERT MEMBER
HON'BLE DR. AFROZ AHMAD, EXPERT MEMBER**

Applicant: Dr. Bishwanath Prasad Singh, Wing Commander (Retd.), Applicant
in Person in OA 136/2020

Respondent: Mr. Nalin Kohli, Adv. for HPSPCB

ORDER

1. Both the above matters are being taken up together as the issue involved is of discharge of toxic industrial pollution in river Balad in Baddi industrial area in District Solan and rivers Sirsa and Satluj. Vide order dated 23.06.2021, scope of O.A. No. 801/2018 was noted to be "the remedial action against pollution of River Balad in Baddi industrial area in

District Solan, on account of leakage from the Common Effluent Treatment Plant (CETP)" while scope of O.A. No. 136/20220 was noted to be, "remedial action against discharge of waste from CETP at Baddi and from Acme Life Sciences, Nalagarh and Helio Pharmaceuticals at Solan, to prevent pollution of rivers Sirsa and Satluj. According to the applicant, the CETP is not connected to pharmaceutical units at Barotiwala and Nalagarh who are discharging their effluents directly into the rivers. It is further stated that even after treatment in ETP/STPs, pharmaceutical ingredients may still be coming out from the industries unless ETP/STPs are specialized for the purpose. It is further stated that present CETP is not designed to neutralize Active Pharmaceutical Ingredient (API). The TSDF does not receive sludge generated from the industrial units at Nalagarh. The industries located at Baddi area are generating 20779 KLD of industrial effluent, out of which 17894 KLD is being treated at CETP and remaining 2885 KLD is being disposed of by the occupiers directly into river Sirsa. There is no existing sewerage system in BBN area and no demarcation in residential and industrial area. Presence of Ciprofloxacin in the concentration of 296.1 ug/l was found on chemical analysis. Concentration of Ciprofloxacin in the effluent discharge of M/s Acme Life Sciences work out to be 13455 times of the prescribed limit. The increasing occurrence of multi-resistant pathogens is a serious global threat to human health and it is finding its way into the water bodies and drinking water through industrial discharge and also due to heavy use of antibiotics in human and veterinary medicine."

2. The Tribunal noted the status in O.A. No. 801/2018 as follows:-

"2. The matter was considered on several occasions earlier. On 14.01.2020, the Tribunal considered the report dated 06.11.2019 filed by the State PCB to the effect that violation of provisions of the Water (Prevention and Control of Pollution) Act, 1974 was taking place by

discharge of polluted effluents in the water bodies. The same is reproduced below for ready reference:-

"2.0 Inspection of CETP Baddi

- i) The CETP is designed to treat five different categories of effluent as tabulated under

Sr. No.	Category	Sector of Industry	No of Units	Consented effluent quantity (in MLD)
1.	I	Food, Paper and Textile	89	15.55
2.	II	Soap & Detergent	112	2.0
3.	III	Pharmaceutical	213	2.9
4.	IV	Dyeing	4* M/s Auro Textile Unit - I, M/s Auro Dyeing Unit - I, M/s Winsome Textile Industries	2.0
5.	V	Electroplating, Metal surface finishing	31	0.042
Total			449	22.492
				Say 23.00

- ii) It was observed that at an average of 17 mld effluent is treated by the CETP, comprising equalization tank, primary settler, aeration tank, reaction tank, secondary and tertiary clarifier. The treatment process for each stream is appended with the report (**Annexure IV**).
- iii) It was noticed that effluent of category IV is not reaching to its designated equalization tank. M/s Baddi Infrastructure Ltd., has informed that the dedicated pipe network to carry the effluent of category IV is blocked. The effluent of category IV is therefore being discharged through pipe network of Category I.
- iv) It is also observed that the CETP is designed to treat category V effluent by mixing with category IV effluent to optimize the chemical consumption and to achieve effective treatment. Since, the effluent of category IV has been mixed with category-I, in the pipe network itself before reaching CETP, which has resulted in formation of a new complex effluent for which the CETP was not designed. Therefore, it could not able to deliver the desired results w.r.t. treatment and thus, effluents was in non-conformity with the standards, as per the

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monitoring results of HPPCB (Annexure-V). Besides, the effluent of category V remained effectively untreated throughout the CETP process.

v) The performance of CETP is being regularly monitored by HPPCB. The monitoring data (Annexure-V) indicate that the performance of the CETP is far from satisfactory for having not met the discharged standards. The data reveal that effluent quality does not conform the standards of Chloride (limit of 1100 mg/1 max.), Total dissolved Solids (TDS) (LIMIT OF 2100 MG/1 Mmax.) and Biochemical Oxygen Demand (BOD) (limit of 30 mg/1 max.).

vi) The CETP has provided online continuous effluent monitoring system for pH, Total Suspended Solids (TDS), Chemical Oxygen Demand (COD) and Total Organic Content (TOC) and data so recorded are linked with the server of HPPCB and CPCB.

While collecting the sample from the final outlet of tertiary clarifier and discharge point at River Sirsa, difference in colour of effluent was observed. The sample collected from the discharge point was lighter in colour than that of outlet of tertiary clarifier; giving rise to possibility of dilution. (Photograph: Plate-I)

vii) **The Committee also recorded that the Textile Units, which are generating the effluent of Category IV, were earlier operating their own effluent treatment plants prior to commencement of CETP and found it viable to operate due to their scale of production.**

viii) The designed treatment criteria of CETP are to treat effluent, stream-wise, following segregation at source, effluent of Category-I is mixed with Category-IV, resulted in alternation of criteria, hence treated effluent.

ix) For increasing the connectivity, the CETP has proposed of laying conveyance (pipeline) for a total length of 5.8 kms. The status is as under.

Sr. No.	Location	Stretch in meters	Status of permission obtained	Remarks
1.	Zydus Cadilla to Legacy Food on Baddi Barotiwala road	1655	Permission granted by HPPWD	Work has been awarded by M/s Baddi Infrastructure Ltd vide letter dated 27-09-2019. (Annexure-VI)
2.	Maplur-Baddi electrical substation upto Bhud	2250	Permission not granted by NHAI	

	near Maxtar Bio Genics Company			
3.	Bhud to Lehi	1900	Permission granted by HPWD	
Total		5805		

To safeguard the interest of environment from being deteriorated further and having understanding of pollution problem, its cause and remedial measures, the Committee recommends following:

- i) **Textile industries (SI. No.1 to 5, Table 1) engaged in dyeing-process generating effluent of Category-IV, as mentioned above for the purpose of designing and operating CETP, should stop its operations with immediate effect, until and unless the dedicated conduits supposed to carry the said effluent, is brought to back functional.**
- ii) These units shall resume operation of their ETP to impart effective treatment on effluent of Category-IV so as to meet the standards and shall pump treated effluent to the pipe network designated to carry effluent of Category-I for further treatment at CETP.
- iii) **These units shall resume operations only upon satisfactory performance of ETP which was brought back to functional and shall be monitored once in a month by HPCB.**
- iv) M/s Baddi Infrastructure including Ltd. is to ensure proper maintenance of CETP and its infrastructure including pipe network designed to receive effluents from member industrial units. M/s Baddi Infrastructure Ltd. has to ensure operation of CETP as per the defined protocol and in accordance to standard operating practice which is in place. In case, any variation (beyond the designed criteria) of effluent quality is noticed by CETP the same shall be brought to the knowledge of SPCB, in writing. The SPCB shall acknowledge the communications and shall act to identify the cause for taking all necessary steps for taking all necessary steps to eliminate/minimize such variation.
- v) **M/s Baddi Infrastructure Ltd. has to install activated carbon, pressure sand filters and ozonizer before the treated effluent is discharged. This refers the Detailed Project Report of CETP-Baddi, which finds mentioned of the system but has not been provided by M/s Baddi Infrastructure Limited.**

Reference is made on the observations recorded by the Committee constituted by Hon'ble Tribunal in O.A.

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No.916/2018 in the matter of Sobha Singh and Others v/s State of Punjab and Others, wherein the Committee recommended that Rs.1.0 crore to be levied on CETP-Baddi as Environmental Compensation for untreated effluent discharged into River Sirsa. The CETP discharged, joining the river, has failed to meet Bio-assay Test (Toxicity on fish: 0% survival with 100% effluent for 96 hours). This would have caused impact on water and land (soil) environment, plants and vegetation, aquatic life and human health all along downstream of CETP-Baddi.

Thus, Committee also recommends the following:-

- vi) Environmental compensation (EC) to be levied to CETP-Baddi (M/s Baddi Infrastructure Ltd) for not having done effluent treatment upto the standards and to those Textile Industries (dyeing units) responsible for making CETP defunct. The EC would be proportionate as under.
 - a) CETP-Baddi has to pay environmental Compensation to the tune of Rs.1.91 Crores for non-compliance of discharged standards, estimated based on violation recorded by HPPCB over last one and half year [19.10.2017 -01.11.2019] (**Annexure VII**) including compensation to the tune of Rs.87.9 Lakh imposed by HPSPCB dated 15.10.2019 over one year [20.11.2018 to 09.09.2019] (**annexure VIII**).
 - b) Textile Industries (dyeing units) are to pay establishment cost of CETP and cost of pipe network which was brought to state of irreparable.
- vii) HPPCB is to review the notification, dated 17.03.2018 wherein Total Suspended Solids (TSS), Oil & Grease and pH have been notified TDS, BOD, Chloride and Sulphide may also be considered for inclusion in the notification as these have critical bearing on operation and performance of CETP designed to impart effective treatment. HPPCB may undertake similar exercise as done in case of notification, dated 29.06.2019 for CETP Paonta Sahib, wherein eight parameters including those referred here, have been considered. Such notification may be issued in consultation with CPCB.
- viii) **For optimal performance of CETP-Baddi, HPPCB is to ensure regulating and monitoring mechanism be in place by asking all member units (falling under red category) of CETP to install online continuous effluent monitoring system. The data so recorded shall be made available on SPCB and CPCB server for effective control."**

3. The matter was then considered on 18.06.2020 in the light of compliance report dated 11.06.2020 filed by the State PCB. It was observed:

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5. In pursuance of above, the State PCB has filed a 'compliance report' dated 11.06.2020 to the effect that the units gave action plans which are not satisfactory as long timeline have been prescribed.

6. We do not find the report to be as per the mandate of law. **If the pollution is continuing, the State PCB is under obligation to close the polluting activities by exercising its jurisdiction under the Water Act, 1974 and recover compensation from the polluters. Till pollution is stopped, polluting activities, which are punishable crime under the law, cannot continue. The State PCB has failed to take action merely on the ground that action plan was being prepared or had been prepared which was not satisfactory. None appears for the State PCB.**"

4. The matter was last considered on 04.01.2021 in the light of the report of the State PCB dated 01.01.2021 mentioning the steps taken for closure and recovery of compensation. The Tribunal found that the action taken was not adequate as CETP was still non-compliant. Untreated effluents were thus being discharged into the water bodies in violation of law. Discussion and direction in the said order are reproduced below:-

"1to3....xxx.....xxx.....xxx

4. Accordingly, the State PCB has filed its report on 01.01.2021. It mentions that the State PCB issued show cause notice dated 23.06.2020 to the concerned textile units for closure and recovery of compensation against which writ petitions were filed before the Himachal Pradesh High Court. The High Court, vide order dated 22.07.2020, directed that the matter be heard by the Principal Secretary, Environment and fresh order passed. The Principal Secretary, Environment passed further order on 30.12.2020 directing the State PCB to take action for enforcement of law since violation of law was established. The Principal Secretary, Environment held:

"xxx

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..... **But this fact cannot be ignored that effluent discharge, FDS in particular, by these units is beyond the prescribed limits which is contributing to pollution. In the light of this discussion, I am of considered view that, keeping in view the above position, SPCB may take action strictly according to the provisions of Law and rules applicable in this case.**"

5. The State PCB accordingly issued fresh show cause notice on 28.12.2020 and passed further order dated 01.01.2021 as follows:

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Whereas, the effluent of category-IV being contributed by the unit M/s Auro Textiles, Sai Road Baddi, Distt. Solan, H.P to the CETP for final disposal and treatment by unit is not complying since 25-7-2020 till date to the discharge standards as prescribed in the schedule-1 of EP Rules, 1986 as well as the inlet quality standards notified by the State Government and thereby causing water pollution.

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Now, therefore, in consideration of the facts stated above, in view of the directions of Hon'ble High Courts orders, Hon'ble NGT and the orders passed by Principal Secretary (Env, S&T) Govt of HP and in exercise of the powers conferred under section 32 and 33-A of Water (Prevention & Control of Pollution) Act, 1974 M/s Auro Textiles, Sai Road Baddi, Distt. Solan, H.P. is hereby directed to:

1. Immediately shut down the dyeing process of the textile unit contributing towards the category- IV effluent to CETP, Baddi, till the unit becomes compliant.
2. Pay Environment Compensation to the tune of Rs. 42 lakhs (Forty Two Lakhs only) for the violation period w.e.f. 25-07-2020 to 31-12-2020 (140 days excluding the period of compliance)."

Identical orders are said to have been passed against four textile units.

6. We have heard Shri Nalin Kohli, learned Counsel appearing for the State PCB.

7. We find that though in the show cause notice the State PCB proposed disconnecting power supply, this direction has not been given in the final order. We also find that the CETP has still not complied with the environmental norms for which remedial action needs to be taken by the State PCB, by improving quality and reducing the load of inlet so as to be consistent with the designed capacity of the CETP or closing such units contributing to the waste for which the CETP is not designed till the concerned units make their own arrangement for treating the effluents. The member industries may be considered non-compliant, if they do not undertake primary treatment as per EC conditions of the CETP. The industries having effluent generation more than 200 KLD may be directed to treat the effluents and recycle/reuse to the maximum extent and also reducing the FDS. Wherever required, water audit of red category non-compliant units be conducted. The requisite pipeline may also be required to be constructed by the CETP to carry the waste.

8. Let further progress report be filed before the next date by e-mail at judicial-ngt@gov.in preferably in the form of

searchable PDF/OCR Support PDF and not in the form of Image PDF.”

5. The State PCB has filed interim report dated 06.05.2021 followed by further report dated 16.06.2021. It will suffice to refer to the last report to the effect that the samples were taken and were not found to be within the limits. The State PCB gave directions to the concerned industries. While some units have achieved the norms, further action is being taken in the matter. The status as mentioned in the report is reproduced below:-

“In compliance to afore-cited order dated 04-01-2021 it is submitted that earlier the State Board had filed an Interim Report vide letter No. PCB/OA No. 801/2018 /-1549 dated 6-5-2021 wherein it was submitted that Board has taken steps to make the CETP, Baddi compliant. The FDS level was found 2364mg/Itr as per sampling conducted at that time, though not within the prescribed limits. It is further submitted that now the latest sample taken on 21-5-2021 and 7- 6-2021 has been found within the prescribed limits w.r.t. FDS as the same has been reduced to the 2019mg/Itr and 2072 mg/ltr respectively. The sampling chart of the CETP Baddi is annexed as Annexure —A which reveals that there is continuous improvement and now the analysis results of latest sample taken are meeting the norms w.r.t. FDS.

It is further submitted that as regard to the issue of industries having effluent generation of more than 200 KLD, the State Board had identified and issued directions to 16 numbers of industries to operate their treatment plants i.e. primary, secondary and tertiary treatment system for the effluent treatment as per Environment Conditions of CETP and also directed to recycle / reuse to the maximum extent and also to reduce the FDS. Now as per report received from the Regional Office Baddi, these 16 units are operating the effluent treatment plants prior to their effluent discharge to CETP. The State Board has conducted inspection and sampling of these 16 units. The earlier results of sampling conducted on 21-1-2021, 29-1-2021, 1- 3-2021, 23-3-2021 and 16-4-2021, were found within limits (except of three units of M/s Vardhman and one unit of Winsome Textile) which has already been placed on record alongwith interim report dated 6-5-2021. However, the latest results of sampling conducted on 21-5-2021 the results of three units namely M/s P&G Home Products Baddi, M/s Torrent Pharmaceutical Ltd. Baddi and M/s Abbott Health care, Baddi were found above the prescribed limits for which notices dated 16-6-2021 has been issued to these units. Copy of sample results and notices issued are annexed as Annexure-B and Annexure-C (colly). The sample results of other units were found within the prescribed limits. It is further submitted that as reported by Regional Officer, Baddi the member industries having flow less than 200 KLD are disposing off their effluent to CETP, Baddi after primary treatment.

As regard to the compliance by the four textile units namely Auro Textile, Auro Textile unit —II, Auro Dyeing of

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Vardhman Textile and one unit of Winsome Textile, it is submitted that as per report received from the Regional Office, Baddi, **the work of installation of advance treatment system by M/s Vardhman textile to reduce FDS is under progress and Reverse Osmosis system of capacity of 2 MLD shall be operational by 30-6-2021.** In addition to Reverse Osmosis, M/s Vardhman Textile is also installing the Multi Effect Evaporator of capacity of 370 KLD. As regard to progress of installation of advance treatment system by M/s Winsome Textile it is submitted that as per report received from Regional Office, Baddi the unit has completed the civil construction work. **The installation of Reverse Osmosis system and other components is under progress.** Copies of progress report of these textile units received from Regional Office are annexed as Annexure D and E. **The latest sample results of these four textile units are still not meeting the norms.** Sample results are annexed as Annexure-F. As already submitted in interim progress report dated 6-5-2021, it is again submitted here that **State Board had issued directions on 1-1-2021 to these four textile units under section 33-A of Water Act, 1974 for closure and levied Environmental Compensation which were challenged by these units before the Hon'ble High Court of HP vide CWP No. 414/2021, 416/2021 417/2021 and 418/2021. The Hon'ble High Court of HP vide order dated 11-1-2021 and 15-3-2021 has stayed the operation of the directions issued by the State Board and the matter is still pending before the Hon'ble High Court of Himachal Pradesh for adjudication.** Copies of order dated 15-3-2021 are annexed as Annexure-G.

It is further submitted that due to constant efforts of all stakeholders, the two consecutive latest samples of CETP outlet are meeting the norms prescribed by the MoEF &CC vide notification dated 1-1-2016. In future, the State Board shall continue to make all efforts in form of surveillance, regular monitoring and regulation on the CETP and member industries, so that the CETP remains compliant in future as well."

6. From the above, it is clear that violations are still continuing. Stay of order of closure and assessment of compensation for the past violations does not justify inaction for failure to take action for further violations after the order of stay and to initiate prosecution of the industrial units in question, including their Owners/Directors and the CETP operators. We also find that merely keeping an eye on units discharging more than 200 KLD is not enough. Violation by those discharging less than 200 KLD is not less serious violation nor less harmful for the environment and public health.

7. Accordingly, let further remedial action be taken to enforce the environmental rule of law in the interest of protection of environment and public health and a report of status of compliance filed after inspection by a four Member joint Committee comprising a representative of MoEF&CC,

CPCB, State PCB and District Magistrate, Solan by e-mail at judicial-ngt@gov.in preferably in the form of searchable PDF/ OCR Support PDF and not in the form of Image PDF. The State PCB will be the nodal agency for coordination and compliance."

3. In O.A. No. 136/2020, extracts from last order dated 23.06.2021 are as follows:-

"3. The matter was last considered on 04.01.2021 in the light of the report of State PCB dated 30.12.2020 noticing the violations of environmental norms. The Tribunal directed remedial action and filing of compliance report. The operative part of the discussion and order of the Tribunal are reproduced below:-

"3. Accordingly, the Himachal Pradesh State PCB has filed its report dated 30.12.2020 to the effect that the joint Committee visited the area and noticed as follows:

"xxx

xxx

xxx

i. **The CETP has not installed the system to completely treat category IV effluent (High TDS/FDS Stream). Despite the fact that CETP does not have the capacity to treat this type of effluent, CETP has entered into the tripartite agreement with the Industries generating Category IV effluent has been receiving this category of effluent since 2016.**

ii. **As per Environmental Clearance granted to CETP Baddi by the Ministry of Environment, Forests and Climate Change (MoEF&CC), the member industries with hydraulic loading more than 200 KLD shall treat the effluent in the existing onsite ETPs and then discharge into CETP for further treatment and discharge. However, it was informed that Units with hydraulic loading of 200 KLD are not treating effluent in the onsite ETPs and supplying primary treated effluent to CETP. Therefore, CETP has not been complying with this condition of the Environmental Clearance granted by MoEF&CC for the last 04 years. Accordingly, the sampling of these units was done by HPPCB team on 10/12/2020 and the samples were sent to HPPCB Central Laboratory. The results of the analysis are expected by 10/01/2021.**

iii. **The observations made by the Joint Committee during visit to the two Pharma units i.e. M/s Acme Life Sciences and M/s Helios Pharmaceuticals mentioned in the original application are as follows:**

- **Both the pharma units have connectivity with the CETP for supplying the primary treated effluent, for further treatment at CETP.**

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- No effluent was found to be discharged directly by the Units, in the drain.
- The Joint Committee collected the samples from the final outlet of the pharma units under reference, to see the concentration of residual antibiotics in the primary treated effluent which is being sent to CETP for further treatment. The results of the analysis are expected by 09/02/2021.

iv. The evaluation of the results of the analysis of the CETP samples collected by the Joint Committee on 12-13 October, 2020, indicated intended dilution by CETP so as to achieve the prescribed norms. Therefore, the Joint Committee conducted unannounced re-sampling and sent the samples for analysis from three different laboratories.

v. **The results of analysis for the samples collected by the Joint Committee have been analyzed in HPPCB Regional Laboratory, Paonta Sahib and evaluation of the results indicated that CETP is not meeting the norms prescribed for COD (264 mg/l > 250 mg/l), BOD (35 mg/l > 30 mg/l), FDS (2252 mg/l > 2100 mg/l) and Chloride (1838 mg/l > 1000 mg/l). Therefore, it is concluded that CETP is discharging the effluent into the Sirsa River without complying with the prescribed norms.** The results of the analysis of the samples are awaited from two other laboratories.

vi. The samples from CETP, upstream and downstream of Sirsa River and the pharma units under question, were collected by the joint committee on 09/12/2020 for analysis of 12 Nos. residual antibiotic residues from Shri Ram Institute of Industrial Research, Delhi. The results of analysis of effluent samples for residual antibiotics is expected by 09/02/2021. The issue of discharge of residual antibiotics as raised by the applicant may be concluded by the Joint Committee after receipt of the analysis results.

In view of the fact that complete analysis reports will be available by 09/02/2021, it is humbly prayed to Hon'ble National Green Tribunal that Joint Committee may kindly be permitted to file the final conclusive report by 15/02/2020."

4. Accordingly, further action taken report may be separately filed by the State PCB before the next date by e-mail at judicial-ngt@gov.in preferably in the form of searchable PDF/OCR Support PDF and not in the form of Image PDF. The directions in the connected matter being OA No. 801/2018, Jasmeet Singh v. State of Himachal Pradesh, dealt with by a separate order, to the extent relevant for the present matter, may also be followed."

4. The State PCB has filed its report dated 10.03.2021 giving the analysis results of samples calculated from the units as follows:-

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"Supplementary Report:

The analysis results from the remaining two laboratories w.r.t samples collected by the Joint Committee have been received (Annexure-2 and Annexure-3). Further, the report of analysis w.r.t. samples collected by the Joint Committee from CETP, Pharma Units and Sirsa River for the presence of antibiotics from the approved external laboratory has also been received (Annexure-4). Accordingly, supplementary report in this matter is being filed by the Joint Committee as follows:

- i) The results of analysis as received from three different laboratories of HPPCB, indicated that CETP is not meeting the norms prescribed for BOD (41, 35 & 38 mg/l > 30 mg/l), FDS (2252 & 3190 mg/l > 2100 mg/l) and Chloride (1209, 1838 & 1209 mg/l > 1000 mg/l). Therefore, it may be concluded that CETP is discharging the effluent into the Sirsa River without complying with the prescribed norms.
- ii) The results of analysis of the samples collected from various stages of CETP and also final discharge point in River Sirsa for the presence of residual antibiotics indicate that two antibiotics viz. Ciprofloxacin and Ofloxacin are present in the final treated effluent of CETP as a concentration of 22.8 ug/l and 69.8 ug/l respectively.
- iii) There are no standards notified by MoEF&CC for residual antibiotics in industrial effluents. However, these values are 1140 times higher for Ciprofloxacin (22.8 ug/l Vs. 0.02 ugh) and 349 times higher for Ofloxacin (69.8 ug/l Vs. 0.2 ugh) when compared with the proposed standards in the draft notification issued by MoEF&CC vide No. CG-DL-E-27012020- 215690 dated January 23, 2020 (Annexure-5), for pharmaceutical industry effluent and CETPs with membership of Bulk drug and formulation units.
- iv) Similarly, the samples collected by the Joint Committee from the outlets of two Pharmaceutical Industries viz. Helios Pharmaceutical and M/s Acme City Tech LLP, leading to CETP, were found to be much higher than the standards proposed in the draft notification issued by MoEF&CC. Also, the values reported as below quantification limit (BQL), in the analysis report of the external laboratories may not be considered as conclusive and within the proposed limits as draft notified by MoEF&CC, since the BQLs of external laboratory for various antibiotics tested in the samples, as shared with the Joint Committee, are much higher than the proposed standards.
- v) As per reports and research data available in the literature, the concentration of residual antibiotics has been found to be reduced by 60-90 % in conventional biological treatment plant. In view to assess the

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performance of the biological treatment system installed by CETP, the samples were collected from various stages of CETP. The results of analysis indicated that the performance of biological treatment system installed by CETP is not in line with the reports and data available in the literature, w.r.t. treatment of residual antibiotics. The inefficient performance of biological treatment system is also evident from the noncompliance of CETP with regard to biochemical oxygen demand (BOD).

Conclusion and Recommendations:

In view of the fact that:

- i) *There are no standards notified by MoEF&CC w.r.t. residual antibiotics in industrial effluents;*
- ii) *Draft notified standards are yet to be decided by MoEF&CC;*
- iii) *The concentration of residual antibiotics at outlet of CETP in Sirsa River, is much higher than the draft notified standards;*
- iv) *The treatment efficiency of CETP w.r.t residual antibiotics is not at par with the reports and data available in the literature;*
- v) *The CETP is not meeting the prescribed norms of BOD, FDS and chloride and discharging effluent into Sirsa River without complying with the prescribed norms.*

It is recommended that Pharmaceutical (both bulk drug and formulation units) may be directed by Himachal Pradesh Pollution Control Board to provide primary treatment to the level of predicted no effect concentration (PNEC) as developed by members of AMR Industry Alliance (Annexure-6), as a site (Baddi) specific preventing measure, so that there is no adverse impact of residual antibiotics on the environment and also to prevent development of antimicrobial resistance (AMR)."

5. *The report is followed by further report dated 05.05.2021 as follows:-*

"It is further submitted that now the joint committee has submitted its supplementary report which is annexed as Annexure R-1/1. Based on the inspections and sampling conducted the conclusion and recommendations made by the joint committee are as under:-

- "i) There are no standards notified by MoEF & CC w.r.t. residual antibiotics in industrial effluents.*
- ii) Draft notified standards are yet to be decided by MoEF & CC.*

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- iii) *The concentration of residual antibiotics at outlet of CETP in Sirsa river is much higher than the draft notified standards.*
- iv) *The treatment efficiency of CETP w.r.t. residual antibiotics is not at par with the reports and data available in the literature.*
- v) *The CETP is not meeting the prescribed norms of BOD, FDS and chloride and discharging effluent into Sirsa River without complying with the prescribed norms....."*

The copy of Supplementary Report submitted by the joint committee dated 10-03-2021 (annexed as Annexure R-1/1) may be placed on record please.

It is submitted that as of now there are no specific standards notified by the Govt. of India for residual antibiotics parameters in the existing notification of standards for pharmaceutical (Manufacturing and Formulation Industry). However, it is worthwhile to mention here that all the bulk drugs/pharmaceutical manufacturing units (if not connected with CETP) are being regulated for the compliance as per standards notified in MoEF & CC Notification dated 9-7-2009 (copy annexed as Annexure R-1/2). If the pharmaceutical (manufacturing and formulation industry) is member of CETP, then the unit is bound to comply with inlet quality standards notified by the Govt. of HP vide notification dated 17-3-2018 and 26-12-2019 (copies annexed as Annexure R-1/3 and R-1/4) The notification of specific standards for residual antibiotics (annexed as Annexure -5 with joint report) is still under proposed stage and shall be implemented for regulatory aspect as and when finalized by the MoEFF & CC."

6. *The industrial units in question have also filed their Counter Affidavits. The said Counter Affidavits are of no assistance.*

7. *As against the above, the applicant has filed written submission on 11.06.2021 pointing out that the analysis of the samples shows presence of antibiotics in the water.*

8. *The conclusion drawn from the analytical results is as follows:-*

"

1. Ciprofloxacin (22.8µg/L) and Ofloxacin(69.8µg/L) were detected in higher concentrations in the effluent released to Sirsa river from CETP (Sr. no 4), i.e., 1139 and 348 times higher than the prescribed MoEF& CC draft notification limits.

2. The higher concentrations of antibiotics in the effluent released to Sirsa river (Sr. no 4) clearly indicate that CETP is unable to completely remove or degrade these antibiotics.

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3. Ofloxacin (960µg/L) was found in the effluent from M/S Helios Pharmaceutical (Sr. no 13) release to CETP, which is much higher than the draft notification limit (0.2 µg/L). It clearly raises doubt on the level of pre-treatment of the pharma effluent from this industry before it is released to the CETP.
4. The samples drawn from the effluent of M/S Acme City Tech LLP (Sr. no 14 and 15) release to CETP shows reasonably high concentrations of Ofloxacin (170 µg/L) and Azithromycin (423µg/L) even after primary treatment, indicate inefficient pre-treatment at this industry.
5. In the research methodology Limit of quantification (LOQ) for a compound by any method indicates the lowest concentration that can be quantified with accuracy and precision. The values below LOQ cannot be correctly quantified during the analysis and are reported as Below Quantification Limit (BQL). In the present analysis, the LOQs of the compounds fixed for the analysis by the lab are very high; namely, Ciprofloxacin (5 µg/L), Ofloxacin (5 µg/L), Piperacillin (5 µg/L), Azithromycin (10 µg/L), Tazobactam (5 µg/L), Cefazidime (50 µg/L), Cefixime (20 µg/L), Amoxicillin (10 µg/L), Ampicillin (10 µg/L), Cefpodoxime (10 µg/L), Sulbactam (10 µg/L), Ceftriaxone (50 µg/L) and Cefoperazone (10 µg/L). The above LOQs of the compounds are much higher than even the antibiotic discharge limits set by the MoEF & CC draft notification for these compounds; except for Tazobactam.
6. Incidentally Piperacillin and Amoxicillin are the antibiotics are known for the very adverse impact on the human health even in the very low concentration. In this laboratory analysis, BQL limit for these compounds are set as (5 µg/L) and (10 µg/L) which is significantly higher than the limit fixed in the draft standards. In the draft standards the limit set for these two compounds are (0.1µg/L).
7. This implies that the Limit of Quantification (LOQ) set up by the lab is significantly higher than the limit set by the draft notification and therefore many of the compounds are not being detected as has been marked as BQL in the analysis results.
8. Therefore, the samples analysis should be conducted using an analytical method to precisely and accurately quantify lower concentrations of the compounds (LOQs should be kept as close or even lower than the draft notification limits) to quantify all the compounds at lower concentrations with accuracy and precision. This raises the question mark on integrity of the overall analysis by the lab.
9. Further the findings also imply that the CETP is not designed to efficiently treat class IV effluents; however, operator of CETP has entered into agreement with various pharma manufacturing units who are releasing class IV effluents to the CETP since 2017."

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9. *Further submissions are reproduced below:-*

"14. The migration of antimicrobials into the environment has significant impacts. They can disrupt wastewater treatment processes and adversely affect ecosystem because they are toxic to beneficial bacteria. Some antimicrobials also bio accumulates; for example, erythromycin has been found to have both a high bio accumulation factor of 45.31 and a tendency to accumulate in soil. Antimicrobials can also be persistence for extended periods of time, the environmental persistence of erythromycin for example, is longer than one year.

15. Although not well studied, the presence of antimicrobials in natural waters may be exerting selective pressure leading to the development of antibiotics resistance in bacteria. The threat of growing antibiotics resistance has been recognised by, among others, the WHO, the National Academy of Science, the American Medical Association, the American Public Health Association and the US government Accountability. In fact the Centre for Disease Control and prevention (CDC) has identified antibiotics resistance as one of the most pressing public health problem facing the nation. Infections caused by bacteria with resistance to at least one antibiotic have been estimated to kill over 60,000 hospitalized patients each year. Methicillin resistant strains of Staphylococcus aureus, although previously limited primarily to hospital and health facilities, are becoming more widespread. In 2007, Consumer Reports tested over 500 whole chickens for bacterial contamination and antibiotic resistance. They found wide spread bacterial contamination in their samples and 84 percent of the salmonella and 67 percent of the campylobacter organisms that were isolated showed resistance to one or more antibiotic.

16. Antibiotic resistance is caused by a number of factors including repeated and improper use of antibiotics in both humans and animals. Half of the antibiotics used in livestock are in the same classes of drug that are used in humans and animals. The U.S. institute of Medicine and the WHO have both stated that widespread use of antibiotics in agriculture is contributing to antibiotic resistance.

17. The above study done by the HPPCB shows that from whichever place samples have been taken by HPPCB these are having antibiotics discharge which should not have been there. There is not a single sample in which the aforesaid antibiotics discharging into surface water and also seeping into the subsoil water is not there. This would lead to harmful antibiotic resistance amongst human and animal population and, thus, reducing the chances of their recovering from diseases where absence of resistance from these antibiotic would have helped. The above table and the subsequent narration would show that the antibiotics found in the discharge include some of the ultimate antibiotics developing resistance of which may be a death warrant for different life forms – human and animal – if

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infected with diseases where these antibiotics could have provided a cure.

18. A situation where all random samples show the same results, in technical terms, is called '100% random test positivity'. In view of the '100% random test positivity', the study conducted by HPPCB cannot be stated to be complete and conclusive. It only indicates that a whole lot of polluting antibiotics are being discharged into the surface and subsoil water which is harmful for human and animal population.

19. As per information available at internet, there are more than 270 Pharmaceutical Companies operating in Baddi-Barotiwala-Nalagarh area. List of such Pharmaceutical Companies along with their addresses, as obtained through internet sites, is placed at Annexure A.

20. This necessarily requires a further and more detailed study as a sequel to 'the sample study' done by HPPCB to understand the entire extent of damage because of the aforesaid antibiotic discharge into the water bodies. It is being called 'sample study' because of the fact that it has '100% random test positivity' and therefore, in scientific tradition, there is an absolute need for following it up with a detailed, wide and more in depth study of the antibiotic discharge into river sirsa."

10. We have heard the applicant in person and the Learned Counsel for State PCB.

11. **We find that there is gross failure on the part of the State PCB to act as per public trust doctrine in preventing discharge of toxic effluents containing harmful residue of antibiotics in water posing threat to aquatic life (reference: "biomonitoring of Sirsa River in Baddi area of Himachal Pradesh by Bhagat S. Chauhan, et al, International Journal of Theoretical and Applied Sciences 5 (1): 183-185(2013)) which is also in violation of the Water (Prevention and Control of Pollution) Act, 1974. Such failure of statutory duties is at the cost of public health and protection of environment for which Chairman and Member Secretary of the PCB owe an explanation which may be furnished before the next date. Mere fact that standards have not been revised by MoEF&CC of the residual antibiotics in industrial effluents can be no justification for State PCB not taking steps to prevent. Pending finalization of standards by MoEF&CC, State PCB can go by earlier standards or lay down standards by itself under section 17 of the Water Act. MoEF&CC needs to expedite the process of finalizing the standards in the interest of protection of environment.**

12. Accordingly, MoEF&CC and the State PCB may take further remedial action expeditiously. The State PCB may ensure that no harmful components in the effluents are discharged into the water by the units in question or any other API unit. A joint Committee of nominee of MoEF&CC, CPCB, State PCB and District Magistrate, Solan may conduct

*inspection of the area and give a report of the status of violations and the remedial action taken within three months by e-mail at judicial-ngt@gov.in preferably in the form of searchable PDF/ OCR Support PDF and not in the form of Image PDF. The State PCB will be the nodal agency for compliance. The Committee may interact with the concerned stake holders, including the concerned Industries. The report may inter alia give status of performance of individual pharmaceutical units, particularly with reference to removal of API residue by them and by the CETP, the number of pharma industries connected to CETP and those discharging effluents directly into the drain and the river. The report may further indicate chemical and biological water quality of rivers in question - Sirsa and Satluj, including the status of residue at relevant locations. CPCB may also suggest monitoring mechanism for API residue through a credible system so as to cover all pharma industries in the country discharging API residue directly or indirectly in river systems. CPCB may propose the timelines to undertake monitoring which may also take a note of water quality monitoring guidelines of CPCB titled "Guidelines on Water Quality Monitoring, 2017" and the performance audit report dated 18.09.2020 filed by CPCB in OA 95/2018, *Aryavart Foundation v. M/s Vapi Green Enviro Ltd. & Ors.* and the directions of the Tribunal dated 05.02.2021. Relevant direction is reproduced below:*

"22. The directions on the subject are summed up as follows:

i to vi xxx.....xxx.....xxx

- vii. CPCB and State PCBs/PCCs, as directed earlier, may utilise EC funds on laboratory set up/upgradation, and on the mentioned areas in the report as well as on approved District Environment Plans. No approval of Central/State Government will be necessary in this regard in view of section 33 of the NGT Act, supra."*

CPCB may file report on the above aspects before the next date of hearing by e-mail at judicial-ngt@gov.in preferably in the form of searchable PDF/ OCR Support PDF and not in the form of Image PDF."

4. In pursuance of above, reports have been filed by the State PCB. In O.A. No. 801/2018, report filed on 18.01.2022 mentions the visit to the site on 01.10.2021 and 23.11.2021 and non-compliances found. The report mentions that 97 industries were found to be non-compliant. In view of the fact that there is an interim order granted by the Himachal Pradesh High Court on 01.09.2021 and 10.11.2021 against industries having less than 200 KLD discharge, applicable to action in pursuance of Notification

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dated 26.12.2019 issued by the HP Government laying down inlet norms of the CETP. CETP itself was found to be non-compliant due to toxicity of the waste received. CETP is now to be upgraded by the funds received from the Central Government. The report also mentions compliance status of the industrial units covered in O.A 136/2020 and it is found that in post-monsoon sampling, there is deterioration of water quality, downstream of CETP. The relevant extracts from the report are:-

“2.0. Findings of the Joint Committee and Status of Compliance:

In compliance of the directions of the Hon'ble NGT, HPPCB submitted report of the Joint Committee on 30/9/2021, followed by supplementary report on 23/11/2021. In continuation of the above reports, the final report/findings of the Joint Committee are submitted as follows:

- i. **Total Number of Industrial units in BBN (Baddi, Barotiwala, Nalagarh) Area covered under Consent Mechanism are 2444 (Red Category 219, Orange 900 and Green category 1325)**
- ii. **Out of 2444 industrial units in BBN Area, 1703 units are located in Baddi Barotiwala area and remaining 741 units are located in Nalagarh region.**
- iii. **Total number of water polluting industries in BBN Area is 576.**
- iv. **Out of total 576 water polluting industries, 456 industries are located in Baddi area and 120 industries are located in Nalagarh area. All these 456 industries located in Baddi Barotiwala area, are connected to CETP either through pipe line or tankers. Further, out of these 456 Industries located in Baddi Barotiwala area, 376 industries are operational and remaining 80 are temporarily closed.**
- v. **Out of 120 water polluting industries located in Nalagarh area, 24 industries are connected to CETP, Baddi through tankers and remaining 96 water polluting industries have installed their own ETP to treat the industrial effluent. As per information provided by HPPCB, none of these units are discharging treated effluent into the water bodies.**
- vi. **All 456 industries of Baddi Barotiwala area were monitored by HPPCB, during July to October, 2021 in this matter. Joint Committee also monitored randomly selected 13 No. Industries out of these 456 industries, during 1-2**

November, 2021, for cross verification of the compliance **(Annexure-I).**

- vii. Out of these 456 industries monitored by the HPPCB and Joint Committee, **97 industries were found to be non-compliant w.r.t norms prescribed by HPPCB** for discharge at the inlet of CETP for further treatment. The list of **97** industries not complying with the prescribed norms is attached as **Annexure-II.**
- viii. MoEF&CC has prescribed limits for the discharge parameters of CETP vide notification dated January 1, 2016, wherein, it is also mentioned that **"For each Common Effluent Treatment Plant (CETP), the State Board will prescribe Inlet Quality Standards for General Parameters, Ammonical Nitrogen and Heavy metals as per design of the Common Effluent Treatment Plant (CETP) and local needs & conditions" (Annexure-III).** Accordingly, in compliance of the MoEF&CC notification, **CETP inlet norms have been prescribed vide notification dated 26/12/2019 issued by Govt. of HP (Department of Environment Science & Technology).**
- ix. No action was taken by HPPCB against **97 Nos.** industries having hydraulic loading less than 200 KLD, which were found to be not complying with the CETP inlet norms, since, the Baddi Barotiwalla Nalagarh Industrial Association(BBHIA) has filed a petition in the High Court of Shimla (CWP No. 4961 of 2021), wherein the CETP inlet norms as per notification dated 26/12/2019 issued by Govt. of HP (Department of Environment Science & Technology) in compliance of MoEF&CC Notification dated January 1, 2016, have been challenged, taking a plea that the environmental clearance has specified condition of treatment and inlet norms which may be specified by State Pollution Board for units discharging more than 200 KLD and direction has been issued to the State Pollution Control Board. Hon'ble High Court vide orders dated 01/09/2021 and 10/11/2021, had directed not to take coercive action against them. The copies of petition filed by the industries, Hon'ble High Court Order dated 1/09/2021, order dated 10/11/2021 and order dated 29/12/2021 and the reply filed by HPPCB before the Hon'ble High Court are enclosed as **Annexure IV.** The orders passed by Hon'ble High Court is as under:

"...In the meanwhile, respondents are restrained from taking any coercive action against petitioners.... order dated 01-09-2021"

"... The order dated 01-09-2021 is clarified to the extent that the same shall only be applicable to those industries having less than 200 KLD hydraulic discharge....order dated 10-11-2021"

Now, the above matter is listed for hearing before the Hon'ble High Court on 12-04-2022"

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- x. The analysis results of primary treated Category-I effluent (Discharged to CETP for further treatment) from M/s Vardhman Textiles Limited (Auro Textile-I, Auro Textile-II & Auro Dyeing-I) is complying with CETP inlet norms w.r.t Category-I effluent. However, as per Environmental Clearance granted to CETP vide F. No. 1053/2011-IA-III Dated 8.01.2013 (copy attached as **Annexure-V**), the member industries with hydraulic loading more than 200 KLD shall treat in the existing onsite ETPs (as these industries have already provided on site ETP consisting of Primary/Secondary and Tertiary Treatment System) to the level of treatment and standards prescribed in the consent orders issued by the State PCB before discharging into the CETP for further treatment.
- xi. M/s Vardhman Textiles Limited and M/s Winsome textiles Limited, have installed the tertiary treatment system only for treatment of Category-IV and it was verified by the Joint Committee. M/s Vardhman Textiles Limited and Winsome Textile Limited have discontinued discharging CAT-IV effluent to CETP Treatment in the RO and MEE seemed to help the CETP meet the discharge norms of FDS/TDS as indicated in the analysis results of the samples collected by HPPCB from the discharge point located at River Sirsa, since May 2021.
- xii. The Hon'ble High Court vide CWP No. 414 of 2021, 416 of 2021, 417 of 2021 and 418 of 2021 have stayed the action taken by the State Board under section 33 A of Water Act, 1974 against the above two units, for previous violations (**Annexure-VI**). Further, vide order dated 22/12/2021. Hon'ble High court has directed that "no coercive action shall be taken against the petitioner pursuant to the notification dated 26/12/2019" (whereby Govt. of HP, Deptt. of Env't., Sci, and Technology notified inlet quality standards in respect of CETP, Baddi). The Matter is now listed before the Hon'ble High Court of HP on 21/03/2022 (**Annexure-VII**).
- xiii. Baddi CETP was also monitored by the Joint Committee for compliance of prescribed norms. **CETP was found to be non-compliant w.r.t. Bio-assay Test (Zero % survival of fish in 100% sample after 96 hours against the standard of 90% survival of fish in 100% sample after 96 hours).** Bio-assay test is an important parameter for determining the toxicity of waste water. **All other parameters including FDS were found to be within the prescribed limits and CETP was found to be compliant in this regard.** (Report annexed as **Annexure-VIII**)

Further, the joint committee was informed by the CETP Baddi that a funding support to the tune of Rs. 28 Crores from the Ministry of Commerce and Industry, Government of India, under "Trade Infrastructure for Export Scheme" has been sanctioned for their proposal on "3 MLD Effluent Refractory Management and TDS reduction in CETP". The Govt. of Himachal Pradesh has already sanctioned and partially released the funds, for this proposal. Further, CETP Baddi has invited tenders for design, supply, construction, installation, commissioning, testing and trial run of 3 MLD capacity for

effluent refractory management and TDS/FDS Reduction at their existing 25 MLD capacity CETP & MLD STP located at Baddi, Distt. Solan (HP) and this project shall be completed within one year i.e. upto 31.10.2022, as informed to the Joint Committee by CETP, Baddi (**Annexure-IX**).

- xiv. The same Joint Committee has been constituted in the matter of OA No. 136 of 2020; Veteran form, has also conducted the monitoring of River Sirsa during Monsoon and post monsoon seasons. The Joint Monitoring conducted sampling of River Sirsa from following locations:

Sr. No.	Sampling Location	Pre-monsoon	Post-monsoon
		Class as be Designated Best Use	
1.	Point Upstream of CETP	B	B
2.	Point Downstream Of CETP	B	D
3.	River Sirsa D/s Nalagarh Bridge	B	B

The analysis data shows that the water quality of river Sirsa before CETP and when it is leaving Himachal Pradesh Boundary at D/s Nalagarh Bridge falls under Class B in both samplings i.e. pre-monsoon and post-monsoon. However in the post-monsoon sampling there is deterioration in the water quality at location downstream of CETP. The analysis reports are annexed as **Annexure-X**.

- xv. **An email dated 8/11/2021 from. Mr. R.N. Jindal, Executive Director, TSDF Facility, Nimbua Greenfield (Punjab) Limited was also received, giving comments on the HPPCB w.r.t inlet norms, compliance by CETP and the member industries (Annexure-XI). However, Joint Committee didn't find it appropriate to influence its report with his comments, since no such request was made by the Joint Committee for his comments and forwarded his mail to HPPCB, for reference and taking any action HPPCB deemed necessary."**

5. There is a separate report in O.A. No. 136/2020 with following conclusions and recommendations:-

"3.7. Conclusion and Recommendations:

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Based on the outcome of the study conducted by the Joint Committee in this matter, it is concluded and recommended as follows:

- i. **Out of 111 antibiotic manufacturing industries** monitored by Himachal Pradesh Pollution Control Board in this matter, **37 industries were found to be non-complying w.r.t. limits prescribed for discharging into the CETP.**
- ii. **No action could be taken by HPPCB against the above 37 pharmaceutical formulation industries (engaged in the manufacturing of antibiotics), which were found to be not complying with the CETP inlet norms, due to stay by Hon'ble High Court of Himachal Pradesh.** Now, the matter is listed for hearing before the Hon'ble High Court on 12-04-2022.
- iii. **Some of the antibiotics viz. Azithromycin, Ciprofloxacin, Ofloxacin, Levofloxacin etc. were found to be significantly present (no comparison could be made as MOEF&CC has not prescribed any standards for residual antibiotic) at the outlet of the industry's leading to CETP for further treatment.** The removal efficiency in the primary treatment plants installed by the industries before discharging into the CETP, **was found to be 0-74% for Azithromycin, 90% for Ciprofloxacin, 67-73% for Ofloxacin, 0% for Levofloxacin and Cefpodoxime.**
- iv. **Similarly, the antibiotics viz. Ofloxacin (63 ug/l) and levofloxacin (8 ug/l) were found to be in significantly present at the final discharge of CETP into the Sirsa River.** With regard to removal efficiency of antibiotic residues in the Category-III (Pharma) effluent treatment section of CETP, **it was observed that Ofloxacin was found to be reduced by 31%, Azithromycin by 9%, Levofloxacin by 31% and Roxithroycin by 71%.** This concentration was found be further reduced to lower limits after mixing with treated effluent of other categories' effluent, before discharging into the Sirsa River.
- v. **Antibiotic residue viz. Azithromycin was found to be significantly present in River Sirsa both at the Up-stream (2.5 ug/l) and Down-stream of CETP (2.1 ug/l), which was further increased to 2.9 ug/l in the Nalagarh area.** Further, during the post-monsoon sampling, deterioration in the water quality downstream of CETP was observed during monitoring by the Joint Committee.
- vi. **Other antibiotics were found to be present at below quantification limits (BQL) in the study conducted by the Joint Committee in this matter. However, it may not be considered as absence of antibiotic residues in view of the fact the quantification limit of analysis in the Lab engaged for analysis of antibiotic residues, was 2-300 times more than the Predicted No effect Concentration (PNEC) of different antibiotics. PNEC is the concentration of antibiotic, which mark the limit, below which no adverse impact on the ecosystem is measured.**

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- vii. **It is pertinent to apprise the Hon'ble National Green Tribunal that though MOEF&CC has notified the standards for pharma industry vide Notification dated 06.08.2021 but the limit of Antibiotic residues (as mentioned in the draft Notification) has been withdrawn/dropped. Hence there is no parameter for residual antibiotic which Joint Committee could compare with.**
- viii. **Ail. Representative of BBN Industries Association informed during stakeholders' consultation that the association has received the funding support to the tune of Rs. 28 Crores from the Ministry of Commerce and Industry, Government of India, under "Trade Infrastructure for Export Scheme" for their proposal on "3 MLD Effluent Refractory Management and TDS reduction in CETP". The 3 MLD effluent proposed to be treated under this proposal includes pharmaceutical industrial effluent for treatment of API and Antibiotic residues and the content of antibiotic residue and API in the final outlet after treatment in this proposed add on facility in CETP, Baddi will be Nil. It was also informed that the implementation of the above proposal will be completed within one year.**

In view of the fact that i) antibiotic residues were found to be present significantly at the outlet of industries leading to CETP, outlet of CETP and River Sirsa, ii) MoEF&CC has dropped the limits of antibiotics in the final standards for Pharmaceutical Industries notified vide notification vide 6/8/2021 and iii) As informed by BBN Industries Association regarding funding of Rs. 28 Crores for upgrading the CETP/add on facility, including treatment of antibiotic residues with claim of achieving the concentration of antibiotic residues as nil, It is recommended that all the Pharmaceutical Industries of BBN area (located outside the catchment area of CETP) may be connected to CETP Baddi, and the "limit of antibiotic residues as BDL/<PNEC" may be incorporated by HP State Pollution Control Board (HPSPCB) as one of the terms of Consent to Operate (CTO) granted to CETP Baddi, after commissioning of the proposed "add on facility" in CETP, Baddi."

6. The reports show alarming situation of serious non-compliance having continuous adverse impact on public health and environment. CETP is inefficient in its working and individual units are also non-compliant. This requires immediate effective regulatory action. Pharma units need to monitor API and take remedial steps. MoEF&CC needs to

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address such vital issue and assist the State to handle the situation in the interest of environment and public health.

7. Only explanation of the State is helplessness due to interim order of the High Court. Learned Counsel has stated that clarification is proposed to be sought in the matter from the High Court so that remedial action for protection of environment and public health is taken as violations are not only of prescribed inlet norms but also statutory provisions of the Water (Prevention and Control of Pollution) Act, 1974 and standards of water laid down under other relevant statutory provisions which are not covered by the stay order. We note that confusion pleaded is resulting in undesirable state of affairs, to the detriment of helpless public against the mandate of law which does not appear to have been properly brought to the notice of the High Court or any other higher forum. We do not find any reason why the State PCB could not enforce law even against violators who are not covered by the interim order granted by the High Court, particularly the pharma units discharging more than 200 KLD.

8. The State may accordingly take further corrective measures to enforce the law for protecting public health and the environment. CPCB may circulate monitoring mechanism to the State PCBs on API, as directed earlier and file the action taken report before the next date. MoEF&CC may clarify the issue of API standards.

List again on 29.03.2022.

A copy of this order be forwarded to CPCB and MoEF&CC by e-mail for compliance.

Adarsh Kumar Goel, CP

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Sudhir Agarwal, JM

Brijesh Sethi, JM

Prof. A. Senthil Vel, EM

Dr. Afroz Ahmad, EM

January 21, 2022
Original Application No. 801/2018 &
Original Application No. 136/2020
SN

Brijesh
True Copy

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ANNEXURE A-9

BEFORE THE HON'BLE NATIONAL GREEN TRIBUNAL,
PRINCIPAL BENCH, NEW DELHI
O.A. NO. 136 OF 2020

IN THE MATTER OF:-

VETERANS FORUM FOR TRANSPARENCY
IN PUBLIC LIFE

...APPLICANT(S)

-VERSUS-

HIMACHAL PRADESH POLLUTION
CONTROL BOARD & ORS

...RESPONDENT(S)

DATE OF HEARING: 06.04.2022

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Filed by: Balendu Shekhar

BALENDU SHEKHAR
Advocate for MoEF&CC
LB-17, 5 GauriSadan,

Hailey Road, New Delhi-110001

Mob. No. 9999666769

New Delhi

Dated: 04.04.2022 Email: officeofbalendu@gmail.com

BEFORE THE HON'BLE NATIONAL GREEN TRIBUNAL,

PRINCIPAL BENCH, NEW DELHI

O.A. NO. 136 OF 2020

IN THE MATTER OF:-

VETERANS FORUM FOR TRANSPARENCY
IN PUBLIC LIFE

...APPLICANT(S)

-VERSUS-

HIMACHAL PRADESH POLLUTION
CONTROL BOARD & ORS

...RESPONDENT(S)

**SUBMISSION/CLARIFICATION ON BEHALF OF
MINISTRY OF ENVIRONMENT, FOREST & CLIMATE
CHANGE (MoEF&CC) ON THE ISSUE OF RESIDUAL
ANTIBIOTICS IN INDUSTRIAL EFFLUENTS PURSUANT
AND API STANDARD IN VIEW OF ORDER DATED
21.01.2022 PASSED IN O.A. NO. 136 OF 2020.**

MOST RESPECTFULLY SHOWETH:

1. In the above titled case, Hon'ble Tribunal is examining the issue related with the discharge of Active Pharmaceutical Ingredients (API) and toxic industrial pollution in river Balad in Baddi industrial area in District Solan and rivers Sirsa and Satluj.
2. That in the earlier order dated 21.01.2022 passed in OA No 136/2020, Hon'ble Tribunal had observed:

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"...11. We find that there is gross failure on the part of the State PCB to act as per public trust doctrine in preventing discharge of toxic effluents containing harmful residue of antibiotics in water posing threat to aquatic life (reference: "bio monitoring of Sirsa River in Baddi area of Himachal Pradesh by Bhagat S. Chauhan, et al, International Journal of Theoretical and Applied Sciences 5 (1): 183-185(2013)) which is also in violation of the Water (Prevention and Control of Pollution) Act, 1974. Such failure of statutory duties is at the cost of public health and protection of environment for which Chairman and Member Secretary of the PCB owe an explanation which may be furnished before the next date. Mere fact that standards have not been revised by MoEF&CC of the residual antibiotics in industrial effluents can be no justification for State PCB not taking steps to prevent. Pending finalization of standards by MoEF&CC, State PCB can go by earlier standards or lay down standards by itself under

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section 17 of the Water Act. MoEF&CC needs to expedite the process of finalizing the standards in the interest of protection of environment.

12. Accordingly, MoEF&CC and the State PCB may take further remedial action expeditiously. The State PCB may ensure that no harmful components in the effluents are discharged into the water by the units in question or any other API unit. A joint Committee of nominee of MoEF&CC, CPCB, State PCB and District Magistrate, Solan may conduct inspection of the area and give a report of the status of violations and the remedial action taken within three months by e-mail at judicial-ngt@gov.in preferably in the form of searchable PDF/ OCR Support PDF and not in the form of Image PDF. The State PCB will be the nodal agency for compliance. The Committee may interact with the concerned stake holders, including the concerned Industries. The report may inter alia give status of performance of individual pharmaceutical units, particularly with reference to removal of API residue

by them and by the CETP, the number of pharma industries connected to CETP and those discharging effluents directly into the drain and the river. The report may further indicate chemical and biological water quality of rivers in question - Sirsa and Satluj, including the status of residue at relevant locations. CPCB may also suggest monitoring mechanism for API residue through a credible system so as to cover all pharma industries in the country discharging API residue directly or indirectly in river systems..."

3. That answering respondent's is submitting the following facts and details upon the issue of formulating policy on Active Pharmaceutical Ingredient (API) which are as under:

- a. MoEF&CC is the nodal agency in the Country regarding all the Environmental issues coupled with their responsibility to adhere to all the International commitments related with the environment. Accordingly, all its policies, guidelines and formulated

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yardsticks are expected to be evolved upon constructive and effective deliberation as per the prescribed norms with keeping fine balance among all the stakeholders.

b. It is worth to mention that issues involved in the instant case i.e., regarding desirable standard parameters to measure Active Pharmaceutical Ingredient (API) and acceptable norms regarding antibiotics residues value, for the drug related industries are in a highly nascent stage worldwide. Accordingly, much deliberation and discussion are still going on in all the countries about the ideal and acceptable measuring limit about antibiotics residues for drug industries. Simultaneously, untold rivalry among large drug manufacturing countries are also going on for imposing such a measuring limit of antibiotics residues for the drug manufacturers in other competitive countries.

c. That the Expert Committees formulated by MoEF&CC are constantly deliberating upon evolving the

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Environmental standard for various industrial sectors/categories. For the bulk drug and formulation industry too, various such deliberations have taken place by assimilating the views of various stakeholders. Relevant excerpts of 17th Expert Committee meeting dated 26.04.2019 is as under:

".... 5.2 Environmental Standard for Bulk Drug and Formulation Industry

The proposed revised draft Environmental Standard for Bulk Drug and Formulation Industry was presented by CPCB before the Expert Committee. It was informed that the draft notification was earlier discussed in the 16th Expert Committee Meeting held on 13/12/2018. After a detailed discussion on the proposed revised draft notification and following suggestions were made by the Committee:

- i. The title name of Pharmaceutical Industry should be changed to Bulk Drug and Formulation Industry.*

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- ii. In Additional Parameters, the limits shall be applicable to industries those are using Benzene, Toluene, Xylene, Methylene Chloride, Chlorobenzene in the effluent discharged.
- iii. API limits shall be applicable for units manufacturing API other than antibiotics in the effluent standard.
- iv. In order to control VOC emission, the condition of solvent recovery should be imposed, accordingly, the standard was introduced i.e. the total losses of solvent should not be more than 3% of the solvent consumed.

The Committee advised the CPCB to submit the revised notification based on the aforesaid observations to MoEF&CC to take a final view in the matter. (Action: CPCB)...."

Copy of the 17th Expert Committee meeting dated 26.04.2019 is attached herewith and marked as **Annexure R-1**

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d. That 18th Expert Committees formulated by MoEF&CC while deliberating upon the Environmental Standard for the bulk drug and formulation industry in its meeting dated 09.08.2019 held:

"..... 4.3. Environmental Standard for Bulk Drug and Formulation (Pharmaceutical) Industry

The proposed revised draft Environmental Standard for Bulk Drug and Formulation (Pharmaceutical) Industry was presented by CPCB before the Expert Committee. It was informed that the draft notification was earlier discussed in the 17th Expert Committee Meeting held on 26/04/2019 and suggestions made during the meeting by the committee were incorporated. The revised standards were again discussed and the Committee suggested incorporating following:

- 1) The standard for COD in effluent may be considered as 250 mg/l in place of 200 mg/l as the*

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250 mg/l is already prescribed in other similar types of industries.

2) The CPCB should develop guidelines for State Pollution Control Boards/ Pollution Control Committees (SPCBs/PCCs) for laboratory analysis of antibiotics in the effluent for implementation of proposed standards in future.

After incorporating the above suggestions the Committee recommended the Ministry may issue the draft notification inviting public suggestion in accordance with EPA 1986...."

Copy of the 18th Expert Committee meeting dated 09.08.2019 is attached herewith and marked as **Annexure R-2**

e. The answering respondent being conscious about the facts that in the field of drug manufacturing activities due to higher cost, India is facing stiff competition from other countries, especially from China and has in recent times become no. 2 in API manufacturing. For

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MoEF&CC, it is equally obligated that any norms should not compromise with the environmental requirements, but should be prescribed in such a proposition that there is no excess financial burden to the industry as well to retain their international competitiveness. During one of the deliberation before Expert Committee of MoEF&CC in its meeting dated 9th December, 2020, it has been observed:

"...3.2 Agenda A (ii): Environmental Standard for Bulk Drug and Formulation (Pharmaceutical) Industry

The draft notification for Environmental Standard for Bulk Drug and Formulation (Pharmaceutical) Industry was presented by CPCB in the 19th meeting of the Expert Committee held on 20.05.2020. It was informed that the draft notification was placed on the website of the Ministry for public consultation on 23.01.2020 and more than 35 numbers of suggestions were

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received which includes association, NGOs, Individual experts and industry. The comment(s)/suggestion(s) received have been assessed for their acceptability based on the concern raised vis-a-vis their feasibility, viability and relevance to the objective of prescribing norms. The committee deliberated on each para of the proposed standard.

The Joint Secretary, Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals as a special invitee highlighted the present status of the pharma industry and the challenges arising due to COVID-19 demand. It was highlighted that due to higher cost, India is facing stiff competition from other countries, specially China and has in recent times become no. 2 in API manufacturing. He stressed that the norms should not compromise with the environmental requirements, but should be prescribed in such a proposition that there is no excess financial

burden to the industry to ²⁵⁰ retain their international competitiveness. He also highlighted the concern raised by association of Bulk drug and pharmaceutical manufacturing units specially on monitoring location proposed in the draft. He requested that in the present situation, prescribing standard on Antibiotic residues may be a challenge for the industry to meet and it was expressed that the committee may take appropriate consideration of the concern raised by the associations.

The draft was deliberated point wise and based on the discussion; the Committee recommended certain modifications on additional parameters, the solvent losses, and provision of land disposal etc. for consideration of the Ministry.

Further the matter was re-examined in the Ministry in light of representation received from

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the Department of Pharma. A meeting under the chairmanship of Secretary- EFCC with various stakeholders, including CPCB, pharma association, Ministry of Health, Department of Pharma and experts was held. Owing to the concern on the PNEC value and its dynamic nature, it was observed that it will be a compliance challenge for any static treatment option to meet the dynamic nature of the PNEC values published by a consortium of Antibiotics Manufacturer. Considering the implementation, monitoring and compliance challenges, it was decided that CPCB may explore these challenges and also compare international practices on imposing PNEC values as regulatory provision for discharge standard to address such concerns. In view of the above, the standard was revised and placed before the expert committee for consideration on the concerns of compliance, dynamic value of PNEC and prevailing

international practices on the evolving nature of PNEC understanding.

ShriSundeep, Scientist F, MoEFCC made a detailed presentation before the committee and clarified the apprehensions of Industry Associations and Department of Pharma that the standards are applicable on the units involved in discharge and emissions, since April 1996. The present proposals are aligned with the emission norms stipulated for similar processes and applicable to other industries. A timeline relief of one year for meeting the newly introduced emission and discharge norms is also proposed for consideration by the committee owing to COVID-19 impact.

The committee after details deliberation on each aspect of the modified discharge norms in notification recommended to modified/incorporated the followings:

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1. Ammonia and Nitrate was considered to be an important parameter in light of concern of polluted river stretches, and therefore it may be removed from additional parameters and made as compulsory parameter applicable to all units and CETP at discharge point.
2. Industry permitted to discharge/dispose their effluent to CETP shall be governed by the provision of notified CETP norms dated 01/01/2016.
3. Additional Parameters of Chlorides and Sulphate may be removed and concern of impact on land disposal may be addressed by introducing Sodium Adsorption Ratio (SAR) with upper limit of 26. CPCB may provide appropriate norms of SAR.
4. Owing to the complexity and non-availability of any universally accepted standardized method to test Total API concentration in wastewater

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matrix, the committee felt necessary to remove the proposed norms of Total API from the additional parameter as of now.

5. Any discharge to inland water bodies or for horticulture or irrigation or land disposal of treated process wastewater from any industry and or to CETP shall not be considered as Zero Liquid Discharge (ZLD) and the stipulated norms in the notification shall be applicable to all such discharges.

6. The total loss from annual inventory of solvents from storage area shall not be more than 5% of cumulative on an annual basis.

7. CPCB shall prepare a standard protocol for determining the loss and relevant record maintenance practices for verification purposes in consultation with industry associations and other organizations. Provision of One year time may be allowed to the industry for compliance of these

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norms considering the time required to make necessary abatement cum control arrangement.

8. Antibiotic residues concentration in the ambient environment is rising and its consequences are far reaching. Predicted No-Effect Concentrations (PNECs) value of Antibiotic residues are the probable values at the mixing point in the receiving environment, which reflects the critical level of any adverse impact on the receiving ecology or its component.

The proposed values of various Antibiotic residues (PNEC) in draft notification were for its applicability at the inlet of treatment facility (applicable on raw influent). It was felt that the purpose was to avoid any adverse impact on the receiving environment and also to promote comprehensive and efficient performance of the treatment facility. CPCB has observed that there is significant reduction in monitored Antibiotic

residues concentration in efficient operating treatment facilities. The present notification proposal is for discharge norms and therefore, any stipulation of norms before treatment facility doesn't serve the purpose or objective, as the outcome will be dependent on the efficacy of the treatment facility.

It was also observed that the PNEC values considered were based on the studies carried out by international Alliance of Antibiotic manufacturers and presently it is yet to be accepted as a discharge regulatory provision anywhere. The rationale of the proposed values was not scientifically derived based on field performance studies for all proposed parameters.

Further, the PNEC values are dynamic and are in process of evolving. The parameter and its values both keep on changing based on the API under use and imposing all parameters will lead to

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uncalled challenges of standardization of monitoring protocol in a dynamic environment. The challenge associated with meeting dynamic values with static infrastructure or through regular retrofitting may lead to more non-compliance of other parameters as well.

Considering the evolving nature of PENC values and associated challenges of infrastructural implementation, monitoring constraints and absences of acceptable standardized testing of samples in complex metrics of pollutants, the committee felt that the discharge norms based on dynamics PNEC values for Antibiotics residue may be dropped from the proposed standard for discharge.

The present ecosystem for monitoring and implementation of Antibiotics residue concentration in complex wastewater matrix at low concentration with dynamic PNEC values

based standard will lead to challenges of monitoring and compliance. However, it was felt that infrastructure and capacity development and readiness of the regulatory bodies, stability in PNEC values in varying Indian conditions are some of the essentials for adopting any regulatory provision on AMR.

It was decided that association of Antibiotics manufacturing industries in India shall undertake a comprehensive study on AMR impact at all major critical locations identified by CPCB. The study shall be obligatory on the Antibiotics manufacturer and protocol for the study may be prepared in consultation with CPCB and Department of Pharma, Ministry of Chemicals & Fertilizers.

Accordingly, the committee recommended to drop the proposal of Antibiotics residue discharge norms and suggested that MoEF&CC may ask

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CPCB to issue necessary direction to Department of Pharma, Ministry of Chemicals & Fertilizers to ensure a database is created on the AMR status in the country with the help of association of Antibiotics manufacturing units. CPCB shall provide the monitoring protocol for the purpose.

9. To contain any adverse impact arising from the disposal of contaminated sludge and or concentrate or reject or residue generated from wastewater treatment and management facility of industry or CETP, it is felt necessary to have their management and disposal with utmost care. Therefore, all sludge (chemical or biological) or any residue, reject, concentrate generated from wastewater treatment or its management facility at Industry engaged in manufacturing of bulk drug or formulation of Pharmaceuticals or CETP catering such industries shall be classified as Hazardous Waste within the provision of subsection 17 of section 3 of Hazardous and

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Other Wastes (Management and Trans boundary Movement) Rules, 2016 and shall be managed within the applicable provisions thereof.

10. All new norms / parameters introduced in this notification shall be applicable after one year from the date of this notification in due consideration of COVID-19 Impact. Based on above deliberations and recommendation of the committee the draft notification was modified as attached at Annexure II of the First Expert Committee's report. The committee recommend for considering the notification under Environment (Protection) Rules, 1986 with appropriate legal modification..."

Copy of the First Expert Committee Meeting to Environmental Standards (through video conferencing) dated 09.12.2020 is attached herewith and marked as **Annexure R-3**

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- f. It is submitted that during the deliberation Expert Committee members views such as, that the PNEC numbers for a specific chemical is a deterministic approach to estimate environmental risk at local or regional scales. Further, these values are not limited to API and may include other chemical having similar risk on the receiving environment. Therefore, in case of assessment of PNEC values for a particular chemical, the standard formulation requires site and eco-system studies and with due consideration of point sources as well as diffuse sources or multiple point sources discharges contributing from households, sewage and other sources.
- g. Further, it is submitted that discussion also included that scientific rationale and the present derivation of PNEC for use in environmental risk lacks some scientific validity because the assessment factors are derived empirically. Accordingly, Expert Committee suggested to create appropriate data before determining any value for PNEC or API.

- h. Further, it is submitted that views during discussion of Expert committee also included that ecosystem are as sensitive as the most sensitive species and that the ecosystem function is dependent on the ecosystem structure. Therefore, PNECs derived from single-species toxicity data may not represent the sensitivity of site specific ecosystem and its toxicology.
- i. That the MoEF&CC for laying the standards for Bulk Drug and Formulation (Pharmaceutical) Industry including Antibiotics residue had also initiated the needed process for bringing notifications for handling the instant issues which are as under:
- i. The draft of the notifications was brought in the public domain for seeking suggestions/objections for statutory 60 days' time period for laying the standards for Bulk Drug and Formulation (Pharmaceutical) Industry including Antibiotics residue parameters were notified in the Gazette of India vide notification GSR 44(E) dated 23.01.2020.

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Copy of the draft notification vide notification GSR 44(E) dated 23.01.2020 is attached herewith and marked as **Annexure R-4**

- ii. Upon the instant issues, a meeting on 28.07.2020 under the chairmanship of Secretary- Environment, Forest, and Climate & Change was also conducted with all stakeholders, including Central Pollution Control Board (CPCB), Pharma association, Ministry of Health (MoHFW), Department of Pharma and experts. where it was unanimously observed that there is technical challenge in compliance for any static treatment option to meet the dynamic nature of the predicted no-effect Concentration (PNEC)** values published by a consortium of Antibiotics manufacturers.
- iii. Considering the implementation, monitoring and compliance challenges, it was decided that CPCB may explore these challenges and also compare international practices on imposing PNEC values as regulatory provision for discharge standard to address such concerns.

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- iv. The expert committee of MOEF&CC in its meeting held on 20th May, 2020 had also recommended that owing to the complexity and non-availability of any universally accepted standardized method to test Total API concentration in complex wastewater matrix; it was felt necessary to remove the proposed norms of Total API from the additional parameter as of now. Accordingly, the parameter for total API concentration was also removed.
- v. That keeping all the aforesaid facts and public comments received upon the draft notification dated 23.01.2020, the final standards were notified under Environment (Protection) Rules, 1986 vide GSR 541(E) dated 06.08.2021.

Copy of final Standard under Environment (Protection) Rules, 1986 vide GSR 541(E) dated 06.08.2021 is attached herewith and marked as **Annexure R-5**

4. Central Pollution Control Board (CPCB) have been entrusted to develop database as well as methodology

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for analysis of identified API and also the corresponding site specific PNEC values to enable a scientific rationale for deriving standards for such parameters. It is submitted that CPCB has made some progress on development of methodology for sampling and analysis of certain APIs, which is based on in house competency and is broadly based on US-EPA guidelines. These methodologies have been circulated to all SPCBs/PCCs. The proposed methodologies are yet to be validated by laboratory of SPCBs or other scientific laboratories by carrying an inter-laboratory competency comparison. These methodology needs to be further improvised to have its acceptability by undertaking inter-laboratory comparison, Standardization of the process to be made acceptable to the provisions of NABL accreditation, which is minimum requirement for qualifying the methodology and process to be acceptable under the provisions of E(P) Act, 1986 for acceptance of analytical results to be used for regulatory purpose.

5. It is submitted UN- UNEP/IPCS Training Module No. 3

- Section B - Environmental Risk Assessment -

Chapter 3,- Effect Assessment (para 3.1) has suggested some methodology, including the limitation, to be adopted for development of PNEC values to have environmental risk assessment arising out of API and other chemicals. These PNAC values are site specific and eco-system based. A details study on toxology vis-à-vis the expected chemicals needs to be done to standardized PNEC values. However, these values may also have risk of being dynamic over a period of time and therefore, more research is required to standardized the criteria for legal regulation purpose.

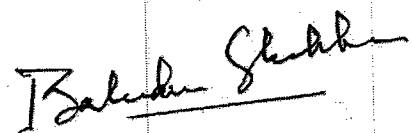
6. That MoEF&CC as on date has already formulated the necessary provisions for dealing the "API" issue for drug industries in India. Though, CPCB has also been enshrined the responsibilities to explore more on this issue which would eventually lead to a better handling of such effluents while enhancing the current structure to bear the current level of such discharge.

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7. That, apart from the above mentioned facts and details, as per Section 17 of the Water (Prevention and Control of Pollution) Act, 1974; it is evident that the State Pollution Control Board equally possesses the power to evolve efficient methods of disposal of sewage and trade effluents on land.

8. That the answering respondent MoEF&CC is presently placing the actual facts and development upon the instant issues. However, as the issue regarding evolution of API and PNEC standard is at a nascent stage worldwide, answering respondents would keep tuning its standards and yardsticks as per desirable terms.

FILED BY:



BALENDU SHEKHAR
Advocate for MoEF&CC

LB-17, 5 Gauri Sadan,
Hailey Road, New Delhi-110001

Mob. No. 9999666769

New Delhi

Dated: 04.04.2022

Email: officeofbalendu@gmail.com

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F. No. 15017/42/2007-CPW

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ANNEXURE R-1

GOVERNMENT OF INDIA

**MINISTRY OF ENVIRONMENT, FOREST & CLIMATE CHANGE
(CP DIVISION)**

Indira Paryavaran Bhawan
Level-II, Prithvi Wing, Jorbagh Road
New Delhi-110003

Dated: 10th May, 2019

To

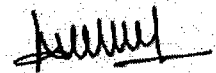
As per list enclosed

Subject: Minutes of the 17th Expert Committee Meeting on Environmental Standards held on 26/04/2019 at Indira Paryavaran Bhawan, MoEF&CC, New Delhi- regarding.

Sir,

Please find herewith a copy of minutes of the 17th Expert Committee Meeting on Environmental Standards held on 26/04/2019 under the Chairmanship of Shri Arvind Kumar Nautiyal, Joint Secretary, Ministry of Environment Forest & Climate Change, New Delhi on the mentioned subject for your perusal and necessary action.

Yours faithfully,



(Dr. H. Kharkwal)
Additional Director/
Scientist 'E'

Encl: as above

List of Members

1. Joint Secretary/Adviser (CP Division) : Chairman
2. Representative of Ministry of Heavy Industries, Udyog Bhawan, Rafi Marg, New Delhi- 110001 : Member
3. Director & Head (Chemical), BIS, 9, Bahadur Shah Zafar Marg New Delhi : Member
4. Executive Director, (R&D) IOCL, Faridabad, Sector-13, Faridabad, Haryana : Member
5. Director, Department of Health & Family Welfare, M/o Health, Family & Welfare, Udyog Bhawan, New Delhi : Member
6. Advisor (Tech), Ministry of Coal, Shashtri Bhawan New Delhi-110001 : Member
7. Controller General, Indian Bureau of Mines, Civil lines-440001 Nagpur : Member
8. Director, National Institute of Occupational Health (NIOH), ICMR, Ahmadabad-380016 : Member
9. Director/Addl. Director (CPDiv), MoEF&CC : Member Convener
10. Head (Env Division), CII, ITC Centre of Excellence for sustainable, 2nd Floor, Thapar House, 124, Janpath New Delhi : Member
11. Head (Env. Division), PHD Chamber of Commerce and Industries Kranti Marg, Siri Institutional Area, Block-a, Nipccd Campus, Hauz Khas, New Delhi-110016: Member
12. Chief Engineer (EMO), Central Water Commission, Sewa Bhawan, R.K. Puram, Delhi : Member
13. Secretary, Central Electricity Authority, Sewa Bhawan, Sector-5, R.K. Puram, Delhi : Member
14. Sh. K.P. Nyati, Environment Professor, D-1-C/56, A, Janakpuri New Delhi-110058 : Member
15. Dr. S. P. Chakraborty, Ex-Member Secretary/Director, CPCB, A-601, Mansara Apartment, C-line Calcutta- Vasundhara Enclave, Delhi : Member
16. Member Secretary, Central Pollution Control Board, Delhi : Member

Res of the 17th Expert Committee Meeting held on 26th April, 2019 at Indira Paryavaran Bhawan, MoEF&CC, New Delhi for finalization of the Environmental Standards for different industries.

The 17th Meeting of the Expert Committee was held on 26th April, 2019 at Indira Paryavaran Bhawan, MoEF&CC, New Delhi under the Chairmanship of Shri A.K. Nautiyal, Joint Secretary, MoEF&CC for finalization of Two Amendment, Five Final and Two draft environmental standards in respect of Nine Industrial Sector / Categories, which are as follows:

(A) Proposed for issue of the Amendment notification under EPA 1986:-

- i. Water Quality Standard for Coastal Water Marine Outfalls in respect of Primary Water Quality Criteria for Class SW-III Waters and Class SW-V Water
- ii. Standards for Boilers using Industries for SO₂ and NO_x

(B) Proposed for issue of the Final notification under EPA 1986:-

- i. Automobile Service Stations, Bus Depots or Workshop
- ii. Fermentation Industry,
- iii. Coffee Industry,
- iv. Tannery Industry,
- v. Revised Discharge Standards for STP vide NGT order dated 21/12/2018

(C) Proposed for issue of the Draft notification under EPA 1986:-

- i. Diesel Locomotives Standards
- ii. Bulk Drug and Formulation Industry Standards

1.1. At the outset, the Chairman welcomed the Members of the Expert Committee and the stakeholders representing the above sectors/categories. In his opening remarks he appraised the background of the standards for emission or discharge of environmental pollutants viz. Air pollutants, water pollutants and noise limits from industries, operations or processes with an aim to protect and improve the quality of the environment and abate environmental pollution. He requested Dr. H. Kharkwal, Member Secretary / Scientist 'E', MoEF&CC to brief about the meeting.

1.2. Dr. Kharkwal has appraised the background of the meeting and also gave brief background for finalization of the Environmental Standards for different industries / categories. Afterwards, he requested CPCB to present the details of each proposed Amendment standards for (A) above, public comments received with regards to i to iv draft notification at (B) above and the proposed draft standards for (C) above. The list of participants is at **Annexure-A**.

1.3. The Expert Committee took up amendment/final/draft notifications as indicated above. The stakeholders from each of the above sectors were invited for discussions when the sectors/categories were taken.

2. Confirmation of Minutes of the 16th Expert Committee Meeting

The Comments sought on draft minutes of the 16th Expert Committee Meeting held on dated 13th December, 2018. Since, there is no comment, this minute were confirmed.

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3. Proposed for issue of the Amendment Notification under EPA 1986:-

3.1. **Consideration of Amendment regarding Water Quality Standard for Coastal Water Marine Outfalls in respect of Primary Water Quality Criteria for Class SW-III Waters and Class SW-V Water.**

The proposed amendment draft notification for Water Quality Standard for Coastal Water Marine Outfalls in respect of Primary Water Quality Criteria for Class SW-III Waters and Class SW-V Water under Environment (Protection) Rules, 1986 was presented by Dr. S. R. Marigoudar, Scientist 'D', National Centre for Coastal Research (NCCR), Ministry of Earth Science (MoES). It was informed that the draft notification was earlier discussed in the 16th Expert Committee Meeting held on 13/12/2018 and also explained the background, purpose, comments provided by the coastal SPCBs, PCCs, concerned Government Departments and Institutions as well as the proposed criteria.

After detailed deliberations, Expert Committee suggested for CPCB and MoES to check the values of proposed standards vis-à-vis existing BIS standards. The CPCB and MoES shall consult each other on the aforesaid and CPCB shall propose the draft notification to be issued under EP Act, 1986. **(Action: CPCB)**

3.2. **Environmental Standards for Boilers using Industries for SO₂ and NO_x**

The proposed amendment notification for Boilers using Industries for SO₂ and NO_x was presented by Dr. Nazimuddin, Scientist 'E', CPCB. It was informed that the final notification was issued on 29/01/2018. In the draft notification for the same pet coke boilers was mentioned as a separate category about which there was a foot note regarding continuous monitoring requirement whereas in the final notification, the 'pet coke' boilers had been merged along with 'other fuels' boiler as a result of which the continuous monitoring requirement proposed for pet coke boilers have been inadvertently applied to all boilers. The CPCB requested amendment after table in para 2 shall be substituted as:

***** "The emission from industrial boilers using Petcoke of Fuel/Furnace oil (FO) as fuel would be required to install online monitoring system as per online monitoring mechanism put in place by Central Pollution Control Board from time to time".***

After detailed discussion on the notification, Committee recommended the amendment and suggested to notify under Environment (Protection) Rules, 1986.

(Action: MoEF&CC)

4. Proposed for issue of the Final Notification under EPA 1986:-

4.1 **Environmental Standard for Automobile Service Stations, Bus Depots or Workshop**

The proposed final notification for environmental standard Automobile Service Stations, Bus Depots or Workshop was presented by CPCB before the Expert Committee. The proposed draft notification was placed on website of MoEF&CC for public consultation on 05/12/2018. On the draft notification only one comment /suggestion was received from Society of Indian Automobile Manufacturers (SIAM) and CPCBs response was noted by the Committee.

After detailed discussion on the notification, Committee recommended to notify the final notification by adding a foot note 'Solid Wastes/ Hazardous Waste, if any shall be

disposed off as per the Solid Waste Management Rules 2016 and Hazardous and Other Waste (Management & Trans-boundary Movement) Rules, 2016', under Environment (Protection) Rules, 1986 as at **Annexure B**.
(Action: CPCB)

4.2 Environmental Standard for Fermentation Industry

The final notification for Environmental Standard for Fermentation Industry was presented by CPCB before the Expert Committee. It was informed that the draft notification was placed on website of MoEF&CC for public consultation on 06/07/2018. On the draft notification comments / suggestions were received from different Stakeholders and same were forwarded to CPCB. Based on the comments / suggestions, CPCB proposed the final notification. On which Committee made following observations:

I. Molasses and grain based distillery- The Committee agreed to the proposal of imposing Zero Liquid Discharge standards in these sectors. However the Expert Committee observed that specifying technologies in the notification for environmental standards should be avoid as far as possible. It was clarified by CPCB representatives that available and established technologies for achieving ZLD based on the experience and monitoring data available with CPCB was included in the proposed revised standard notification and option for alternate technologies which achieves the desired output has been kept open, with the approval of SPCB. It was informed by CPCB representatives that all operating units in Ganga Basin have implemented ZLD through proposed routes and requirements. CPCB representatives further clarified that the output limits in terms of volume reduction with solid concentration of concentrated spent wash has been specified to ensure that substantial volume reduction and recovery & reuse of water is achieved and possibility of dilution is avoided. The Committee concluded that indicative technologies and options for achieving ZLD can be part of foot notes or separate directions to install the required systems and achieve ZLD, as per the specified technical routes, shall be issued by CPCB and there may not be part of the main standard.

II. Breweries & Malteries - The Committee generally agreed to the proposed standards as notified and also to correct the anomaly of BOD standard for land discharge as 100 mg/l maximum against the published standard of 20 mg/l maximum. The Committee, after discussion agreed to the effluent discharge standards of pH-6.5-8.5, BOD-20 mg/l & 100 mg/l respectively for surface water and land discharge, SS-50 mg/l & Colour-350 PCU for Malteries & Breweries.

III. Emission standards for Spent wash incineration boilers: After discussion, it was decided by the Committee that an emission standard of P.M-100mg/Nm³ shall be made applicable for both new and existing Spent Wash incineration boilers. The existing incineration boilers, presently few in number, may be phased out or retrofitted in the stipulated time line for achieving the proposed standard. CPCB representatives and the representatives from the industries also agreed to this decision of the committee.

IV. Time lines for achieving the standard: As decided in the previous meeting, the Committee agreed that a timeline of 2 years from the date of publication shall be given to the industries for achieving the above proposed standards.

The Committee advised CPCB to submit the revised notification based on the aforesaid observations to MoEF&CC to take a final view in the matter.

(Action: CPCB)

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4.3 Environmental Standard for Coffee Industry

The final notification for Environmental Standard for Coffee Industry was presented by CPCB before the Expert Committee. It was informed that the draft notification was placed on website of MoEF&CC for public consultation on 24/10/2018. On the draft notification comments /suggestions were received from different Stakeholders and same forwarded to CPCB. Based on the comments / suggestions, CPCB proposed the final notification. CPCB proposed revision of the existing notified standards as:

- The revised standard for instant & dry processing and wet/parchment processing for land application.
- Options for discharge on surface water bodies and proposed standards for the same.
- Revised Liner system specification for solar evaporation.
- Options for alternative lining material.

After detailed discussions, the Committee recommended that:

- The standards for land application for instant / dry processing and wet / parchment processing should be in uniformity with other sector.
- The representative from Coffee Board and Coffee Planter Association requested that option for discharge on surface water body should not be given. The Committee discussed the issues and recommended that as desired by the Coffee Board and Planter Association, Coffee Estates should not be allowed to discharge on surface water body/stream/river and accordingly this option and corresponding standard are now removed with appropriate foot note in this regard.

The Committee advised CPCB to submit the revised notification based on the aforesaid observations to MoEF&CC to take a final view in the matter. **(Action: CPCB)**

4.4 Environmental Standard for Tannery Industry

The proposed final notification for Environmental Standard Tannery Industry was presented by CPCB before the Expert Committee. The draft notification was placed on website of MoEF&CC for public consultation on 01/08/2018. On the draft notification comments /suggestions were received from different Stakeholders and same forwarded to CPCB. Based on the comments / suggestions, CPCB proposed the final notification. After detailed discussions, the following decisions were taken:

- BOD and TSS limits to be kept as 20 mg/l and 50 mg/l. Industry should make necessary improvements in ETPs to comply with these stringent limits.
- TDS parameter to be introduced with its limits as 2100 mg/l to provide level playing field for standalone units and units in clusters.
- In view of inadequate information about total nitrogen content in raw effluent and thus cost implications of the new parameters and keeping in view that introducing NH₃-N parameter will have impact not only on standalone tanneries for which the revision in standards is proposed but also on CETPs which cover 90% tanneries, the Members agreed to defer introduction of this parameter.

Cr⁶⁺ parameter to be introduced with its limits as 0.1mg/l as proposed and Industry should take necessary precautions in chemical handling to comply with the prescribed limit.

In view of the difficulties expressed by the industry representatives in complying the proposed limits for Maximum Specific Water Consumption (SWC) for different raw materials / sets of processes, the Committee agreed to accept following changes in Maximum SWC limits:

- Raw to Wet blue / Wet white / Vegetable tanning - 20 m³ per ton hide/skin
- Post tanning processes - 20 m³ per ton hide/skin
- Raw to Finished - 40 m³ per ton hide/skin

The Committee advised CPCB to submit the revised notification based on the aforesaid observations to MoEF&CC to take a final view in the matter. (Action: CPCB)

4.5. Revised Discharge Standards for STP vide NGT order dated 21/12/2018

It was informed by Dr. H. Kharkwal, Scientist 'E', MoEF&CC that in the matter O.A No. 1069/2018 (M.A.Nos. 1792/2018 & 1793/2018), Nitin Shankar Deshpande Vs. UOI & Ors, the Hon'ble NGT was constituted an Expert Committee comprising of the Director or his nominee (Senior Professor of Environment Engineering) IIT Kanpur and IIT Roorkee, Senior representative of NEERI and Senior Scientist nominated by CPCB to review the matter of formulation of Discharge Standards for Sewage Treatment Plant and suggested to submit a report. The relevant para of the NGT Order is reproduced here-below:

"19. The report may be furnished by the CPCB to the MoEF&CC as well as to this Tribunal by email at ngt.filing@gmail.com on or before 31.03.2019. It will be open to MoEF&CC to take a fresh view in the light of the report and furnish its comments by email before the next date. The registry may forward the report to the applicant also who may file his comments, if any, before the next date."

In compliance of above NGT Order, the CPCB had forwarded a report of the Expert Committee constituted by Hon'ble NGT and same was discussed with concerned CPCB Officers on 18/04/2019 and suggested it should be placed in the next meeting of the Expert Committee on Environmental Standard for consideration. The Report was placed before the Expert Committee on 26/04/2019.

After detailed discussion the Expert Committee noted that the matter of Environmental Standards for STP a Sub-judice before Hon'ble NGT. The matter shall be taken in next meeting of the Expert Committee accordingly. (Action: MoEF&CC)

5. Proposed for issue of the Draft Notification under EPA 1986:-

5.1 Environmental Standard for Diesel Locomotives

The proposed draft notification for environmental standard Diesel Locomotives was presented by CPCB before the Expert Committee and intimated that the proposed standard formulated by the CPCB constituted a Standing Committee. Before presentation, Dr. H.Kharkwal, Scientist 'E', MoEF&CC informed the Expert Committee that in compliance of Hon'ble NGT vide order dated 23rd December, 2016 in the matter O.A.No.356 of 2013, S.K. Goyal Vs Chairperson, CPCB and Ors, emission norms need to be framed for diesel locomotives was earlier discussed in the 13th Expert Committee

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Meeting held on 8th & 9th November, 2017. In this connection meetings have been held on 02/02/2017 with the Ministry of Railway (MoR), RITES, RDSO, CPCB and MoEF&CC. In the meeting, it was decided for that the emission data of total 59 (38 ALCO + 21 EMD) locomotives are required to be considered as representative sample for the study to achieve confidence level of 95% and margin of error of 10% and issued by March 2019. CPCB in consultation of MoR, so far was examined only 23 representative's diesel locomotives. In view of the above the committee was of the opinion that CPCB shall complete the examination of the balance locomotives and formulate the standards at the earliest within a period of three months. Thereafter, the Ministry shall issue the draft notification inviting public comments under EPA 1986. The Report from CPCB was received end of March, 2019.

The Ministry of Railway representative intimated that Railway is going for 100% electrification and hence development of Standards for Railway Loco engines is uncalled for. The Expert Committee wanted to know from the Railway representatives about the time line for conversion to electric loco engines, which was not responded to in clear terms. Moreover, the Hon'ble NGT's directives need to be complied with, irrespective of the no's of Diesel Locomotives.

After detailed deliberations, the Expert Committee noted that the proposed standard by CPCB had not been shared with Ministry of Railway and suggested that Ministry of Railway advise their observations to CPCB / MoEF&CC by 17/05/2019 for further consideration. Thereafter CPCB shall propose the revised draft notification to MoEF&CC and Ministry shall issue the draft notification inviting public comments under EP Act, 1986.

(Action: CPCB)

5.2 Environmental Standard for Bulk Drug and Formulation Industry

The proposed revised draft Environmental Standard for Bulk Drug and Formulation Industry was presented by CPCB before the Expert Committee. It was informed that the draft notification was earlier discussed in the 16th Expert Committee Meeting held on 13/12/2018. After detailed discussion on the proposed revised draft notification and following suggestions were made by the Committee:

- i. The title name of Pharmaceutical Industry should be changed to Bulk Drug and Formulation Industry.
- ii. In Additional Parameters, the limits shall be applicable to industries those are using Benzene, Toluene, Xylene, Methylene Chloride, Chlorobenzene in the effluent discharged.
- iii. API limits shall be applicable for units manufacturing API other than antibiotics in the effluent standard.
- iv. In order to control VOC emission, the condition of solvent recovery should be imposed, accordingly the standard was introduced i.e. the total losses of solvent should not be more than 3% of the solvent consumed.

The Committee advised the CPCB to submit the revised notification based on the aforesaid observations to MoEF&CC to take a final view in the matter. (Action: CPCB)

6. The meeting ended with vote of thanks to the Chair.

List of the Participants who attended the 17th meeting of the Expert Committee to finalize the Environment Standards held on 26th April, 2019 at Indira Paryavaran Bhawan, Jor Bagh Road, New Delhi.

S. No.	Name	Designation & Name of Organisation
1.	Shri A. K. Nautiyal	Chairman & Joint Secretary, MoEF&CC
2.	Dr. K. P. Nyati	Expert Member
3.	Shri S.P. Chakrabarti	Expert Member, Ex-MS, CPCB,
4.	Shri A.K. Diwakar	Expert Member (Representative), Sr. Manager, Ministry of Coal / CIL
5.	Ms. B. Sandhya	Expert Member (Representative), Scientist 'D', BIS, New Delhi
6.	Shri R. K. Jaiswal	Expert Member (Representative), Development Officer, D/o Heavy Industry
7.	Shri Makarand Phadke	Special Invitee, Director (Sugar & Veg. Oil), Department of Food & Public Distribution, New Delhi
8.	Shri S. Anil Kumar	Special Invitee, JTO, Department of Food & Public Distribution
9.	Ms. Supriya Devasthali	Special Invitee, Director, DIPP
10.	Ms. Remya Prabha	Special Invitee, Deputy Director (Policy)
11.	Dr. D.S. Kharat	Invitee, Scientist 'E', CPCB
12.	Shri P.K. Mishra	Invitee, Scientist 'E' CPCB
13.	Shri Gurnam Singh	Invitee, Scientist 'E' CPCB
14.	Shri Dinbandhu Gouda	Invitee, Scientist 'E' CPCB
15.	Shri Nazimuddin	Invitee, Scientist 'E' CPCB
16.	Shri J.Chandra Babu	Invitee, Scientist 'D' CPCB
17.	Ms. Smriti Upadhyay	Invitee, Scientist 'D' CPCB
18.	Shri Vivek K.	Invitee, Scientist 'D' CPCB
19.	Shri Mukesh Balodhi	Invitee, Scientist 'D' CPCB
20.	Shri Kamlesh Singh	Invitee, Scientist 'D' CPCB
21.	Shri Y. N. Mishra	Invitee, Scientist 'C' CPCB
22.	Shri Kedarnath Das	Invitee, Scientist 'C' CPCB
23.	Ms. Alka Srivastava	Invitee, SSA, CPCB
24.	Dr. H. Kharkwal	Member Convener, Scientist 'E', MoEF&CC
Environmental Standards for Sea Water Criteria for Metal & Pesticides:		
25.	Dr. S.R. Marigoudar	Scientist 'D', National Centre for Coastal Research (NCCR), Ministry of Earth Science (MoES).
Automobile Service Station and Bus Depot:		
26.	Dr. Rashid Hasan	Advisor, SIAM
Environmental Standards for Fermentation Industry:		
27.	Shri G.K.Thakur	Director, Indian Sugar Mills Association
28.	Shri V.N. Raina	AIDA
29.	Shri K.P. Singh	AIDA

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30.	Shri Narendra Kumar Jain	AIDA
31.	Shri Sandeep Kumar Misra	AIDA (Mawana Sugar)
32.	Shri Ashish Awasthi	Triveni Engg. & Ind. Ltd
Environmental Standards for Coffee Industry		
33.	Dr. J. S. Nagaraja	Coffee Board, CCRI, CRS
34.	Dr. M. M. Chersgappa	Karnataka Planters Association
35.	Shri Vijay Karnad	Karnataka Planters Association
Tannery Industry		
36.	Shri Anil Kumar Mishra	Regional Director, CLE
37.	Shri Vinay Singh	Calcutta Leather Complex Tanners Association
38.	Shri Arshad Jamal	Leather Industries Welfare Association
39.	Shri Ghular	Gujarat Tanners
40.	Shri C.M. Zaffarullah	Secretary, South India Tanners & Dealers Association
41.	Shri Adeel Arshad	All India Skin & Hide Tanners & Merchants Association (AISHTMA)
42.	Shri Faiyaz Ahmed	All India Skin & Hide Tanners & Merchants Association (AISHTMA)
43.	Shri R. Ramesh Prasad	All India Skin & Hide Tanners & Merchants Association AISHTMA)
44.	Shri C. Ramesh D.	All India Skin & Hide Tanners & Merchants Association AISHTMA)
Diesel Locomotives		
45.	Shri S.K. Tanti	DME(Tr) Railway Board
46.	Shri Sanjeev Wadehre	SSE, Railway Board
47.	Shri Vineet Singhal	Director, RDSO

Environmental Standard for Automobile Service Stations, Bus Depots or Workshop:

S.No.	Industry	Parameter	Standard
(1)	(2)	(3)	(4)
	Automobile Service Station, Bus Depot or Workshop	Effluent Standard	
		(Concentration not to exceed, in mg/l except for pH)	
		Inland Surface water/land for irrigation/Public Sewer	
		pH	6.5-8.5
		Total Suspended Solids	50
		Chemical Oxygen Demand	150
		Oil & Grease	10

Note:

- For Service Stations, Bus Depots and Workshops with metal pre-treatment facilities, limit of 5 mg/l of dissolved phosphates (as P) and 5 mg/l of zinc shall also apply
- Solid Wastes/ Hazardous Waste, if any shall be disposed off as per the Solid Waste Management Rules 2016 and Hazardous and Other Waste (Management & Trans-boundary Movement) Rules, 2016.

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ANNEXURE R-2

**F. No. 15017/42/2007-CPW
GOVERNMENT OF INDIA
MINISTRY OF ENVIRONMENT, FOREST & CLIMATE CHANGE
(CP DIVISION)**

Indira Paryavaran Bhawan
Level-II, Prithvi Wing, Jorbagh Road
New Delhi-110003

Dated: 25th September, 2019

To

As per list enclosed

Subject: Minutes of the 18th Expert Committee Meeting on Environmental Standards held on 09/08/2019 at Indira Paryavaran Bhawan, MoEF&CC, New Delhi- regarding.

Sir,

I am directed to forward herewith a copy of minutes of the 18th Expert Committee Meeting on Environmental Standards held on 09/08/2019 under the Chairmanship of Shri A.K. Nautiyal, Joint Secretary, Ministry of Environment Forest & Climate Change, New Delhi on the mentioned subject for your perusal and necessary action.

Yours faithfully,

Encl: as above

Vinod Kumar
25/9/19
(Vinod Kumar Kushwaha)
Section Officer

List of Members

1. Joint Secretary/Adviser (CP Division) : Chairman
2. Representative of Ministry of Heavy Industries, Udyog Bhawan, Rafi Marg, New Delhi- 110001 : Member
3. Director & Head (Chemical), BIS, 9, Bahadur Shah Zafar Marg New Delhi : Member
4. Executive Director, (R&D) IOCL, Faridabad, Sector-13, Faridabad, Haryana : Member
5. Director, Department of Health & Family Welfare, M/o Health, Family & Welfare, Udyog Bhawan, New Delhi : Member
6. Advisor (Tech), Ministry of Coal, Shashtri Bhawan New Delhi-110001 : Member
7. Controller General, Indian Bureau of Mines, Civil lines-440001 Nagpur : Member
8. Director, National Institute of Occupational Health (NIOH), ICMR, Ahmadabad-380016 : Member
9. Director/Addl. Director (CPDiv), MoEF&CC : Member Convener
10. Head (Env Division), CII, ITC Centre of Excellence for sustainable, 2nd Floor, Thapar House, 124, Janpathn New Delhi : Member
11. Head (Env. Division), PHD Chamber of Commerce and Industries Kranti Marg, Siri Institutional Area, Block-a, Nipccd Campus, Hauz Khas, New Delhi-110016: Member
12. Chief Engineer (EMO), Central Water Commission, Sewa Bhawan, R.K. Puram, Delhi : Member
13. Secretary, Central Electricity Authority, Sewa Bhawan, Sector-5, R.K. Puram, Delhi : Member
14. Sh. K.P. Nyati, Environment Professor, D-1-C/56, A, Janakpuri New Delhi-110058 : Member
15. Dr. S. P. Chakraborty, Ex-Member Secretary/Director, CPCB : Member
16. Member Secretary, Central Pollution Control Board, Delhi : Member

Minutes of the 18th Expert Committee Meeting held on 9th August, 2019 at Indira Paryavaran Bhawan, MoEF&CC, New Delhi for finalization of the Environmental Standards for different industries.

The 18th Meeting of the Expert Committee was held on 9th August, 2019 at Indira Paryavaran Bhawan, MoEF&CC, New Delhi under the Chairmanship of Shri A.K. Nautiyal, Joint Secretary, MoEF&CC for finalization of Four Final, Three Draft and One New Draft proposed environmental standards in respect of Eight(8) Industrial Sector / Categories, which are as follows:

(A) Proposed for issue of the Final Notification under EPA 1986: -

- i. Fermentation Industry,
- ii. Coffee Industry,
- iii. Tannery Industry,
- iv. Discharge Standards for Sewage Treatment Plants (STP) - Revised

(B) Proposed for issue of the Draft Notification under EPA 1986:-

- i. Water Quality Standard for Coastal Water Marine Outfalls in respect of Primary Water Quality Criteria for Class SW-III Waters and Class SW-V Water-Amendment,
- ii. Diesel Locomotives Standards
- iii. Bulk Drug and Formulation (Pharmaceutical) Industry Standards

(C) New Proposed Draft Notification under EPA 1986:-

- i. Environmental Standards for Hot Mix Plants

1.1. At the outset, the Chairman welcomed the Members of the Expert Committee and the Stakeholders representing the above sectors / categories. In his opening remarks he appraised the background of the proposed Final, Draft and New Notifications for different Eight (8) sectors. He requested CPCB to present the details of each of the notifications at (A), (B) and (C) above. The list of participants is at **Annexure-A**.

1.2. The Expert Committee took up final / draft / new notifications as indicated above. The CPCB concerned officers from each of the above sectors were invited for brief presentation when the sectors / categories were taken.

2. Confirmation of Minutes of the 17th Expert Committee Meeting

The Comments sought on draft minutes of the 17th Expert Committee Meeting held on dated 26th April, 2019. Since, there is no comment, this minute were confirmed.

3. Proposed for issue of the Final Notification under EPA 1986: -

3.1 Environmental Standard for Tannery Industry

The final revised notification for Environmental Standard Tannery Industry was presented by CPCB after incorporating the suggestions / recommendations of the 17th Expert Committee meeting held on 26/04/2019. After detailed discussions

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on the revised notification, Committee recommended a footnote should be added that: 'Standards for TDS shall not be applicable in case of marine disposal through proper marine outfall' and notify the final notification under Environment (Protection) Rules, 1986 as at Annexure B.

3.2 Environmental Standard for Coffee Industry

The final revised notification for Environmental Standard Coffee Industry was presented by CPCB after incorporating the suggestions / recommendations of the 17th Expert Committee meeting held on 26/04/2019. After detailed discussions on the proposed final revised notification, Committee recommended to notify the final notification under Environment (Protection) Rules, 1986 as at Annexure C.

3.3. Standard for Fermentation Industry

The final revised notification for Environmental Standard Fermentation Industry was presented by CPCB after incorporating the suggestions / recommendations of the 17th Expert Committee meeting held on 26/04/2019. After detailed discussions the Committee suggested / incorporate the following:

1. In footnote a) may be change as: "Molasses based distilleries shall achieve minimum volume reduction of 60% for raw spent wash through evaporation-concentration before utilizing in bio composting with press mud/incineration/dryer for achieving ZLD. The distilleries practicing incineration/drying or equivalent routes shall additionally achieve a minimum of 45 % solids in the concentrated spent wash."
2. Additionally, the following shall be inserted at footnote point no.d):
"Any proposal for alternate technology for achieving ZLD by molasses and grain based distilleries shall be evaluated by SPCBs/ MoEF&CC while issuing CTE/CTO/EC"
3. The maximum limit for Colour shall be read as 150 PCU instead of 350 PCU, which was a typographical error, in the draft notification. The same value of 150 PCU has been stipulated in the notified standards for Textile Industry vide G.S.R. (E) 978, dated 10/10/2016.

After incorporating the above suggestions, the Committee recommended to notify the final notification under Environment (Protection) Rules, 1986 as at Annexure D.

3.4. Environmental Standard for Sewage Treatment Plants (Revised)

The final notification for Environmental Standard for Sewage Treatment Plants (STP) - revised was presented by CPCB and informed that the MoEF&CC standards for STP vide G.S.R. No. 1265(E), dated 13/10/2017 was challenged in O.A No. 1069/2018 (M.A.Nos. 1792/2018 & 1793/2018), filed by Shri Nitin Shankar Deshpande before Hon'ble NGT. The Hon'ble NGT vide order dated 21/12/2018 stayed notified standards and constituted an Expert Committee comprising of the Director or his nominee (Senior Professor of Environment Engineering) IIT Kanpur and IIT Roorkee, Senior representative of NEERI and Senior Scientist nominated by CPCB to review the matter of formulation of Discharge Standards for Sewage Treatment Plant and suggested to submit a report. The Expert Committee

recommended standards for 07 parameters viz pH, BOD, COD, Total Nitrogen, Phosphorus, Fecal Coliform. The Expert Committee have been recommended more stringent for Mega and Metropolitan Cities than Class 1 cities followed by Others Towns and Deep Marine Outfall in that order. Hon'ble Tribunal vide its order dated 30/04/2019 accepted the report of the Expert Committee with the modification that the standards recommended for Mega and Metropolitan Cities will also apply to rest of the country.

Being aggrieved by the order dated 30/04/2019 pronounced by the NGT the Municipal Corporation of Greater Mumbai filed the instant appeal under section 22 of the National Green Tribunal, 2010. Municipal Corporation of Greater Mumbai filed Civil Appeal before Supreme Court. MCGM prayed that Impugned order passed by Hon'ble NGT in OA No. 1069 of 2018 dated 30/04/2019 may be set aside and the standards prescribed by the expert committee constituted by Hon'ble NGT vide order dated 21/12/2018 may be implemented.

Meeting convened with concerned organizations on July 12, 2019 at MoEF & CC and following points were observed. Current standards notified by MoEF & CC comparable with STP discharge standards applicable in other countries. Standards suggested by Expert Committee for Mega / Metropolitan Cities, as mandated by NGT will not be practical to implement uniformly across the country and majority of STPs would become non-compliant. 46 metropolitan cities contribute 33099 MLD of sewage which is about 51 % of the total sewage generation across India and hence there is need for stringent standards for metropolitan cities so as to reduce pollution load on recipient river / water bodies in metropolitan cities. During the meeting it was decided the CPCB shall propose draft environmental standard for effluent discharge from STP.

After detailed discussions on the submitted revised notification by CPCB, Committee recommended the proposed standards for adoption as at Annexure E. However, since the matter is sub-judice, further decision will take out after the direction of Hon'ble Court.

4. Proposed for issue of the Draft Notification under EPA 1986: -

4.1 Water Quality Standard for Coastal Water Marine Outfalls in respect of Primary Water Quality Criteria for Class SW-III Waters and Class SW-V Water-Amendment

The revised amendment draft notification for Water Quality Standard for Coastal Water Marine Outfalls in respect of Primary Water Quality Criteria for Class SW-III Waters and Class SW-V Water was presented by CPCB. The CPCB informed that as per recommendations of 17th MoEF & CC Experts Committee, an expert committee meeting was held on 24/05/2019 at NCCR (MoES), Chennai in consultation with CPCB and suggestions of the Experts Consultation Meeting were presented i.e. proposed standards for seven metals and one Pesticide in addition to the existing Primary Water Quality Criteria for Class SW-III Waters [for Industrial Cooling, Recreation (non-contact) and Aesthetics] and Primary Water Quality Criteria for Class SW-V Waters [for Navigation and Controlled Waste Disposal].

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CPCB representative also informed the Committee that in order to impart knowledge on assessing criterion continuous concentration of the proposed additional parameters (seven heavy metals and pesticides), a hands-on training on measurement of such heavy metals and pesticide at marine outfall is also being organised to the coastal States/UTs, during 21-23 August, 2019 at NCCR, Chennai.

During the discussion, Committee suggested to carry out such studies by NCCR, Chennai in association with CPCB to derive such standards for Primary Water Quality Criteria for Class SW-I, Class SW-II and Class SW-IV waters by including heavy metals as well as predominantly used pesticides in the coastal States/UTs in India and also to propose such amendments in second phase.

After deliberations, the Committee recommended inclusion of proposed additional parameters (seven metals and one pesticide) to the existing Primary Water Quality Criteria for Class SW-III Waters [for Industrial Cooling, Recreation (non-contact) and Aesthetics] and Class SW-V Waters [for Navigation and Controlled Waste Disposal] and to notify the draft notification inviting public suggestion in accordance with EPA 1986 is at Annexure F.

4.2. Environmental Standard for Diesel Locomotives

The background of environmental standard for Diesel Locomotives was presented by CPCB before the Expert Committee. The CPCB informed that as suggested by Experts Committee in its 17th meeting held on 26/04/2019, the senior officials from Railways had met Chairman CPCB in July 2019 and informed that the RITES Report shall be submitted in September 2019. The Report was to be submitted in June 2019. CPCB further informed that Railways had been asked to incorporate the financial and technical requirement for the proposed emission standards proposed for Diesel Locomotives as well the detailed phase-out plan for Diesel Locomotives as informed by the Railways. After detailed discussions, the Chair directed the Railways to submit the complete report as per CPCB requirements to CPCB at the earliest. The CPCB may also pursue the same with Ministry of Railway.

4.3. Environmental Standard for Bulk Drug and Formulation (Pharmaceutical) Industry

The proposed revised draft Environmental Standard for Bulk Drug and Formulation (Pharmaceutical) Industry was presented by CPCB before the Expert Committee. It was informed that the draft notification was earlier discussed in the 17th Expert Committee Meeting held on 26/04/2019 and suggestions made during meeting by the committee were incorporated. The revised standards were again discussed and the Committee suggested incorporating following:

- 1) The standard for COD in effluent may be considered as 250 mg/l in place of 200 mg/l as the 250 mg/l is already prescribed in other similar type of industries.
- 2) The CPCB should develop guidelines for State Pollution Control Boards/ Pollution Control Committees (SPCBs/PCCs) for laboratory analysis of antibiotics in the effluent for implementation of proposed standards in future.

After incorporating the above suggestions the Committee recommended Ministry may issue the draft notification inviting public suggestion in accordance with EPA 1986 is at Annexure G.

5. New Proposed Draft Notification under EPA 1986: -

5.1 Environmental Emission Standards for Hot Mix Plants

The proposed revised draft Environmental Emission Standard for Hot Mix Plants (HMPs) was presented by CPCB before the Expert Committee covering aspects related to classification/type of HMPs, manufacturing process, sources of pollution, main pollutants, and comments from stakeholders, formulation of standards, etc. CPCB also informed that the emission standards for Hot Mix Plants were earlier considered in the 16th Expert Committee meeting held on 13/12/2018 and recommended to consult the proposed standards with stakeholders. Accordingly, the proposed standards were forwarded to the stakeholders and the comments/views received from the 14 stakeholders were considered. During the meeting, Committee was of the view that the normalization of particulate matter (PM) results at 5% CO₂ is too low and goes against the fuel / energy economy.

After detailed discussions, the Committee agreed for draft notification of the proposed emission standards for HMPs delete the footnote on CO₂ correction and recommended Ministry may issue the draft notification inviting public suggestion in accordance with EPA 1986 is at **Annexure H**.

6. The meeting ended with vote of thanks to the Chair.

List of the Participants who attended the 18th meeting of the Expert Committee to finalize the Environment Standards held on 9th August, 2019 at Indira Paryavaran Bhawan, Jor Bagh Road, New Delhi.

S. No.	Name	Designation & Name of Organisation
1.	Shri A. K. Nautiyal	Chairman & Joint Secretary, MoEF&CC
2.	Dr. K. P. Nyati	Expert Member
3.	Shri Gyan Prakash	Scientist 'B', BIS, New Delhi
4.	Mohd. Zakir Hussain	Director, D/o Heavy Industry
5.	Shri Sushil hakra	Consultant, D/o Heavy Industry
6.	Ms. Anita Gahlot	Director, CEA
7.	Shri Chetan Sharma	Assistant Director, CEA
8.	Shri P.K. Mishra	Invitee, Scientist 'E' CPCB
9.	Shri Ajay Aggarwal	Invitee, Scientist 'E' CPCB
10.	Ms. Divya Sinha	Invitee, Scientist 'E' CPCB
11.	Ms. Smriti K. Upadhyay	Invitee, Scientist 'E' CPCB
12.	Shri J.Chandra Babu	Invitee, Scientist 'E' CPCB
13.	Shri Vishal Gandhi	Invitee, Scientist 'D' CPCB
14.	Shri Vivek K.	Invitee, Scientist 'D' CPCB
15.	Shri Mukesh Balodhi	Invitee, Scientist 'D' CPCB
16.	Shri Kamlesh Singh	Invitee, Scientist 'D' CPCB
17.	Shri Y. N. Mishra	Invitee, Scientist 'C' CPCB
18.	Shri K.N.Dash	Invitee, Scientist 'C' CPCB
19.	Ms. Deepa Chaudhary	Invitee, SRF, CPCB
Water Quality Standard for Coastal Water Marine Outfalls- Amendment		
20.	Dr. S.R. Marigoudar	Scientist 'D', National Centre for Coastal Research (NCCR), Ministry of Earth Science (MoES).
21.	Shri K. Venkatarama Sharma	NCCR
Tannery Industry		
22.	Shri Shahid Parnez	Jt. Secretary, CLC Tanners Association
23.	Shri Anshuman Mishra	Jt. Convenor, CLC Tanners Association
Diesel Locomotives		
24.	Shri S.K. Tanti	DME(Tr) Railway Board
25.	Shri Sanjeev Wadehre	SSE, Railway Board

Environmental Standards for Discharge of Effluent from Tannery Industry

S. No.	Industry	Parameter	Standards (applicable for all modes of disposal*)
1	2	3	4
57	Tanneries	Treated Effluent	Max. permissible values (in mg/l, except for pH)
		pH	6 to 9
		Biochemical Oxygen Demand (BOD ₅ at 27 °C)	20
		Chemical Oxygen Demand (COD)	250
		Total Suspended Solids (TSS)	50
		Total Dissolved Solids (TDS)	2100**
		Sulphides (as S)	2
		Total Chromium (as Cr)	2
		Hexavalent Chromium (as Cr ⁺⁶)	0.1
		Oils and Grease	10
		Notes:	
		1. **TDS limit with respect to treated effluent shall be 2100 milligram per litre; however, in case where TDS in intake water is above 1100 milligram per litre, a maximum contribution up to 1000 milligram per litre shall be permitted provided the maximum limit of 3100 milligrams per litre is not exceeded in the treated effluent. 2. Standards for TDS shall not be applicable in case of marine disposal through proper marine outfall. 3. Standards are equally applicable to all types of stand-alone tanneries irrespective of their scale of production. 4. Chrome tanning units shall ensure installation of 'Chrome Recovery Plant' for treatment of spent chrome liquor so as to recover chromium sulphate. 5. The tannery shall ensure salt recovery through soak liquor segregation. 6. The standalone units shall meet prescribed discharge norms; however, SPCB / PCC shall mandate recycle / reuse of the treated water in water scarce / environmentally sensitive / critical areas. 7. In case of discharge of treated effluent on land for irrigation, the impact on soil and groundwater quality shall be monitored twice a year (pre- and post- monsoon) by the tannery unit.	
		Maximum specific water consumption for processing hides/ skins: (monthly average values)	
		Raw to Wet blue/Wet white/Vegetable tanning	20 m ³ per ton of hides /skins
		Post tanning processes	20 m ³ per ton of hides /skins
		Raw to finished	40 m ³ per ton of hides /skins

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		Maximum wastewater discharge= 85% of maximum water consumption.
		Factors to re-calculate Finished leather into Wet blue/white and Hide: Shoe upper leather: 15 ton of Raw hides /skins = 7.84 ton of Wet blue = 2.94 ton of finished leather Upholstery leather: 15 ton of Raw hides/skins = 5.08 ton of Wet blue = 1.48 ton of finished leather

Environmental Standards for Coffee Industry

Sl. No. 1	Industry 2	Parameter 3	Standards 4
35	Coffee Industry	Instant / Dry Processing	
			Limiting value for concentration in mg/l except for pH
		pH	6.5 – 8.5
		BOD _{3days.27 °C}	100 (for discharge on land for irrigation)
		Wet / Parchment Coffee Processing	
		pH	6.5 – 8.5
		BOD _{3days.27 °C}	
		A. For storage in lined lagoons	1000
		B. For discharge on land for irrigation	100
		Notes:	
1. Raw, treated and / or diluted effluent shall not be discharged into surface water body or used for recharging grounder water under any circumstances what so ever.			
2. The non-permeable lining system shall be constructed by using well graded, highly impervious clay or geosynthetic liners such as geosynthetic clay liners (GCL), HDPE or a combination of both and shall achieve an in-situ coefficient of permeability of less than 1x10 ⁻⁷ cm/sec. The compacted clay liner must have a minimum of thickness of 300 mm (or two compacted layers of 150 mm minimum thickness each). The finished lining must be tested to ensure that it meets the permeability criteria.			
3. The effluent storage facilities/lagoons/solar evaporation ponds shall be located above high flood level mark of the nearby stream, rivulet etc. with below mentioned free board and away from any water body/stream at a distance.			
Free Board (cm) 60			
Distance (m) 100			
4. The liner system specification and lagoon specification to be achieved in one year.			

Environmental Standards Fermentation Industry (Distilleries, Malteries and Breweries)

(A) Effluent Standards

Sl. No.	Category	Standard		
1.	Molasses based distilleries including yeast manufacturing, grain based distilleries and any other process / industry producing alcohol by distillation	Zero Liquid Discharge (ZLD) All effluent streams including spent wash/stillage, spent lees, condensate/permeate, washings, etc shall be suitably treated** and disposed/recycled/reused and shall not be discharged within or outside the industrial premises		
2.	Breweries, Malteries and Standalone bottling units	Sl. No.	Parameter	Limiting Standard (Concentration not to exceed mg/l except for pH and colour)
		1.	pH	6.5-8.5
		2.	Colour	150 PCU
		3.	Suspended solids	50
		4.	BOD (3 days at 27°C)	
			Disposal to inland surface water or river / streams	20
			Disposal on land or for irrigation	100
	Note: ** a) Molasses based distilleries shall achieve minimum volume reduction of 60% for raw spent wash through evaporation-concentration before utilizing in bio composting with press mud/incineration/dryer for achieving ZLD. The distilleries practicing incineration/drying or equivalent routes shall additionally achieve a minimum of 45 % solids in the concentrated spent wash. b) Grain based distillery shall achieve ZLD through DDGS production (max. 10 % moisture) or equivalent route. c) All other effluent streams shall be suitably treated and reused/recycled. Discharge/Land application of treated/partially treated effluent is not permitted. d) Any proposal for alternate route in achieving ZLD by molasses and grain based distilleries shall be evaluated by SPCBs/MoEF&CC while issuing CTE/CTO/EC.			

(B) Emission Standard:

Sl. No.	Category	Standard	
1.	Spent wash incineration boilers	Parameter	Limiting Standard (Concentration not to exceed mg/Nm ³)
		Particulate Matter	100

Environmental Standard for Sewage Treatment Plants (Revised)

Sl. No.	Industry	Parameters	Standards		
1	2	3	4		
105	Sewage Treatment Plants (STPs)	Effluent discharge standards(applicable to all mode of disposal)			
			Metropolitan Cities (>10 Lakhs)	Class 1 Cities (>1 Lakhs)	Others
		pH	5.5-9.0	5.5-9.0	5.5-9.0
		Bio-Chemical Oxygen Demand (BOD)	10	20	30
		Total Suspended Solids (TSS)	20	50	100
105	Sewage Treatment Plants (STPs)	Chemical Oxygen Demand (COD)	100	150	250
		Fecal Coliform (FC) (Most Probable Number per 100 milliliter, MPN/100ml)	1000	1000	1000

Note:

- Metropolitan Cities- Population More than 10 Lakhs and Class-I-Population more than 1 Lakh
- All values in mg/l except for pH and Fecal Coliform.
- These standards shall be applicable for discharge into water bodies as well as for land disposal/applications.
- The standards for Fecal Coliform shall not apply in respect of use of treated effluent for industrial purposes.
- Old/existing STPs shall achieve these standards within a period of three years from date of publication of this notification in the Official Gazette.
- In case of discharge of treated effluent into sea, it shall be through proper marine outfall and the existing shore discharge shall be converted to marine outfalls, and in cases where the marine outfall provides a minimum initial dilution of 150 times at the point of discharge and a minimum dilution of 1500 times at a point 100 meters away from discharge point, then, the existing norms shall apply as specified in the general discharge standards vide G.S.R. 422(E) dated 19/05/1993.
- Reuse/Recycling of treated effluent shall be encouraged and in cases where part of the treated effluent is reused and recycled involving possibility of human contact, standards as specified above shall apply.
- Central Pollution Control Board / State Government /Union Territory may issue more stringent norms taking account to local condition and identified polluted river stretches under section 5 of the Environment (Protection) Act, 1986".

Water Quality Standard for Coastal Water Marine Outfalls in respect of Primary Water Quality Criteria for Class SW-III Waters and Class SW-V Water-Amendment

In the Environment (Protection) Rules, 1986, in Schedule-I, for serial number 86 relating to water quality standards for coastal waters marine outfalls, the following entries shall be inserted namely:-

(a) under Table 1.3- Primary Water Quality Criteria for Class SW-III Waters [For Industrial Cooling, Recreation (non-contact) and Aesthetics], serial number 9 to 16, the standards for the additional parameters shall be inserted after Sl.No.8, as follows: -

S. No.	Parameter	Standards	Rationale /Remarks
9.	Cadmium (as Cd)	3.03 µg/1 or less	Based on Criterion Continuous Concentration (CCC)**
10.	Copper (as Cu)	4.1µg/1 or less	
11.	Mercury (as Hg)	0.38µg/1 or less	
12.	Zinc (as Zc)	10.6µg/1 or less	
13.	Lead (as Pb)	4.6µg/1 or less	
14.	Arsenic (as As)	3.5 µg/1 or less	
15.	Chromium (as Cr)	8.0µg/1 or less	
16.	Monocrotophos	89 ng/1 or less	

** Criterion Continuous Concentration (CCC)- an estimate of the highest concentration of the material in ambient water (based on bio-assay toxicity) to which an aquatic community can be exposed indefinitely without resulting in an unacceptable adverse effect.

(b) under Table 1.5-Primary Water Quality Criteria for Class SW-V Waters [For Navigation and Controlled Waste Disposal], serial number 6 to 13 and the parameters shall be inserted after S1.No. 5 as follows: -

S No.	Parameter	Standards	Rationale /Remarks
6.	Cadmium (as Cd)	3.03 µg/1 or less	*Based on Criterion Continuous Concentration (CCC)
7.	Copper (as Cu)	4.1µg/1 or less	
8.	Mercury (as Hg)	0.38µg/1 or less	
9.	Zinc (as Zc)	10.6 µg/1 or less	
10.	Lead (as Pb)	4.6µg/1 or less	
11.	Arsenic (as As)	3.5µg/1 or less	
12.	Chromium (as Cr)	8.0µg/1 or less	
13.	Monocrotophos	89 ng/1 or less	

* Criterion Continuous Concentration (CCC) - an estimate of the highest concentration of the material in ambient water (based on bio-assay toxicity) to which an aquatic community can be exposed indefinitely without resulting in an unacceptable adverse effect.

Bulk Drug and Formulation (Pharmaceutical) Industry Standards (Draft)

Sl. No.	Industry	Parameters	Standard
1	2	3	4
73	Bulk Drug and Formulation (Pharmaceutical)	A. EFFLUENT STANDARDS	
		For final outlet of ETP Limiting value for concentration (in mg/l except for pH and Bio assay)	
		i) Compulsory Parameters	
		pH	6.0 -8.5
		BOD (3 days 27°C)	30
		COD	250
		TSS	100
		TDS	2100
		Oil & Grease	10
		Bio - Assay Test**	90% Survival of Fish after first 96 hours in 100% effluent
		ii) Additional Parameters	
		Ammonical Nitrogen	50
		Nitrate Nitrogen	10
		***Benzene	0.05
		***Toluene	0.05
		***Xylene	0.06
		***Methylene Chloride	0.9
		Phosphates as P	5
		Chlorides	1000
		Sulphates as SO ₄	1000
		Fluoride	2
		Sulphides as S	2
		Phenolic Compounds	1
		Total Residual Chlorine	1
		Zinc	5
		Iron	3
		Copper	3
		Total Chromium	2
		Hexavalent Chromium (Cr ⁶⁺)	0.1
		Cyanide	0.1
		Arsenic	0.2
		Mercury	0.01
		Lead	0.1

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		****Active Pharmaceutical Ingredient (API)	0.05
		iii) for final outlet of Industries discharging to CETP	
		For each Common Effluent Treatment Plant(CETP), the state Board will prescribe inlet quality Standards for general parameters, Ammonical Nitrogen and Heavy Metals as per the design of the Common Effluent Treatment Plant(CETP) and local needs & conditions. As per notification S.O. 4 (E) dated 1 st January, 2016	
		Note:	
		ZLD = Zero Liquid Discharge system in <i>Bulk Drug and formulation</i> industry is considered when treated effluent meeting the limits prescribed for compulsory parameters shall be used in Process or Utilities (boiler/ Cooling tower etc.). The reuse of treated effluent in gardening/ horticulture shall not be considered as ZLD in Bulk Drug and formulation industries.	
		** The Bio assay test shall be conducted as per IS : 6582-1971	
		i) Parameters listed as "Additional Parameters" shall be prescribed depending upon the process and product.	

		ii) Limits shall be applicable to industries those are using Benzene, Toluene, Xylene, Methylene Chloride, Chlorobenzene.	

		(iii) API limits shall be applicable for units manufacturing API other than antibiotics.	
		B. EMISSION STANDARDS from Process Reactor Vents/ Tank farm Vents	
		Parameter	Limiting value for concentration (mg/Nm ³)
		Chlorine	15
		Hydrochloric acid vapour	35
		Ammonia	30
		Benzene	5
		Toluene	100
		Acetonitrile	1000
		Dichloromethane	200
		Xylene	100
		Acetone	2000
		C. The total losses of solvent should not be more than 3% of the solvent consumed.	

23/3/2019

D. Antibiotic Residues in the treated effluent of Bulk Drug and Formulation Industry and CETP with membership of Bulk Drug and formulation Units
Individual antibiotic residues will be equal to or less than the values given in the below table.

Parameter	Limiting value for concentration (µg/l)
i. Amikacin	6.40
ii. Amoxicillin	0.10
iii. Amphotericin B	0.01
iv. Ampicillin	0.10
v. Anidulafungin	0.01
vi. Avilamycin	3.20
vii. Azithromycin	0.01
viii. Aztreonam	0.20
ix. Bacitracin	3.20
x. Bedaquiline	0.03
xi. Benzylpenicillin	0.10
xii. Capreomycin	0.80
xiii. Cefaclor	0.20
xiv. Cefadroxil	0.80
xv. Cefalonium	8.40
xvi. Cefaloridine	1.60
xvii. Cefalothin	0.80
xviii. Cefazolin	0.40
xix. Cefdinir	0.10
xx. Cefepime	0.20
xxi. Cefixime	0.02
xxii. Cefoperazone	0.20
xxiii. Cefotaxime	0.04
xxiv. Cefoxitin	3.20
xxv. Cefpirome	0.02
xxvi. Cefpodoxime	0.10
xxvii. Cefquinome	0.64
xxviii. Ceftaroline	0.02
xxix. Ceftazidime	0.20
xxx. Cefibuten	0.10
xxxi. Ceftiofur	0.02
xxxii. Ceftobiprole	0.09
xxxiii. Ceftolozane	0.76
xxxiv. Ceftriaxone	0.01
xxxv. Cefuroxime	0.20
xxxvi. Cephalixin	0.03
xxxvii. Chloramphenicol	3.20
xxxviii. Ciprofloxacin	0.02
xxxix. Clarithromycin	0.03
xl. Clavulanic Acid	22.40
xli. Clinafloxacin	0.20
xlii. Clindamycin	0.04
xliii. Cloxacillin	0.05
xliv. Colistin	0.80
xlvi. Daptomycin	0.40
xlvi. Delamanid	0.02
xlvi. Doripenem	0.04

	xlvi. Doxycycline	0.80
	xlix. Enramycin	1.92
	I. Enrofloxacin	0.02
	II. Ertapenem	0.05
	lii. Erythromycin	0.20
	liii. Ethambutol	0.80
	liv. Faropenem	0.01
	lv. Fidaxomicin	0.01
	lvi. Florfenicol	0.80
	lvii. Fluconazole	0.10
	lviii. Flumequine	0.10
	lix. Fosfomycin	0.80
	lx. Fusidic acid	0.20
	lxi. Gatifloxacin	0.05
	lxii. Gemifloxacin	0.02
	lxiii. Gentamicin	0.08
	lxiv. Imipenem	0.05
	lxv. Isoniazid	0.05
	lxvi. Itraconazole	0.004
	lxvii. Kanamycin	0.44
	lxviii. Levofloxacin	0.10
	lxix. Lincomycin	0.72
	lxx. Linezolid	2.68
	lxxi. Loracarbef	0.80
	lxxii. Mecillinam	0.40
	lxxiii. Meropenem	0.02
	lxxiv. Metronidazole	0.05
	lxxv. Minocycline	0.40
	lxxvi. Moxifloxacin	0.05
	lxxvii. Mupirocin	0.10
	lxxviii. Nalidixic acid	6.40
	lxxix. Narasin	0.20
	lxxx. Neomycin	0.01
	lxxxi. Netilmicin	0.20
	lxxxii. Nitrofurantoin	25.60
	lxxxiii. Norfloxacin	0.20
	lxxxiv. Ofloxacin	0.20
	lxxxv. Oxacillin	0.40
	lxxxvi. Oxytetracycline	0.20
	lxxxvii. Pefloxacin	3.20
	lxxxviii. Phenoxymethylpenicillin	0.02
	lxxxix. Piperacillin	0.20
	xc. Polymixin	0.80
	xc. Retapamulin	0.02
	xcii. Rifampicin	0.02
	xciii. Roxithromycin	0.40
	xciv. Secnidazole	0.40
	xcv. Sparfloxacin	0.02
	xcvi. Spectinomycin	12.80
	xcvii. Spiramycin	0.20
	xcviii. Streptomycin	6.40
	xcix. Sulbactam	6.40
	c. Sulfadiazine	288.00
	ci. Sulfadimethoxine	20.00
	cii. Sulfadoxine	0.24

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ciii.	Sulfamethoxazole	0.24
civ.	Tazobactam	17.60
cv.	Tedizolid	3.92
cvi.	Teicoplanin	0.20
cvi.	Telithromycin	0.02
cvi.	Tetracycline	0.40
cix.	Thiamphenicol	0.40
cx.	Tiamulin	0.40
cx.	Ticarcillin	3.20
cxii.	Tigecycline	0.40
cxiii.	Tildipirosin	0.17
cxiv.	Tilmicosin	0.40
cxv.	Tobramycin	0.40
cxvi.	Trimethoprim	0.20
cxvii.	Trovaflaxacin	0.01
cxviii.	Tylosin	0.33
cxix.	Vancomycin	3.20
cxx.	Viomycin	0.80
cxxi.	Virginiamycin	0.80

Note:- The sludge containing antibiotic residues shall be incinerated and the standard of incinerator notified for common hazardous waste incinerator or industry specific incinerator shall be applicable.

Annexure-H**Environmental Standards for Hot Mix Plants (Draft)**

Sl. No.	Type of hot mix plant	Concentration of particulate matter (mg/Nm ³) in stack emission shall not exceed
1.	Batch hot mix plant	150
2.	Drum hot mix plant	300

Note:

1. The stack height shall be calculated as (a) Stack height (Hs) = $14(Q)^{0.3}$ where, Q is the SO₂ emission rate in kg/h; and (b) Stack height (Hpm) = $74(Q)^{0.27}$ where, Q is the PM emission rate in ton/h. The stack height whichever is higher shall apply.
2. Use of furnace oil and rubber process oil shall be avoided.
3. Dust emission from material handling shall be contained with water sprinkling or covering of the points of dust emission.
4. The internal roads, working platform, loading and unloading areas in premises should be paved and kept clean all times.
5. Use of recycled asphalt pavement (RSP) shall be allowed.
6. Any process rejects or left over of the hot mix should be recycled in the process.
7. The site shall be reinstated at the end of operation phase i.e. after dismantling the plant.

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No. Q-15017/04/2020-CPW
GOVERNMENT OF INDIAMINISTRY OF ENVIRONMENT, FOREST & CLIMATE CHANGE
(CP Division)

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ANNEXURE R

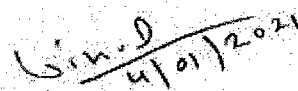
Indira Paryavaran Bhawan
Level -II, Prithvi Wing, Jorbagh Road
New Delhi-110003Dated: 4th January, 2021**Subject: Minutes of the First Expert Committee Meeting to Environmental Standards (through Video Conference) on 09th December, 2020 -reg.**

Sir,

I am directed to forward herewith a copy of minutes of the First Expert Committee Meeting to Environmental Standards (through Video Conference) was held on 09/12/2020 at 11.00 AM under the Chairmanship of Shri Jigmet Takpa, Joint Secretary, Indira Paryavaran Bhawan, Jor Bagh Road, New Delhi for perusal and necessary action.

Yours faithfully,

Encl: As above


(V.K. Kushwaha)
Section Officer (CPW)

To,

1. Shri Navdeep Rinwa, Joint Secretary, Ministry of Chemical and Fertilizers, Department of Pharmaceuticals Shastri Bhawan, New Delhi-110001-Special Invitee in respect of agenda item no. A (ii).
2. Shri Subodh Yadav, Joint Secretary, Ministry of Jal Shakti, Department of Water Resources, River Development & Ganga Rejuvenation, Shram Shakti Bhawan, Rafi Marg, New Delhi -110001-Special Invitee in respect of agenda item no. A (iv).
3. Prof. (Dr.) S. K. Nayak, Director General – CIPET, CIPET Head Office, T.V.K. Industrial Estate, Guindy, Chennai - 600 032-Special Invitee in respect of agenda item no. A (v).
4. Dr. S.R. Marigoudar, Scientist 'D', National Centre for Coastal Research (NCCR), Ministry of Earth Sciences, NIOT Campus, Pallikaranai, Chennai-600100- Special Invitee in respect of agenda item no. A (i).
5. Shri Manish Jain, Executive Director, Mechanical Engineer (Traction), Ministry of Railways, New Delhi-110001-Special Invitee in respect of agenda item no. A (iii).

All Members of Expert Committee
(As per list enclosed)

AD (RJ)

JD (Ak)

Copy to:

1. PPS to JS (JT)/PPS to JS(NPG)
2. PS to Director (CP/W)

List of Members

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Sl. No.	Name & Organization	Role
Permanent Members		
1.	Joint Secretary / Adviser (CP Division)	Chairman
2.	Scientist & Head, Chemical Department, Bureau of Indian Standards (BIS), 9, Bahadur Shah Zafar Marg, New Delhi-110002	Member
3.	Director / Head (Env. Division), PHD Chamber of Commerce, PHD House, 4/2, August Kranti Marg, Siri Institutional Area, Block A, Nipccd Campus, Hauz Khas, New Delhi- 110016 Dr. J.P. Gupta, Chairman E-mail-jpglobalconsultinggroup@gmail.com, president@phdcci.in Tel. No. 011-49545454, 49545400 Dr. Ranjeet Mehta, Director E-mail-ranjeetmehta@phdcci.in Tel. No. 011-26863801-4, 49545514	Member
4.	Head, Environment Division, PHD Chamber of Commerce and Industry (CII), The Mantosh Sondhi Centre, 23, Lodhi Rd, Institutional Area, New Delhi-110003 Sh. Shikhar Jain, Principal Counsellor, CII-ITC CESD E-mail - shikhar.jain@cii.in, cb@cii.in Tel. No. - +91-124-4346372	Member
5.	Sh. K.P. Nyati, D-1-C/56-A, Janakpuri, New Delhi-110058 E-mail-kpnyati@hotmail.com	Member (Non-Official)
6.	Dr. Rashid Hasan, Former Advisor & MoEFCC, 428 Satyam, Sector-19, Vasundhara, Ghaziabad -201012 (U.P.) E-mail-hasan@siam.in, hasan.mef@gmail.com	Member (Non-Official)
7.	Dr. Ajay A. Deshpande, Flat A-26, Flat 403, Happy Valley Homes, Manpada, Near Tikujini Wadi, Ghodbunder Road, Thane (West)-400610, Maharashtra E-mail-ajaydeshpande1@rediffmail.com	Member (Non-Official)
8.	Sh. Sundeep, Scientist 'F', MoEF&CC New Delhi	Member
9.	Dr. Sonu Singh, Scientist 'E', MoEFCC New Delhi / or Officer dealing the Programme	Member Secretary
Special Invitee		
10.	Joint Secretary or his Representatives of Concerned Ministry / Department related to Environmental Standards of Industrial sectors schedule to be considered	Member
11.	Experts co-opted / independent (specific subject) in the field of related to Environmental Standards of Industrial sectors schedule to be considered	Member (Non-Official / Official)

Minutes of First Meeting (through Video Conference) of Expert Committee for Environmental Standards on 09th December, 2020

1. The first meeting of Expert Committee for Environmental Standard was held on 09th December, 2020 at Indira Paryavaran Bhawan, MoEF&CC, New Delhi under the Chairmanship of Shri Jigmet Takpa, Joint Secretary, MoEF&CC for consideration of proposed New norms and amendment in existing standards in respect of Industrial Sector / Categories as given below. The list of participants who attended the VC is at **Annexure-I**.

(A) Notifications for finalization after public consultation:

- i. Water Quality Standard for Coastal Water Marine Outfalls in respect of Primary Water Quality Criteria for Class SW-III Waters and Class SW-V Water
- ii. Bulk Drug and Formulation (Pharmaceutical) Industry
- iii. Membrane based water purification system (MWPS).
- iv. Use of Lead Stabilizer in Polyvinyl Chloride (PVC) Pipes and Fittings

(B) Notifications at draft Stage for public consultation:

- i. Diesel Locomotive
- ii. Emission norms for Genset engines (CPCB stage IV+)

2. At the outset, the Chairman welcomed all Members of the Expert Committee and the representatives from concerned Department and line Ministries and other special invitees. In his opening remarks he appraised the background of the proposed final and draft notifications for different Six (6) sectors. It was highlighted that minutes of the 19th Meeting of Expert Committee held on dated 20th May, 2020 was circulated to the members and comments were sought and no comments were received, consequently the minutes were confirmed and necessary follow-up action was initiated.

The CPCB was thereafter requested to present the details of each of the notifications agenda wise at Para 1 (A) and 1 (B) above except agenda item A (ii) which was presented by Shri Sundeep, Scientist F, MoEF&CC and A(iv), which was presented by Dr. Ritesh Joshi, Scientist 'E'-MoEF&CC.

3. Standards for finalization after public consultation: -

3.1 Agenda No. A(i): Water Quality Standard for Coastal Water Marine Outfalls in respect of Primary Water Quality Criteria for Class SW-III Waters and Class SW-V Water- Amendment

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The proposal is for amendment in notification for Water Quality Standard for Coastal Water in respect of Primary Water Quality Criteria for Class SW-III Waters and Class SW-V Water. The draft notification was put on Ministry's website for public consultation on 17.02.2020. It was informed that no suggestion/comment has been received from Public. The proposal was presented before the committee in its 19th meeting held on 20th May 2020 by CPCB / National Centre for Coastal Research (NCCR), Ministry of Earth Sciences. After detailed discussions the Committee suggested to incorporate the following:

1. The concentration values proposed shall be rounded to nearest whole number.
2. The proposed amendment is in sea water usability quality based on its best designated use. Therefore, it was felt by the committee that the water quality shall be consistent / in-agreement with the best designated use of other water quality (River/ in-land surface water bodies) for the same purpose. CPCB may examine the consistency in reference to designated purpose of use and resubmit the proposal for further perusal.

The revised proposal was placed before the committee and detailed presentation was made by the CPCB. The Committee was of the view that these standards will have very wide ramifications, and suggested that reports and data related to the study for formulation of standards may be shared to the members and a separate one-day presentation on the topic should be scheduled.

(Action: CPCB & MoES (ICMAM))

3.2 Agenda A(ii): Environmental Standard for Bulk Drug and Formulation (Pharmaceutical) Industry

The draft notification for Environmental Standard for Bulk Drug and Formulation (Pharmaceutical) Industry was presented by CPCB in the 19th meeting of the Expert Committee held on 20.05.2020. It was informed that the draft notification was placed on website of Ministry for public consultation on 23.01.2020 and more than 35 numbers of suggestions were received which includes association, NGOs, Individual experts and industry. The comment(s)/suggestion(s) received have been assessed for their acceptability based on the concern raised vis-a-vis their feasibility, viability and relevance to the objective of prescribing norms. The committee deliberated on each para of the proposed standard.

The Joint Secretary, Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals as a special invitee highlighted the present status of the pharma industry and the challenges arising due to COVID-19 demand. It was highlighted that due to higher cost, India is facing stiff competition from other countries, specially China and has in recent times become no. 2 in API manufacturing. He stressed that the norms should not compromise with the environmental requirements, but should be prescribed in such proposition that there is no excess financial burden to the industry to retain their international competitiveness. He also highlighted the concern raised by association of Bulk drug and pharmaceutical manufacturing units specially on monitoring location proposed in the draft. He requested that in present situation, prescribing

standard on AMR may be a challenge for the industry to meet and it was expressed that the committee may take appropriate consideration of the concern raised by the associations.

The draft was deliberated point wise and based on the discussion; the Committee recommended certain modification on additional parameters, the solvent losses, and provision of land disposal etc. for consideration of Ministry.

Further the matter was re-examined in the Ministry in light of representation received from Department of Pharma. A meeting under the chairmanship of Secretary- EFCC with various stakeholders, including CPCB, pharma association, Ministry of Health, Department of Pharma and experts was held. Owing to the concern on the PNEC value and its dynamic nature, it was observed that it will be compliance challenge for any static treatment option to meet the dynamic nature of the PNEC values published by a consortium of AMR manufacturer. Considering the implementation, monitoring and compliance challenges, it was decided that CPCB may explore these challenges and also compare international practices on imposing PNEC values as regulatory provision for discharge standard to address such concerns. In view of above, standard was revised and placed before the expert committee for consideration on the concerns of compliance, dynamic value of PNEC and prevailing international practices on the evolving nature of PNEC understanding.

Shri Sundeep, Scientist F, MoEFCC made a detailed presentation before the committee and clarified the apprehensions of Industry Associations and Department of Pharma that the standards are applicable on the units involved in discharge and emissions, since April 1996. The present proposal are aligned with the emission norms stipulated for similar process and applicable to other industries. A time line relief of one year for meeting the newly intraosuced emission and discharge norms is also proposed for consideration by the committee owing to COVID-19 impact.

The committee after details deliberation on each aspect of the modified discharge norms in notification recommended to modified/incorporated the followings:

1. Ammonia and Nitrate was considered to be an important parameter in light of concern of polluted river stretches, and therefore it may be removed from additional parameter and made as compulsory parameter applicable to all units and CETP at discharge point.
2. Industry permitted to discharge/dispose their effluent to CETP shall be govern by the provision of notified CETP norms dated 01/01/2016.
3. Additional Parameters of Chlorides and Sulphate may be removed and concern of impact on land disposal may be addressed by introducing Sodium Adsorption Ration (SAR) with upper limit of 26. CPCB may provide appropriate norms of SAR.
4. Owing to the complexity and non-availability of any universally accepted standardized method to test Total API concentration in wastewater matrix, the committee

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felt necessary to remove the proposed norms of Total API from the additional parameter as of now.

5. Any discharge to inland water bodies or for horticulture or irrigation or land disposal of treated process wastewater from any industry and or to CETP shall not be considered as Zero Liquid Discharge (ZLD) and the stipulated norms in the notification shall be applicable to all such discharges.
6. The total loss from annual inventory of solvents from storage area shall not be more than 5% of cumulative on annual basis.
7. CPCB shall prepared a standard protocol for determining the loss and relevant record maintenance practices for verification purpose in consultation with industry association and other organization. Provision of One year time may be allowed to the industry for compliance of this norms considering the time required to make necessary abatement cum control arrangement.
8. AMR concentration in ambient environment is rising and its consequences are far reaching. Predicted No-Effect Concentrations (PNECs) value of AMR are the probable values at the mixing point in receiving environment, which reflects the critical level of any adverse impact on the receiving ecology or its component.

The proposed values of various AMR (PNEC) in draft notification was for its applicability at the inlet of treatment facility (applicable on raw influent). It was felt that the purpose was to avoid any adverse impact on the receiving environment and also to promote comprehensive and efficient performance of treatment facility. CPCB has observed that there is significant reduction in monitored AMR concentration in efficient operating treatment facilities. The present notification proposal is for discharge norms and therefore, any stipulation of norms before treatment facility doesn't serve the purpose or objective, as the outcome will be depend on the efficacy of the treatment facility.

It was also observed that the PNEC value considered were based on the studies carried out by an international Alliance of AMR manufacturer and presently it is yet to be accepted as a discharge regulatory provision anywhere. The rationale of the proposed values were not scientifically derived based on field performance studies for all proposed parameter.

Further, the PNEC values are dynamic and is in process of evolving. The parameter and its values both keep on changing based on the API under use and imposing all parameter will lead to uncalled challenges of standardization of monitoring protocol in dynamic environment. The challenge associated with meeting a dynamic values with static infrastructure or through regular retrofitting may lead to more non-compliance of other parameters as well.

Considering the evolving nature of PENC values and associated challenges of infrastructural implementation, monitoring constraints and absences of acceptable standardized testing of samples in complex metrics of pollutants, the committee felt that the

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discharge norms based on dynamic PNEC values for AMR may be dropped from the proposed standard for discharge.

The present ecosystem for monitoring and implementation of AMR concentration in complex wastewater matrix at low concentration with dynamic PNEC values based standard will lead to challenges of monitoring and compliance. However, it was felt that infrastructure and capacity development and readiness of the regulatory bodies, stability in PNEC values in varying Indian condition are some of the essentials for adopting any regulatory provision on AMR.

It was decided that association of AMR manufacturing industries in India shall undertake comprehensive study on AMR impact at all major critical locations identified by CPCB. The study shall be obligatory on the AMR manufacturer and protocol for the study may be prepared in consultation with CPCB and Department of Pharma, Ministry of Chemicals & Fertilizers.

Accordingly, the committee recommended to drop the proposal of AMR discharge norms and suggested that MoEF&CC may ask CPCB to issue necessary direction to Department of Pharma, Ministry of Chemicals & Fertilizers to ensure a database is created on the AMR status in the country with the help of association of AMR manufacturing units. CPCB shall provide the monitoring protocol for the purpose.

9. To contain any adverse impact arising from the disposal of contaminated sludge and or concentrate or reject or residue generated from wastewater treatment and management facility of industry or CETP, it is felt necessary to have their management and disposal with utmost care. Therefore, all sludge (chemical or biological) or any residue, reject, concentrate generated from wastewater treatment or its management facility at Industry engaged in manufacturing of bulk drug or formulation of Pharmaceuticals or CETP catering such industries shall be classified as Hazardous Waste within the provision of sub-section 17 of section 3 of Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016 and shall be managed within the applicable provisions thereof.

10. All new norms / parametrs introduced in this notification shall be applicable after after one year from the date of this notification in due consideration of COVID-19 Impact.

Based on above deliberations and recommendation of the committee the draft notification was modified as attached at Annexure II. The committee recommend for considering the notification under Environment (Protection) Rules, 1986 with appropriate legal modification.

(Action: MoEFCC)

3.3 Agenda A(iii): Environmental Standard Membrane based water purification system (MWPS).

Hon'ble NGT in the matter O.A. No. 134 OF 2015 (MA No. 757 of 2015 & 477 of 2016) titled "Friends through its General Secretary Vs. Ministry of Water Resources & Ors. directed

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MoEFCC to issue appropriate notification prohibiting use of RO where TDS in water is less than 500 mg/l and wherever RO is permitted, a requirement is laid down for recovery of water be more than 60%. Further, provision be laid down for recovery of water upto 75% and use of such RO reject water for purposes such as utensil washing, flushing, gardening, cleaning of vehicles and floor mopping. These directions were based on the Expert Committee report "Appropriate use of Reverse Osmosis (RO) plant and disposal of RO Reject" submitted by CPCB in this matter to Hon'ble NGT.

Based on above report and direction the notification was drafted and stakeholder consultations were held and subsequently the draft Notification on was uploaded on 04.02.2020 on the Website of the Ministry inviting suggestions and comments from public.

It was informed that more than 4000 suggestions has been received and the analysis of such suggestion has been completed. A draft notification has been made. However, in compliance to the order of Hon'ble Supreme Court, Secretary- EF&CC has called a meeting of major Stakeholders representing Manufacture, BIS, Element manufacturers, NEERI, CPCB, Bulk Water Suppliers and users, to have their input before it is finalised. The stakeholders were again requested to provide their inputs based on draft notification for consideration by ministry. The finalisation of draft after consideration of input was made and is due for consideration of Secretary. Due to some urgency, the draft could not get placed before by Secretary and therefore the proposal could not be placed before the committee.

The committee agreed to the proposal of taking as an agenda item in its next meeting.

(Action: MoEFCC)

3.4 Agenda A(iv): Regulation on Lead Stabilizers in Manufacturing of PVC Pipes and Fittings Rules, 2018

The draft 'Regulation on Lead Stabilizers in Manufacturing of PVC Pipes and Fittings Rules, 2018' was evolved by MoEF&CC in compliance of the judgement dated 25th May, 2017 of Hon'ble NGT in the matter O.A. No. 477/ 2015 titled 'Jan Sahyog Manch Vs. Union of India & Ors.' in which Ministry was directed by Hon'ble Tribunal to lay down standards for eliminating lead from PVC pipes. The draft notification was placed on website of MoEF&CC for public consultation on 12.12.2019. The concern raised by the petitioners was that the lead compounds used as stabilizers in manufacture of PVC pipes and fittings impose health hazard due to the lead leaching out of such products, thereby contaminating water. Ministry was directed to notify, with concerned agencies the quality standards of lead to be used for PVC pipes and to lay down the standards for presence of lead in PVC pipes, in consultation with BIS; and to draw up a programme for phasing out of lead as stabilizer in PVC pipes.

Accordingly, the draft rules were formulated on the basis of several rounds of consultations held with various Ministries/ Departments. These rules cover 3 categories of PVC pipes and fittings used for (A) potable water supply, (B) suction and delivery lines of agricultural pumps and rain water systems and (C) drainage and sewerage. The Public objections and suggestions received on the draft rules were examined in consultation with BIS. Proposed final rules were placed before

the Expert Committee for Environment Standards in its 19th meeting held on 20th May 2020. The Committee suggested certain modifications and it was decided that the draft may be modified in consultation with BIS and thereafter submit before the Expert Committee in the next meeting for its final consideration.

Thereafter, in the month of September 2020, a presentation was made before the Secretary (EFCC) on draft rules, wherein Secretary (EFCC) directed to cross-check the cost implications for replacing the use of lead with Ca-Zn (Calcium zinc)/Tin in manufacturing and preparedness of the industries/stakeholders for better compliance of the rules. Secretary (EFCC) also suggested for regulating the sale within the country, except export. Subsequently views of CIPET, CPCB, members of AIPMA and other manufacturers were taken.

Further, a meeting was also organized with concerned stakeholders on 5th November 2020 under the chairmanship of the Joint Secretary, CPW Division, MoEFCC to discuss about the percentage increase in the cost for replacing lead stabilizer with other non-toxic material in PVC pipes and fittings. The meeting was attended by the representatives of AIPMA, CIPET, Ministry of Housing and Urban Affairs, BIS, CPCB, and some other manufacturers. In the meeting, it was agreed that for technological and other associated changes and its compliance, at least one-year time is needed.

After detailed deliberations, the Committee recommended the notification, subject to verification by BIS on referred codes in the notification.

The committee highlighted that the published notification shall be shared with the line ministries (users) for incorporating in the required specification of the materials in their schemes/projects/programs.

The notification was recommended by the committee for publication under Environment (Protection) Rules, 1986.

(Action: MoEFCC)

3.5 Agenda B (i): Environmental Standard for Diesel Locomotives

The background of environmental standard for Diesel Locomotives was presented by CPCB before the Expert Committee meeting held on 09.08.2019. The CPCB informed that as suggested by Experts Committee in its 17th meeting held on 26.04.2019, the senior officials from Railways had met Chairman CPCB in July 2019 and informed that the RITES Report shall be submitted in September 2019. The Report was to be submitted in June 2019. CPCB further informed that Railways had been asked to incorporate the financial and technical requirement for the proposed emission standards proposed for Diesel Locomotives as well the detailed phase-out plan for Diesel Locomotives as informed by the Railways. After detailed discussions, the Chair directed the Railways to submit the complete report as per CPCB requirements to CPCB at the earliest. The CPCB may also pursue the same with Ministry of Railway.

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The proposal was placed in the present meeting and CPCB made a presentation. Further, representative of Railways mentioned the railways is proposing to phase-out 2695 out of 5780 loco engines by the year 2026. Railway reiterated its stand that it consumes only 4% of the total Diesel consumption, Life of Diesel Loco engines is around 36 years and hence no Loco standard for Diesel Loco engines are required considering phase-out plan. It was also discussed that existing Diesel Loco engines need to be retrofitted to comply the proposed one stage below emission norms. During the discussions it also noted that total phase-out of Diesel Locomotives is not possible due to land diversity and emergency issues.

The committee recommended that CPCB should organize a meeting with all stakeholders after sharing all documents/reports with railways and members of this Committee. The proposal shall be work out in consultation with Railways with clarity on the implementing agency, monitoring protocol, and reporting mechanism on compliance etc.

(Action: CPCB & Railways)

3.6 Agenda B (ii): Environmental Standard for emission norms for Genset engines

Emission norms for Petrol/Kerosene, Diesel and dedicated Gas based and dual/ bi fuel Genset engines were revised/ developed vide GSR 353(E) ; dated 07.08.2013 for Kerosene and Petrol, GSR 771(E) ; dated 11.12.13 for Diesel and GSR 281(E) ; dated 07.03.2016 for dedicated Gas based and dual/ bi fuel Genset engines. Considering availability of better fuel quality, advancement in technology and present achievability of more stringent norms by different manufacturer, it was proposed by CPCB to revise the present emission norms of Genset engines.

The present emission standards are as follows:

Power Category	Emission Limits (g/kW-hr)			Smoke Limit (m ⁻¹)
	NO _x +HC	CO	PM	
Upto 19 kW	≤ 7.5	≤ 3.5	≤ 0.3	≤ 0.7
19 to 75 kW	≤ 4.7	≤ 3.5	≤ 0.3	≤ 0.7
More than 75 to 800 kW	≤ 4.0	≤ 3.5	≤ 0.2	≤ 0.7

The proposed emission norms are as follows:

Power Category	HC*+ NO _x	NO _x	HC *	CO	PM	Smoke m ⁻¹
	g/kW-h					
≤ 8 kW	≤ 7.5	NA	NA	≤ 3.5	≤ 0.3	≤ 0.7

$<8 \text{ kW} \leq 19 \text{ kW}$	≤ 4.7	NA	NA	≤ 3.5	≤ 0.3	≤ 0.7
$<19 \text{ kW} \leq 56 \text{ kW}$	≤ 4.7	NA	NA	≤ 3.5	≤ 0.03	≤ 0.7
$<56 \text{ kW} \leq 560 \text{ kW}$	NA	≤ 0.40	≤ 0.19	≤ 3.5	≤ 0.02	≤ 0.7
$<560 \text{ kW} \leq 800 \text{ kW}$	NA	≤ 0.67	≤ 0.19	≤ 3.5	≤ 0.03	≤ 0.7

The CPCB made a presentation. After detailed deliberated committee recommended following:

1. The monitoring mechanism (post installation) for emission compliance verification shall be incorporated in the proposal.
2. The effective implementation date should be finalized in consultation with industry.
3. Phasing plan for the existing DG sets shall also be proposed in due consideration of an effective service life.
4. Justification and need of enforcing such a standard should be provided by CPCB.
5. The stack height or necessary installation guidelines for the DG sets may also be considered to meet the objective of stipulating norms
6. Why BSIV genset engine emission standard are proposed when the vehicles have to comply with the BSVI norms.

(Action: CPCB)

4. The meeting ended with vote of thanks to the Chair.

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Annexure- I

List of the Participants who attended the Video Conference First meeting of the Expert Committee to finalize the Environment Standards held on 09th December, 2020.

S. No.	Name	Designation/ Department/ Organisation	e-mail address
1.	Shri Jigmet Takpa (Chairman)	Joint Secretary, MoEF&CC	takpa.jigmet@gov.in
2.	Shri Navdeep Rinwa	Joint Secretary, Ministry of Chemical & Fertilizers, Depatt. of Pharmaceutical -Invitee	Js.pharma@nic.in
3.	Shri Ajay Deshpande	Expert Member	ajaydeshpandel@rediffmail.com
4.	Dr. Rashid Hasan	Expert Member	hasan@siam.in, hasan.mef@gmail.com
5.	Dr. J.P. Gupta	Representative PHD Chamber of Commerce	jpglobalconsultinggroup@gmail.com,
6.	Dr. Ranjeet Mehta	Representative PHD Chamber of Commerce	ranjeetmehta@phdcci.in
7.	Dr. J.S. Sharma	Representative PHD Chamber of Commerce	sharmajswarup@hotmail.com
8.	Shri Shikhar Jain	Representative CII	shikhar.jain@cii.in
9.	Ms. Madhurima Madhav	Sci 'D' Expert Member Representative BIS	madhurima@bis.gov.in
10.	Shri Mohit Janoiya	Sci. C/CMD-1, Representative BIS	cmd1@bis.gov.in
11.	Shri Ashish Kumar	Sci. C/CMD-3, Representative BIS	cmd3@bis.gov.in
12.	Shri Gyan Prakash	Sci 'B', BIS, Representative BIS	chd@bis.gov.in
13.	Shri Manish Kumar	Sci. 'B' HLPPD, Representative BIS	hrd@bis.org.in
14.	Shri Dinbandhu Gouda	Sci. 'E', CPCB	Dinabandhu.cpcb@nic.in
15.	Ms. Divya Sinha	Sci. 'E', CPCB	divyasinha.cpcb@nic.in

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16.	Shri J.C. Babu	Sci. 'E', CPCB	Jcb.cpcb@nic.in
17.	Dr. Kedarnath Das	Sci. 'D', CPCB	kndin@yahoo.com ; knd.cpcb@nic.in
18.	Shri Mukesh Balodhi	Sci. 'D', CPCB	Mbalodhi.cpcb@nic.in
19.	Shri Vishal Gandhi	Sci. 'D', CPCB	vishalcpb@gmail.com
20.	Shri Sundeep	Expert Member, Director, MoEF&CC	sundeep.cpcb@nic.in
21.	Dr. Ritesh Joshi	Sci. 'E', MoEF&CC	ritesh.joshi@nic.in
22.	Dr. Sonu Singh	Member Convener, Sci. 'E', MoEF&CC	sonu.singh@gov.in
Diesel Locomotives and Emission norms for Genset engines			
23.	Shri Kishore Kumar, PEDEE RS	Executive Director/EE(RS) Railway Board	dycmmg@cr.railnet.gov.in
24.	Shri Anivash K. Agrawal	Professor, IIT, Kanpur	akag@iitk.ac.in
25.	Shri Neelkanth Marathe	Representative ARAI	nvmarathe.edl@araiindia.com
26.	Dr. Prashanth Ravi	Representative IDEMA	prashanth_ravi@cat.com
27.	Shri Ankit Trivedi	Representative ICAT	ankit.trivedi@icat.in
28.	Dr M N Kumar, ,	IDEMA	m.kumar@kirloskar.com
Primary Water Quality Criteria for Class SW-III Waters and Class SW-V Water and RO standards			
29.	Shri Ramana Murthy	Director, MoES-NCCR	mvr@nccr.gov.in
30.	K. Venkatarama Sharma	Scientist-F, MoES-NCCR	venkat@nccr.gov.in
31.	Dr.S.R.Marigoudar	Scientist-D, MoES-NCCR	srmarigoudar@nccr.gov.in
32.	Dr. Sudhir Srivastava	Scientist-D (Sr. Chemist), CGWB	sksrivastava-cgwb@gov.in
33.	Shri Sanjay Marwaha	Regional Director CGWB	smarwaha-cgwb@nic.in; mhq-cgwb@gov.in
Bulk Drug and Formulation (Pharmaceutical) Industry			
34.	Shri R.K. Agrawal	Senior Vice President - Bulk Drugs Manufacturers Association	agrawal@nakodachemical.com / info@bdmai.org

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35.	Shri Yogin Majmudar	Representative IDMA	ym@bakulpharma.com
36.	Shri Harish Verma,	Representative IDMA	harish.verma@piramal.com
37.	Shri Kaushik	Representative IDMA	kaushiksamanta@lupin.com

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Annexure-II

Proposed Notification Bulk Drug

[To be published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i)]
GOVERNMENT OF INDIA
MINISTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE
NOTIFICATION

New Delhi, the, 2020

G.S.R.(E) Whereas, certain draft rules, namely the Environment (Protection) Amendment Rules, 2020 were published in the Gazette of India, Extraordinary, as required under sub-rule (3) of rule 5 of the Environment (Protection) Rules, 1986, *vide* notification of the Government of India in the Ministry of Environment, Forest and Climate Change *vide* number G.S.R. 44 (E), dated the 23rd January, 2020, inviting objections and suggestions from all persons likely to be affected thereby within a period of sixty days from the dated on which copies of the Gazette containing the said notification were made available to the public;

And Whereas, copies of the Gazette containing the aforesaid notification were made available to the public on the 23rd January, 2020;

And Whereas, objections and suggestions received from all persons and stakeholders in response to the aforesaid notification have been duly considered by the Central Government;

Now, therefore, in exercise of the powers conferred by sections 6 and 25 of the Environment (Protection) Act, 1986 (29 of 1986) read with sub-rule (3) of rule 5 of the Environment (Protection) Rules, 1986, the Central Government hereby makes the following rules further to amend the Environment (Protection) Rules, 1986, namely: -

1. **Short title and commencement.** - (1) These rules may be called the Environment (Protection) Amendment Rules, 2020.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Environment (Protection) Rules, 1986, in Schedule-1, for serial number 73 and the entries relating thereto, the following serial number and entries shall be substituted, namely:

S.No.	Industry	Parameters	Standard
1	2	3	4

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“73	Bulk Drug and Formulation (Pharmaceutical)	A. EFFLUENT STANDARDS*	
			Limiting value for concentration (in mg/l except for pH and Bio assay)
		i) Compulsory Parameters	
		pH	6.0 -8.5
		BOD (3 days 27°C)	30
		COD	250
		TSS	100
		Oil & Grease	10
		Ammonical Nitrogen	50
		Nitrate Nitrogen	10
		Bio - Assay Test**	90% Survival of Fish after first 96 hours in 100% effluent
		ii) Additional Parameters##	
		***Benzene	0.05
		***Toluene	0.05
		***Xylene	0.06
		***Methylene Chloride	0.9
		***Chlorobenzene	0.15
		Phosphates as P	5
		Fluoride	2
		Sulphides as S	2
		Phenolic Compounds	1
		Zinc	5
		Iron	3
		Copper	3
		Total Chromium	2
		Hexavalent Chromium (Cr ⁶⁺)	0.1
		Cyanide (as HCN)	0.1
		Arsenic	0.2
		Mercury	0.01
		Lead	0.1
		Sodium Absorption Ratio	Less than 26
		iii) Industry connected with CETP	

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	• The discharge norms for industry connected with CETP and of CETP shall be governed by MoEF&CC notification S.O. 4 (E) dated 1st January, 2016. • State Pollution Control Board shall prescribe additional relevant parameters as given at para A (ii) of this notification as per needs and discharge potential of member industries and specify the frequency of monitoring considering the receiving environment conditions.																				
	Note: The standards in para A is applicable to all discharges except to CETP. *Not applicable to industry discharging to CETP, and shall be applicable to all discharge to land and surface water bodies including use of treated wastewater for horticulture or irrigation purpose ** The Bio assay test shall be conducted as per IS : 6582-1971 ## Parameters listed as “Additional Parameters” shall be prescribed by SPCB depending on the process and product and its monitoring frequency shall be monthly/quarterly as decided by SPCBs ***Limits shall be applicable to industries those are using Benzene, Toluene, Xylene, Methylene Chloride, Chlorobenzene.																				
	B. EMISSION STANDARDS (Tank farm Vents) <table><tr><th>Parameter</th><th>Limiting value for concentration (mg/Nm³)</th></tr><tr><td>Chlorine</td><td>15</td></tr><tr><td>Hydrochloric acid vapor</td><td>35</td></tr><tr><td>Ammonia</td><td>30</td></tr><tr><td>Benzene</td><td>5</td></tr><tr><td>Toluene</td><td>100</td></tr><tr><td>Acetonitrile</td><td>1000</td></tr><tr><td>Dichloromethane</td><td>200</td></tr><tr><td>Xylene</td><td>100</td></tr><tr><td>Acetone</td><td>2000</td></tr></table>	Parameter	Limiting value for concentration (mg/Nm ³)	Chlorine	15	Hydrochloric acid vapor	35	Ammonia	30	Benzene	5	Toluene	100	Acetonitrile	1000	Dichloromethane	200	Xylene	100	Acetone	2000
Parameter	Limiting value for concentration (mg/Nm ³)																				
Chlorine	15																				
Hydrochloric acid vapor	35																				
Ammonia	30																				
Benzene	5																				
Toluene	100																				
Acetonitrile	1000																				
Dichloromethane	200																				
Xylene	100																				
Acetone	2000																				
	C. The total cumulative losses of solvent should not be more than 5% of the solvent on annual basis from storage inventory																				

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		D. Chemical and Biological sludge or any residue, reject, concentrate generated from wastewater treatment or its management facility at Industry or CETP catering to industries engaged in manufacturing of bulk drug or formulation of Pharmaceuticals, shall be classified as Hazardous Waste as per the provision of sub-section 17 of section 3 of Hazardous and Other Wastes (Management and Trans-boundary Movement) Rules, 2016 and shall be subjected to the provision made therein.
	Note:	Newly introduced norms in comparison with prevailing norms shall be effective after one year from the date of this notification



भारत का राजपत्र The Gazette of India

सी.जी.-डी.एल.-अ.-27012020-215690
CG-DL-E-27012020-215690

असाधारण
EXTRAORDINARY
भाग II—खण्ड 3—उप-खण्ड (i)
PART II—Section 3—Sub-section (i)
प्राधिकार से प्रकाशित
PUBLISHED BY AUTHORITY

सं. 41]
No. 41]

नई दिल्ली, बृहस्पतिवार, जनवरी 23, 2020/माघ 3, 1941
NEW DELHI, THURSDAY, JANUARY 23, 2020/MAGHA 03, 1941

पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय

अधिसूचना

नई दिल्ली, 23 जनवरी, 2020

सा. का. नि. 44(अ).—अधिसूचना, जिसे केन्द्रीय सरकार, पर्यावरण (संरक्षण) अधिनियम, 1986 (1986 का 29) की धारा 6 और धारा 25 में प्रदत्त शक्तियों का प्रयोग करते हुए जारी करने का प्रस्ताव करती है, का निम्नलिखित प्रारूप पर्यावरण (संरक्षण) नियम, 1986 के नियम 5 के उपनियम (3) की अपेक्षानुसार, जनसाधारण जिनके उसके द्वारा प्रभावित होने की संभावना है, की जानकारी के लिए, एतद्वारा प्रकाशित किया जाता है; और एतद्वारा सूचना दी जाती है कि उक्त प्रारूप अधिसूचना पर उस तारीख से, जिसको भारत के राजपत्र की प्रतियां, जिसमें यह अधिसूचना अंतर्विष्ट है, जनसाधारण को उपलब्ध करा दी जाती है, साठ दिन की अवधि की समाप्ति पर या उसके पश्चात विचार किया जाएगा।

ऐसा कोई व्यक्ति, जो प्रारूप अधिसूचना में अंतर्विष्ट प्रस्तावों पर कोई आपत्ति या सुझाव देने में हितबद्ध है, इस प्रकार ऊपर विनिर्दिष्ट की गई अवधि के भीतर, केन्द्रीय सरकार द्वारा विचार किए जाने के लिए, आपत्ति या सुझाव सचिव, पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय, इंदिरा पर्यावरण भवन, जोर बाग रोड, नई दिल्ली - 110003 को या ई-मेल पते अर्थात् mscb.cpcb@nic.in और h.kharkwal@nic.in पर सदस्य सचिव, केन्द्रीय प्रदूषण नियंत्रण बोर्ड और मंत्रालय के वैज्ञानिक 'ई' को लिखित रूप में भेज सकेगा।

प्रारूप अधिसूचना

केन्द्रीय सरकार, पर्यावरण (संरक्षण) अधिनियम, 1986 में और अधिक संशोधन करने के लिए एतद्वारा निम्नलिखित नियम बनाती है, अर्थात्-

1. संक्षिप्त शीर्षक और प्रारम्भ—(1) इन नियमों को पर्यावरण (संरक्षण) संशोधन नियम, 2019 कहा जाएगा।
(2) ये आधिकारिक राजपत्र में उनके अंतिम प्रकाशन की तारीख से लागू होंगे।
2. पर्यावरण (संरक्षण) अधिनियम, 1986 में, अनुसूची-1 में क्रम संख्या 73 और उससे संबंधित प्रविष्टियों के लिए निम्नलिखित क्रम संख्या और प्रविष्टियां प्रतिस्थापित की जाएगी अर्थात:-

क्रम सं.	उद्योग	पैरामीटर	मानक
1	2	3	4
73	थोक दवा और निर्माण (फार्मास्युटिकल)	क. बहिस्त्राव मानक	
		ईटीपी का अंतिम आउटलेट सांद्रण के लिए सीमित मान) पीएच और जैव परख को छोड़कर मिलीग्राम / एल में(	
		i) अनिवार्य पैरामीटर	
		पीएच	6.0 -8.5
		बीओडी) 3 दिन 27 डिग्री सेल्सियस(	30
		सीओडी	250
		टीएसएस	100
		टीडीएस	2100
		तेल और चिकनाई (ग्रीज)	10
		जैव - परख परीक्षण**	100% बहिस्त्राव में पहले 96 घंटों के बाद मछली की 90% उत्तरजीविता
		ii) अतिरिक्त पैरामीटर	
		अमोनिकल नाइट्रोजन	50
		नाइट्रेट नाइट्रोजन	10
		*** बेजीन	0.05
		*** टाल्विन	0.05
		*** ज़ाइलीन	0.06
		***मीथाइलीन क्लोराइड	0.9
		फॉस्फेट पी के रूप में	5
		क्लोराइड	1000
		सल्फेट SO ₄ के रूप में	1000
		फ्लोराइड	2
		एस के रूप में सल्फाइड	2
		फेनोलिक यौगिक	1
		कुल अवशिष्ट क्लोरीन	1
		जस्ता	5
		लोहा	3
		तांबा	3
		कुल क्रोमियम	2
		हेक्सावैलेंट क्रोमियम (Cr ⁶⁺)	0.1

साइनाइड	0.1
आर्सेनिक	0.2
पारा	0.01
लेड	0.1
**** सक्रिय दवा संघटक) एपीआई(	0.05
iii) साझा बहिष्काव शोधन संयंत्र में निस्सारित कर रहे उद्योगों के अंतिम आउटलेट के लिए	
दिनांक 1 जनवरी, 2016 की अधिसूचना का के अनुसार प्रत्येक (अ) 4 .आ.साझा बहिष्काव शोधन संयंत्र) सीईटीपी) के लिए, राज्य बोर्ड साझा बहिष्काव शोधन संयंत्र) सीईटीपी) के डिजाइन और स्थानीय जरूरतों और स्थितियों के अनुसार सामान्य मापदंडों, अमोनियम नाइट्रोजन और हेवी मेटल्स के लिए इनलेट क्वालिटी स्टैंडर्ड्स निर्धारित करेगा।	
टिप्पणी: जेडएलडी= थोक दवा और निर्माण उद्योग में शून्य तरल निस्सारण प्रणाली पर विचार किया जाता है, जब अनिवार्य पैरामीटरों के लिए निर्धारित की गई सीमाओं को पूरा करते हैं। शोधित बहिष्कावों को प्रक्रिया अथवा उपयोगिताओं के प्रयोग में लाया जाएगा। (क्लिंग टॉवरो आदि/बॉयलर) बागवानी / बागवानी में शोधित अपशिष्ट के पुनः उपयोग को थोक दवा और निर्माण उद्योगों में जेडएलडी नहीं माना जाएगा।	
** जैव परख परीक्षण आईएस :6582-1971 के अनुसार आयोजित किया जाएगा	
"अतिरिक्त पैरामीटर "के रूप में सूचीबद्ध पैरामीटर प्रक्रिया और उत्पाद के आधार पर निर्धारित किए जाएंगे।	
*** ये सीमाएं उन उद्योगों पर लागू होंगी जो बेंजीन, टाल्विन, ज़ाइलीन, मिथाइलीन क्लोराइड, क्लोरोबेंजीन का उपयोग कर रहे हैं।	
*** * एपीआई सीमाएं एंटीबायोटिक दवाओं के अलावा एपीआई बनाने वाली इकाइयों के लिए लागू होगी।	
ख प्रक्रिया .रिएक्टर वेंटस / टैंक फार्म वेंटस से उत्सर्जन मानक	
पैरामीटर	सांद्रण के लिए सीमित मान)मिलीग्राम/एनएम³)
क्लोरीन	15
हाइड्रोक्लोरिक एसिड वाष्प	35
अमोनिया	30
बेंजीन	5
टाल्विन	100
ऐसिटोनाईट्राईल	1000
डिक्लोरोमीथेन	200
ज़ाइलीन	100
एसीटोन	2000
ग विलायक का कुल नुकसान, उपभोग किए गए विलायक के 3% से अधिक नहीं होना चाहिए।	
घ. थोक दवा और निर्माण उद्योग में शोधित बहिष्काव में एंटीबायोटिक अवशिष्ट और थोक दवा और निर्माण इकाइयों की सदस्यता सहित सीईटीपी।	
पृथक एंटीबायोटिक अवशिष्ट नीचे तालिका में दिए गए मानों के बराबर या उससे कम होंगे।	
पैरामीटर	सांद्रण के लिए सीमित मान) u/g / l)
i. एमिकासिन	6.40

	ii. एमोक्सिसिलिन	0.10
	iii. एम्फोटेरिसिन बी	0.01
	iv. एम्पीसिलीन	0.10
	v. एनीड्युलाफगिन	0.01
	vi. एविलामाईसिन	3.20
	vii. एजिथ्रोमाईसिन	0.01
	viii. एजट्रियोनाम	0.20
	ix. बेसिट्रेसिन	3.20
	x. बेडाक्विलिन	0.03
	xi. बेन्ज़ाइलपेन्सिलीन	0.10
	xii. केप्रियोमाईसिन	0.80
	xiii. सेफेक्लोर	0.20
	xiv. सेफाड्रोक्सिल	0.80
	xv. सेफालोनियम	8.40
	xvi. सेफालोरिडीन	1.60
	xvii. सेफालोथिन	0.80
	xviii. सेफाजोलिन	0.40
	xix. सेफडिनिर	0.10
	xx. सेफेपाईम	0.20
	xxi. सेफीजाईम	0.02
	xxii. सेफोपेराजोन	0.20
	xxiii. सेफोटैक्सिम	0.04
	xxiv. सेफोएक्सिटिन	3.20
	xxv. सेफपिरोम	0.02
	xxvi. सेफपोडोक्सिन	0.10
	xxvii. सेफक्विनोम	0.64
	xxviii. सेफटेरोलिन	0.02
	xxix. सेफटाजिडिम	0.20
	xxx. सेफटीब्यूटेन	0.10
	xxxi. सेफटीओफर	0.02
	xxxii. सेफटोबिप्रोल	0.09
	xxxiii. सेफटोलोजेन	0.76
	xxxiv. सेफाट्रियोक्सन	0.01
	xxxv. सेफुरोक्सिम	0.20
	xxxvi. सेफालेक्सिन	0.03
	xxxvii. क्लोरामफेनिकोल	3.20
	xxxviii. सिपरोफ्लोक्सासिन	0.02
	xxxix. क्लेरिथ्रोमाईसिन	0.03
	xl. क्लेब्युलेनिक एसिड	22.40

	xli. क्लिनाफ्लोक्सासिन	0.20
	xlii. क्लिन्डामाईसिन	0.04
	xliii. क्लोक्सासिलीन	0.05
	xliv. कोलिस्टिन	0.80
	xliv. डेपटोमाईसिन	0.40
	xlvi. डेलमानिड	0.02
	xlvi. डोरीपेनेम	0.04
	xlvi. डॉक्सीसाइक्लिन	0.80
	xlix. एनरामाईसिन	1.92
	I. एनरोफ्लोक्ससिन	0.02
	li. एरटापेनेम	0.05
	lii. एरिथ्रोमाईसिन	0.20
	liii. एथामब्युटोल	0.80
	liv. फेरोपेनेम	0.01
	lv. फिडाएक्सोमाईसिन	0.01
	lvi. फ्लोरफेनिकोल	0.80
	lvii. फ्लूकोनेज़ोल	0.10
	lviii. फ्लूमेक्विन	0.10
	lix. फॉस्फोमाईसिन	0.80
	lx. फ्युसीडिक एसिड	0.20
	lxi. सेटीफ्लोक्सासिन	0.05
	lxii. जेमीफ्लोक्सासिन	0.02
	lxiii. जेंटामाईसिन	0.08
	lxiv. इनीपेनेम	0.05
	lxv. आइसोनियाजिड	0.05
	lxvi. इट्राकोनेज़ोल	0.004
	lxvii. कानामाईसिन	0.44
	lxviii. लेवोफ्लोक्सासिन	0.10
	lxix. लिंकोमाईसिन	0.72
	lxx. लाईनज़ोलिड	2.68
	lxxi. लोराकार्बेफ	0.80
	lxxii. मसिलिनेम	0.40
	lxxiii. मेरोपेनेम	0.02
	lxxiv. मेट्रोनिडेज़ोल	0.05
	lxxv. माइनोसाइक्लिन	0.40
	lxxvi. मॉक्सीफ्लोक्सिन	0.05
	lxxvii. म्युरीरोसिन	0.10
	lxxviii. नेलीडिक्सिक एसिड	6.40
	lxxix. नारासिन	0.20

	lxxx. नियोमाईसिन	0.01
	lxxxi. नेटीलमिसिन	0.20
	lxxxii. निट्रोफ्यूरेनटोएन	25.60
	lxxxiii. नॉरफ्लोक्सिन	0.20
	lxxxiv. ऑफ्लोक्सिन	0.20
	lxxxv. ऑक्सासिलिन	0.40
	lxxxvi. ऑक्सीटेट्रासाइक्लिन	0.20
	lxxxvii. पेफक्लोसिन	3.20
	lxxxviii. फेनक्सीमेथिलपेनसिलिन	0.02
	lxxxix. पिपेरासिलिन	0.20
	xc. पॉलीमिक्सिन	0.80
	xc. रेटापाम्युलिन	0.02
	xcii. रिफाम्पसिन	0.02
	xciii. रॉक्सीथ्रोमाईसिन	0.40
	xciv. सेक्नीडेजोल	0.40
	xcv. स्पाराफ्लोक्सिन	0.02
	xcvi. स्पेक्टीनोमाईसिन	12.80
	xcvii. स्पिरामाईसिन	0.20
	xcviii. स्ट्रेप्टोमाईसिन	6.40
	xcix. सल्बेक्टम	6.40
	c. सल्फाडियाजिन	288.00
	ci. सल्फाडिमिथियोजिन	20.00
	cii. सल्फाडॉक्सिन	0.24
	ciii. सल्फामेथोक्साजोल	0.24
	civ. टेजोबेक्टम	17.60
	cv. टेडीजोलिड	3.92
	cvi. टेईकोप्लानिन	0.20
	cvii. टेलीथ्रोमाईसिन	0.02
	cviii. टेट्रासाइक्लिन	0.40
	cix. थियाम्फेनीकोल	0.40
	cx. टियाम्युलिन	0.40
	cx. टिकार्सिलिन	3.20
	cxii. टिगेसाइक्लिन	0.40
	cxiii. टिल्डीपीरोसिन	0.17
	cxiv. टिल्मीकोसिन	0.40
	cxv. टोबरामाईसिन	0.40
	cxvi. ट्रिमेथोप्रिम	0.20
	cxvii. ट्रोवाफ्लोक्सासिन	0.01
	cxviii. टाइलोसिन	0.33

		cxix.बेंकोमाईसिन	3.20
		cxx.वियोमाईसिन	0.80
		cxxi.विर्जिनियामाईसिन	0.80. "

टिप्पणी: - एंटीबायोटिक अवशिष्ट युक्त गाद को जलाकर राख किया जाएगा और साझा खतरनाक अपशिष्ट भस्मक अथवा उद्योग विशिष्ट भस्मक के लिए अधिसूचित किए गए भस्मक का मानक लागू होगा।

[फा.सं.क्यू.-15017/12/2018-सीपीडब्ल्यू]

जिगमेत टक्पा, संयुक्त सचिव

टिप्पणी: मूल नियम भारत के राजपत्र असाधारण, भाग- II, खंड 3, उप-खंड (i) में दिनांक 19 नवम्बर, 1986 को संख्या का.आ. 844 (अ) द्वारा प्रकाशित किए गए थे और उन्हें अंतिम बार दिनांक 26 दिसम्बर, 2019 को सा.का.नि. 952 (अ) की अधिसूचना द्वारा संशोधित किया गया था।

MINISTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE NOTIFICATION

New Delhi, the 23rd January, 2020

G.S.R. 44(E).— The following draft of the notification, which the Central Government proposes to issue in exercise of the powers conferred by sections 6 and 25 of the Environment (Protection) Act, 1986 (29 of 1986) is hereby published, as required under sub-rule (3) of rule 5 of the Environment (Protection) Rules, 1986, for the information of the public likely to be affected thereby; and notice is hereby given that the said draft notification shall be taken into consideration on or after the expiry of a period of sixty days from the date on which copies of the Gazette containing this notification are made available to the public.

Any person interested in making any objections or suggestions on the proposals contained in the draft notification may forward the same in writing, for consideration of the Central Government within the period specified above to the Secretary, Ministry of Environment, Forest and Climate Change, Indira Paryavaran Bhawan, Jor Bagh Road, New Delhi-110003, or send it to Member Secretary, CPCB and Scientist 'E' Ministry at the e-mail address i.e. mscb.cpcb@nic.in and h.kharkwal@nic.in.

Draft Notification

The Central Government hereby makes the following rules further to amend the Environment (Protection) Rules, 1986, namely:-

- Short title and commencement-** (1) These rules may be called the Environment (Protection) Amendment Rules, 2019.
(2) They shall come into force on the date of their final publication in the Official Gazette.
- In the Environment (Protection) Rules, 1986, in Schedule-I, for serial number 73 and the entries relating thereto, the following serial number and entries shall be substituted, namely:-

Sl. No.	Industry	Parameters	Standard
1	2	3	4
“73	Bulk Drug and Formulation (Pharmaceutical)	A. EFFLUENT STANDARDS	
		For final outlet of ETP	
		Limiting value for concentration (in mg/l except for pH and Bio assay)	
		i) Compulsory Parameters	
		pH	6.0 -8.5

BOD (3 days 27°C)	30
COD	250
TSS	100
TDS	2100
Oil & Grease	10
Bio - Assay Test**	90% Survival of Fish after first 96 hours in 100% effluent
ii) Additional Parameters	
Ammonical Nitrogen	50
Nitrate Nitrogen	10
***Benzene	0.05
***Toluene	0.05
***Xylene	0.06
***Methylene Chloride	0.9
Phosphates as P	5
Chlorides	1000
Sulphates as SO ₄	1000
Fluoride	2
Sulphides as S	2
Phenolic Compounds	1
Total Residual Chlorine	1
Zinc	5
Iron	3
Copper	3
Total Chromium	2
Hexavalent Chromium (Cr ⁶⁺)	0.1
Cyanide	0.1
Arsenic	0.2
Mercury	0.01
Lead	0.1
****Active Pharmaceutical Ingredient (API)	0.05
iii) for final outlet of Industries discharging to CETP	
For each Common Effluent Treatment Plant(CETP), the state Board will prescribe inlet quality Standards for general parameters, Ammonical Nitrogen and Heavy Metals as per the design of the Common Effluent Treatment Plant(CETP) and local needs and conditions. As per notification S.O. 4 (E) dated 1 st January, 2016	
Note: ZLD = Zero Liquid Discharge system in <i>Bulk Drug and formulation</i> industry is considered when treated effluent meeting the limits prescribed for compulsory parameters shall be used in Process or Utilities (boiler/ Cooling tower etc.). The reuse of treated effluent in gardening/ horticulture shall not be considered as ZLD in Bulk Drug and formulation industries. ** The Bio assay test shall be conducted as per IS : 6582-1971 Parameters listed as “Additional Parameters” shall be prescribed depending upon the process and product. *** Limits shall be applicable to industries those are using Benzene, Toluene, Xylene, Methylene Chloride, Chlorobenzene. ****API limits shall be applicable for units manufacturing API other than antibiotics.	
B. EMISSION STANDARDS from Process Reactor Vents/ Tank farm Vents	
Parameter	Limiting value for concentration (mg/Nm³)
Chlorine	15
Hydrochloric acid vapour	35
Ammonia	30
Benzene	5
Toluene	100
Acetonitrile	1000
Dichloromethane	200

	Xylene	100
	Acetone	2000
C. The total losses of solvent should not be more than 3% of the solvent consumed.		
D. Antibiotic Residues in the treated effluent of Bulk Drug and Formulation Industry and CETP with membership of Bulk Drug and formulation Units		
Individual antibiotic residues will be equal to or less than the values given in the below table.		
	Parameter	Limiting value for concentration (µg/l)
i.	Amikacin	6.40
ii.	Amoxicillin	0.10
iii.	Amphotericin B	0.01
iv.	Ampicillin	0.10
v.	Anidulafungin	0.01
vi.	Avilamycin	3.20
vii.	Azithromycin	0.01
viii.	Aztreonam	0.20
ix.	Bacitracin	3.20
x.	Bedaquiline	0.03
xi.	Benzylpenicillin	0.10
xii.	Capreomycin	0.80
xiii.	Cefaclor	0.20
xiv.	Cefadroxil	0.80
xv.	Cefalonium	8.40
xvi.	Cefaloridine	1.60
xvii.	Cefalothin	0.80
xviii.	Cefazolin	0.40
xix.	Cefdinir	0.10
xx.	Cefepime	0.20
xxi.	Cefixime	0.02
xxii.	Cefoperazone	0.20
xxiii.	Cefotaxime	0.04
xxiv.	Cefoxitin	3.20
xxv.	Cefpirome	0.02
xxvi.	Cefpodoxime	0.10
xxvii.	Cefquinome	0.64
xxviii.	Ceftaroline	0.02
xxix.	Ceftazidime	0.20
xxx.	Ceftibuten	0.10
xxxi.	Ceftiofur	0.02
xxxii.	Ceftobiprole	0.09
xxxiii.	Ceftolozane	0.76
xxxiv.	Ceftriaxone	0.01
xxxv.	Cefuroxime	0.20
xxxvi.	Cephalexin	0.03
xxxvii.	Chloramphenicol	3.20
xxxviii.	Ciprofloxacin	0.02
xxxix.	Clarithromycin	0.03
xl.	Clavulanic Acid	22.40
xli.	Clinafloxacin	0.20
xlii.	Clindamycin	0.04
xliii.	Cloxacillin	0.05
xliv.	Colistin	0.80
xlvi.	Daptomycin	0.40
xlvi.	Delamanid	0.02
xlvi.	Doripenem	0.04
xlvi.	Doxycycline	0.80
xlix.	Enramycin	1.92
l.	Enrofloxacin	0.02

	li.	Ertapenem	0.05
	lii.	Erythromycin	0.20
	liii.	Ethambutol	0.80
	liv.	Faropenem	0.01
	lv.	Fidaxomicin	0.01
	lvi.	Florfenicol	0.80
	lvii.	Fluconazole	0.10
	lviii.	Flumequine	0.10
	lix.	Fosfomicin	0.80
	lx.	Fusidic acid	0.20
	lxi.	Gatifloxacin	0.05
	lxii.	Gemifloxacin	0.02
	lxiii.	Gentamicin	0.08
	lxiv.	Imipenem	0.05
	lxv.	Isoniazid	0.05
	lxvi.	Itraconazole	0.004
	lxvii.	Kanamycin	0.44
	lxviii.	Levofloxacin	0.10
	lxix.	Lincomycin	0.72
	lxx.	Linezolid	2.68
	lxxi.	Loracarbef	0.80
	lxxii.	Mecillinam	0.40
	lxxiii.	Meropenem	0.02
	lxxiv.	Metronidazole	0.05
	lxxv.	Minocycline	0.40
	lxxvi.	Moxifloxacin	0.05
	lxxvii.	Mupirocin	0.10
	lxxviii.	Nalidixic acid	6.40
	lxxix.	Narasin	0.20
	lxxx.	Neomycin	0.01
	lxxxi.	Netilmicin	0.20
	lxxxii.	Nitrofurantoin	25.60
	lxxxiii.	Norfloxacin	0.20
	lxxxiv.	Ofloxacin	0.20
	lxxxv.	Oxacillin	0.40
	lxxxvi.	Oxytetracycline	0.20
	lxxxvii.	Pefloxacin	3.20
	lxxxviii.	Phenoxymethylp enicillin	0.02
	lxxxix.	Piperacillin	0.20
	xc.	Polymixin	0.80
	xc.	Retapamulin	0.02
	xcii.	Rifampicin	0.02
	xciii.	Roxithromycin	0.40
	xciv.	Secnidazole	0.40
	xcv.	Sparfloxacin	0.02
	xcvi.	Spectinomycin	12.80
	xcvii.	Spiramycin	0.20
	xcviii.	Streptomycin	6.40
	xcix.	Sulbactam	6.40
	c.	Sulfadiazine	288.00
	ci.	Sulfadimethoxin e	20.00
	cii.	Sulfadoxine	0.24
	ciii.	Sulfamethoxazol e	0.24
	civ.	Tazobactam	17.60
	cv.	Tedizolid	3.92
	cvi.	Teicoplanin	0.20
	cvii.	Telithromycin	0.02

	cvi. Tetracycline	0.40
	cix. Thiamphenicol	0.40
	cx. Tiamulin	0.40
	cxi. Ticarcillin	3.20
	cxii. Tigecycline	0.40
	cxiii. Tildipirosin	0.17
	cxiv. Tilmicosin	0.40
	cxv. Tobramycin	0.40
	cxvi. Trimethoprim	0.20
	cxvii. Trovafloxacin	0.01
	cxviii. Tylosin	0.33
	cxix. Vancomycin	3.20
	cxx. Viomycin	0.80
	cxxi. Virginiamycin	0.80."

Note:- The sludge containing antibiotic residues shall be incinerated and the standard of incinerator notified for common hazardous waste incinerator or industry specific incinerator shall be applicable.

[F.No. Q-15017/12/2018-CPW]

JIGMET TAKPA, Jt. Secy.

Note: The principal rules were published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number S.O. 844 (E), dated the 19th November, 1986 and last amended vide notification number G.S.R. 952(E), dated the 26th December, 2019.



भारत का राजपत्र The Gazette of India

सी.जी.-डी.एल.-अ.-06082021-228807
CG-DL-E-06082021-228807

असाधारण
EXTRAORDINARY

भाग II—खण्ड 3—उप-खण्ड (i)
PART II—Section 3—Sub-section (i)

प्राधिकार से प्रकाशित
PUBLISHED BY AUTHORITY

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No. 442]

नई दिल्ली, शुक्रवार, अगस्त 6, 2021/श्रावण 15, 1943
NEW DELHI, FRIDAY, AUGUST 6, 2021/SHRAVANA 15, 1943

पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय

अधिसूचना

नई दिल्ली, 6 अगस्त, 2021

सा.का.नि. 541(अ).—जहां, कतिपय प्रारूप नियम अर्थात् पर्यावरण (संरक्षण) संशोधन नियम, 2020 भारत सरकार के पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय में अधिसूचना संख्या सा.का.नि. 44(अ), तारीख 23 जनवरी, 2020 की अधिसूचना द्वारा पर्यावरण (संरक्षण) नियम, 1986, के नियम 5 के उपनियम (3) के अधीन यथा अपेक्षानुसार भारत के राजपत्र, असाधारण में प्रकाशित किए गए थे, जिसमें सभी व्यक्तियों से जिनके उसके द्वारा प्रभावित होने की संभावना है उस तारीख से जिसको उक्त अधिसूचना में अंतर्विष्ट राजपत्र की प्रतियां जनता को उपलब्ध करा दी गई थी, साठ दिन की अवधि के भीतर आक्षेप और सुझाव आमंत्रित किए गए थे;

और पूर्वोक्त अधिसूचना में अंतर्विष्ट राजपत्र की प्रतियां 23 जनवरी, 2020 को जनता को उपलब्ध करा दी गई थीं;

और, पूर्वोक्त अधिसूचना के प्रतिउत्तर में सभी व्यक्तियों और पणधारियों से प्राप्त आक्षेपों और सुझावों को केंद्रीय सरकार द्वारा सम्यक रूप से विचार किया गया;

अतः, अब, केंद्रीय सरकार, पर्यावरण (संरक्षण) नियम, 1986 के नियम 5 के उपनियम (3) के साथ पठित पर्यावरण (संरक्षण) अधिनियम, 1986 का 29 की धारा 6 और धारा 25 द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए पर्यावरण (संरक्षण) नियम, 1986 का और संशोधन करने के लिए निम्नलिखित नियम बनाती है, अर्थात्: -

1. संक्षिप्त नाम और प्रारंभ- (1) इन नियमों का संक्षिप्त नाम पर्यावरण (संरक्षण) दूसरा संशोधन नियम, 2021 है।

(2) ये राजपत्र में उनके प्रकाशन की तारीख से एक वर्ष के पश्चात् प्रवृत्त होंगे।

2. पर्यावरण (संरक्षण) नियम, 1986 की अनुसूची-I में क्रमांक 73 और उससे संबंधित प्रविष्टियों के स्थान पर निम्नलिखित क्रमांक और प्रविष्टियां रखी जाएंगी, अर्थात्:-

क्र. सं.	उद्योग	पैरामीटर	मानक
1	2	3	4
73।	थोक दवा और निर्माण (फार्मास्युटिकल)	क. बहिःस्त्राव मानक*	
			एकाग्रता के लिए सीमित मूल्य (पीएच और जैव परख को छोड़कर मिलीग्राम / एल में)
		(i) अनिवार्य पैरामीटर	
		पीएच	6.0 -8.5
		बीओडी (3 दिन 27 डिग्री सेल्सियस)	30
		सीओडी	250
		टीएसएस	100
		तेल और ग्रीस	10
		अमोनिकल नाइट्रोजन	100
		जैव - परख परीक्षण**	100% में पहले 96 घंटों के बाद 90% मछली की उत्तरजीविता
		(ii) अतिरिक्त पैरामीटर###	
		***बेन्जीन	0.1
		***जाइलीन	0.12
		***मीथाइलीन क्लोराइड	0.9
		***क्लोरोबेन्जीन	0.2
		पी . के रूप में फॉस्फेट	5
		एस . के रूप में सल्फाइड	2
		फेनोलिक यौगिक	1
		जस्ता	5
		लोहा	3
		कुल क्रोमियम	2
		हेक्सावैलेंट क्रोमियम (क्रो6+)	0.1
		साइनाइड (एचसीएन के रूप में)	0.1
		आर्सेनिक	0.2
		मर्करी	0.01
		लेड	0.1
		एसएआर	26 से कम (भूमि पर केवल वाहन के लिए लागू)
		(iii) सीईटीपी के साथ उद्योग	
		सीईटीपी के साथ और सीईटीपी के लिए उद्योग हेतु निर्वहन किए गए मानक पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय की अधिसूचना का.आ. 4(अ), तारीख 1 जनवरी, 2016 द्वारा शासित होंगे।	

	राज्य प्रदूषण नियंत्रण बोर्ड अतिरिक्त सुसंगत पैरामीटर को विहित करेगा जैसा कि उद्योगों के सदस्य के आवश्यकता और निर्वहन के अनुसार इस अधिसूचना के पैरा क (ii) में दिया गया है और पर्यावरण शर्तों को प्राप्त करने के विचार की निगरानी को तत्परता से विनिर्दिष्ट करता हो। टिप्पण :- पैरा क में मानक सीईटीपी के सिवाय सभी निर्वहन के लिए लागू हैं *सीईटीपी के लिए उद्योग निर्वहन को लागू नहीं किया जाता है और भूमि तथा सतह जल निकाय के सभी निर्वहन को लागू होगा जिसके अंतर्गत उद्यान और सिंचाई प्रयोजन के लिए जल निस्तारण का प्रयोग किया जाना सम्मिलित है। ** जैव परख परीक्षण आई एस. 6582-1971 के अनुसार आयोजित किया जाएगा। “अतिरिक्त पैरा मीटर” के रूप में सूचिबद्ध पैरामीटर प्रक्रिया और उत्पाद पर निर्भर रहते हुए एसपीसीवी द्वारा विहित किए जाएंगे और एसपीसीवी एस द्वारा निर्णय के अनुसार उसकी तत्परता से मानीटरी मासिक/तिमाही रूप से की जाएगी। ***ये सीमाएं उन उद्योगों पर लागू होंगी जो बेन्जीन, जाइलीन मिथाइलीन क्लोराइड, क्लोरोबेन्जीन का उपयोग कर रहे हैं।																				
	ख. उत्सर्जन मानक (टैंक फार्म वेंट) <table border="1"> <thead> <tr> <th>पैरामीटर</th><th>एकाग्रता के लिए सीमित मूल्य (मिलीग्राम/एनएम 3)</th></tr> </thead> <tbody> <tr> <td>क्लोरीन</td><td>15</td></tr> <tr> <td>हाइड्रोक्लोरिक एसिड वाष्प</td><td>35</td></tr> <tr> <td>अमोनिया</td><td>30</td></tr> <tr> <td>बेंजीन</td><td>5</td></tr> <tr> <td>टोल्यूनि</td><td>100</td></tr> <tr> <td>एसीटोनिट्राइल</td><td>1000</td></tr> <tr> <td>डाइक्लोरोमेथेन</td><td>200</td></tr> <tr> <td>जाइलीन</td><td>100</td></tr> <tr> <td>एसीटोन</td><td>2000</td></tr> </tbody> </table> ग. विलायक का कुल संचयी नुकसान भंडारण सूची से वार्षिक आधार पर विलायक 5% से अधिक नहीं होना चाहिए	पैरामीटर	एकाग्रता के लिए सीमित मूल्य (मिलीग्राम/एनएम 3)	क्लोरीन	15	हाइड्रोक्लोरिक एसिड वाष्प	35	अमोनिया	30	बेंजीन	5	टोल्यूनि	100	एसीटोनिट्राइल	1000	डाइक्लोरोमेथेन	200	जाइलीन	100	एसीटोन	2000
पैरामीटर	एकाग्रता के लिए सीमित मूल्य (मिलीग्राम/एनएम 3)																				
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डाइक्लोरोमेथेन	200																				
जाइलीन	100																				
एसीटोन	2000																				
	घ. थोक दवा के विनिर्माण या फार्मास्युटिकल के प्रतिपादन में लगे उद्योग के लिए उद्योग या सीईटीपी कैटरिंग पर बेकार जल या उसके प्रबंध सुविधा से उत्पन्न होने वाले केमिकल और बायोलोजिकल गाढ़ा कीचड़ या किसी अवशेष, हटाए जाने, खतरनाक और अन्य अपशिष्ट (मैनेजमेंट एंड ट्रांस-बाउंडरी मूवमेंट) नियम 2016 के नियम 3 के उपनियम (1) के खंड 17 के उपबंध के अनुसार खतरनाक अपशिष्ट के रूप में वर्गीकृत किया जाएगा और उसमें किए गए उपबंध के अधीन होगा।																				

[फा. सं. क्यू-15017/12/2018-सीपीडब्ल्यू]

नरेश पाल गंगवार, संयुक्त सचिव

टिप्पण : मूल नियम भारत के राजपत्र, असाधारण, भाग II, खंड 3, उप-खंड (i) में संख्यांक का. आ. 844(अ) तारीख 19 नवंबर, 1986 में प्रकाशित किए गए थे और अंतिम बार अधिसूचना संख्यांक सा.का.नि. 243(अ) तारीख 31 मार्च, 2021 द्वारा अंतिम रूप से संशोधित किया गया था।

MINISTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE

NOTIFICATION

New Delhi, the 6th August, 2021

G.S.R. 541(E).—Whereas, certain draft rules, namely the Environment (Protection) Amendment Rules, 2020 were published in the Gazette of India, Extraordinary, as required under sub-rule (3) of rule 5 of the Environment (Protection) Rules, 1986, *vide* notification of the Government of India in the Ministry of Environment, Forest and Climate Change *vide* number G.S.R. 44 (E), dated the 23rd January, 2020, inviting objections and suggestions from all persons likely to be affected thereby within a period of sixty days from the date on which copies of the Gazette containing the said notification were made available to the public;

And Whereas, copies of the Gazette containing the aforesaid notification were made available to the public on the 23rd January, 2020;

And Whereas, objections and suggestions received from all persons and stakeholders in response to the aforesaid notification have been duly considered by the Central Government;

Now, therefore, in exercise of the powers conferred by sections 6 and 25 of the Environment (Protection) Act, 1986 (29 of 1986) read with sub-rule (3) of rule 5 of the Environment (Protection) Rules, 1986, the Central Government hereby makes the following rules further to amend the Environment (Protection) Rules, 1986, namely: -

1. **Short title and commencement.** - (1) These rules may be called the Environment (Protection) Second Amendment Rules, 2021.

(2) They shall come into force after one year from the date of publication of this notification in the Official Gazette.

2. In the Environment (Protection) Rules, 1986, in Schedule-1, for serial number 73 and the entries relating thereto, the following serial number and entries shall be substituted, namely:-

S.No.	Industry	Parameters	Standard
1	2	3	4
“73.	Bulk Drug and Formulation (Pharmaceutical)	A. EFFLUENT STANDARDS*	
			Limiting value for concentration (in mg/l except for pH and Bio assay)
		(i) Compulsory Parameters	
		pH	6.0 -8.5
		BOD (3 days 27°C)	30
		COD	250
		TSS	100
		Oil & Grease	10
		Ammonical Nitrogen	100
		Bio - Assay Test**	90% Survival of Fish after first 96 hours in 100% effluent

(ii) Additional Parameters^{##}

***Benzene	0.1
***Xylene	0.12
***Methylene Chloride	0.9
***Chlorobenzene	0.2
Phosphates as P	5
Sulphides as S	2
Phenolic Compounds	1
Zinc	5
Copper	3
Total Chromium	2
Hexavalent Chromium (Cr ⁶⁺)	0.1
Cyanide (as HCN)	0.1
Arsenic	0.2
Mercury	0.01
Lead	0.1
SAR	Less than 26 (applicable only for discharge on land)

(iii) Industry connected with CETP

- The discharge norms for industry connected with CETP and of CETP shall be governed by Ministry of Environment, Forest & Climate Change notification S.O. 4 (E), dated the 1st January, 2016.
- State Pollution Control Board shall prescribe additional relevant parameters as given at para A (ii) of this notification as per needs and discharge potential of member industries and specify the frequency of monitoring considering the receiving environment conditions.

Note:

The standards in para A is applicable to all discharges except to CETP.

*Not applicable to industry discharging to CETP, and shall be applicable to all discharge to land and surface water bodies including use of treated wastewater for horticulture or irrigation purpose.

** The Bio assay test shall be conducted as per IS : 6582-1971

Parameters listed as “Additional Parameters” shall be prescribed by SPCB depending on the process and product and its monitoring frequency shall be monthly/quarterly as decided by SPCBs

***Limits shall be applicable to industries those are using Benzene, Xylene, Methylene Chloride, Chlorobenzene.

B. EMISSION STANDARDS	
(Tank farm Vents)	
Parameter	Limiting value for concentration (mg/Nm ³)
Chlorine	15
Hydrochloric acid vapor	35
Ammonia	30
Benzene	5
Toluene	100
Acetonitrile	1000
Dichloromethane	200
Xylene	100
Acetone	2000
C. <i>The total cumulative losses of solvent should not be more than 5% of the solvent on annual basis from storage inventory</i>	
D. Chemical and Biological sludge or any residue, reject, concentrate generated from wastewater treatment or its management facility at Industry or CETP catering to industries engaged in manufacturing of bulk drug or formulation of Pharmaceuticals, shall be classified as Hazardous Waste as per the provision of clause 17 of sub-rule (i) of rule 3 of the Hazardous and Other Wastes (Management and Trans-boundary Movement) Rules, 2016 and shall be subject to the provision made therein.	

[F. No. Q-15017/12/2018-CPW]

NARESH PAL GANGWAR, Jt. Secy.

Note : The principle rules were published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) *vide* number S.O. 844(E), dated the 19th November, 1986 and lastly amended *vide* notification G.S.R. 243(E), dated the 31st March, 2021.

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Item Nos. 09&10

(Court No. 1)

**BEFORE THE NATIONAL GREEN TRIBUNAL
PRINCIPAL BENCH, NEW DELHI**

(By Video Conferencing)

Original Application No. 801/2018

With

Original Application No. 136/2020

(With reports dated 18.01.2022 & 20.01.2022)

Jasmeet Singh

Applicant

Versus

State of Himachal Pradesh

Respondent

With

Veterans Forum for Transparency in Public Life

Applicant

Versus

State of Himachal Pradesh & Ors.

Respondent(s)

Date of hearing: 21.01.2022

**CORAM: HON'BLE MR. JUSTICE ADARSH KUMAR GOEL, CHAIRPERSON
HON'BLE MR. JUSTICE SUDHIR AGARWAL, JUDICIAL MEMBER
HON'BLE MR. JUSTICE BRIJESH SETHI, JUDICIAL MEMBER
HON'BLE PROF. A. SENTHIL VEL, EXPERT MEMBER
HON'BLE DR. AFROZ AHMAD, EXPERT MEMBER**

Applicant: Dr. Bishwanath Prasad Singh, Wing Commander (Retd.), Applicant
in Person in OA 136/2020

Respondent: Mr. Nalin Kohli, Adv. for HPSPCB

ORDER

1. Both the above matters are being taken up together as the issue involved is of discharge of toxic industrial pollution in river Balad in Baddi industrial area in District Solan and rivers Sirsa and Satluj. Vide order dated 23.06.2021, scope of O.A. No. 801/2018 was noted to be "the remedial action against pollution of River Balad in Baddi industrial area in

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District Solan, on account of leakage from the Common Effluent Treatment Plant (CETP)" while scope of O.A. No. 136/20220 was noted to be, "remedial action against discharge of waste from CETP at Baddi and from Acme Life Sciences, Nalagarh and Helio Pharmaceuticals at Solan, to prevent pollution of rivers Sirsa and Satluj. According to the applicant, the CETP is not connected to pharmaceutical units at Barotiwala and Nalagarh who are discharging their effluents directly into the rivers. It is further stated that even after treatment in ETP/STPs, pharmaceutical ingredients may still be coming out from the industries unless ETP/STPs are specialized for the purpose. It is further stated that present CETP is not designed to neutralize Active Pharmaceutical Ingredient (API). The TSDF does not receive sludge generated from the industrial units at Nalagarh. The industries located at Baddi area are generating 20779 KLD of industrial effluent, out of which 17894 KLD is being treated at CETP and remaining 2885 KLD is being disposed of by the occupiers directly into river Sirsa. There is no existing sewerage system in BBN area and no demarcation in residential and industrial area. Presence of Ciprofloxacin in the concentration of 296.1 ug/l was found on chemical analysis. Concentration of Ciprofloxacin in the effluent discharge of M/s Acme Life Sciences work out to be 13455 times of the prescribed limit. The increasing occurrence of multi-resistant pathogens is a serious global threat to human health and it is finding its way into the water bodies and drinking water through industrial discharge and also due to heavy use of antibiotics in human and veterinary medicine."

2. The Tribunal noted the status in O.A. No. 801/2018 as follows:-

"2. The matter was considered on several occasions earlier. On 14.01.2020, the Tribunal considered the report dated 06.11.2019 filed by the State PCB to the effect that violation of provisions of the Water (Prevention and Control of Pollution) Act, 1974 was taking place by

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discharge of polluted effluents in the water bodies. The same is reproduced below for ready reference:-

"2.0 Inspection of CETP Baddi

- i) The CETP is designed to treat five different categories of effluent as tabulated under

Sr. No.	Category	Sector of Industry	No of Units	Consented effluent quantity (in MLD)
1.	I	Food, Paper and Textile	89	15.55
2.	II	Soap & Detergent	112	2.0
3.	III	Pharmaceutical	213	2.9
4.	IV	Dyeing	4* M/s Auro Textile Unit - I, M/s Auro Dyeing Unit - I, M/s Winsome Textile Industries	2.0
5.	V	Electroplating, Metal surface finishing	31	0.042
Total			449	22.492
				Say 23.00

- ii) It was observed that at an average of 17 mld effluent is treated by the CETP, comprising equalization tank, primary settler, aeration tank, reaction tank, secondary and tertiary clarifier. The treatment process for each stream is appended with the report (**Annexure IV**).
- iii) It was noticed that effluent of category IV is not reaching to its designated equalization tank. M/s Baddi Infrastructure Ltd., has informed that the dedicated pipe network to carry the effluent of category IV is blocked. The effluent of category IV is therefore being discharged through pipe network of Category I.
- iv) It is also observed that the CETP is designed to treat category V effluent by mixing with category IV effluent to optimize the chemical consumption and to achieve effective treatment. Since, the effluent of category IV has been mixed with category-I, in the pipe network itself before reaching CETP, which has resulted in formation of a new complex effluent for which the CETP was not designed. Therefore, it could not able to deliver the desired results w.r.t. treatment and thus, effluents was in non-conformity with the standards, as per the

monitoring results of HPPCB (Annexure-V). Besides, the effluent of category V remained effectively untreated throughout the CETP process.

v) The performance of CETP is being regularly monitored by HPPCB. The monitoring data (Annexure-V) indicate that the performance of the CETP is far from satisfactory for having not met the discharged standards. The data reveal that effluent quality does not conform the standards of Chloride (limit of 1100 mg/1 max.), Total dissolved Solids (TDS) (LIMIT OF 2100 MG/1 Mmax.) and Biochemical Oxygen Demand (BOD) (limit of 30 mg/1 max.).

vi) The CETP has provided online continuous effluent monitoring system for pH, Total Suspended Solids (TDS), Chemical Oxygen Demand (COD) and Total Organic Content (TOC) and data so recorded are linked with the server of HPPCB and CPCB.

While collecting the sample from the final outlet of tertiary clarifier and discharge point at River Sirsa, difference in colour of effluent was observed. The sample collected from the discharge point was lighter in colour than that of outlet of tertiary clarifier; giving rise to possibility of dilution. (Photograph: Plate-I)

vii) **The Committee also recorded that the Textile Units, which are generating the effluent of Category IV, were earlier operating their own effluent treatment plants prior to commencement of CETP and found it viable to operate due to their scale of production.**

viii) The designed treatment criteria of CETP are to treat effluent, stream-wise, following segregation at source, effluent of Category-I is mixed with Category-IV, resulted in alternation of criteria, hence treated effluent.

ix) For increasing the connectivity, the CETP has proposed of laying conveyance (pipeline) for a total length of 5.8 kms. The status is as under.

Sr. No.	Location	Stretch in meters	Status of permission obtained	Remarks
1.	Zydus Cadilla to Legacy Food on Baddi Barotiwala road	1655	Permission granted by HPPWD	Work has been awarded by M/s Baddi Infrastructure Ltd vide letter dated 27-09-2019. (Annexure-VI)
2.	Maplur-Baddi electrical substation upto Bhud	2250	Permission not granted by NHAI	

	near Maxtar Bio Genics Company			
3.	Bhud to Lehi	1900	Permission granted by HPWD	
Total		5805		

To safeguard the interest of environment from being deteriorated further and having understanding of pollution problem, its cause and remedial measures, the Committee recommends following:

- i) **Textile industries (SI. No.1 to 5, Table 1) engaged in dyeing-process generating effluent of Category-IV, as mentioned above for the purpose of designing and operating CETP, should stop its operations with immediate effect, until and unless the dedicated conduits supposed to carry the said effluent, is brought to back functional.**
- ii) These units shall resume operation of their ETP to impart effective treatment on effluent of Category-IV so as to meet the standards and shall pump treated effluent to the pipe network designated to carry effluent of Category-I for further treatment at CETP.
- iii) **These units shall resume operations only upon satisfactory performance of ETP which was brought back to functional and shall be monitored once in a month by HPCB.**
- iv) M/s Baddi Infrastructure including Ltd. is to ensure proper maintenance of CETP and its infrastructure including pipe network designed to receive effluents from member industrial units. M/s Baddi Infrastructure Ltd. has to ensure operation of CETP as per the defined protocol and in accordance to standard operating practice which is in place. In case, any variation (beyond the designed criteria) of effluent quality is noticed by CETP the same shall be brought to the knowledge of SPCB, in writing. The SPCB shall acknowledge the communications and shall act to identify the cause for taking all necessary steps for taking all necessary steps to eliminate/minimize such variation.
- v) **M/s Baddi Infrastructure Ltd. has to install activated carbon, pressure sand filters and ozonizer before the treated effluent is discharged. This refers the Detailed Project Report of CETP-Baddi, which finds mentioned of the system but has not been provided by M/s Baddi Infrastructure Limited.**

Reference is made on the observations recorded by the Committee constituted by Hon'ble Tribunal in O.A.

No.916/2018 in the matter of Sobha Singh and Others v/s State of Punjab and Others, wherein the Committee recommended that Rs.1.0 crore to be levied on CETP-Baddi as Environmental Compensation for untreated effluent discharged into River Sirsa. The CETP discharged, joining the river, has failed to meet Bio-assay Test (Toxicity on fish: 0% survival with 100% effluent for 96 hours). This would have caused impact on water and land (soil) environment, plants and vegetation, aquatic life and human health all along downstream of CETP-Baddi.

Thus, Committee also recommends the following:-

- vi) Environmental compensation (EC) to be levied to CETP-Baddi (M/s Baddi Infrastructure Ltd) for not having done effluent treatment upto the standards and to those Textile Industries (dyeing units) responsible for making CETP defunct. The EC would be proportionate as under.
 - a) CETP-Baddi has to pay environmental Compensation to the tune of Rs.1.91 Crores for non-compliance of discharged standards, estimated based on violation recorded by HPPCB over last one and half year [19.10.2017 -01.11.2019] (**Annexure VII**) including compensation to the tune of Rs.87.9 Lakh imposed by HPSPCB dated 15.10.2019 over one year [20.11.2018 to 09.09.2019] (**annexure VIII**).
 - b) Textile Industries (dyeing units) are to pay establishment cost of CETP and cost of pipe network which was brought to state of irreparable.
- vii) HPPCB is to review the notification, dated 17.03.2018 wherein Total Suspended Solids (TSS), Oil & Grease and pH have been notified TDS, BOD, Chloride and Sulphide may also be considered for inclusion in the notification as these have critical bearing on operation and performance of CETP designed to impart effective treatment. HPPCB may undertake similar exercise as done in case of notification, dated 29.06.2019 for CETP Paonta Sahib, wherein eight parameters including those referred here, have been considered. Such notification may be issued in consultation with CPCB.
- viii) **For optimal performance of CETP-Baddi, HPPCB is to ensure regulating and monitoring mechanism be in place by asking all member units (falling under red category) of CETP to install online continuous effluent monitoring system. The data so recorded shall be made available on SPCB and CPCB server for effective control."**

3. The matter was then considered on 18.06.2020 in the light of compliance report dated 11.06.2020 filed by the State PCB. It was observed:



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"xxx

xxx

xxx

5. In pursuance of above, the State PCB has filed a 'compliance report' dated 11.06.2020 to the effect that the units gave action plans which are not satisfactory as long timeline have been prescribed.

6. We do not find the report to be as per the mandate of law. **If the pollution is continuing, the State PCB is under obligation to close the polluting activities by exercising its jurisdiction under the Water Act, 1974 and recover compensation from the polluters. Till pollution is stopped, polluting activities, which are punishable crime under the law, cannot continue. The State PCB has failed to take action merely on the ground that action plan was being prepared or had been prepared which was not satisfactory. None appears for the State PCB."**

4. The matter was last considered on 04.01.2021 in the light of the report of the State PCB dated 01.01.2021 mentioning the steps taken for closure and recovery of compensation. The Tribunal found that the action taken was not adequate as CETP was still non-compliant. Untreated effluents were thus being discharged into the water bodies in violation of law. Discussion and direction in the said order are reproduced below:-

"1to3....xxx.....xxx.....xxx

4. Accordingly, the State PCB has filed its report on 01.01.2021. It mentions that the State PCB issued show cause notice dated 23.06.2020 to the concerned textile units for closure and recovery of compensation against which writ petitions were filed before the Himachal Pradesh High Court. The High Court, vide order dated 22.07.2020, directed that the matter be heard by the Principal Secretary, Environment and fresh order passed. The Principal Secretary, Environment passed further order on 30.12.2020 directing the State PCB to take action for enforcement of law since violation of law was established. The Principal Secretary, Environment held:

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..... But this fact cannot be ignored that effluent discharge, FDS in particular, by these units is beyond the prescribed limits which is contributing to pollution. In the light of this discussion, I am of considered view that, keeping in view the above position, SPCB may take action strictly according to the provisions of Law and rules applicable in this case."

5. The State PCB accordingly issued fresh show cause notice on 28.12.2020 and passed further order dated 01.01.2021 as follows:

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Whereas, the effluent of category-IV being contributed by the unit M/s Auro Textiles, Sai Road Baddi, Distt. Solan, H.P to the CETP for final disposal and treatment by unit is not complying since 25-7-2020 till date to the discharge standards as prescribed in the schedule-1 of EP Rules, 1986 as well as the inlet quality standards notified by the State Government and thereby causing water pollution.

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Now, therefore, in consideration of the facts stated above, in view of the directions of Hon'ble High Courts orders, Hon'ble NGT and the orders passed by Principal Secretary (Env, S&T) Govt of HP and in exercise of the powers conferred under section 32 and 33-A of Water (Prevention & Control of Pollution) Act, 1974 M/s Auro Textiles, Sai Road Baddi, Distt. Solan, H.P. is hereby directed to:

1. Immediately shut down the dyeing process of the textile unit contributing towards the category- IV effluent to CETP, Baddi, till the unit becomes compliant.
2. Pay Environment Compensation to the tune of Rs. 42 lakhs (Forty Two Lakhs only) for the violation period w.e.f. 25-07-2020 to 31-12-2020 (140 days excluding the period of compliance)."

Identical orders are said to have been passed against four textile units.

6. We have heard Shri Nalin Kohli, learned Counsel appearing for the State PCB.

7. We find that though in the show cause notice the State PCB proposed disconnecting power supply, this direction has not been given in the final order. We also find that the CETP has still not complied with the environmental norms for which remedial action needs to be taken by the State PCB, by improving quality and reducing the load of inlet so as to be consistent with the designed capacity of the CETP or closing such units contributing to the waste for which the CETP is not designed till the concerned units make their own arrangement for treating the effluents. The member industries may be considered non-compliant, if they do not undertake primary treatment as per EC conditions of the CETP. The industries having effluent generation more than 200 KLD may be directed to treat the effluents and recycle/reuse to the maximum extent and also reducing the FDS. Wherever required, water audit of red category non-compliant units be conducted. The requisite pipeline may also be required to be constructed by the CETP to carry the waste.

8. Let further progress report be filed before the next date by e-mail at judicial-ngt@gov.in preferably in the form of

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searchable PDF/OCR Support PDF and not in the form of Image PDF.”

5. The State PCB has filed interim report dated 06.05.2021 followed by further report dated 16.06.2021. It will suffice to refer to the last report to the effect that the samples were taken and were not found to be within the limits. The State PCB gave directions to the concerned industries. While some units have achieved the norms, further action is being taken in the matter. The status as mentioned in the report is reproduced below:-

“In compliance to afore-cited order dated 04-01-2021 it is submitted that earlier the State Board had filed an Interim Report vide letter No. PCB/OA No. 801/2018 /-1549 dated 6-5-2021 wherein it was submitted that Board has taken steps to make the CETP, Baddi compliant. The FDS level was found 2364mg/Itr as per sampling conducted at that time, though not within the prescribed limits. It is further submitted that now the latest sample taken on 21-5-2021 and 7- 6-2021 has been found within the prescribed limits w.r.t. FDS as the same has been reduced to the 2019mg/Itr and 2072 mg/ltr respectively. The sampling chart of the CETP Baddi is annexed as Annexure —A which reveals that there is continuous improvement and now the analysis results of latest sample taken are meeting the norms w.r.t. FDS.

It is further submitted that as regard to the issue of industries having effluent generation of more than 200 KLD, the State Board had identified and issued directions to 16 numbers of industries to operate their treatment plants i.e. primary, secondary and tertiary treatment system for the effluent treatment as per Environment Conditions of CETP and also directed to recycle / reuse to the maximum extent and also to reduce the FDS. Now as per report received from the Regional Office Baddi, these 16 units are operating the effluent treatment plants prior to their effluent discharge to CETP. The State Board has conducted inspection and sampling of these 16 units. The earlier results of sampling conducted on 21-1-2021, 29-1-2021, 1- 3-2021, 23-3-2021 and 16-4-2021, were found within limits (except of three units of M/s Vardhman and one unit of Winsome Textile) which has already been placed on record alongwith interim report dated 6-5-2021. However, the latest results of sampling conducted on 21-5-2021 the results of three units namely M/s P&G Home Products Baddi, M/s Torrent Pharmaceutical Ltd. Baddi and M/s Abbott Health care, Baddi were found above the prescribed limits for which notices dated 16-6-2021 has been issued to these units. Copy of sample results and notices issued are annexed as Annexure-B and Annexure-C (colly). The sample results of other units were found within the prescribed limits. It is further submitted that as reported by Regional Officer, Baddi the member industries having flow less than 200 KLD are disposing off their effluent to CETP, Baddi after primary treatment.

As regard to the compliance by the four textile units namely Auro Textile, Auro Textile unit —II, Auro Dyeing of

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Vardhman Textile and one unit of Winsome Textile, it is submitted that as per report received from the Regional Office, Baddi, **the work of installation of advance treatment system by M/s Vardhman textile to reduce FDS is under progress and Reverse Osmosis system of capacity of 2 MLD shall be operational by 30-6-2021.** In addition to Reverse Osmosis, M/s Vardhman Textile is also installing the Multi Effect Evaporator of capacity of 370 KLD. As regard to progress of installation of advance treatment system by M/s Winsome Textile it is submitted that as per report received from Regional Office, Baddi the unit has completed the civil construction work. **The installation of Reverse Osmosis system and other components is under progress.** Copies of progress report of these textile units received from Regional Office are annexed as Annexure D and E. **The latest sample results of these four textile units are still not meeting the norms.** Sample results are annexed as Annexure-F. As already submitted in interim progress report dated 6-5-2021, it is again submitted here that **State Board had issued directions on 1-1-2021 to these four textile units under section 33-A of Water Act, 1974 for closure and levied Environmental Compensation which were challenged by these units before the Hon'ble High Court of HP vide CWP No. 414/2021, 416/2021 417/2021 and 418/2021. The Hon'ble High Court of HP vide order dated 11-1-2021 and 15-3-2021 has stayed the operation of the directions issued by the State Board and the matter is still pending before the Hon'ble High Court of Himachal Pradesh for adjudication.** Copies of order dated 15-3-2021 are annexed as Annexure-G.

It is further submitted that due to constant efforts of all stakeholders, the two consecutive latest samples of CETP outlet are meeting the norms prescribed by the MoEF &CC vide notification dated 1-1-2016. In future, the State Board shall continue to make all efforts in form of surveillance, regular monitoring and regulation on the CETP and member industries, so that the CETP remains compliant in future as well."

6. From the above, it is clear that violations are still continuing. Stay of order of closure and assessment of compensation for the past violations does not justify inaction for failure to take action for further violations after the order of stay and to initiate prosecution of the industrial units in question, including their Owners/Directors and the CETP operators. We also find that merely keeping an eye on units discharging more than 200 KLD is not enough. Violation by those discharging less than 200 KLD is not less serious violation nor less harmful for the environment and public health.

7. Accordingly, let further remedial action be taken to enforce the environmental rule of law in the interest of protection of environment and public health and a report of status of compliance filed after inspection by a four Member joint Committee comprising a representative of MoEF&CC,

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CPCB, State PCB and District Magistrate, Solan by e-mail at judicial-ngt@gov.in preferably in the form of searchable PDF/ OCR Support PDF and not in the form of Image PDF. The State PCB will be the nodal agency for coordination and compliance."

3. In O.A. No. 136/2020, extracts from last order dated 23.06.2021 are as follows:-

"3. The matter was last considered on 04.01.2021 in the light of the report of State PCB dated 30.12.2020 noticing the violations of environmental norms. The Tribunal directed remedial action and filing of compliance report. The operative part of the discussion and order of the Tribunal are reproduced below:-

"3. Accordingly, the Himachal Pradesh State PCB has filed its report dated 30.12.2020 to the effect that the joint Committee visited the area and noticed as follows:

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i. **The CETP has not installed the system to completely treat category IV effluent (High TDS/FDS Stream). Despite the fact that CETP does not have the capacity to treat this type of effluent, CETP has entered into the tripartite agreement with the Industries generating Category IV effluent has been receiving this category of effluent since 2016.**

ii. **As per Environmental Clearance granted to CETP Baddi by the Ministry of Environment, Forests and Climate Change (MoEF&CC), the member industries with hydraulic loading more than 200 KLD shall treat the effluent in the existing onsite ETPs and then discharge into CETP for further treatment and discharge. However, it was informed that Units with hydraulic loading of 200 KLD are not treating effluent in the onsite ETPs and supplying primary treated effluent to CETP. Therefore, CETP has not been complying with this condition of the Environmental Clearance granted by MoEF&CC for the last 04 years. Accordingly, the sampling of these units was done by HPPCB team on 10/12/2020 and the samples were sent to HPPCB Central Laboratory. The results of the analysis are expected by 10/01/2021.**

iii. **The observations made by the Joint Committee during visit to the two Pharma units i.e. M/s Acme Life Sciences and M/s Helios Pharmaceuticals mentioned in the original application are as follows:**

- **Both the pharma units have connectivity with the CETP for supplying the primary treated effluent, for further treatment at CETP.**

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- No effluent was found to be discharged directly by the Units, in the drain.
- The Joint Committee collected the samples from the final outlet of the pharma units under reference, to see the concentration of residual antibiotics in the primary treated effluent which is being sent to CETP for further treatment. The results of the analysis are expected by 09/02/2021.

iv. The evaluation of the results of the analysis of the CETP samples collected by the Joint Committee on 12-13 October, 2020, indicated intended dilution by CETP so as to achieve the prescribed norms. Therefore, the Joint Committee conducted unannounced re-sampling and sent the samples for analysis from three different laboratories.

v. The results of analysis for the samples collected by the Joint Committee have been analyzed in HPPCB Regional Laboratory, Paonta Sahib and evaluation of the results indicated that CETP is not meeting the norms prescribed for COD (264 mg/l > 250 mg/l), BOD (35 mg/l > 30 mg/l), FDS (2252 mg/l > 2100 mg/l) and Chloride (1838 mg/l > 1000 mg/l). Therefore, it is concluded that CETP is discharging the effluent into the Sirsa River without complying with the prescribed norms. The results of the analysis of the samples are awaited from two other laboratories.

vi. The samples from CETP, upstream and downstream of Sirsa River and the pharma units under question, were collected by the joint committee on 09/12/2020 for analysis of 12 Nos. residual antibiotic residues from Shri Ram Institute of Industrial Research, Delhi. The results of analysis of effluent samples for residual antibiotics is expected by 09/02/2021. The issue of discharge of residual antibiotics as raised by the applicant may be concluded by the Joint Committee after receipt of the analysis results.

In view of the fact that complete analysis reports will be available by 09/02/2021, it is humbly prayed to Hon'ble National Green Tribunal that Joint Committee may kindly be permitted to file the final conclusive report by 15/02/2020."

4. Accordingly, further action taken report may be separately filed by the State PCB before the next date by e-mail at judicial-ngt@gov.in preferably in the form of searchable PDF/OCR Support PDF and not in the form of Image PDF. The directions in the connected matter being OA No. 801/2018, Jasmeet Singh v. State of Himachal Pradesh, dealt with by a separate order, to the extent relevant for the present matter, may also be followed."

4. The State PCB has filed its report dated 10.03.2021 giving the analysis results of samples calculated from the units as follows:-

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"Supplementary Report:

The analysis results from the remaining two laboratories w.r.t samples collected by the Joint Committee have been received (Annexure-2 and Annexure-3). Further, the report of analysis w.r.t. samples collected by the Joint Committee from CETP, Pharma Units and Sirsa River for the presence of antibiotics from the approved external laboratory has also been received (Annexure-4). Accordingly, supplementary report in this matter is being filed by the Joint Committee as follows:

- i) The results of analysis as received from three different laboratories of HPPCB, indicated that CETP is not meeting the norms prescribed for BOD (41, 35 & 38 mg/l > 30 mg/l), FDS (2252 & 3190 mg/l > 2100 mg/l) and Chloride (1209, 1838 & 1209 mg/l > 1000 mg/l). Therefore, it may be concluded that CETP is discharging the effluent into the Sirsa River without complying with the prescribed norms.
- ii) The results of analysis of the samples collected from various stages of CETP and also final discharge point in River Sirsa for the presence of residual antibiotics indicate that two antibiotics viz. Ciprofloxacin and Ofloxacin are present in the final treated effluent of CETP as a concentration of 22.8 ug/l and 69.8 ug/l respectively.
- iii) There are no standards notified by MoEF&CC for residual antibiotics in industrial effluents. However, these values are 1140 times higher for Ciprofloxacin (22.8 ug/l Vs. 0.02 ugh) and 349 times higher for Ofloxacin (69.8 ug/l Vs. 0.2 ugh) when compared with the proposed standards in the draft notification issued by MoEF&CC vide No. CG-DL-E-27012020- 215690 dated January 23, 2020 (Annexure-5), for pharmaceutical industry effluent and CETPs with membership of Bulk drug and formulation units.
- iv) Similarly, the samples collected by the Joint Committee from the outlets of two Pharmaceutical Industries viz. Helios Pharmaceutical and M/s Acme City Tech LLP, leading to CETP, were found to be much higher than the standards proposed in the draft notification issued by MoEF&CC. Also, the values reported as below quantification limit (BQL), in the analysis report of the external laboratories may not be considered as conclusive and within the proposed limits as draft notified by MoEF&CC, since the BQLs of external laboratory for various antibiotics tested in the samples, as shared with the Joint Committee, are much higher than the proposed standards.
- v) As per reports and research data available in the literature, the concentration of residual antibiotics has been found to be reduced by 60-90 % in conventional biological treatment plant. In view to assess the

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performance of the biological treatment system installed by CETP, the samples were collected from various stages of CETP. The results of analysis indicated that the performance of biological treatment system installed by CETP is not in line with the reports and data available in the literature, w.r.t. treatment of residual antibiotics. The inefficient performance of biological treatment system is also evident from the noncompliance of CETP with regard to biochemical oxygen demand (BOD).

Conclusion and Recommendations:

In view of the fact that:

- i) *There are no standards notified by MoEF&CC w.r.t. residual antibiotics in industrial effluents;*
- ii) *Draft notified standards are yet to be decided by MoEF&CC;*
- iii) *The concentration of residual antibiotics at outlet of CETP in Sirsa River, is much higher than the draft notified standards;*
- iv) *The treatment efficiency of CETP w.r.t residual antibiotics is not at par with the reports and data available in the literature;*
- v) *The CETP is not meeting the prescribed norms of BOD, FDS and chloride and discharging effluent into Sirsa River without complying with the prescribed norms.*

It is recommended that Pharmaceutical (both bulk drug and formulation units) may be directed by Himachal Pradesh Pollution Control Board to provide primary treatment to the level of predicted no effect concentration (PNEC) as developed by members of AMR Industry Alliance (Annexure-6), as a site (Baddi) specific preventing measure, so that there is no adverse impact of residual antibiotics on the environment and also to prevent development of antimicrobial resistance (AMR)."

5. *The report is followed by further report dated 05.05.2021 as follows:-*

"It is further submitted that now the joint committee has submitted its supplementary report which is annexed as Annexure R-1/1. Based on the inspections and sampling conducted the conclusion and recommendations made by the joint committee are as under:-

- "i) There are no standards notified by MoEF & CC w.r.t. residual antibiotics in industrial effluents.*
- ii) Draft notified standards are yet to be decided by MoEF & CC.*

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- iii) The concentration of residual antibiotics at outlet of CETP in Sirsa river is much higher than the draft notified standards.
- iv) The treatment efficiency of CETP w.r.t. residual antibiotics is not at par with the reports and data available in the literature.
- v) The CETP is not meeting the prescribed norms of BOD, FDS and chloride and discharging effluent into Sirsa River without complying with the prescribed norms....."

The copy of Supplementary Report submitted by the joint committee dated 10-03-2021 (annexed as Annexure R-1/1) may be placed on record please.

It is submitted that as of now there are no specific standards notified by the Govt. of India for residual antibiotics parameters in the existing notification of standards for pharmaceutical (Manufacturing and Formulation Industry). However, it is worthwhile to mention here that all the bulk drugs/pharmaceutical manufacturing units (if not connected with CETP) are being regulated for the compliance as per standards notified in MoEF & CC Notification dated 9-7-2009 (copy annexed as Annexure R-1/2). If the pharmaceutical (manufacturing and formulation industry) is member of CETP, then the unit is bound to comply with inlet quality standards notified by the Govt. of HP vide notification dated 17-3-2018 and 26-12-2019 (copies annexed as Annexure R-1/3 and R-1/4) The notification of specific standards for residual antibiotics (annexed as Annexure -5 with joint report) is still under proposed stage and shall be implemented for regulatory aspect as and when finalized by the MoEFF & CC."

6. The industrial units in question have also filed their Counter Affidavits. The said Counter Affidavits are of no assistance.

7. As against the above, the applicant has filed written submission on 11.06.2021 pointing out that the analysis of the samples shows presence of antibiotics in the water.

8. The conclusion drawn from the analytical results is as follows:-

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1. Ciprofloxacin (22.8µg/L) and Ofloxacin(69.8µg/L) were detected in higher concentrations in the effluent released to Sirsa river from CETP (Sr. no 4), i.e., 1139 and 348 times higher than the prescribed MoEF& CC draft notification limits.
2. The higher concentrations of antibiotics in the effluent released to Sirsa river (Sr. no 4) clearly indicate that CETP is unable to completely remove or degrade these antibiotics.

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3. Ofloxacin (960µg/L) was found in the effluent from M/S Helios Pharmaceutical (Sr. no 13) release to CETP, which is much higher than the draft notification limit (0.2 µg/L). It clearly raises doubt on the level of pre-treatment of the pharma effluent from this industry before it is released to the CETP.
4. The samples drawn from the effluent of M/S Acme City Tech LLP (Sr. no 14 and 15) release to CETP shows reasonably high concentrations of Ofloxacin (170 µg/L) and Azithromycin (423µg/L) even after primary treatment, indicate inefficient pre-treatment at this industry.
5. In the research methodology Limit of quantification (LOQ) for a compound by any method indicates the lowest concentration that can be quantified with accuracy and precision. The values below LOQ cannot be correctly quantified during the analysis and are reported as Below Quantification Limit (BQL). In the present analysis, the LOQs of the compounds fixed for the analysis by the lab are very high; namely, Ciprofloxacin (5 µg/L), Ofloxacin (5 µg/L), Piperacillin (5 µg/L), Azithromycin (10 µg/L), Tazobactam (5 µg/L), Cefprozidime (50 µg/L), Cefixime (20 µg/L), Amoxicillin (10 µg/L), Ampicillin (10 µg/L), Cefpodoxime (10 µg/L), Sulbactam (10 µg/L), Ceftriaxone (50 µg/L) and Cefoperazone (10 µg/L). The above LOQs of the compounds are much higher than even the antibiotic discharge limits set by the MoEF & CC draft notification for these compounds; except for Tazobactam.
6. Incidentally Piperacillin and Amoxicillin are the antibiotics are known for the very adverse impact on the human health even in the very low concentration. In this laboratory analysis, BQL limit for these compounds are set as (5 µg/L) and (10 µg/L) which is significantly higher than the limit fixed in the draft standards. In the draft standards the limit set for these two compounds are (0.1µg/L).
7. This implies that the Limit of Quantification (LOQ) set up by the lab is significantly higher than the limit set by the draft notification and therefore many of the compounds are not being detected as has been marked as BQL in the analysis results.
8. Therefore, the samples analysis should be conducted using an analytical method to precisely and accurately quantify lower concentrations of the compounds (LOQs should be kept as close or even lower than the draft notification limits) to quantify all the compounds at lower concentrations with accuracy and precision. This raises the question mark on integrity of the overall analysis by the lab.
9. Further the findings also imply that the CETP is not designed to efficiently treat class IV effluents; however, operator of CETP has entered into agreement with various pharma manufacturing units who are releasing class IV effluents to the CETP since 2017."

9. Further submissions are reproduced below:-

"14. The migration of antimicrobials into the environment has significant impacts. They can disrupt wastewater treatment processes and adversely affect ecosystem because they are toxic to beneficial bacteria. Some antimicrobials also bio accumulates; for example, erythromycin has been found to have both a high bio accumulation factor of 45.31 and a tendency to accumulate in soil. Antimicrobials can also be persistence for extended periods of time, the environmental persistence of erythromycin for example, is longer than one year.

15. Although not well studied, the presence of antimicrobials in natural waters may be exerting selective pressure leading to the development of antibiotics resistance in bacteria. The threat of growing antibiotics resistance has been recognised by, among others, the WHO, the National Academy of Science, the American Medical Association, the American Public Health Association and the US government Accountability. In fact the Centre for Disease Control and prevention (CDC) has identified antibiotics resistance as one of the most pressing public health problem facing the nation. Infections caused by bacteria with resistance to at least one antibiotic have been estimated to kill over 60,000 hospitalized patients each year. Methicillin resistant strains of *Staphylococcus aureus*, although previously limited primarily to hospital and health facilities, are becoming more widespread. In 2007, Consumer Reports tested over 500 whole chickens for bacterial contamination and antibiotic resistance. They found wide spread bacterial contamination in their samples and 84 percent of the salmonella and 67 percent of the campylobacter organisms that were isolated showed resistance to one or more antibiotic.

16. Antibiotic resistance is caused by a number of factors including repeated and improper use of antibiotics in both humans and animals. Half of the antibiotics used in livestock are in the same classes of drug that are used in humans and animals. The U.S. institute of Medicine and the WHO have both stated that widespread use of antibiotics in agriculture is contributing to antibiotic resistance.

17. The above study done by the HPPCB shows that from whichever place samples have been taken by HPPCB these are having antibiotics discharge which should not have been there. There is not a single sample in which the aforesaid antibiotics discharging into surface water and also seeping into the subsoil water is not there. This would lead to harmful antibiotic resistance amongst human and animal population and, thus, reducing the chances of their recovering from diseases where absence of resistance from these antibiotic would have helped. The above table and the subsequent narration would show that the antibiotics found in the discharge include some of the ultimate antibiotics developing resistance of which may be a death warrant for different life forms – human and animal – if

infected with diseases where these antibiotics could have provided a cure.

18. A situation where all random samples show the same results, in technical terms, is called '100% random test positivity'. In view of the '100% random test positivity', the study conducted by HPPCB cannot be stated to be complete and conclusive. It only indicates that a whole lot of polluting antibiotics are being discharged into the surface and subsoil water which is harmful for human and animal population.

19. As per information available at internet, there are more than 270 Pharmaceutical Companies operating in Baddi-Barotiwala-Nalagarh area. List of such Pharmaceutical Companies along with their addresses, as obtained through internet sites, is placed at Annexure A.

20. This necessarily requires a further and more detailed study as a sequel to 'the sample study' done by HPPCB to understand the entire extent of damage because of the aforesaid antibiotic discharge into the water bodies. It is being called 'sample study' because of the fact that it has '100% random test positivity' and therefore, in scientific tradition, there is an absolute need for following it up with a detailed, wide and more in depth study of the antibiotic discharge into river sirsa."

10. We have heard the applicant in person and the Learned Counsel for State PCB.

11. **We find that there is gross failure on the part of the State PCB to act as per public trust doctrine in preventing discharge of toxic effluents containing harmful residue of antibiotics in water posing threat to aquatic life (reference: "biomonitoring of Sirsa River in Baddi area of Himachal Pradesh by Bhagat S. Chauhan, et al, International Journal of Theoretical and Applied Sciences 5 (1): 183-185(2013)) which is also in violation of the Water (Prevention and Control of Pollution) Act, 1974. Such failure of statutory duties is at the cost of public health and protection of environment for which Chairman and Member Secretary of the PCB owe an explanation which may be furnished before the next date. Mere fact that standards have not been revised by MoEF&CC of the residual antibiotics in industrial effluents can be no justification for State PCB not taking steps to prevent. Pending finalization of standards by MoEF&CC, State PCB can go by earlier standards or lay down standards by itself under section 17 of the Water Act. MoEF&CC needs to expedite the process of finalizing the standards in the interest of protection of environment.**

12. **Accordingly, MoEF&CC and the State PCB may take further remedial action expeditiously. The State PCB may ensure that no harmful components in the effluents are discharged into the water by the units in question or any other API unit. A joint Committee of nominee of MoEF&CC, CPCB, State PCB and District Magistrate, Solan may conduct**

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inspection of the area and give a report of the status of violations and the remedial action taken within three months by e-mail at judicial-ngt@gov.in preferably in the form of searchable PDF/ OCR Support PDF and not in the form of Image PDF. The State PCB will be the nodal agency for compliance. The Committee may interact with the concerned stake holders, including the concerned Industries. The report may inter alia give status of performance of individual pharmaceutical units, particularly with reference to removal of API residue by them and by the CETP, the number of pharma industries connected to CETP and those discharging effluents directly into the drain and the river. The report may further indicate chemical and biological water quality of rivers in question - Sirsa and Satluj, including the status of residue at relevant locations. CPCB may also suggest monitoring mechanism for API residue through a credible system so as to cover all pharma industries in the country discharging API residue directly or indirectly in river systems. CPCB may propose the timelines to undertake monitoring which may also take a note of water quality monitoring guidelines of CPCB titled "Guidelines on Water Quality Monitoring, 2017" and the performance audit report dated 18.09.2020 filed by CPCB in OA 95/2018, Aryavart Foundation v. M/s Vapi Green Enviro Ltd. & Ors. and the directions of the Tribunal dated 05.02.2021. Relevant direction is reproduced below:

"22. The directions on the subject are summed up as follows:

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- vii. CPCB and State PCBs/PCCs, as directed earlier, may utilise EC funds on laboratory set up/upgradation, and on the mentioned areas in the report as well as on approved District Environment Plans. No approval of Central/State Government will be necessary in this regard in view of section 33 of the NGT Act, supra."**

CPCB may file report on the above aspects before the next date of hearing by e-mail at judicial-ngt@gov.in preferably in the form of searchable PDF/ OCR Support PDF and not in the form of Image PDF."

4. In pursuance of above, reports have been filed by the State PCB. In O.A. No. 801/2018, report filed on 18.01.2022 mentions the visit to the site on 01.10.2021 and 23.11.2021 and non-compliances found. The report mentions that 97 industries were found to be non-compliant. In view of the fact that there is an interim order granted by the Himachal Pradesh High Court on 01.09.2021 and 10.11.2021 against industries having less than 200 KLD discharge, applicable to action in pursuance of Notification

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dated 26.12.2019 issued by the HP Government laying down inlet norms of the CETP. CETP itself was found to be non-compliant due to toxicity of the waste received. CETP is now to be upgraded by the funds received from the Central Government. The report also mentions compliance status of the industrial units covered in O.A 136/2020 and it is found that in post-monsoon sampling, there is deterioration of water quality, downstream of CETP. The relevant extracts from the report are:-

"2.0. Findings of the Joint Committee and Status of Compliance:

In compliance of the directions of the Hon'ble NGT, HPPCB submitted report of the Joint Committee on 30/9/2021, followed by supplementary report on 23/11/2021. In continuation of the above reports, the final report/findings of the Joint Committee are submitted as follows:

- i. *Total Number of Industrial units in BBN (Baddi, Barotiwala, Nalagarh) Area covered under Consent Mechanism are **2444 (Red Category 219, Orange 900 and Green category 1325)***
- ii. *Out of 2444 industrial units in BBN Area, **1703 units are located in Baddi Barotiwala area and remaining 741 units are located in Nalagarh region.***
- iii. *Total number of **water polluting industries in BBN Area is 576.***
- iv. *Out of total 576 water polluting industries, **456 industries are located in Baddi area and 120 industries are located in Nalagarh area. All these 456 industries located in Baddi Barotiwala area, are connected to CETP either through pipe line or tankers. Further, out of these 456 Industries located in Baddi Barotiwala area, 376 industries are operational and remaining 80 are temporarily closed.***
- v. *Out of 120 water polluting industries located in Nalagarh area, **24 industries are connected to CETP, Baddi through tankers and remaining 96 water polluting industries have installed their own ETP to treat the industrial effluent. As per information provided by HPPCB, none of these units are discharging treated effluent into the water bodies.***
- vi. ***All 456 industries of Baddi Barotiwala area were monitored by HPPCB, during July to October, 2021 in this matter. Joint Committee also monitored randomly selected 13 No. Industries out of these 456 industries, during 1-2***

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November, 2021, for cross verification of the compliance (**Annexure-I**).

- vii. Out of these 456 industries monitored by the HPPCB and Joint Committee, **97 industries were found to be non-compliant w.r.t norms prescribed by HPPCB** for discharge at the inlet of CETP for further treatment. The list of **97 industries** not complying with the prescribed norms is attached as **Annexure-II**.
- viii. MoEF&CC has prescribed limits for the discharge parameters of CETP vide notification dated January 1, 2016, wherein, it is also mentioned that "**For each Common Effluent Treatment Plant (CETP), the State Board will prescribe Inlet Quality Standards for General Parameters, Ammonical Nitrogen and Heavy metals as per design of the Common Effluent Treatment Plant (CETP) and local needs & conditions**" (**Annexure-III**). Accordingly, in compliance of the MoEF&CC notification, **CETP inlet norms have been prescribed vide notification dated 26/12/2019 issued by Govt. of HP (Department of Environment Science & Technology)**.
- ix. No action was taken by HPPCB against **97 Nos.** industries having hydraulic loading less than 200 KLD, which were found to be not complying with the CETP inlet norms, since, the Baddi Barotiwala Nalagarh Industrial Association(BBHIA) has filed a petition in the High Court of Shimla (CWP No. 4961 of 2021), wherein the CETP inlet norms as per notification dated 26/12/2019 issued by Govt. of HP (Department of Environment Science & Technology) in compliance of MoEF&CC Notification dated January 1, 2016, have been challenged, taking a plea that the environmental clearance has specified condition of treatment and inlet norms which may be specified by State Pollution Board for units discharging more than 200 KLD and direction has been issued to the State Pollution Control Board. Hon'ble High Court vide orders dated 01/09/2021 and 10/11/2021, had directed not to take coercive action against them. The copies of petition filed by the industries, Hon'ble High Court Order dated 1/09/2021, order dated 10/11/2021 and order dated 29/12/2021 and the reply filed by HPPCB before the Hon'ble High Court are enclosed as **Annexure IV**. The orders passed by Hon'ble High Court is as under:

"...In the meanwhile, respondents are restrained from taking any coercive action against petitioners.... order dated 01-09-2021"

"... The order dated 01-09-2021 is clarified to the extent that the same shall only be applicable to those industries having less than 200 KLD hydraulic discharge....order dated 10-11-2021"

Now, the above matter is listed for hearing before the Hon'ble High Court on 12-042022"

- x. The analysis results of primary treated Category-I effluent (Discharged to CETP for further treatment) from M/s Vardhman Textiles Limited (Auro Textile-I, Auro Textile-II & Auro Dyeing-I) is complying with CETP inlet norms w.r.t Category-I effluent. However, as per Environmental Clearance granted to CETP vide F. No. 1053/2011-IA-III Dated 8.01.2013 (copy attached as **Annexure-V**), the member industries with hydraulic loading more than 200 KLD shall treat in the existing onsite ETPs (as these industries have already provided on site ETP consisting of Primary/Secondary and Tertiary Treatment System) to the level of treatment and standards prescribed in the consent orders issued by the State PCB before discharging into the CETP for further treatment.
- xi. M/s Vardhman Textiles Limited and M/s Winsome textiles Limited, have installed the tertiary treatment system only for treatment of Category-IV and it was verified by the Joint Committee. M/s Vardhman Textiles Limited and Winsome Textile Limited have discontinued discharging CAT-IV effluent to CETP Treatment in the RO and MEE seemed to help the CETP meet the discharge norms of FDS/TDS as indicated in the analysis results of the samples collected by HPPCB from the discharge point located at River Sirsa, since May 2021.
- xii. The Hon'ble High Court vide CWP No. 414 of 2021, 416 of 2021, 417 of 2021 and 418 of 2021 have stayed the action taken by the State Board under section 33 A of Water Act, 1974 against the above two units, for previous violations (**Annexure-VI**). Further, vide order dated 22/12/2021. Hon'ble High court has directed that "no coercive action shall be taken against the petitioner pursuant to the notification dated 26/12/2019" (whereby Govt. of HP, Deptt. of Env., Sci, and Technology notified inlet quality standards in respect of CETP, Baddi). The Matter is now listed before the Hon'ble High Court of HP on 21/03/2022 (**Annexure-VII**).
- xiii. Baddi CETP was also monitored by the Joint Committee for compliance of prescribed norms. **CETP was found to be non-compliant w.r.t. Bio-assay Test (Zero % survival of fish in 100% sample after 96 hours against the standard of 90% survival of fish in 100% sample after 96 hours).** Bio-assay test is an important parameter for determining the toxicity of waste water. **All other parameters including FDS were found to be within the prescribed limits and CETP was found to be compliant in this regard.** (Report annexed as **Annexure-VIII**)

Further, the joint committee was informed by the CETP Baddi that a funding support to the tune of Rs. 28 Crores from the Ministry of Commerce and Industry, Government of India, under "Trade Infrastructure for Export Scheme" has been sanctioned for their proposal on "3 MLD Effluent Refractory Management and TDS reduction in CETP". The Govt. of Himachal Pradesh has already sanctioned and partially released the funds, for this proposal. Further, CETP Baddi has invited tenders for design, supply, construction, installation, commissioning, testing and trial run of 3 MLD capacity for

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effluent refractory management and TDS/FDS Reduction at their existing 25 MLD capacity CETP & MLD STP located at Baddi, Distt. Solan (HP) and this project shall be completed within one year i.e. upto 31.10.2022, as informed to the Joint Committee by CETP, Baddi (**Annexure-IX**).

- xiv. The same Joint Committee has been constituted in the matter of OA No. 136 of 2020; Veteran form, has also conducted the monitoring of River Sirsa during Monsoon and post monsoon seasons. The Joint Monitoring conducted sampling of River Sirsa from following locations:

Sr. No.	Sampling Location	Pre-monsoon	Post-monsoon
		Class as be Designated Best Use	
1.	Point Upstream of CETP	B	B
2.	Point Downstream Of CETP	B	D
3.	River Sirsa D/s Nalagarh Bridge	B	B

The analysis data shows that the water quality of river Sirsa before CETP and when it is leaving Himachal Pradesh Boundary at D/s Nalagarh Bridge falls under Class B in both samplings i.e. pre-monsoon and post-monsoon. However in the post-monsoon sampling there is deterioration in the water quality at location downstream of CETP. The analysis reports are annexed as **Annexure-X**.

- xv. **An email dated 8/11/2021 from. Mr. R.N. Jindal, Executive Director, TSDF Facility, Nimbua Greenfield (Punjab) Limited was also received, giving comments on the HPPCB w.r.t inlet norms, compliance by CETP and the member industries (Annexure-XI). However, Joint Committee didn't find it appropriate to influence its report with his comments, since no such request was made by the Joint Committee for his comments and forwarded his mail to HPPCB, for reference and taking any action HPPCB deemed necessary."**

5. There is a separate report in O.A. No. 136/2020 with following conclusions and recommendations:-

"3.7. Conclusion and Recommendations:

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Based on the outcome of the study conducted by the Joint Committee in this matter, it is concluded and recommended as follows:

- i. **Out of 111 antibiotic manufacturing industries** monitored by Himachal Pradesh Pollution Control Board in this matter, **37 industries were found to be non-complying w.r.t. limits prescribed for discharging into the CETP.**
- ii. **No action could be taken by HPPCB against the above 37 pharmaceutical formulation industries (engaged in the manufacturing of antibiotics), which were found to be not complying with the CETP inlet norms, due to stay by Hon'ble High Court of Himachal Pradesh.** Now, the matter is listed for hearing before the Hon'ble High Court on 12-04-2022.
- iii. **Some of the antibiotics viz. Azithromycin, Ciprofloxacin, Ofloxacin, Levofloxacin etc. were found to be significantly present (no comparison could be made as MOEF&CC has not prescribed any standards for residual antibiotic) at the outlet of the industry's leading to CETP for further treatment.** The removal efficiency in the primary treatment plants installed by the industries before discharging into the CETP, **was found to be 0-74% for Azithromycin, 90% for Ciprofloxacin, 67-73% for Ofloxacin, 0% for Levofloxacin and Cefpodoxime.**
- iv. **Similarly, the antibiotics viz. Ofloxacin (63 ug/l) and levofloxacin (8 ug/l) were found to be in significantly present at the final discharge of CETP into the Sirsa River.** With regard to removal efficiency of antibiotic residues in the Category-III (Pharma) effluent treatment section of CETP, **it was observed that Ofloxacin was found to be reduced by 31%, Azithromycin by 9%, Levofloxacin by 31% and Roxithroycin by 71%.** This concentration was found be further reduced to lower limits after mixing with treated effluent of other categories' effluent, before discharging into the Sirsa River.
- v. **Antibiotic residue viz. Azithromycin was found to be significantly present in River Sirsa both at the Up-stream (2.5 ug/l) and Down-stream of CETP (2.1 ug/l), which was further increased to 2.9 ug/l in the Nalagarh area.** Further, during the post-monsoon sampling, deterioration in the water quality downstream of CETP was observed during monitoring by the Joint Committee.
- vi. **Other antibiotics were found to be present at below quantification limits (BQL) in the study conducted by the Joint Committee in this matter. However, it may not be considered as absence of antibiotic residues in view of the fact the quantification limit of analysis in the Lab engaged for analysis of antibiotic residues, was 2-300 times more than the Predicted No effect Concentration (PNEC) of different antibiotics.** PNEC is the concentration of antibiotic, which mark the limit, below which no adverse impact on the ecosystem is measured.

- vii. **It is pertinent to apprise the Hon'ble National Green Tribunal that though MOEF&CC has notified the standards for pharma industry vide Notification dated 06.08.2021 but the limit of Antibiotic residues (as mentioned in the draft Notification) has been withdrawn/dropped. Hence there is no parameter for residual antibiotic which Joint Committee could compare with.**
- viii. **Ail. Representative of BBN Industries Association informed during stakeholders' consultation that the association has received the funding support to the tune of Rs. 28 Crores from the Ministry of Commerce and Industry, Government of India, under "Trade Infrastructure for Export Scheme" for their proposal on "3 MILD Effluent Refractory Management and TDS reduction in CETP". The 3 MLD effluent proposed to be treated under this proposal includes pharmaceutical industrial effluent for treatment of API and Antibiotic residues and the content of antibiotic residue and API in the final outlet after treatment in this proposed add on facility in CETP, Baddi will be Nil. It was also informed that the implementation of the above proposal will be completed within one year.**

In view of the fact that i) antibiotic residues were found to be present significantly at the outlet of industries leading to CETP, outlet of CETP and River Sirsa, ii) MoEF&CC has dropped the limits of antibiotics in the final standards for Pharmaceutical Industries notified vide notification vide 6/8/2021 and iii) As informed by BBN Industries Association regarding funding of Rs. 28 Crores for upgrading the CETP/add on facility, including treatment of antibiotic residues with claim of achieving the concentration of antibiotic residues as nil, It is recommended that all the Pharmaceutical Industries of BBN area (located outside the catchment area of CETP) may be connected to CETP Baddi, and the "limit of antibiotic residues as BDL/<PNEC" may be incorporated by HP State Pollution Control Board (HSPSCB) as one of the terms of Consent to Operate (CTO) granted to CETP Baddi, after commissioning of the proposed "add on facility" in CETP, Baddi."

6. The reports show alarming situation of serious non-compliance having continuous adverse impact on public health and environment. CETP is inefficient in its working and individual units are also non-compliant. This requires immediate effective regulatory action. Pharma units need to monitor API and take remedial steps. MoEF&CC needs to

address such vital issue and assist the State to handle the situation in the interest of environment and public health.

7. Only explanation of the State is helplessness due to interim order of the High Court. Learned Counsel has stated that clarification is proposed to be sought in the matter from the High Court so that remedial action for protection of environment and public health is taken as violations are not only of prescribed inlet norms but also statutory provisions of the Water (Prevention and Control of Pollution) Act, 1974 and standards of water laid down under other relevant statutory provisions which are not covered by the stay order. We note that confusion pleaded is resulting in undesirable state of affairs, to the detriment of helpless public against the mandate of law which does not appear to have been properly brought to the notice of the High Court or any other higher forum. We do not find any reason why the State PCB could not enforce law even against violators who are not covered by the interim order granted by the High Court, particularly the pharma units discharging more than 200 KLD.

8. The State may accordingly take further corrective measures to enforce the law for protecting public health and the environment. CPCB may circulate monitoring mechanism to the State PCBs on API, as directed earlier and file the action taken report before the next date. MoEF&CC may clarify the issue of API standards.

List again on 29.03.2022.

A copy of this order be forwarded to CPCB and MoEF&CC by e-mail for compliance.

Adarsh Kumar Goel, CP

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Sudhir Agarwal, JM

Brijesh Sethi, JM

Prof. A. Senthil Vel, EM

Dr. Afroz Ahmad, EM

January 21, 2022
Original Application No. 801/2018 &
Original Application No. 136/2020
SN

Quisha
True Copy

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ANNEXURE A10

BEFORE THE HON'BLE NATIONAL GREEN TRIBUNAL,
PRINCIPAL BENCH AT NEW DELHI

REVIEW APPLICATION NO...14... of 2022

In

ORIGINAL APPLICATION NO.136 OF 2020

IN THE MATTER OF:

VETERANS FORUM FOR TRANSPARENCY
IN PUBLIC LIFE

...APPLICANT

VERSUS

STATE OF HIMACHAL PRADESH & ORS. ...RESPONDENTS

AND IN THE MATTER OF:

Ministry of Environment Forest
& Climate Change

...Review Applicant

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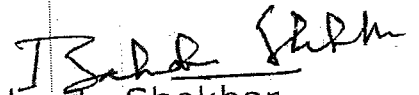
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	2011 read with section 114 and order 47 rule 1 of the Code of Civil Procedure, 1908 alongwith Affidavit	
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Filed by:



Balendu Shekhar

Advocate for MoEF&CC

LB-17, 5 Gauri Sadan,

New Delhi-110001

Mob. No. 9999666769

New Delhi

Dated 10.05.2022

Email: officeofbalendu@gmail.com

BEFORE THE HON'BLE NATIONAL GREEN TRIBUNAL,
PRINCIPAL BENCH AT NEW DELHI

REVIEW APPLICATION NO..... of 2022

In

ORIGINAL APPLICATION NO.136 OF 2020

IN THE MATTER OF:

VETERANS FORUM FOR TRANSPARENCY
IN PUBLIC LIFE

...APPLICANT

VERSUS

STATE OF HIMACHAL PRADESH & ORS. ...RESPONDENTS

AND IN THE MATTER OF:

Ministry of Environment Forest
& Climate Change

...Review Applicant

MEMO OF PARTIES

Veterans Forum for Transparency in Public Life

B-124, SWARN NAGRI,

GREATER NOIDA, DIST-G.B. NAGAR (U.P.) - 201306

THROUGH ITS GENERAL SECRETARY,

WING COMMANDER (RETD.)

DR. BISHWANATH PRASAD SINGH,

E-mail: -2bnpsingh@gmail.com.

Mob: - 9999383602

...Applicant

VERSUS

1. STATE OF HIMACHAL PRADESH

OFFICE AT:- GOVERNMENT SECRETARIAT,

SHIM LA, HIMACHAL PRADESH, - 171002,

2173

4

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THROUGH ITS CHIEF SECRETARY
0177-2621022, cs-hp@nic.in

2. Himachal Pradesh Pollution Control Board
HIM PARIVESH, PHASE- III, NEW SHIMLA,
HIMACHAL PRADESH-171009
THROUGH ITS MEMBER SECRETARY
E-Mail: mshpcb-hp@nic.in. 0177 2673766

3. STATE DRUG CONTROLLER,
GOVERNMENT OF HIMACHAL,
DIST- SOLAN, BADDI,
HIMACHAL PRADESH- 173205
94183-26111 sdh4hp@gmail.com

4. CENTRAL POLLUTION CONTROL BOARD,
PRIVESH BHAWAN, EAST VINOD NAGAR,
DELHI-110032
THROUGH ITS CHAIRMAN
011-43102030 ccb.cpcb@nic.in

5. ACME LIFE SCIENCES, NALAGARH,
DIST-SOLAN, HIMACHAL PRADESH-173205
info@acmeformulation.com, 01795-228501-03
THROUGH ITS MANAGING DIRECTOR/DIRECTOR/CS

6. HELIOS PHARMACEUTICALS,

2174

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VILL-MALPURP.O-BHUD,

DIST-SOLAN, HIMACHAL PRADESH-173205

ho@heliospharma.com. 079 - 4 0 2 3 2000

THROUGH ITS MANAGING DIRECTOR/

DIRECTOR/CS

...Respondents

And in the matter of:

7. Ministry of Environment Forest

& Climate Change

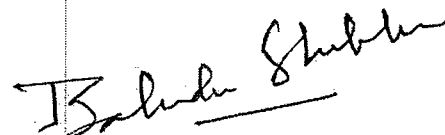
Through

Director (MoEF&CC)

Indira Paryavaran Bhawan,

Jor Bagh, New Delhi-110003 ...Review Applicant

Filed by:



Balendu Shekhar

Advocate for MoEF&CC

LB-17, 5 Gauri Sadan,

New Delhi-110001

Mob. No. 9999666769

New Delhi

Dated 10.05.2022

Email: officeofbalendu@gmail.com

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SYNOPSIS & LIST OF DATED

The present review petition has been filed for seeking review of this Hon'ble Tribunal's order dated 06.04.2022 passed in O.A. No. 136 of 2020 where Hon'ble Tribunal is examining the issue related with discharge of Active Pharmaceuticals Ingredients (API) and toxic Industrial Pollution in rivers Balad, Sirsa and Satluj. The review is only for the observation made by this Hon'ble Tribunal in its order dated 06.04.2022 wherein Ministry's issued final notification dated 06.8.2021 has been mentioned as draft notification and has also been mentioned that MOEF&CC is unable to finalise the draft standards (In para 15 which is contrary to para 8 of the impugned order dated 06.04.2022).

It is worth mentioning here on the instant issue, earlier draft notification was released vide dated 23.01.2020 for inviting public comments and further deliberation. Accordingly, upon following all the statutory compliances, standards for bulk drugs including

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Antibiotics Residue Parameter were formulated, finalised and notified on 06.8.2021 by the answering Ministry. Hence, this review application.

LIST OF DATES AND EVENTS	
22/07/2020	Original Application No. 136/2020 Veterans Forum for Transparency in Public Life Versus State of Himachal Pradesh & Ors. filed before NGT Principal bench, New Delhi Salient issues raised in the OA are as under: Discharge of waste in CETP at Baddi by Acme Life Sciences, Nalagarh and Helio Pharmaceuticals at Solan to prevent pollution of rivers Sirsa and Satluj. CETP is not connected to pharmaceutical units at Barotiwala and Nalagarh who are discharging their effluents directly into the rivers.
04/01/2021	Hon'ble Tribunal constituted a joint Committee of CPCB, State PCB and District

	Magistrate, Solan to furnish a factual and action taken report in the matter.
23/01/2020	MoEF&CC issued draft notification for effluent standard from Bulk Drug and Formation (Pharmaceutical)
23/06/2021	Hon'ble NGT directed the MoEF&CC to expedite the process of finalizing the standards in the interest of protection of environment.
06.8.2021	MoEF&CC issued final notification for Bulk Drug and Formation (Pharmaceutical) for ascertaining parameters of (A) Effluent Standards: (i) Compulsory Parameters (ii) Additional Parameters (iii) Industry Connected with CETP and (C) Emission Standards.
21/01/2022	Vide this Order, Hon'ble Tribunal observed:- 1. The MoEF&CC needs to address such vital issue and assist the State to handle the

situation in the interest of environment and public health.

2. State may accordingly take further corrective measures to enforce the law for protecting public health and the environment. CPCB may circulate monitoring mechanism to the State PCBs on API, as directed earlier and file the action taken report before the next date. MoEF&CC may clarify the issue of API standards.

06/04/2022

Vide this Order, Hon'ble Tribunal observed::

"The draft Notification dated 23.01.2020 as well as final Notification dated 06.08.2021 and also the stand of the parties that the standards proposed in the draft notification have yet to be finalized, except and to the extent of those mentioned in the Notification dated 06.08.2021. Draft standards were

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formulated and notified on 23.1.2020 i.e. more than two years ago, based on study by the experts. Regulatory mechanism is such important issues cannot remain in abeyance for indefinite period on the ground that the MoEF&CC is unable to finalise the draft standards even after two years. In view of serious consequences of unregulated discharge of API residue to the detriment of environment and public health, we consider it appropriate to direct under Section 15(1) of the NGT Act that pending finalisation by the MoEF&CC, standards proposed in the draft Notification dated 23.01.2020, which are based on expert studies, be strictly followed by all concerned. It is also necessary to abide by the guidelines of CPCB circulated on 31.1.2022, quoted above in the matter of standards and methodology on the subject. The State PCB may take further action

01

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*accordingly to prevent and remedy the
situation of unregulated discharge of harmful
pollutants of pharma industries in the rivers..."*

(UNDER LINES HAS BEEN ADDED TO GIVE
EXTRA EMPHASIS)

10.05.2022 Hence the Present Review Application.

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BEFORE THE HON'BLE NATIONAL GREEN TRIBUNAL,
PRINCIPAL BENCH AT NEW DELHI

REVIEW APPLICATION NO..... of 2022

In

ORIGINAL APPLICATION NO.136 OF 2020

IN THE MATTER OF:

VETERANS FORUM FOR TRANSPARENCY
IN PUBLIC LIFE

...APPLICANT

VERSUS

STATE OF HIMACHAL PRADESH & ORS. ...RESPONDENTS

AND IN THE MATTER OF:

Ministry of Environment Forest
& Climate Change

...Review Applicant

**REVIEW APPLICATION UNDER SECTION 19(4)(F)
OF THE NATIONAL GREEN TRIBUNAL ACT, 2010
READ WITH RULE 22 OF THE NATIONAL GREEN
TRIBUNAL (PRACTICES AND PROCEDURE) RULES,
2011 READ WITH SECTION 114 AND ORDER 47
RULE 1 OF THE CODE OF CIVIL PROCEDURE, 1908
WITH THE PRAYER THAT THIS HON'BLE COURT MAY
KINDLY REVIEW/MODIFY/RECALL THE ORDER
DATED 06.04.2022 PASSED IN O.A. NO. 136 OF
2020 BY THIS HON'BLE TRIBUNAL IN THE FACTS
AND CIRCUMSTANCES AND TO EXTENT DETAILED
HEREIN BELOW, IN THE INTEREST OF JUSTICE.**

AND/OR

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ANY OTHER SUITABLE ORDER OR DIRECTION WHICH THIS HON'BLE COURT MAY DEEM FIT AND PROPER IN THE FACTS AND CIRCUMSTANCES OF THE CASE MAY ALSO BE ISSUED IN FAVOUR OF THE APPLICANTS, IN THE INTEREST OF JUSTICE.

MOST RESPECTFULLY SHOWETH:-

1. DETAILS OF THE APPLICATION PARTICULARS OF THE ORDER AGAINST WHICH THE APPLICATION IS MADE/REVIEW IS SOUGHT:

That the applicant is praying for review of the order dated 06.04.2022 passed in O.A. No. 136 of 2020 where Hon'ble Tribunal is examining the issue related with discharge of Active Pharmaceuticals Ingredients (API) and toxic Industrial Pollution in rivers Balad, Sirsa and Satluj. The review is only for the observation made by this Hon'ble Tribunal in its order dated 06.04.2022 wherein Ministry's issued final notification dated 06.8.2021 has been mentioned as draft notification and has also been mentioned that MOEF&CC is unable to finalise the

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draft standards (in para 15 which is contrary to para 8 of the impugned order dated 06.04.2022).

2. JURISDICTION OF THE TRIBUNAL:

That the order Annexure R-1 has been passed by this Hon'ble Tribunal; therefore this Hon'ble Tribunal has the jurisdiction to decide the instant review application.

3. THAT THE BRIEF FACTS OF THE ORIGINAL APPLICATION:

1. The issue for consideration before the Hon'ble Tribunal was remedial action against discharge of waste from CETP at Baddi and from Acme Life Sciences, Nalagarh and Helio Pharmaceuticals at Solan, to prevent pollution of rivers Sirsa and Satluj. According to the applicant, the CETP is not connected to pharmaceutical units at Barotiwala and Nalagarh who are discharging their effluents directly

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into the rivers. It is further stated that even after treatment in ETP/STPs, pharmaceutical ingredients may still be coming out from the industries unless ETP/STPs are specialized for the purpose. It is further stated that present CETP is not designed to neutralize Active Pharmaceutical Ingredient (API).

2. It is submitted that the averment mentioned in the earlier filed submission of behalf of MoEF& CC dated 04.04.2022 may kindly be read as part and parcel to the instant application as the same is not being repeated herein for the sake of brevity. It is submitted that brief details about finalisation of API standard by the applicant Ministry MOEF&CC vide its notification dated 06.08.2021 are as under:

a. MoEF&CC is the nodal agency in the Country regarding all the Environmental issues coupled with their responsibility to adhere to all the International commitments related with the

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environment and also expected to carry out constructive and effective deliberation as per the prescribed norms while formulating any regulations with keeping fine balance among all the stakeholders.

b. Issues involved in the instant case i.e., regarding desirable standard parameters to measure Active Pharmaceutical Ingredient (API) and acceptable norms regarding antibiotics residues value, for the drug related industries are in a highly nascent stage worldwide. Accordingly, much deliberation and discussion are still going on in all the countries about the ideal and acceptable measuring limit about antibiotics residues for drug industries.

c. That the Expert Committees formulated by MoEF&CC at its 17th Expert Committee meeting dated 26.04.2019 held as under:

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".... 5.2 Environmental Standard for Bulk Drug and Formulation Industry

The proposed revised draft Environmental Standard for Bulk Drug and Formulation Industry was presented by CPCB before the Expert Committee. It was informed that the draft notification was earlier discussed in the 16th Expert Committee Meeting held on 13/12/2018. After a detailed discussion on the proposed revised draft notification and following suggestions were made by the Committee:

- i. The title name of Pharmaceutical Industry should be changed to Bulk Drug and Formulation Industry.*
- ii. In Additional Parameters, the limits shall be applicable to industries those are using Benzene, Toluene, Xylene, Methylene Chloride, Chlorobenzene in the effluent discharged.*

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iii. API limits shall be applicable for units manufacturing API other than antibiotics in the effluent standard.

iv. In order to control VOC emission, the condition of solvent recovery should be imposed, accordingly, the standard was introduced i.e. the total losses of solvent should not be more than 3% of the solvent consumed.

The Committee advised the CPCB to submit the revised notification based on the aforesaid observations to MoEF&CC to take a final view in the matter. (Action: CPCB)...."

d. That again the 18th Expert Committee took convened its meeting dated 09.08.2019 wherein salient observation are as such:

"..... 4.3. Environmental Standard for Bulk Drug and Formulation (Pharmaceutical) Industry

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The proposed revised draft Environmental Standard for Bulk Drug and Formulation (Pharmaceutical) Industry was presented by CPCB before the Expert Committee. It was informed that the draft notification was earlier discussed in the 17th Expert Committee Meeting held on 26/04/2019 and suggestions made during the meeting by the committee were incorporated. The revised standards were again discussed and the Committee suggested incorporating following:

1) The standard for COD in effluent may be considered as 250 mg/l in place of 200 mg/l as the 250 mg/l is already prescribed in other similar types of industries.

2) The CPCB should develop guidelines for State Pollution Control Boards/ Pollution Control Committees (SPCBs/PCCs) for laboratory analysis of antibiotics in the effluent for implementation of proposed standards in future.

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After incorporating the above suggestions the Committee recommended the Ministry may issue the draft notification inviting public suggestion in accordance with EPA 1986...."

e. During one of the deliberation before Expert Committee of MOEF&CC in its meeting dated 9th December, 2020, it has been observed:

"...3.2 Agenda A (ii): Environmental Standard for Bulk Drug and Formulation (Pharmaceutical) Industry

The draft notification for Environmental Standard for Bulk Drug and Formulation (Pharmaceutical) Industry was presented by CPCB in the 19th meeting of the Expert Committee held on 20.05.2020. It was informed that the draft notification was placed on the website of the Ministry for public consultation on 23.01.2020 and more than 35 numbers of suggestions were received which

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includes association, NGOs, Individual experts and industry. The comment(s)/suggestion(s) received have been assessed for their acceptability based on the concern raised vis-a-vis their feasibility, viability and relevance to the objective of prescribing norms. The committee deliberated on each para of the proposed standard.

The Joint Secretary, Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals as a special invitee highlighted the present status of the pharma industry and the challenges arising due to COVID-19 demand. It was highlighted that due to higher cost, India is facing stiff competition from other countries, specially China and has in recent times become no. 2 in API manufacturing. He stressed that the norms should not compromise with the environmental requirements, but should be prescribed in such a proposition that there is no

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excess financial burden to the industry to retain their international competitiveness. He also highlighted the concern raised by association of Bulk drug and pharmaceutical manufacturing units specially on monitoring location proposed in the draft. He requested that in the present situation, prescribing standard on Antibiotic residues may be a challenge for the industry to meet and it was expressed that the committee may take appropriate consideration of the concern raised by the associations.

The draft was deliberated point wise and based on the discussion; the Committee recommended certain modifications on additional parameters, the solvent losses, and provision of land disposal etc. for consideration of the Ministry.

Further the matter was re-examined in the Ministry in light of representation received from

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the Department of Pharma. A meeting under the chairmanship of Secretary- EFCC with various stakeholders, including CPCB, pharma association, Ministry of Health, Department of Pharma and experts was held. Owing to the concern on the PNEC value and its dynamic nature, it was observed that it will be a compliance challenge for any static treatment option to meet the dynamic nature of the PNEC values published by a consortium of Antibiotics Manufacturer. Considering the implementation, monitoring and compliance challenges, it was decided that CPCB may explore these challenges and also compare international practices on imposing PNEC values as regulatory provision for discharge standard to address such concerns. In view of the above, the standard was revised and placed before the expert committee for consideration on the concerns of compliance, dynamic value of PNEC

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and prevailing international practices on the evolving nature of PNEC understanding.

Shri Sundeep, Scientist F, MoEFCC made a detailed presentation before the committee and clarified the apprehensions of Industry Associations and Department of Pharma that the standards are applicable on the units involved in discharge and emissions, since April 1996. The present proposals are aligned with the emission norms stipulated for similar processes and applicable to other industries. A timeline relief of one year for meeting the newly introduced emission and discharge norms is also proposed for consideration by the committee owing to COVID-19 impact.

The committee after details deliberation on each aspect of the modified discharge norms in notification recommended to

modified/incorporated the followings:

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1. Ammonia and Nitrate was considered to be an important parameter in light of concern of polluted river stretches, and therefore it may be removed from additional parameters and made as compulsory parameter applicable to all units and CETP at discharge point.

2. Industry permitted to discharge/dispose their effluent to CETP shall be governed by the provision of notified CETP norms dated 01/01/2016.

3. Additional Parameters of Chlorides and Sulphate may be removed and concern of impact on land disposal may be addressed by introducing Sodium Adsorption Ratio (SAR) with upper limit of 26. CPCB may provide appropriate norms of SAR.

4. Owing to the complexity and non-availability of any universally accepted standardized method to test Total API

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concentration in wastewater matrix, the committee felt necessary to remove the proposed norms of Total API from the additional parameter as of now.

5. Any discharge to inland water bodies or for horticulture or irrigation or land disposal of treated process wastewater from any industry and or to CETP shall not be considered as Zero Liquid Discharge (ZLD) and the stipulated norms in the notification shall be applicable to all such discharges.

6. The total loss from annual inventory of solvents from storage area shall not be more than 5% of cumulative on an annual basis.

7. CPCB shall prepare a standard protocol for determining the loss and relevant record maintenance practices for verification purposes in consultation with industry associations and other organizations. Provision of One year time

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may be allowed to the industry for compliance of these norms considering the time required to make necessary abatement cum control arrangement.

8. Antibiotic residues concentration in the ambient environment is rising and its consequences are far reaching. Predicted No-Effect Concentrations (PNECs) value of Antibiotic residues are the probable values at the mixing point in the receiving environment, which reflects the critical level of any adverse impact on the receiving ecology or its component.

The proposed values of various Antibiotic residues (PNEC) in draft notification was for its applicability at the inlet of treatment facility (applicable on raw influent). It was felt that the purpose was to avoid any adverse impact on the receiving environment and also to promote

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comprehensive and efficient performance of the treatment facility. CPCB has observed that there is significant reduction in monitored Antibiotic residues concentration in efficient operating treatment facilities. The present notification proposal is for discharge norms and therefore, any stipulation of norms before treatment facility doesn't serve the purpose or objective, as the outcome will be dependent on the efficacy of the treatment facility.

It was also observed that the PNEC values considered were based on the studies carried out by international Alliance of Antibiotic manufacturers and presently it is yet to be accepted as a discharge regulatory provision anywhere. The rationale of the proposed values was not scientifically derived based on field performance studies for all proposed parameters.

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Further, the PNEC values are dynamic and are in process of evolving. The parameter and its values both keep on changing based on the API under use and imposing all parameters will lead to uncalled challenges of standardization of monitoring protocol in a dynamic environment. The challenge associated with meeting dynamic values with static infrastructure or through regular retrofitting may lead to more non-compliance of other parameters as well.

Considering the evolving nature of PNEC values and associated challenges of infrastructural implementation, monitoring constraints and absences of acceptable standardized testing of samples in complex metrics of pollutants, the committee felt that the discharge norms based on dynamics PNEC values for Antibiotics residue may be dropped from the proposed standard for discharge.

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The present ecosystem for monitoring and implementation of Antibiotics residue concentration in complex wastewater matrix at low concentration with dynamic PNEC values based standard will lead to challenges of monitoring and compliance. However, it was felt that infrastructure and capacity development and readiness of the regulatory bodies, stability in PNEC values in varying Indian conditions are some of the essentials for adopting any regulatory provision on AMR.

It was decided that association of Antibiotics manufacturing industries in India shall undertake a comprehensive study on AMR impact at all major critical locations identified by CPCB. The study shall be obligatory on the Antibiotics manufacturer and protocol for the study may be prepared in consultation with CPCB and Department of Pharma, Ministry of Chemicals & Fertilizers.

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Accordingly, the committee recommended to drop the proposal of Antibiotics residue discharge norms and suggested that MoEF&CC may ask CPCB to issue necessary direction to Department of Pharma, Ministry of Chemicals & Fertilizers to ensure a database is created on the AMR status in the country with the help of association of Antibiotics manufacturing units. CPCB shall provide the monitoring protocol for the purpose.

9. To contain any adverse impact arising from the disposal of contaminated sludge and or concentrate or reject or residue generated from wastewater treatment and management facility of industry or CETP, it is felt necessary to have their management and disposal with utmost care. Therefore, all sludge (chemical or biological) or any residue, reject, concentrate generated from wastewater treatment or its management facility at Industry engaged in

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manufacturing of bulk drug or formulation of Pharmaceuticals or CETP catering such industries shall be classified as Hazardous Waste within the provision of subsection 17 of section 3 of Hazardous and Other Wastes (Management and Trans boundary Movement) Rules, 2016 and shall be managed within the applicable provisions thereof.

10. All new norms / parameters introduced in this notification shall be applicable after one year from the date of this notification in due consideration of COVID-19 Impact. Based on above deliberations and recommendation of the committee the draft notification was modified as attached at Annexure II of the First Expert Committee's report. The committee recommend for considering the notification under Environment (Protection) Rules, 1986 with appropriate legal modification..."

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- f. The draft of the notifications was brought by the MOEF&CC in the public domain for seeking suggestions/objections for statutory 60 days' time period for laying the standards for Bulk Drug and Formulation (Pharmaceutical) Industry including Antibiotics residue parameters were notified in the Gazette of India vide notification GSR 44(E) dated 23.01.2020.
- g. Subsequent thereto, a meeting on 28.07.2020 under the chairmanship of Secretary-Environment, Forest, Climate & Change was also conducted with all stakeholders, including Central Pollution Control Board (CPCB), Pharma association, Ministry of Health (MoHFW), Department of Pharma and experts. where it was unanimously observed that there is technical challenge in compliance for any static treatment option to meet the dynamic nature of the predicted no-effect Concentration (PNEC)

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values published by a consortium of Antibiotics manufacturers.

- h. Considering the implementation, monitoring and compliance challenges, it was decided that CPCB may explore these challenges and also compare international practices on imposing PNEC values as regulatory provision for discharge standard to address such concerns.
- i. The expert committee of MOEF&CC in its meeting held on 20th May, 2020 had also recommended that owing to the complexity and non-availability of any universally accepted standardized method to test Total API concentration in complex wastewater matrix; it was felt necessary to remove the proposed norms of Total API from the additional parameter as of now. Accordingly, the parameter for total API concentration was also removed.

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j. That keeping all the aforesaid facts and public comments received upon the draft notification dated 23.01.2020, the final standards were notified under Environment (Protection) Rules, 1986 vide GSR 541(E) dated 06.08.2021.

3. That as the applicant ministry has already issued final notification dated 06.08.2021, draft notification dated 23.01.2020 has been merged in the same. It is submitted that Submission/clarification filed on behalf of MoEF&CC on the issue of residual antibiotics in Industrial effluents pursuant and API standard in view of order dated 21.01.2022 passed in O.A. NO. 136 OF 2020 were duly mentioned there. However Hon'ble Tribunal has observed as follow:

"....Draft standards were formulated and notified on 23.1.2020 i.e. more than two years ago, based on study by the experts. Regulatory mechanism is such important issues cannot remain in abeyance for indefinite period on the ground that

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the MoEF&CC is unable to finalise the draft standards even after two years. In view of serious consequences of unregulated discharge of API residue to the detriment of environment and public health, we consider it appropriate to direct under Section 15(1) of the NGT Act that pending finalisation by the MoEF&CC, standards proposed in the draft Notification dated 23.01.2020, which are based on expert studies, be strictly followed by all concerned. It is also necessary to abide by the guidelines of CPCB circulated on 31.1.2022, quoted above in the matter of standards and methodology on the subject. The State PCB may take further action accordingly to prevent and remedy the situation of unregulated discharge of harmful pollutants of pharma industries in the rivers..."

**4. THAT THE APPLICANT IS SEEKING THE KIND
INDULGENCE TO REVIEW THE AFORESAID
ORDER ON THE FOLLOWING GROUNDS:-**

GROUND FOR REVIEW

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- a. For that in the instant case i.e., regarding desirable standard parameters to measure Active Pharmaceutical Ingredient (API) and acceptable norms regarding antibiotics residues value, final Standard under Environment (Protection) Rules, 1986 vide GSR 541(E) dated 06.08.2021 has already been issued. Accordingly, no such draft notification is pending with the answering Ministry which is needed to be finalised.
- b. For that as on date there is no such draft notification in the instant issue is pending for its finalisation, answering Ministry is not in a position to issue any final notification. Ministry in its filed submission has duly appraised the said facts before this Hon'ble Tribunal. Accordingly, the observation made in the order dated 06.04.2022 may kindly be modified in the light of present submission.

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c. For that answering respondent being conscious to the facts that scope of review is very narrow and at the best can raise the factual issue. As the answering Ministry had raised all such issue in its earlier filed submission, order dated 06.04.2022 may be reviewed by this Hon'ble Tribunal at this stage. Moreso, observation made in para 8 of the impugned order is contrary to para 15.

d. For that it is worth to mention here that the Central Pollution Control Board (CPCB) have been entrusted to develop database as well as methodology for analysis of identified API and also the corresponding site specific PNEC values to enable a scientific rationale for deriving standards for such parameters. It is submitted that CPCB has made some progress on development of methodology for sampling and analysis of certain APIs, which is based on in house competency and is broadly based on US-EPA guidelines. These methodologies have been circulated to all SPCBs/PCCs. The proposed

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methodologies are yet to be validated by laboratory of SPCBs or other scientific laboratories by carrying an inter-laboratory competency comparison. These methodology needs to be further improvised to have its acceptability by undertaking inter-laboratory comparison, Standardization of the process to be made acceptable to the provisions of NABL accreditation, which is minimum requirement for qualifying the methodology and process to be acceptable under the provisions of E(P) Act, 1986 for acceptance of analytical results to be used for regulatory purpose.

- e. For that it is worth to mention here that UN-
UNEP/IPCS Training Module No. 3 - Section B -
Environmental Risk Assessment - Chapter 3,- Effect
Assessment (para 3.1) has also suggested some
methodology, including the limitation, to be adopted
for development of PNEC values to have
environmental risk assessment arising out of API
and other chemicals. These PNAC values are site

specific and eco-system based. A detailed study on
toxology vis-à-vis the expected chemicals are still
needed to be done to standardized PNEC values.
However, these values may also have risk of being
dynamic over a period of time and therefore, more
research is required to standardized the criteria for
legal regulation purpose.

f. For that it is worth to mention here that MoEF&CC as
on date has already formulated the necessary
provisions for dealing the "API" issue for drug
industries in India. Though, CPCB has also been
enshrined the responsibilities to explore more on
this issue which would eventually lead to a better
handling of such effluents while enhancing the
current structure to bear the current level of such
discharge.

g. For that it is worth to mention here that apart from
the above mentioned facts and details, as per
Section 17 of the Water (Prevention and Control of

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Pollution) Act, 1974; it is evident that the State Pollution Control Board equally possesses the power to evolve efficient methods of disposal of sewage and trade effluents on land.

h. For that it is worth to mention here that the answering respondent MoEF&CC is presently placing the actual facts and development upon the instant issues. However, as the issue regarding evolution of API and PNEC standard is at a nascent stage worldwide, answering respondents would keep tuning its standards and yardsticks as per desirable terms.

5. LIMITATION:

The Hon'ble Tribunal has passed the detailed order on 06.04.2022 upon hearing the parties. The Copy of Order dated 06.04.2022 has been downloaded on 10.04.2022 when the same was made available on the official website of Hon'ble Tribunal. The present application is being filed within the period of

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limitation as order dated 06.04.2022 passed by the Hon'ble Tribunal was uploaded only on 10.05.2022.

6. RELIEF SOUGHT/PRAYED:-

In view of the above mentioned facts, it is, therefore, most respectfully prayed that this application may kindly be allowed and the order dated 06.04.2022 may kindly be reviewed, recalled or modified in the interest of justice:

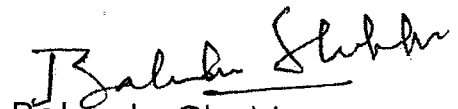
- i. Review the order dated 06.04.2022 in O.A. NO. 136 OF 2020 passed by Hon'ble Tribunal
- ii. there is no pendency on the part of MOEF&CC and the issue related notification has already attained finality in the form of notification dated 06.08.2021;
- iii. regulatory authorities of union as well as states are independent to form their policy, rules and other regulatory measures as per the available laws according to their local need and requirement;
- iv. Any other suitable order or direction which this Hon'ble Tribunal may deem fit and proper in the

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facts and circumstances of the present case may also kindly be issued in favour of the applicants, in the interest of justice.

Filed by:



Balendu Shekhar

Advocate for MoEF&CC

LB-17, 5 Gauri Sadan,

New Delhi-110001

Mob. No. 9999666769

New Delhi

Dated 10.05.2022

Email: officeofbalendu@gmail.com

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BEFORE THE HON'BLE NATIONAL GREEN TRIBUNAL,
PRINCIPAL BENCH, NEW DELHI

REVIEW APPLICATION NO.....OF 2022

IN

ORIGINAL APPLICATION NO.136 OF 2020

IN THE MATTER OF:-

Veterans Forum for Transparency

in Public Life

.....Applicant

-Versus-

State of Himachal Pradesh & Ors.

....Respondents

AND IN THE MATTER OF:

Ministry of Environment Forest &

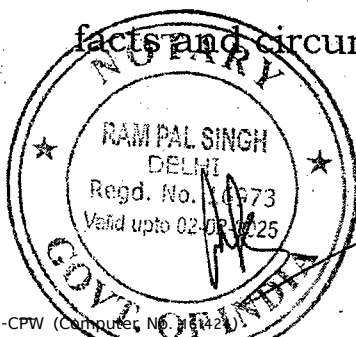
Climate Change.

....Review Applicant

AFFIDAVIT

I, Ved Prakash Mishra S/o. Sh. Ram Sidh Mishra Age about 48 years, working as Director in Ministry of Environment Forest and Climate Change (MoEF&CC), Indira Paryavaran Bhawan, Jor Bagh, New Delhi-110003, do hereby solemnly affirm and declare as under:

1. That I am the Director of the Review Applicant in the above noted Review application and am fully conversant with the facts and circumstances of the present case.



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2. That the Review Application has been drafted by my counsel under my instructions and I state that the contents of the same are true and correct to my knowledge, that Annexures filed along with the review application are the true copies of their respective originals.



DEPONENT
VED PRAKASH MISHRA
निदेशक/Director

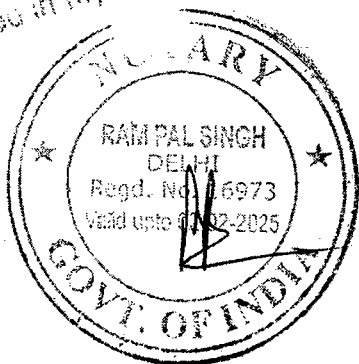
पर्यावरण, वन एवं जलवायु परिवर्तन मंत्रालय
Min. Environment, Forest and Climate Change
भारत सरकार, नई दिल्ली
Govt. of India, New Delhi

VERIFICATION:

09 MAY 2022

Verified at New Delhi on this the 09 day of May, 2022 that the contents of the above affidavit in paras 1 to 2 are true and correct to my knowledge. No part of it is false and nothing material has been concealed therefrom.

[Signature]
I Identify the Deponent who
has Signed in my Presence




DEPONENT

वेद प्रकाश मिश्रा
VED PRAKASH MISHRA
निदेशक/Director

पर्यावरण, वन एवं जलवायु परिवर्तन मंत्रालय
Min. Environment, Forest and Climate Change
भारत सरकार, नई दिल्ली
Govt. of India, New Delhi

CERTIFIED THAT THE DEPONENT
Sd/- Smt./Mm. *[Signature]*
Sd/- Mr./Ms. *[Signature]*
Identified as *[Signature]*
has solemnly affirmed me at Delhi
on 09 day of May 2022
that the contents of the affidavit which
has been read & explained to him are
true and correct to his knowledge.

[Signature]
Notary Public, Delhi (INDIA)

09 MAY 2022

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Annexure RA-1

Item Nos. 01 & 02

(Court No. 1)

**BEFORE THE NATIONAL GREEN TRIBUNAL
PRINCIPAL BENCH, NEW DELHI**

(By Video Conferencing)

Original Application No. 801/2018

Jasmeet Singh

Applicant

Versus

State of Himachal Pradesh

Respondent

WITH

Original Application No. 136/2020

Veterans Forum for Transparency
in Public Life

Applicant

Versus

State of Himachal Pradesh & Ors.

Respondent(s)

Date of hearing: 06.04.2022

**CORAM: HON'BLE MR. JUSTICE ADARSH KUMAR GOEL, CHAIRPERSON
HON'BLE MR. JUSTICE SUDHIR AGARWAL, JUDICIAL MEMBER
HON'BLE MR. JUSTICE ARUN KUMAR TYAGI, JUDICIAL MEMBER
HON'BLE PROF. A. SENTHIL VEL, EXPERT MEMBER
HON'BLE DR. VIJAY KULKARNI, EXPERT MEMBER
HON'BLE DR. AFROZ AHMAD, EXPERT MEMBER**

Applicant: Dr. Bishwanath Prasad, Wing Commander (Retd.), Applicant in
Person in OA 136/2020

Respondent(s): Mr. Balendu Shekhar, Advocate for MoEF & CC
Mr. Anuj Bhandari, Advocate for CPCB
Mr. Nalin Kohli, Advocate for HPSPCB

ORDER

1. Issue for consideration is the remedial action against failure of the authorities in the State of Himachal Pradesh in preventing pollution of rivers Balad, Sirsa and Sutlej in Baddi Industrial area in Solan District.

One of the sources of pollution is on account of lack of sewerage system resulting in discharge of untreated sewage in the rivers contrary to the

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mandate inter alia in judgement of the Hon'ble Supreme Court in Paryavaran Suraksha (2017) 5 SCC 326 and various orders of this Tribunal in the light thereof. Other source is discharge of toxic industrial pollution on account of leakage from the Common Effluent Treatment Plant (CETP) (as alleged in O.A. No. 801/2018). Third major and serious source of pollution is discharge of toxic waste from pharma industries which cannot be treated by CETP and even by ETPs. (as alleged in O.A. No. 136/2020). CETP is not designed to neutralize Active Pharmaceutical Ingredient (API). TSDF does not receive sludge generated from the industrial units at Nalagarh. The industries located at Baddi area are generating 20779 KLD of industrial effluent, out of which 17894 KLD is being treated at CETP and remaining 2885 KLD is being disposed of by the occupiers directly into river Sirsa. There is no existing sewerage system in BBN area and no demarcation in residential and industrial area. Presence of Ciprofloxacin in the concentration of 296.1 ug/l was found on chemical analysis. Concentration of Ciprofloxacin in the effluent discharge of M/s Acme Life Sciences work out to be 13455 times of the prescribed limit. The increasing occurrence of multi-resistant pathogens is a serious global threat to human health and it is finding its way into the water bodies and drinking water through industrial discharge and also due to heavy use of antibiotics in human and veterinary medicine.

Compliance status as noted in earlier orders

OA 801/2018 – industrial pollution due to inadequacy of CETP

2. The Tribunal noted the status in O.A. No. 801/2018 as follows:-

"2. The matter was considered on several occasions earlier. On 14.01.2020, the Tribunal considered the report dated 06.11.2019 filed by the State PCB to the effect that violation of provisions of the

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Water (Prevention and Control of Pollution) Act, 1974 was taking place by discharge of polluted effluents in the water bodies. The same is reproduced below for ready reference:-

"2.0 Inspection of CETP Baddi

- i) The CETP is designed to treat five different categories of effluent as tabulated under

Sr. No.	Category	Sector of Industry	No of Units	Consented effluent quantity (in MLD)
1.	I	Food, Paper and Textile	89	15.55
2.	II	Soap & Detergent	112	2.0
3.	III	Pharmaceutical	213	2.9
4.	IV	Dyeing	4* M/s Auro Textile Unit - I, M/s Auro Dyeing Unit - I, M/s Winsome Textile Industries	2.0
5.	V	Electroplating, Metal surface finishing	31	0.042
Total			449	22.492
				Say 23.00

- ii) It was observed that at an average of 17 mld effluent is treated by the CETP, comprising equalization tank, primary settler, aeration tank, reaction tank, secondary and tertiary clarifier. The treatment process for each stream is appended with the report (**Annexure IV**).
- iii) It was noticed that effluent of category IV is not reaching to its designated equalization tank. M/s Baddi Infrastructure Ltd., has informed that the dedicated pipe network to carry the effluent of category IV is blocked. The effluent of category IV is therefore being discharged through pipe network of Category I.
- iv) It is also observed that the CETP is designed to treat category V effluent by mixing with category IV effluent to optimize the chemical consumption and to achieve effective treatment. Since, the effluent of category IV has been mixed with category-I, in the pipe network itself before reaching CETP, which has resulted in formation of a new complex effluent for which the CETP was not designed. Therefore, it could not able to deliver the desired results w.r.t. treatment and thus, effluents was in non-conformity with the

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standards, as per the monitoring results of HPPCB (Annexure-V). Besides, the effluent of category V remained effectively untreated throughout the CETP process.

- v) The performance of CETP is being regularly monitored by HPPCB. The monitoring data (Annexure-V) indicate that the performance of the CETP is far from satisfactory for having not met the discharged standards. The data reveal that effluent quality does not conform the standards of Chloride (limit of 1100 mg/l max.), Total dissolved Solids (TDS) (LIMIT OF 2100 MG/1 Mmax.) and Biochemical Oxygen Demand (BOD) (limit of 30 mg/1 max.).
- vi) The CETP has provided online continuous effluent monitoring system for pH, Total Suspended Solids (TDS), Chemical Oxygen Demand (COD) and Total Organic Content (TOC) and data so recorded are linked with the server of HPPCB and CPCB.
- While collecting the sample from the final outlet of tertiary clarifier and discharge point at River Sirsa, difference in colour of effluent was observed. The sample collected from the discharge point was lighter in colour than that of outlet of tertiary clarifier; giving rise to possibility of dilution. (Photograph: Plate-I)
- vii) The Committee also recorded that the Textile Units, which are generating the effluent of Category IV, were earlier operating their own effluent treatment plants prior to commencement of CETP and found it viable to operate due to their scale of production.
- viii) The designed treatment criteria of CETP are to treat effluent, stream-wise, following segregation at source, effluent of Category-I is mixed with Category-IV, resulted in alternation of criteria, hence treated effluent.
- ix) For increasing the connectivity, the CETP has proposed of laying conveyance (pipeline) for a total length of 5.8 kms. The status is as under.

Sr. No.	Location	Stretch in meters	Status of permission obtained	Remarks
1.	Zydus Cadilla to Legacy Food on Baddi Barotiwala road	1655	Permission granted by HPPWD	Work has been awarded by M/s Baddi Infrastructure Ltd vide letter dated 27-09-2019. (Annexure-VI)
2.	Maplur-Baddi electrical	2250	Permission not granted	

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	substation upto Bhud near Maxtar Bio Genics Company		by NHAI	
3.	Bhud to Lehi	1900	Permission granted by HPWD	
Total		5805		

To safeguard the interest of environment from being deteriorated further and having understanding of pollution problem, its cause and remedial measures, the Committee recommends following:

- i) **Textile industries (SI. No.1 to 5, Table 1) engaged in dyeing-process generating effluent of Category-IV, as mentioned above for the purpose of designing and operating CETP, should stop its operations with immediate effect, until and unless the dedicated conduits supposed to carry the said effluent, is brought to back functional.**
- ii) These units shall resume operation of their ETP to impart effective treatment on effluent of Category-IV so as to meet the standards and shall pump treated effluent to the pipe network designated to carry effluent of Category-I for further treatment at CETP.
- iii) **These units shall resume operations only upon satisfactory performance of ETP which was brought back to functional and shall be monitored once in a month by HPCB.**
- iv) M/s Baddi Infrastructure including Ltd. is to ensure proper maintenance of CETP and its infrastructure including pipe network designed to receive effluents from member industrial units. M/s Baddi Infrastructure Ltd. has to ensure operation of CETP as per the defined protocol and in accordance to standard operating practice which is in place. In case, any variation (beyond the designed criteria) of effluent quality is noticed by CETP the same shall be brought to the knowledge of SPCB, in writing. The SPCB shall acknowledge the communications and shall act to identify the cause for taking all necessary steps for taking all necessary steps to eliminate/minimize such variation.
- v) **M/s Baddi Infrastructure Ltd. has to install activated carbon, pressure sand filters and ozonizer before the treated effluent is discharged. This refers the Detailed Project Report of CETP-Baddi, which finds mentioned of the system but**

has not been provided by M/s Baddi Infrastructure Limited.

Reference is made on the observations recorded by the Committee constituted by Hon'ble Tribunal in O.A. No.916/2018 in the matter of Sobha Singh and Others v/s State of Punjab and Others, wherein the Committee recommended that Rs.1.0 crore to be levied on CETP-Baddi as Environmental Compensation for untreated effluent discharged into River Sirsa. The CETP discharged, joining the river, has failed to meet Bio-assay Test (Toxicity on fish: 0% survival with 100% effluent for 96 hours). This would have caused impact on water and land (soil) environment, plants and vegetation, aquatic life and human health all along downstream of CETP-Baddi.

Thus, Committee also recommends the following:-

- vi) Environmental compensation (EC) to be levied to CETP-Baddi (M/s Baddi Infrastructure Ltd) for not having done effluent treatment upto the standards and to those Textile Industries (dyeing units) responsible for making CETP defunct. The EC would be proportionate as under.
 - a) CETP-Baddi has to pay environmental Compensation to the tune of Rs.1.91 Crores for non-compliance of discharged standards, estimated based on violation recorded by HPPCB over last one and half year [19.10.2017 -01.11.2019] (**Annexure VII**) including compensation to the tune of Rs.87.9 Lakh imposed by HPSPCB dated 15.10.2019 over one year [20.11.2018 to 09.09.2019] (**annexure VIII**).
 - b) Textile Industries (dyeing units) are to pay establishment cost of CETP and cost of pipe network which was brought to state of irreparable.
- vii) HPPCB is to review the notification, dated 17.03.2018 wherein Total Suspended Solids (TSS), Oil & Grease and pH have been notified TDS, BOD, Chloride and Sulphide may also be considered for inclusion in the notification as these have critical bearing on operation and performance of CETP designed to impart effective treatment. HPPCB may undertake similar exercise as done in case of notification, dated 29.06.2019 for CETP Paonta Sahib, wherein eight parameters including those referred here, have been considered. Such notification may be issued in consultation with CPCB.
- viii) **For optimal performance of CETP-Baddi, HPPCB is to ensure regulating and monitoring mechanism be in place by asking all member units (falling under red category) of CETP to install online continuous effluent monitoring system. The data so recorded shall be made available on SPCB and CPCB server for effective control."**

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3. The matter was then considered on 18.06.2020 in the light of compliance report dated 11.06.2020 filed by the State PCB. It was observed:

"xxx

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5. In pursuance of above, the State PCB has filed a 'compliance report' dated 11.06.2020 to the effect that the units gave action plans which are not satisfactory as long timeline have been prescribed.

6. We do not find the report to be as per the mandate of law. **If the pollution is continuing, the State PCB is under obligation to close the polluting activities by exercising its jurisdiction under the Water Act, 1974 and recover compensation from the polluters. Till pollution is stopped, polluting activities, which are punishable crime under the law, cannot continue. The State PCB has failed to take action merely on the ground that action plan was being prepared or had been prepared which was not satisfactory. None appears for the State PCB.**

4. The matter was last considered on 04.01.2021 in the light of the report of the State PCB dated 01.01.2021 mentioning the steps taken for closure and recovery of compensation. The Tribunal found that the action taken was not adequate as CETP was still non-compliant. Untreated effluents were thus being discharged into the water bodies in violation of law. Discussion and direction in the said order are reproduced below:-

"1 to 3.....xxx.....xxx.....xxx"

4. Accordingly, the State PCB has filed its report on 01.01.2021. It mentions that the State PCB issued show cause notice dated 23.06.2020 to the concerned textile units for closure and recovery of compensation against which writ petitions were filed before the Himachal Pradesh High Court. The High Court, vide order dated 22.07.2020, directed that the matter be heard by the Principal Secretary, Environment and fresh order passed. The Principal Secretary, Environment passed further order on 30.12.2020 directing the State PCB to take action for enforcement of law since violation of law was established. The Principal Secretary, Environment held:

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..... But this fact cannot be ignored that effluent discharge, FDS in particular, by these units is beyond the prescribed limits which is contributing to pollution. In the light of this discussion, I am of considered view that, keeping in view the above position, SPCB may take action strictly according to the provisions of Law and rules applicable in this case."

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5. The State PCB accordingly issued fresh show cause notice on 28.12.2020 and passed further order dated 01.01.2021 as follows:

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Whereas, the effluent of category-IV being contributed by the unit M/s Auro Textiles, Sai Road Baddi, Distt. Solan, H.P to the CETP for final disposal and treatment by unit is not complying since 25-7-2020 till date to the discharge standards as prescribed in the schedule-1 of EP Rules, 1986 as well as the inlet quality standards notified by the State Government and thereby causing water pollution.

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Now, therefore, in consideration of the facts stated above, in view of the directions of Hon'ble High Courts orders, Hon'ble NGT and the orders passed by Principal Secretary (Env, S&T) Govt of HP and in exercise of the powers conferred under section 32 and 33-A of Water (Prevention & Control of Pollution) Act, 1974 M/s Auro Textiles, Sai Road Baddi, Distt. Solan, H.P. is hereby directed to:

1. Immediately shut down the dyeing process of the textile unit contributing towards the category- IV effluent to CETP, Baddi, till the unit becomes compliant.
2. Pay Environment Compensation to the tune of Rs. 42 lakhs (Forty Two Lakhs only) for the violation period w.e.f. 25-07-2020 to 31-12-2020 (140 days excluding the period of compliance)."

Identical orders are said to have been passed against four textile units.

6. We have heard Shri Nalin Kohli, learned Counsel appearing for the State PCB.

7. We find that though in the show cause notice the State PCB proposed disconnecting power supply, this direction has not been given in the final order. We also find that the CETP has still not complied with the environmental norms for which remedial action needs to be taken by the State PCB, by improving quality and reducing the load of inlet so as to be consistent with the designed capacity of the CETP or closing such units contributing to the waste for which the CETP is not designed till the concerned units make their own arrangement for treating the effluents. The member industries may be considered non-compliant, if they do not undertake primary treatment as per EC conditions of the CETP. The industries having effluent generation more than 200 KLD may be directed to treat the effluents and recycle/reuse to the maximum extent and also reducing the FDS. Wherever

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required, water audit of red category non-compliant units be conducted. The requisite pipeline may also be required to be constructed by the CETP to carry the waste.

8. Let further progress report be filed before the next date by e-mail at judicial-ngt@gov.in preferably in the form of searchable PDF/OCR Support PDF and not in the form of Image PDF."

5. The State PCB has filed interim report dated 06.05.2021 followed by further report dated 16.06.2021. It will suffice to refer to the last report to the effect that the samples were taken and were not found to be within the limits. The State PCB gave directions to the concerned industries. While some units have achieved the norms, further action is being taken in the matter. The status as mentioned in the report is reproduced below:-

"In compliance to afore-cited order dated 04-01-2021 it is submitted that earlier the State Board had filed an Interim Report vide letter No. PCB/OA No. 801/2018 /-1549 dated 6-5-2021 wherein it was submitted that Board has taken steps to make the CETP, Baddi compliant. The FDS level was found 2364mg/ltr as per sampling conducted at that time, though not within the prescribed limits. It is further submitted that now the latest sample taken on 21-5-2021 and 7-6-2021 has been found within the prescribed limits w.r.t. FDS as the same has been reduced to the 2019mg/ltr and 2072 mg/ltr respectively. The sampling chart of the CETP Baddi is annexed as Annexure --A which reveals that there is continuous improvement and now the analysis results of latest sample taken are meeting the norms w.r.t. FDS.

It is further submitted that as regard to the issue of industries having effluent generation of more than 200 KLD, the State Board had identified and issued directions to 16 numbers of industries to operate their treatment plants i.e. primary, secondary and tertiary treatment system for the effluent treatment as per Environment Conditions of CETP and also directed to recycle / reuse to the maximum extent and also to reduce the FDS. Now as per report received from the Regional Office Baddi, these 16 units are operating the effluent treatment plants prior to their effluent discharge to CETP. The State Board has conducted inspection and sampling of these 16 units. The earlier results of sampling conducted on 21-1-2021, 29-1-2021, 1-3-2021, 23-3-2021 and 16-4-2021, were found within limits (except of three units of M/s Vardhman and one unit of Winsome Textile) which has already been placed on record alongwith interim report dated 6-5-2021. However, the latest results of sampling conducted on 21-5-2021 the results of three units namely M/s P&G Home Products Baddi, M/s Torrent Pharmaceutical Ltd. Baddi and M/s Abbott Health care, Baddi were found above the prescribed limits for which notices dated 16-6-2021 has been issued to these units. Copy of sample results and notices issued are annexed as Annexure-B and Annexure-C (colly). The sample results of other units were found within the

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prescribed limits. It is further submitted that as reported by Regional Officer, Baddi the member industries having flow less than 200 KLD are disposing off their effluent to CETP, Baddi after primary treatment.

As regard to the compliance by the four textile units namely Auro Textile, Auro Textile unit —II, Auro Dyeing of Vardhman Textile and one unit of Winsome Textile, it is submitted that as per report received from the Regional Office, Baddi, **the work of installation of advance treatment system by M/s Vardhman textile to reduce FDS is under progress and Reverse Osmosis system of capacity of 2 MLD shall be operational by 30-6-2021.** In addition to Reverse Osmosis, M/s Vardhman Textile is also installing the Multi Effect Evaporator of capacity of 370 KLD. As regard to progress of installation of advance treatment system by M/s Winsome Textile it is submitted that as per report received from Regional Office, Baddi the unit has completed the civil construction work. **The installation of Reverse Osmosis system and other components is under progress.** Copies of progress report of these textile units received from Regional Office are annexed as Annexure D and E. **The latest sample results of these four textile units are still not meeting the norms.** Sample results are annexed as Annexure-F. As already submitted in interim progress report dated 6-5-2021, it is again submitted here that **State Board had issued directions on 1-1-2021 to these four textile units under section 33-A of Water Act, 1974 for closure and levied Environmental Compensation which were challenged by these units before the Hon'ble High Court of HP vide CWP No. 414/2021, 416/2021 417/2021 and 418/2021. The Hon'ble High Court of HP vide order dated 11-1-2021 and 15-3-2021 has stayed the operation of the directions issued by the State Board and the matter is still pending before the Hon'ble High Court of Himachal Pradesh for adjudication.** Copies of order dated 15-3-2021 are annexed as Annexure-G.

It is further submitted that due to constant efforts of all stakeholders, the two consecutive latest samples of CETP outlet are meeting the norms prescribed by the MoEF &CC vide notification dated 1-1-2016. In future, the State Board shall continue to make all efforts in form of surveillance, regular monitoring and regulation on the CETP and member industries, so that the CETP remains compliant in future as well."

6. From the above, it is clear that violations are still continuing. Stay of order of closure and assessment of compensation for the past violations does not justify inaction for failure to take action for further violations after the order of stay and to initiate prosecution of the industrial units in question, including their Owners/Directors and the CETP operators. We also find that merely keeping an eye on units discharging more than 200 KLD is not enough. Violation by those discharging less than 200 KLD is not less serious

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violation nor less harmful for the environment and public health.

7. Accordingly, let further remedial action be taken to enforce the environmental rule of law in the interest of protection of environment and public health and a report of status of compliance filed after inspection by a four Member joint Committee comprising a representative of MoEF&CC, CPCB, State PCB and District Magistrate, Solan by e-mail at judicial-ngt@gov.in preferably in the form of searchable PDF/ OCR Support PDF and not in the form of Image PDF. The State PCB will be the nodal agency for coordination and compliance."

O.A. No. 136/2020 - Pharma units:

3. In O.A. No. 136/2020, extracts from last order dated 23.06.2021 are as follows:-

"3. The matter was last considered on 04.01.2021 in the light of the report of State PCB dated 30.12.2020 noticing the violations of environmental norms. The Tribunal directed remedial action and filing of compliance report. The operative part of the discussion and order of the Tribunal are reproduced below:-

"3. Accordingly, the Himachal Pradesh State PCB has filed its report dated 30.12.2020 to the effect that the joint Committee visited the area and noticed as follows:

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i. The CETP has not installed the system to completely treat category IV effluent (High TDS/FDS Stream). Despite the fact that CETP does not have the capacity to treat this type of effluent, CETP has entered into the tripartite agreement with the Industries generating Category IV effluent has been receiving this category of effluent since 2016.

ii. As per Environmental Clearance granted to CETP Baddi by the Ministry of Environment, Forests and Climate Change (MoEF&CC), the member industries with hydraulic loading more than 200 KLD shall treat the effluent in the existing onsite ETPs and then discharge into CETP for further treatment and discharge. However, it was informed that Units with hydraulic loading of 200 KLD are not treating effluent in the onsite ETPs and supplying primary treated effluent to CETP. Therefore, CETP has not been complying with this condition of the Environmental Clearance granted by MoEF&CC for the last 04 years. Accordingly, the sampling of these units was done by HPPCB team on 10/12/2020 and the samples were sent to HPPCB Central Laboratory. The results of the analysis are expected by 10/01/2021.

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iii. **The observations made by the Joint Committee during visit to the two Pharma units i.e. M/s Acme Life Sciences and M/s Helios Pharmaceuticals mentioned in the original application are as follows:**

- Both the pharma units have connectivity with the CETP for supplying the primary treated effluent, for further treatment at CETP.
- No effluent was found to be discharged directly by the Units, in the drain.
- The Joint Committee collected the samples from the final outlet of the pharma units under reference, to see the concentration of residual antibiotics in the primary treated effluent which is being sent to CETP for further treatment. The results of the analysis are expected by 09/02/2021.

iv. The evaluation of the results of the analysis of the CETP samples collected by the Joint Committee on 12-13 October, 2020, indicated intended dilution by CETP so as to achieve the prescribed norms. Therefore, the Joint Committee conducted unannounced re-sampling and sent the samples for analysis from three different laboratories.

v. **The results of analysis for the samples collected by the Joint Committee have been analyzed in HPPCB Regional Laboratory, Paonta Sahib and evaluation of the results indicated that CETP is not meeting the norms prescribed for COD (264 mg/l > 250 mg/l), BOD (35 mg/l > 30 mg/l), FDS (2252 mg/l > 2100 mg/l) and Chloride (1838 mg/l > 1000 mg/l). Therefore, it is concluded that CETP is discharging the effluent into the Sirsa River without complying with the prescribed norms. The results of the analysis of the samples are awaited from two other laboratories.**

vi. The samples from CETP, upstream and downstream of Sirsa River and the pharma units under question, were collected by the joint committee on 09/12/2020 for analysis of 12 Nos. residual antibiotic residues from Shri Ram Institute of Industrial Research, Delhi. The results of analysis of effluent samples for residual antibiotics is expected by 09/02/2021. The issue of discharge of residual antibiotics as raised by the applicant may be concluded by the Joint Committee after receipt of the analysis results.

In view of the fact that complete analysis reports will be available by 09/02/2021, it is humbly prayed to Hon'ble National Green Tribunal that Joint Committee may kindly be permitted to file the final conclusive report by 15/02/2020."

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4. Accordingly, further action taken report may be separately filed by the State PCB before the next date by e-mail at judicial-ngt@gov.in preferably in the form of searchable PDF/OCR Support PDF and not in the form of Image PDF. The directions in the connected matter being OA No. 801/2018, *Jasmeet Singh v. State of Himachal Pradesh*, dealt with by a separate order, to the extent relevant for the present matter, may also be followed."

4. The State PCB has filed its report dated 10.03.2021 giving the analysis results of samples calculated from the units as follows:-

"Supplementary Report:

The analysis results from the remaining two laboratories w.r.t samples collected by the Joint Committee have been received (Annexure-2 and Annexure-3). Further, the report of analysis w.r.t. samples collected by the Joint Committee from CETP, Pharma Units and Sirsa River for the presence of antibiotics from the approved external laboratory has also been received (Annexure-4). Accordingly, supplementary report in this matter is being filed by the Joint Committee as follows:

- i) The results of analysis as received from three different laboratories of HPPCB, indicated that CETP is not meeting the norms prescribed for BOD (41, 35 & 38 mg/l > 30 mg/l), FDS (2252 & 3190 mg/l > 2100 mg/l) and Chloride (1209, 1838 & 1209 mg/l > 1000 mg/l). Therefore, it may be concluded that CETP is discharging the effluent into the Sirsa River without complying with the prescribed norms.
- ii) The results of analysis of the samples collected from various stages of CETP and also final discharge point in River Sirsa for the presence of residual antibiotics indicate that two antibiotics viz. Ciprofloxacin and Ofloxacin are present in the final treated effluent of CETP as a concentration of 22.8 ug/l and 69.8 ug/l respectively.
- iii) There are no standards notified by MoEF&CC for residual antibiotics in industrial effluents. However, these values are 1140 times higher for Ciprofloxacin (22.8 ug/l Vs. 0.02 ugh) and 349 times higher for Ofloxacin (69.8 ug/l Vs. 0.2 ugh) when compared with the proposed standards in the draft notification issued by MoEF&CC vide No. CG-DL-E-27012020- 215690 dated January 23, 2020 (Annexure-5), for pharmaceutical industry effluent and CETPs with membership of Bulk drug and formulation units.
- iv) Similarly, the samples collected by the Joint Committee from the outlets of two Pharmaceutical Industries viz. Helios Pharmaceutical and M/s Acme City Tech LLP, leading to CETP, were found to be much higher than the

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standards proposed in the draft notification issued by MoEF&CC. Also, the values reported as below quantification limit (BQL), in the analysis report of the external laboratories may not be considered as conclusive and within the proposed limits as draft notified by MoEF&CC, since the BQLs of external laboratory for various antibiotics tested in the samples, as shared with the Joint Committee, are much higher than the proposed standards.

- v) As per reports and research data available in the literature, the concentration of residual antibiotics has been found to be reduced by 60-90 % in conventional biological treatment plant. In view to assess the performance of the biological treatment system installed by CETP, the samples were collected from various stages of CETP. The results of analysis indicated that the performance of biological treatment system installed by CETP is not in line with the reports and data available in the literature, w.r.t. treatment of residual antibiotics. The inefficient performance of biological treatment system is also evident from the noncompliance of CETP with regard to biochemical oxygen demand (BOD).

Conclusion and Recommendations:

In view of the fact that:

- i) **There are no standards notified by MoEF&CC w.r.t. residual antibiotics in industrial effluents;**
- ii) **Draft notified standards are yet to be decided by MoEF&CC;**
- iii) **The concentration of residual antibiotics at outlet of CETP in Sirsa River, is much higher than the draft notified standards;**
- iv) **The treatment efficiency of CETP w.r.t residual antibiotics is not at par with the reports and data available in the literature;**
- v) **The CETP is not meeting the prescribed norms of BOD, FDS and chloride and discharging effluent into Sirsa River without complying with the prescribed norms.**

It is recommended that Pharmaceutical (both bulk drug and formulation units) may be directed by Himachal Pradesh Pollution Control Board to provide primary treatment to the level of predicted no effect concentration (PNEC) as developed by members of AMR Industry Alliance (Annexure-6), as a site (Baddi) specific preventing measure, so that there is no adverse impact of residual antibiotics on the environment and

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also to prevent development of antimicrobial resistance (AMR)."

5. The report is followed by further report dated 05.05.2021 as follows:-

"It is further submitted that now the joint committee has submitted its supplementary report which is annexed as Annexure R-1/1. Based on the inspections and sampling conducted the conclusion and recommendations made by the joint committee are as under:-

- i) There are no standards notified by MoEF & CC w.r.t. residual antibiotics in industrial effluents.
- ii) Draft notified standards are yet to be decided by MoEF & CC.
- iii) The concentration of residual antibiotics at outlet of CETP in Sirsa river is much higher than the draft notified standards.
- iv) The treatment efficiency of CETP w.r.t. residual antibiotics is not at par with the reports and data available in the literature.
- v) The CETP is not meeting the prescribed norms of BOD, FDS and chloride and discharging effluent into Sirsa River without complying with the prescribed norms....."

The copy of Supplementary Report submitted by the joint committee dated 10-03-2021 (annexed as Annexure R-1/1) may be placed on record please.

It is submitted that as of now there are no specific standards notified by the Govt. of India for residual antibiotics parameters in the existing notification of standards for pharmaceutical (Manufacturing and Formulation Industry). However, it is worthwhile to mention here that all the bulk drugs/pharmaceutical manufacturing units (if not connected with CETP) are being regulated for the compliance as per standards notified in MoEF & CC Notification dated 9-7-2009 (copy annexed as Annexure R-1/2). If the pharmaceutical (manufacturing and formulation industry) is member of CETP, then the unit is bound to comply with inlet quality standards notified by the Govt. of HP vide notification dated 17-3-2018 and 26-12-2019 (copies annexed as Annexure R-1/3 and R-1/4) The notification of specific standards for residual antibiotics (annexed as Annexure -5 with joint report) is still under proposed stage and shall be implemented for regulatory aspect as and when finalized by the MoEFF & CC."

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6. The industrial units in question have also filed their Counter Affidavits. The said Counter Affidavits are of no assistance.

7. As against the above, the applicant has filed written submission on 11.06.2021 pointing out that the analysis of the samples shows presence of antibiotics in the water.

8. The conclusion drawn from the analytical results is as follows:-

1. **Ciprofloxacin (22.8µg/L) and Ofloxacin(69.8µg/L) were detected in higher concentrations in the effluent released to Sirsa river from CETP (Sr. no 4), i.e., 1139 and 348 times higher than the prescribed MoEF& CC draft notification limits.**
2. **The higher concentrations of antibiotics in the effluent released to Sirsa river (Sr. no 4) clearly indicate that CETP is unable to completely remove or degrade these antibiotics.**
3. **Ofloxacin (960µg/L) was found in the effluent from M/S Helios Pharmaceutical (Sr. no 13) release to CETP, which is much higher than the draft notification limit (0.2 µg/L). It clearly raises doubt on the level of pre-treatment of the pharma effluent from this industry before it is released to the CETP.**
4. **The samples drawn from the effluent of M/S Acme City Tech LLP (Sr. no 14 and 15) release to CETP shows reasonably high concentrations of Ofloxacin (170 µg/L) and Azithromycin (423µg/L) even after primary treatment, indicate inefficient pre-treatment at this industry.**
5. **In the research methodology Limit of quantification (LOQ) for a compound by any method indicates the lowest concentration that can be quantified with accuracy and precision. The values below LOQ cannot be correctly quantified during the analysis and are reported as Below Quantification Limit (BQL). In the present analysis, the LOQs of the compounds fixed for the analysis by the lab are very high; namely, Ciprofloxacin (5 µg/L), Ofloxacin (5 µg/L), Piperacillin (5 µg/L), Azithromycin (10 µg/L), Tazobactam (5 µg/L), Cefprozidime (50 µg/L), Cefixime (20 µg/L), Amoxicillin (10 µg/L), Ampicillin (10 µg/L), Cefpodoxime (10 µg/L), Sulbactam (10 µg/L), Ceftriaxone (50 µg/L) and Cefoperazone (10 µg/L). The above LOQs of the compounds are much higher than even the antibiotic discharge limits set by the MoEF & CC draft notification for these compounds; except for Tazobactam.**

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6. Incidentally Piperacillin and Amoxicillin are the antibiotics are known for the very adverse impact on the human health even in the very low concentration. In this laboratory analysis, BQL limit for these compounds are set as (5 µg/L) and (10 µg/L) which is significantly higher than the limit fixed in the draft standards. In the draft standards the limit set for these two compounds are (0.1 µg/L).
7. This implies that the Limit of Quantification (LOQ) set up by the lab is significantly higher than the limit set by the draft notification and therefore many of the compounds are not being detected as has been marked as BQL in the analysis results.
8. Therefore, the samples analysis should be conducted using an analytical method to precisely and accurately quantify lower concentrations of the compounds (LOQs should be kept as close or even lower than the draft notification limits) to quantify all the compounds at lower concentrations with accuracy and precision. This raises the question mark on integrity of the overall analysis by the lab.
9. Further the findings also imply that the CETP is not designed to efficiently treat class IV effluents; however, operator of CETP has entered into agreement with various pharma manufacturing units who are releasing class IV effluents to the CETP since 2017."
9. Further submissions are reproduced below:-
 - "14. The migration of antimicrobials into the environment has significant impacts. They can disrupt wastewater treatment processes and adversely affect ecosystem because they are toxic to beneficial bacteria. Some antimicrobials also bio accumulates; for example, erythromycin has been found to have both a high bio accumulation factor of 45.31 and a tendency to accumulate in soil. Antimicrobials can also be persistence for extended periods of time, the environmental persistence of erythromycin for example, is longer than one year.
 15. Although not well studied, the presence of antimicrobials in natural waters may be exerting selective pressure leading to the development of antibiotics resistance in bacteria. The threat of growing antibiotics resistance has been recognised by, among others, the WHO, the National Academy of Science, the American Medical Association, the American Public Health Association and the US government Accountability. In fact the Centre for Disease Control and prevention (CDC) has identified antibiotics resistance as one of the most pressing public health problem facing the nation. Infections caused by

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bacteria with resistance to at least one antibiotic have been estimated to kill over 60,000 hospitalized patients each year. Methicillin resistant strains of *Staphylococcus aureus*, although previously limited primarily to hospital and health facilities, are becoming more widespread. In 2007, Consumer Reports tested over 500 whole chickens for bacterial contamination and antibiotic resistance. They found wide spread bacterial contamination in their samples and 84 percent of the salmonella and 67 percent of the campylobacter organisms that were isolated showed resistance to one or more antibiotic.

16. Antibiotic resistance is caused by a number of factors including repeated and improper use of antibiotics in both humans and animals. Half of the antibiotics used in livestock are in the same classes of drug that are used in humans and animals. The U.S. institute of Medicine and the WHO have both stated that widespread use of antibiotics in agriculture is contributing to antibiotic resistance.

17. The above study done by the HPPCB shows that from whichever place samples have been taken by HPPCB these are having antibiotics discharge which should not have been there. There is not a single sample in which the aforesaid antibiotics discharging into surface water and also seeping into the subsoil water is not there. This would lead to harmful antibiotic resistance amongst human and animal population and, thus, reducing the chances of their recovering from diseases where absence of resistance from these antibiotic would have helped. The above table and the subsequent narration would show that the antibiotics found in the discharge include some of the ultimate antibiotics developing resistance of which may be a death warrant for different life forms - human and animal - if infected with diseases where these antibiotics could have provided a cure.

18. A situation where all random samples show the same results, in technical terms, is called '100% random test positivity'. In view of the '100% random test positivity', the study conducted by HPPCB cannot be stated to be complete and conclusive. It only indicates that a whole lot of polluting antibiotics are being discharged into the surface and subsoil water which is harmful for human and animal population.

19. As per information available at internet, there are more than 270 Pharmaceutical Companies operating in Baddi-Barotiwala-Nalagarh area. List of such Pharmaceutical Companies along with their addresses, as obtained through internet sites, is placed at Annexure A.

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20. This necessarily requires a further and more detailed study as a sequel to 'the sample study' done by HPPCB to understand the entire extent of damage because of the aforesaid antibiotic discharge into the water bodies. It is being called 'sample study' because of the fact that it has '100% random test positivity' and therefore, in scientific tradition, there is an absolute need for following it up with a detailed, wide and more in depth study of the antibiotic discharge into river Sirsa."

10. We have heard the applicant in person and the Learned Counsel for State PCB.

11. We find that there is gross failure on the part of the State PCB to act as per public trust doctrine in preventing discharge of toxic effluents containing harmful residue of antibiotics in water posing threat to aquatic life (reference: "biomonitoring of Sirsa River in Baddi area of Himachal Pradesh by Bhagat S. Chauhan, et al, International Journal of Theoretical and Applied Sciences 5 (1): 183-185(2013)) which is also in violation of the Water (Prevention and Control of Pollution) Act, 1974. Such failure of statutory duties is at the cost of public health and protection of environment for which Chairman and Member Secretary of the PCB owe an explanation which may be furnished before the next date. Mere fact that standards have not been revised by MoEF&CC of the residual antibiotics in industrial effluents can be no justification for State PCB not taking steps to prevent. Pending finalization of standards by MoEF&CC, State PCB can go by earlier standards or lay down standards by itself under section 17 of the Water Act. MoEF&CC needs to expedite the process of finalizing the standards in the interest of protection of environment.

12. Accordingly, MoEF&CC and the State PCB may take further remedial action expeditiously. The State PCB may ensure that no harmful components in the effluents are discharged into the water by the units in question or any other API unit. A joint Committee of nominee of MoEF&CC, CPCB, State PCB and District Magistrate, Solan may conduct inspection of the area and give a report of the status of violations and the remedial action taken within three months by e-mail at judicial-ngt@gov.in preferably in the form of searchable PDF/ OCR Support PDF and not in the form of Image PDF. The State PCB will be the nodal agency for compliance. The Committee may interact with the concerned stake holders, including the concerned Industries. The report may inter alia give status of performance of individual pharmaceutical units, particularly with reference to removal of API residue by them and by the CETP, the number of pharma industries connected to CETP and those discharging effluents directly into the drain and the river. The report may further indicate chemical and biological water quality of rivers in question - Sirsa and Satluj, including the status of residue at relevant locations. CPCB

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may also suggest monitoring mechanism for API residue through a credible system so as to cover all pharma industries in the country discharging API residue directly or indirectly in river systems. CPCB may propose the timelines to undertake monitoring which may also take a note of water quality monitoring guidelines of CPCB titled "Guidelines on Water Quality Monitoring, 2017" and the performance audit report dated 18.09.2020 filed by CPCB in OA 95/2018, Aryavart Foundation v. M/s Vapi Green Enviro Ltd. & Ors. and the directions of the Tribunal dated 05.02.2021. Relevant direction is reproduced below:

"22. The directions on the subject are summed up as follows:

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- vii. CPCB and State PCBs/PCCs, as directed earlier, may utilise EC funds on laboratory set up/upgradation, and on the mentioned areas in the report as well as on approved District Environment Plans. No approval of Central/State Government will be necessary in this regard in view of section 33 of the NGT Act, supra."

CPCB may file report on the above aspects before the next date of hearing by e-mail at judicial-ngt@gov.in preferably in the form of searchable PDF/ OCR Support PDF and not in the form of Image PDF."

4. The matter was last considered on 21.01.2022 in the light of reports mentioning the non-compliances by 97 industries, the CETP as well as the pharma units. The Tribunal noted the alarming situation of non-compliance and its adverse impact on public health and environment which called for immediate and regulatory action.

Observations of the Tribunal are:

"6. The reports show alarming situation of serious non-compliance having continuous adverse impact on public health and environment. CETP is inefficient in its working and individual units are also non-compliant. This requires immediate effective regulatory action. Pharma units need to monitor API and take remedial steps. MoEF&CC needs to address such vital issue and assist the State to handle the situation in the interest of environment and public health.

7. Only explanation of the State is helplessness due to interim order of the High Court. Learned Counsel has stated that clarification is proposed to be sought in the matter from the High Court so that remedial action for protection of environment and public health is taken as violations are not only of prescribed inlet

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norms but also statutory provisions of the Water (Prevention and Control of Pollution) Act, 1974 and standards of water laid down under other relevant statutory provisions which are not covered by the stay order. We note that confusion pleaded is resulting in undesirable state of affairs, to the detriment of helpless public against the mandate of law which does not appear to have been properly brought to the notice of the High Court or any other higher forum. **We do not find any reason why the State PCB could not enforce law even against violators who are not covered by the interim order granted by the High Court, particularly the pharma units discharging more than 200 KLD.**

8. The State may accordingly take further corrective measures to enforce the law for protecting public health and the environment. **CPCB may circulate monitoring mechanism to the State PCBs on API, as directed earlier and file the action taken report before the next date. MoEF&CC may clarify the issue of API standards."**

Consideration of the matter in today's hearing and further orders

5. In pursuance of above, a note has been filed on behalf of the MoEF&CC on 04.04.2022. An action taken report dated 15.02.2022 has been filed by CPCB and the State PCB has filed its action taken report on 26.03.2022. We proceed to note the three reports and consider further course of action.

MoEF&CC stand about standards for API

6. The stand of the MoEF&CC is that the issue of standards for Active Pharmaceutical Ingredient (API) has been considered by the concerned Expert Committee of the MoEF&CC from time to time. In the 17th Expert Committee meeting held on 26.04.2019 and 18th meeting held on 9.8.2019 and 09.12.2020, standards were proposed for Bulk Drug and Formulation Industry. This led to draft Notification dated 23.01.2020 proposing standards for Bulk Drug and Formulation (Pharmaceutical) Industry, including Antibiotics residue parameters. This was followed by a meeting with stakeholders on 28.07.2020 and final Notification dated 06.08.2021. CPCB was to develop database and methodology for analysis

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of identified API and also the corresponding site specific PNEC values to enable a scientific rationale for deriving standards for such parameters.

Methodologies have been developed and circulated but not finalized.

7. Draft Notification dated 23.01.2020 for effluent standards from Bulk Drug and Formulation (Pharmaceutical) is as follows:

Sl. No.	Industry	Parameters	Standard
1	2	3	4
73	Bulk Drug and Formulation (Pharmaceutical)	A. EFFLUENT STANDARDS	
		For final outlet of ETP	
		Limiting value for concentration (in mg/l except for pH)	
		i) Compulsory Parameters	
		pH	6.0-8.5
		BOD (3 days 27°C)	30
		COD	250
		TSS	100
		TDS	2100
		Oil & Grease	10
		Bio - Assay Test**	90% Survival of Fish after first 96 hours in 100%
		ii) Additional Parameters	
		Ammonical Nitrogen	50
		Nitrate Nitrogen	10
		***Benzene	0.05
		***Toluene	0.05
		***Xylene	0.06
		***Methylene Chloride	0.9
		Phosphates as P	5
		Chlorides	1000
		Sulphates as SO ₄	1000
		Fluoride	2
		Sulphides as S	2
		Phenolic Compounds	1
		Total Residual Chlorine	1
		Zinc	5
		Iron	3
		Copper	3
		Total Chromium	2
		Hexavalent Chromium (Cr ⁶⁺)	0.1
		Cyanide	0.1
		Arsenic	0.2
		Mercury	0.01
		Lead	0.1
		****Active Pharmaceutical Ingredient (API)	0.05
		iii) for final outlet of Industries discharging to CETP	
		For each Common Effluent Treatment Plant(CETP), the state Board will prescribe inlet quality Standards for general parameters, Ammonical Nitrogen and Heavy Metals as per the design of the Common Effluent Treatment Plant(CETP) and local needs and conditions. As per notification S.O. 4 (E) dated 1 st January, 2016	

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Note:

ZLD = Zero Liquid Discharge system in *Bulk Drug and formulation* industry is considered when treated effluent meeting the limits prescribed for compulsory parameters shall be used in Process or Utilities (boiler/ Cooling tower etc). The reuse of treated effluent in gardening/ horticulture shall not be considered as ZLD in Bulk Drug and formulation industries.

**** The Bio assay test shall be conducted as per IS : 6582-1971**

Parameters listed as "**Additional Parameters**" shall be prescribed depending upon the process and product.

***** Limits shall be applicable to industries those are using Benzene, Toluene, Xylene, Methylene Chloride, Chlorobenzene.**

******API limits shall be applicable for units manufacturing API other than antibiotics.**

B. EMISSION STANDARDS from Process Reactor Vents/ Tank farm Vents

Parameter	Limiting value for concentration (mg/Nm ³)
Chlorine	15
Hydrochloric acid vapour	35
Ammonia	30
Benzene	5
Toluene	100
Acetonitrile	1000
Dichloromethane	200
Xylene	100
Acetone	2000

C. The total losses of solvent should not be more than 3% of the solvent consumed.

D. Antibiotic Residues in the treated effluent of Bulk Drug and Formulation Industry and CETP with membership of Bulk Drug and formulation Units
Individual antibiotic residues will be equal to or less than the values given in the below table.

Parameter	Limiting value for concentration (µg/l)
i. Amikacin	6.40
ii. Amoxicillin	0.10
iii. Amphotericin B	0.01
iv. Ampicillin	0.10
v. Anidulafungin	0.01
vi. Avilamycin	3.20
vii. Azithromycin	0.01
viii. Aztreonam	0.20
ix. Bacitracin	3.20
x. Bedaquiline	0.03
xi. Benzylpenicillin	0.10
xii. Capreomycin	0.80
xiii. Cefaclor	0.20
xiv. Cefadroxil	0.80
xv. Cefalonium	8.40
xvi. Cefaloridine	1.60
xvii. Cefalothin	0.80
xviii. Cefazolin	0.40
xix. Cefdinir	0.10
xx. Cefepime	0.20
xxi. Cefixime	0.02
xxii. Cefoperazone	0.20
xxiii. Cefotaxime	0.04
xxiv. Cefoxitin	3.20
xxv. Cefpirome	0.02

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xxvi.	Cefpodoxime	0.10
xxvii.	Cefquinome	0.64
xxviii.	Ceftaroline	0.02
xxix.	Ceftazidime	0.20
xxx.	Ceftibuten	0.10
xxxi.	Ceftiofur	0.02
xxxii.	Ceftobiprole	0.09
xxxiii.	Ceftolozane	0.76
xxxiv.	Ceftriaxone	0.01
xxxv.	Cefuroxime	0.20
xxxvi.	Cephalexin	0.03
xxxvii.	Chloramphenicol	3.20
xxxviii.	Ciprofloxacin	0.02
xxxix.	Clarithromycin	0.03
xl.	Clavulanic Acid	22.40
xli.	Clinafloxacin	0.20
xlii.	Clindamycin	0.04
xliii.	Cloxacillin	0.05
xliv.	Colistin	0.80
xlvi.	Daptomycin	0.40
xlvi.	Delamanid	0.02
xlvi.	Doripenem	0.04
xlvi.	Doxycycline	0.80
xlix.	Enramycin	1.92
i.	Enrofloxacin	0.02
ii.	Ertapenem	0.05
iii.	Erythromycin	0.20
iiii.	Ethambutol	0.80
iv.	Faropenem	0.01
iv.	Fidaxomicin	0.01
vi.	Florfenicol	0.80
lvii.	Fluconazole	0.10
lviii.	Flumequine	0.10
lix.	Fosfomycin	0.80
lx.	Fusidic acid	0.20
lxi.	Gatifloxacin	0.05
lxii.	Gemifloxacin	0.02
lxiii.	Gentamicin	0.08
lxiv.	Imipenem	0.05
lxv.	Isoniazid	0.05
lxvi.	Itraconazole	0.004
lxvii.	Kanamycin	0.44
lxviii.	Levofloxacin	0.10
lxix.	Lincomycin	0.72
lxx.	Linezolid	2.68
lxxi.	Loracarbef	0.80
lxxii.	Mecillinam	0.40
lxxiii.	Meropenem	0.02
lxxiv.	Metronidazole	0.05
lxxv.	Minocycline	0.40
lxxvi.	Moxifloxacin	0.05
lxxvii.	Mupirocin	0.10
lxxviii.	Nalidixic acid	6.40
lxxix.	Narasin	0.20
lxxx.	Neomycin	0.01
lxxxi.	Netilmicin	0.20
lxxxii.	Nitrofurantoin	25.60
lxxxiii.	Norfloxacin	0.20
lxxxiv.	Ofloxacin	0.20
lxxxv.	Oxacillin	0.40
lxxxvi.	Oxytetracycline	0.20
lxxxvii.	Pefloxacin	3.20
lxxxviii.	Phenoxymethylp enicillin	0.02
lxxxix.	Piperacillin	0.20
xc.	Polymixin	0.80

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xcv.	Retapamulin	0.02
xcvi.	Rifampicin	0.02
xcvii.	Roxithromycin	0.40
xcviii.	Secnidazole	0.40
xcix.	Sparfloxacin	0.02
c.	Spectinomycin	12.80
ci.	Spiramycin	0.20
cii.	Streptomycin	6.40
ciii.	Sulbactam	6.40
civ.	Sulfadiazine	288.00
cvi.	Sulfadimethoxin e	20.00
cvi.	Sulfadoxine	0.24
cvi.	Sulfamethoxazol e	0.24
civ.	Tazobactam	17.60
cv.	Tedizolid	3.92
cvi.	Teicoplanin	0.20
cvi.	Telithromycin	0.02
cvi.	Tetracycline	0.40
cix.	Thiamphenicol	0.40
cx.	Tiamulin	0.40
cx.	Ticarcillin	3.20
cxii.	Tigecycline	0.40
cxiii.	Tildipirosin	0.17
cxiv.	Tilmicosin	0.40
cxv.	Tobramycin	0.40
cxvi.	Trimethoprim	0.20
cxvii.	Trovafloxacin	0.01
cxviii.	Tylosin	0.33
cxix.	Vancomycin	3.20
cxix.	Viomycin	0.80
cxix.	Virginiamycin	0.80

8. Final Notification dated 06.08.2021 on the subject is as follows:

"2. In the Environment (Protection) Rules, 1986, in Schedule-I, for serial number 73 and the entries relating thereto, the following serial number and entries shall be substituted, namely:-

S. No.	Industry	Parameters	Standard
1	2	3	4
"73.	Bulk Drug and Formulation (Pharmaceutical)	A. EFFLUENT STANDARDS*	
			Limiting value for concentration (in mg/l except for pH and Bio assay)
		(I) Compulsory Parameters	
		pH	6.0 -8.5
		BOD (3 days 27°C)	30
		COD	250
		TSS	100
		Oil & Grease	10
		Ammonical Nitrogen	100

		Bio - Assay Test**	90% Survival of Fish after first 96 hours in 100% effluent
		***Benzene	0.1
		***Xylene	0.12
		***Methylene Chloride	0.9
		***Chlorobenzene	0.2
		Phosphates as P	5
		Sulphides as S	2
		Phenolic Compounds	1
		Zinc	5
		Copper	3
		Total Chromium	2
		Hexavalent Chromium (Cr ⁶⁺)	0.1
		Cyanide (as HCN)	0.1
		Arsenic	0.2
		Mercury	0.01
		Lead	0.1
		SAR	Less than 26 (applicable only for discharge on land)
		(iii) Industry connected with CETP	
		- The discharge norms for industry connected with CETP and of CETP shall be governed by Ministry of Environment, Forest & Climate Change notification S.O. 4 (E), dated the 1st January, 2016. - State Pollution Control Board shall prescribe additional relevant parameters as given at para A (ii) of this notification as per needs and discharge potential of member industries and specify the frequency of monitoring considering the receiving environment conditions.	
		Note: The standards in para A is applicable to all discharges except to CETP. *Not applicable to industry discharging to CETP, and shall be applicable to all discharge to land and surface water bodies including use of treated wastewater for horticulture or irrigation purpose. ** The Bio assay test shall be conducted as per IS : 6582-1971 ## Parameters listed as "Additional Parameters" shall be prescribed by SPCB depending on the process and product and its monitoring frequency shall be monthly/quarterly as decided by SPCBs ***Limits shall be applicable to industries those are using Benzene, Xylene, Methylene Chloride, Chlorobenzene.	
		B. EMISSION STANDARDS (Tank farm Vents)	
		Parameter	Limiting value for concentration (mg/Nm ³)
		Chlorine	15
		Hydrochloric acid vapor	35

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Ammonia	30
Benzene	5
Toluene	100
Acetonitrile	1000
Dichloromethane	200
Xylene	100
Acetone	2000
C. The total cumulative losses of solvent should not be more than 5% of the solvent on annual basis from storage inventory	
D. Chemical and Biological sludge or any residue, reject, concentrate generated from wastewater treatment or its management facility at Industry or CETP catering to industries engaged in manufacturing of bulk drug or formulation of Pharmaceuticals, shall be classified as Hazardous Waste as per the provision of clause 17 of sub-rule (i) of rule 3 of the Hazardous and Other Wastes (Management and Trans boundary Movement) Rules, 2016 and shall be subject to the provision made therein.	

CPCB Report

9. Report of the CPCB dated 15.02.2022 considers the problem of Antimicrobial resistance (AMR) on account of antibiotic residues discharged in waste water which requires compliance of norms by the manufacturers for which Limit of quantification (LOQ) adopted by the CPCB needs to be followed as per methodology suggested and circulated to State PCBs/PCCs. Recommendations in the report are as follows:

“Recommendations/Mitigation of AMR in the environment

40. *When a new class of antimicrobials comes on the market, it should be considered “critically important” from the outset unless strong evidence suggests otherwise. The risk assessment of new antimicrobial substances for use in food-producing species should be reinforced. One of the possible options would be to introduce an early hazard characterisation, addressing the risk to public health from antimicrobial resistance (AMR), to be assessed prior to the submission of a Marketing Authorization Application (MAA).*
41. *At the time of first approval for new antimicrobial substances/a new class of antimicrobials in veterinary medicine, marketing authorisation holders (MAHs) should have plans in place to monitor susceptibility in zoonotic and indicator bacteria through approved programmes; these data should be provided by the MAH to the regulatory*

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authorities and be comparable with human AMR surveillance data.

42. Based on the outcome of antimicrobial resistance surveillance and monitoring of usage, a new risk assessment could be required for all products of a specific antimicrobial class, encompassing both generic and reference products.
43. Put in place a declaration system in order to assess the extent and evolution of off label use of human only authorised antimicrobials. Monitoring of off label use needs to be facilitated. When collecting data on consumption of off label use of antimicrobials in animals the animal species (body weight), product, indication, regimen (dose, duration, treatment interval, route of administration/formulation) are important to assess.
44. Include in future legislation flexible tools to allow banning or limitation of off label use in animals of certain antimicrobials/classes authorised only in human medicine following an unfavourable hazard characterization or benefit-risk assessment.
45. Existing drugs that are already classified as "critically important" antimicrobials but which are not currently used in food production such as carbapenems, oxazolidinones (linezolid) and lipopeptides (daptomycin) should not be used in the future in food animal production".
46. Recognising the need to preserve the effectiveness of the antimicrobial agents in human medicine, careful consideration should be given regarding their potential use (including extra-label/off label use)."

Reduce the input of antibiotics into environmental

47. Antimicrobials manufacturing industry should possess a valid authorization for discharge of treated effluent. Compliance with each condition in the authorization should be achieved.
48. Levels of antibiotic in process wastewater are quantified e.g. mass balance.
49. Wastewater sources from operations are characterized and evaluated for treatability and control.
50. Effective waste water treatment plant is equipped with primary, secondary and tertiary treatment (e.g., neutralization, clarification, settling, inactivation, biological or chemical treatment) which is efficacious to eliminate the residual Antibiotics. Industries may deploy the Antibiotic deactivation techniques like acidification, neutralization and others to degrade the active Antibiotics moiety.

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51. The technology plays crucial part for conversion and recovery of product i.e. minimizing the product loss into mother liquor. The adoption of best practices during manufacturing process to arrest (minimize) the emission of antibiotics into water stream to reduce the influx into waste water treatment plant or environment.
52. The CETP, waste water treatment plant (WWTP) infrastructure, design and its effectiveness i.e. onsite, offsite and infrastructure & performance of treatment system before discharging to common effluent treatment plant, are to release the emission of residual antibiotics into environment.
53. Sludge from process wastewater treatment is managed in compliance with all local regulations. Assessments are conducted to determine potential risk from sludge application to land.
54. Setting up systems and best practice guidelines to correctly dispose of unused medicines.
55. Limiting the use of antimicrobials (especially critically important compounds).
56. Frequent sampling is important to understand the levels of API residue in the discharge.
57. Samples are collected, stored, and analysed with results reported in accordance with regulatory requirements.
58. Process areas (e.g., tanks, container storage areas, and process sewer systems) are designed, constructed and operated to prevent spills or releases antibiotic residue to the environment.
59. Treatment systems should be in place to prevent soil, surface water, or groundwater contamination.
60. Waste classification, labelling, storage and disposal methods should be in accordance with the hazard characteristics of the waste, and in accordance with regulatory requirements. i) Waste containers are labelled with contents, hazard characteristics (e.g., flammable, biological), and closed once waste is placed in the container. ii) Disposal methods are based on waste characteristics. Records (e.g., waste classification determinations including analytical results, letters from waste contractors/facility, and certificates of destruction) are maintained.
61. Waste disposal contractors/facility should possess authorizations/certifications from SPCBs/PCCs to manage specific waste streams in accordance with regulations."

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10. The recommendation is preceded by discussion which to the extent relevant is reproduced below:

"Introduction

Antimicrobial resistance (AMR) is the ability of a microorganism to survive and multiply in the presence of a compound with antimicrobial properties that would normally inhibit or kill this microorganism. Several different mechanisms are involved in the development of resistance to antimicrobials. Antibiotic residues may find their way to the environment via any of the following three modes:

- i) *Waste water discharge from pharmaceutical manufacturing:*
Although the treatment of wastewater can partly eliminate or remove pharmaceuticals, some traces are still detectable in effluents and surface/groundwater as well depending on the concentration of antibiotics at the inlet of effluent treatment process and efficiency of effluent treatment process. Process Control to minimize the release of antibiotic residues in the effluent for end of the pipe treatment is seen as a viable option.
- ii) *Human and Animal consumption and excretion:* 30-90% of orally consumed dose of pharmaceutical consumed, are excreted as per reports available in the literature. Antibiotics used in aquacultures/poultry farms, animal husbandry etc are posing additional threat in this regard.
- iii) *Non-scientific disposal of expired and/or unused medicines.*

The presence of antibiotic residues in the environment cannot be attributed to a single source, direct release of antibiotic either accidental or due to lack of efficient effluent treatment technologies or process inefficiencies has made pharma industries as a starting point for addressing issue of antibiotic resistance. Besides above, other factors for antibiotic residues in effluents include:

- a) *Direct emissions, if any, by pharma industries, although localized, are being considered as a source of discharge in much higher concentration when compared to other indirect sources.*
- b) *Since the antibiotic residues which are released directly in the pharma effluents, are not consumed and hence not metabolized like other sources and hence reduction in concentration in that ratio may not be achievable. Further, in principle, any compound that is not readily degraded/metabolized, has the potential to reach adverse exposure concentration in environment.*
- c) *It is unlikely that pharma industries will intentionally discharge their final product in the form of antibiotic residues. But at the same time, if discharged even accidentally or due to inefficient working of effluent treatment process, the concentration can always be several time more in comparison to other sources.*

In addition to their indirect discharge, antimicrobials are also used in aquaculture where they are generally used as in-feed preparations. Ultimately, antimicrobials can reach various external environmental

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compartments such as rivers, lakes and soils where they can continue to exert their effects. Once in the environment, some antibiotics bind strongly to soil and sediments, which contributes to their persistence as they become inaccessible to degradation (these 'trapped' compounds can persist in soil for many years).

Resistance to antibiotics among human and veterinary pathogens increases the risks of treatment failure, increases mortality by increasing the time from an initial diagnosis to an effective therapy, and can also lead to morbidity by increasing the use of more toxic antibiotics as replacements for those rendered ineffective due to resistance. This issue also imposes an additional healthcare cost and productivity loss. Hence, it's a necessity to develop guidelines for sampling and monitoring of the Antimicrobials.

Common Antibiotic manufacturing framework should follow the rules as mentioned in the Antimicrobial Industry Alliance (AMR IA). It was found that antibiotics compounds are sold in India in the form of antibiotics either individually or different combinations of 126 antibiotics. The Predicted no-effect concentration (PNEC) data contains two values. PNEC- Environment (PNEC- ENV) values are based on eco-toxicology data generated by Alliance member companies. These values are intended to be protective of ecological species and incorporate assessment factors consistent with standard environmental risk methodologies. The PNEC- Minimum Inhibitory Concentration (PNEC-MIC) values are intended to be protective of resistance promotion. These PNEC values are updated periodically as new reliable and robust data become available. These PNEC values, in absence of national standards for antibiotic residue, may be used as reference limit for self-monitoring purpose to prevent release of high levels of antibiotic residues in the environment.

Limit of Quantification

Trace Organics Laboratory of Central Pollution Control Board, Delhi has validated method for 21 Pharmaceuticals compounds with Limit of quantifications (LOQ) as follows:

S. No.	Name of Antibiotic	Limit of Quantification (LOQ) (µg/L)
	Amoxicillin	0.08
	Cefixime	0.13
	Cefadroxile	0.12
(4)	Fluconazole	0.14
(5)	Levofloxacin	0.16
(6)	Ciprofloxacin	0.15
(7)	Metronidazole	0.12
(8)	Azithromycin	0.03
(9)	Doxycycline	0.03
(0)	Chloramphenicol	0.09

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(1)	Norfloxacin	0.045
(2)	Ofloxacin	0.03
(3)	Ampicillin	0.045
(4)	Nalidixic Acid	0.045
(5)	Spiramycin	0.051
(6)	Roxithromycin	0.026
(7)	Lincomycin	0.028
(8)	Enrofloxacin	0.022
(9)	Cloxacillin	0.088
(10)	Diclofenac	0.14
(11)	Mefenamic Acid	0.14

Guidelines for Sampling:
Sample Collection and locations:

(1) The procedure for sample collection in respect of surface water shall be as under:

- Samples for Baseline and Trend stations shall be collected from well-mixed section of the river or main stem 30 cm below the water surface using a weighted bottle.
- Samples for Impact stations shall be collected 30 cm below the water surface from the point of interest, such as bathing Ghats, downstream of point discharges, water supply intakes and other sources.

(2) The procedure for sample collection in respect of reservoir water shall be as under:

- Reservoir water quality has temporal, spatial as well as depth variation. The water is generally not well-mixed and sampling from a single depth may inadequately represent the overall water quality. It is, therefore necessary to ensure that sampling stations are truly representative of the water body.
- It is necessary to conduct preliminary survey to determine whether and where differences in water quality occur before deciding on the number of stations to establish. The most important feature of water in reservoir is vertical stratification which results in water quality variation along the depth. The vertical stratification at a sampling station can be detected by taking a temperature reading at 1 m below the surface and another at 1 m above the bottom. If there is a significant difference (more than 3 °C) between the two readings, there is a "thermocline" (a layer where the temperature changes rapidly with depth) and the reservoir is stratified. In stratified reservoirs, more than one sample is necessary to describe water quality.

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- c) For reservoirs of 10 m depth or more, it is essential that the position of the thermocline is first assessed by means of regularly-spaced temperature readings through the water column (e.g. metre intervals). Samples should then be taken according to the position and extent (in depth) of the thermocline. As a general guide, the minimum samples should consist of 1 m below the water surface, just above the determined depth of the thermocline, just below the determined depth of the thermocline, and 1 m above the bottom sediment (or closer if possible without disturbing the sediment). If the thermocline extends through several meters depth, additional samples are necessary from within the thermocline in order to characterise fully the water quality variations with depth.
- d) In general, if the water depth at the sampling site is less than 10 m, the minimum sampling programme should consist of a sample taken 1 m below the water surface and another sample taken at 1 m above the bottom sediment.
- e) Access to reservoir sampling stations is usually by boat and returning to precisely to the same locations for subsequent samples can be extremely difficult unless GPS is used or alternatively poles may be installed for the purpose.

(3) The procedure for sample collection in respect of ground water shall be as under:

- (a) Open dug wells, which are not in use or have been abandoned, shall not be considered as water quality monitoring station. However, such well could be considered for water level monitoring. The ground water quality monitoring agencies should close down the unused open dug wells if they are potential source of microbiological contaminations in the areas without affecting the water level monitoring programme by replacing the abandoned dug wells with piezometers.
- (b) Weighted sample bottle to collect sample from an open well about 30 cm below the surface of water may be used. The plastic bucket, which is likely to skim the surface layer only, shall not be used.
- (c) Samples from the production tube wells shall be collected after running the well for about five minutes.
- (d) Non-production piezometers shall be purged using a submersible pump. The purged water volume shall equal 4 to 5 times the standing water volume, before sample is collected.
- (e) For bacteriological samples, when collected from tube wells or hand pump, the spout or outlet of the pump shall be sterilized under flame by spirit lamp before collection of sample in container.

Sample preservation and transportation:

- (1) Samples shall be transported (Cool to 0 - 6 °C) concerned laboratory as soon as possible, preferably within forty-eight hours of collection.
- (2) Analysis for coliforms shall be started within twenty-four hours of collection of sample. If time is exceeded, it should be recorded with the result.
- (3) Departments involved in monitoring should provide adequate training to the persons involved in water quality monitoring on collection and preservation techniques of water samples.
- (4) Departments involved should review the sample collection and analysis programme if it is not in conformity with Protocol norms. If it is not possible to adhere to transport time and analysis time due to large number of samples in one laboratory, the departments should outsource the analysis to nearby existing accredited laboratory.
- (5) Sample identification forms for the water sample analysis for surface and ground water samples shall be as per annexed Form-I and Form-II.

Quantity of samples to be collected:

The quantity of samples to be collected for analysis shall be as follows:

1. General analysis: 1 litre.
2. Bacteriological analysis: 1000 ml. in sterilized bottle.
3. Metal analysis: 250 to 500 ml.
4. Pesticide analysis: 1000 ml in amber color glass bottle with Teflon lid cap Collect samples in amber glass containers following conventional sampling practices.
5. Aqueous samples
 - 5.1 Samples that flow freely are collected as grab samples or in refrigerated bottles using automatic sampling equipment. Collect 1 L each for the acid and base fractions (2 L total). If high concentrations of the analytes of interest are expected, collect two smaller volumes (e.g., 100 mL each) in addition to the 1 L samples. Do not rinse the bottle with sample before collection.
 - 5.2 If residual chlorine is present, add 80 mg sodium thiosulfate per liter of water. Any method suitable for field use may be employed to test for residual chlorine.
 - 5.3 Maintain aqueous samples in the dark at < 6 °C from the time of collection until receipt at the laboratory. If the sample will be frozen, allow room for expansion.

Sample records:

- (1) Each laboratory shall have a bound register, which shall be used for registering samples as they are received. A format for sample receipt register is annexed as Form- III.
- (2) The Laboratory In-Charge shall maintain a register for assignment of works to specific analyst.

Analytical Techniques:

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Each agency shall follow the analytical techniques prescribed in the 'Standard Methods for analysis of Water and Wastewater' published by American Public Health Association (latest edition) or 'Methods for Testing Water and Wastewater-methods of sampling and testing (physical and chemical)' by Bureau of Indian Standards - IS:3025.

Manpower requirements in laboratories:

The manpower requirements shall be optimized by the concerned monitoring agencies in order to get the maximum utilization of man-days for timely completion of analysis.

Data Processing, Reporting and Dissemination:

Each monitoring agency shall process the analytical data and report the data after validation to the Data Centre at the Central Pollution Control Board (CPCB) or Central Water Commission (CWC). The CPCB or CWC shall store the data and disseminate through website or electronic mail to various users on demand. There should be free sharing of data among the various agencies collecting the water quality data.

Accreditation of laboratories:

The water quality laboratories shall seek recognition from the Ministry of Environment, Forests and Climate Change, Government of India and accreditation from National Accreditation Board for Testing and Calibration Laboratories (NABL) under Ministry of Science and Technology, Government of India. The water quality monitoring agencies/organizations should provide adequate financial support for strengthening of their laboratories with adequate manpower and their upgradation with advance instruments for the purpose of recognition / accreditation

Sampling and Analysis:

1. Sampling of effluent shall be done from the inlet and outlet of the effluent treatment systems viz. Effluent Treatment Plant, Multiple Effect Evaporator, Agitated Thin Film Dryer, Reverse Osmosis etc. (wherever required) along with the point of final discharge of the treated effluent to assess effectiveness of effluent treatment.
2. Composite and 24H flow-proportional sampling may be better than single grab sampling as wastewater composition changes significantly over short time scales and individual samples may be "flooded" by homogenous solid material. Although, Grab sampling, which was the most commonly used method, is convenient and avoids significant auto sampler-associated workload and capital costs. However, sampling of influent and composite sampling optimise the chance of identifying human-wastewater AMR correlations and are most suitable for wastewater-based AMR surveillance studies.
3. Use and cleaning of sample Bottles and Caps: For Liquid Samples (waters, sludge and similar materials containing 5

percent solids or less): the sample bottle, amber glass, 1 L minimum, with screw cap must be used. For Solid samples (soil, sediment, sludge, filter cake, compost, and similar materials that contain more than 5 percent solids): Sample bottle, wide mouth, amber glass, 500-mL minimum must be used. If amber bottles are not available, samples must be protected from light, threaded Caps must be lined with fluoropolymer. Before use the bottles are washed with detergent and water, then rinsed with solvent. Similarly, Liners are washed with detergent and water and rinsed with reagent water before use.

4. The determination of pharmaceuticals and personal care products (PPCPs) in multi-media environmental samples must be done by **US EPA Method 1694** [(high performance liquid chromatography combined with tandem mass spectrometry (HPLC/MS/MS)]. This method was developed for use in Clean Water Act (CWA) programs and is based on existing EPA methods. This method is performance-based which means that it may be modified to improve performance (e.g., to overcome interferences or improve the accuracy or precision of the results) provided that all performance requirements of this method are met. The quality of the analysis is assured through reproducible calibration and testing of the extraction, clean-up, and LC/MS/MS systems.
5. For good quality of analysis proper cleaning of glassware is extremely important, because glassware may not only contaminate the samples but may also remove the analytes of interest by adsorption on the glass surface. Hence, before use Glassware should be rinsed with solvent and washed with a detergent solution. After detergent washing, glassware should be rinsed immediately, first with methanol, then with hot tap water. The tap water rinse is followed by another methanol rinse, then acetone, and then methylene chloride.
6. Safety measures taken during analysis: The toxicity or carcinogenicity of each chemical used in analysis method has not been precisely determined; however, each compound should be treated as a potential health hazard. Pure standards of the compounds should be handled only by highly trained personnel thoroughly familiar with handling and cautionary procedures and the associated risks. The laboratory is responsible for maintaining a current awareness file of OSHA regulations regarding the safe handling of the chemicals.
7. A reference file of material safety data sheets (MSDSs) should also be made available to all personnel involved in these analyses.
8. It is also suggested that the laboratory perform personal hygiene monitoring of each analyst who perform the analysis.
9. The analyst and all personnel involved in these analyses must wear Protective equipment viz. Disposable plastic gloves (Latex or non-Latex (such as nitrile)), apron or lab coat, safety glasses or mask, and a glove box or fume hood should be used. During analytical operations that may give

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rise to aerosols or dusts, personnel should wear respirators equipped with activated carbon filters. Eye protection (preferably full face shields) should be worn while working with exposed samples or pure analytical standards. Latex or non-Latex (such as nitrile) gloves are commonly used to reduce exposure of the hands.

10. Workers must be trained in the proper method of removing contaminated gloves and clothing without contacting the exterior surfaces.
11. Personal hygiene of all personnel involved in these analyses: Hands and forearms should be washed thoroughly after each operation involving high concentrations of the analytes of interest, and before breaks (coffee, lunch, and shift).
12. Waste handling or techniques for minimizing contaminated waste: Plastic bag liners should be used in waste cans. Janitors (a caretaker or doorkeeper of a building) and other personnel should be trained in the safe handling of waste.
13. Bio solids samples may contain high concentrations of biohazards, and must be handled with gloves and opened in a hood or biological safety cabinet to prevent exposure. Laboratory staff should know and observe the safety procedures required in a microbiology laboratory that handles pathogenic organisms when handling bio solids samples.
14. Sample collection from field: Liquid samples that flow freely are collected as grab samples or in refrigerated bottles using automatic sampling equipment. If residual chlorine is present in the sample, add 80 mg sodium thiosulfate per liter of water.
15. Solid, mixed-phase, and semi-solid samples, including bio solids: Collect samples as grab samples using wide-mouth jars. Collect a sufficient amount of wet material to produce a minimum of 10 g of solids. If the sample will not be extracted within 48 hours of collection, the laboratory should adjust the pH of aqueous samples to 5.0 to 9.0 with a sodium hydroxide or sulfuric acid solution. Record the volume of acid or base used. If extraction of samples within 48 hours is not practical, then samples should be frozen to increase the holding time to seven days. If aqueous samples are stored frozen, extraction should begin within 48 hours of removal from the freezer.

Requirements for The Analysis of Antibiotics

S. No.	Requirements	Quantity	Size	Remarks
Requirement of Space				
01	Room with AC and Exhaust	04	• ≈ 625.0 Square Feet (Instrument Room) • ≈ 400.0 Square Feet (Process Room) • ≈ 400.0 Square Feet (Sample Storage Room) • ≈ 400.0 Square Feet (Chemical and CRM Storage Room)	
Requirement of Instruments and Equipment				

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02	LC-MS/MS (Tandem Mass)	01		For Qualitative & Quantitative Analysis
03	Solid Phase Extraction System	01	12 or 24 port	For Extraction & Cleanup
04	Ultra Sonicator	01		For sonication of mobile phase and cleaning of HPLC parts
05	MiniVap or Turbovap Concentrator	01	06-10 port	For Concentration
06	Rotatory Evaporator	01		For Concentration
07	Millipore Filtration Assembly	01		For Filtration of sample And Mobile phase
08	MQ Water Assembly	01		For MQ Water
09	Deep Freezer	01		CRM Storage
10	Vici cooler	01		Sample Storage
11	UPS 20KVA	01	20 KVA	Only for LC-MS/MS
12	UPS 10KVA	01	120 KVA	For others equipment
Miscellaneous Requirement				
Chemicals and Glassware/100 Sample (Approx.)				
13	Methanol	1.5L		LC-MS/MS Grade
14	Acetonitrile	1.5L		LC-MS/MS Grade
15	HPLC Water	3.0L		LC-MS/MS Grade
16	Formic Acid	5.0ml		LC-MS/MS Grade
17	Ammonium Acetate	5.0gm		LC-MS/MS Grade
18	Ammonia Liquid	5.0ml		LC-MS/MS Grade
19	Orthophosphoric Acid	100.0ml		AR-Grade
20	Sulphuric Acid	20.0ml		AR-Grade
21	pH paper	150 strip		
22	Filter Paper GF/A	200	0.45µm / 47mm	
23	Filter Paper GF/A	10	0.25 µm / 47mm	
24	Syringe Filter	100	0.25 µm nylon	
25	HLB Cartridge	100	60 mg / 20cc	
26	Micropipette	01	100-1000µl (Variable)	
27	Micropipette	01	10µl (Fixed)	
28	Micropipette	01	25µl (Fixed)	

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29	Micropipette	01	50µl (Fixed)	
30	Micropipette tip		As per requirements	
31	Sample Storage Vial	100		
32	Reference Standards for Antibiotics		As per requirements	
(I) Others				
33	Argon Gas Cylinder with Regulator	01	Approx. one cylinder for 500 sample	For LC-MS/MS
34	Nitrogen Gas Cylinder with regulator	01	Approx. one cylinder (47L.) for 06 sample	For Sample Preparation
Requirement of Manpower				
35	Manpower	01		1.For Instrument operation, calibration & Analysis.
36	Manpower	02		2.For Sampling, processing including extraction, clean up. & sample preparation.

16.

- I) *Pollution Prevention: comprises techniques that reduces or eliminates the quantity or toxicity of waste at the point of generation. Many opportunities for pollution prevention exist in laboratory operation. EPA has established a preferred hierarchy of environmental management techniques that places pollution prevention as the management option of first choice. Whenever feasible, laboratory personnel should use pollution prevention techniques to address waste generation. When wastes cannot be reduced at the source, the Agency recommends recycling as the next best option.*
- II) *Waste Management: Samples at pH<2, or pH >12 are hazardous and must be neutralized before being poured down a drain, or must be handled as hazardous waste.*
- III) *Low-level waste such as absorbent paper, tissues, animal remains, and plastic gloves may be burned in an appropriate incinerator. Gross quantities (milligrams) should be packaged securely and disposed of through commercial or governmental channels that are capable of handling toxic wastes.*

Duties of SPCBs/PCCs and frequency of monitoring

17. *The State Pollution Control Boards (SPCBs) and Pollution Control Committees (PCCs) shall conduct regular monitoring of every Technical grade pharmaceutical/ Bulk drug manufacturing /Formulation unit (hereinafter referred as pharma unit) under their jurisdiction. The monitoring of USP grade/ Laboratory grade pharmaceutical manufacturing units*

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shall be conducted at least on half yearly basis and the inspection of Formulation units shall be conducted at least on annual basis.

18. The inspections/monitoring shall be conducted as surprise inspections. Any prior information pertaining to inspection shall not be provided to the industrial units that are to be inspected.
19. On the basis of violations / shortcomings as observed during the inspection/monitoring, the action on the defaulter unit may be taken independently by SPCBs / PCCs as applicable, under the provisions of the extant laws.
20. The inspections shall involve monitoring of treated / discharged effluent w.r.t prescribed parameters including pharmaceutical parameters. The inspections have to be conducted irrespective of mode of treated effluent discharge by the pharmaceutical unit.
21. It shall essentially be verified during inspection whether the pharmaceutical unit (under inspection) is discharging treated /untreated effluent or disposing hazardous wastes in unauthorized manner. In case any unauthorized discharge of effluent/unauthorized disposal of Hazardous Waste is observed, action on the defaulter pharmaceutical unit under extant laws shall immediately be taken.
22. In case, the pharmaceutical unit (under inspection) claims Zero Liquid Discharge (ZLD) compliance, an assessment of feasibility of ZLD compliance shall be made thorough effluent monitoring and mass balance of effluent and it shall be ascertained that the unit does not practise effluent bypassing or discharge of effluent by any other means. ZLD may be defined as 'The entire quantity of effluent is treated to recover water and recovered water is reused in process and / or utilities, and only solids are discharged (or reused, if possible) in environmentally sound manner. Reuse of treated effluent for horticulture or agriculture purposes will be considered as discharge on land and not as means to achieve ZLD. Similarly, effluent from individual industries being sent to CETP for treatment will not be considered as ZLD.'
23. Excessive concentrations of Pharmaceutical ingredients may be toxic to living being. Hence, it shall essentially be verified during monitoring about any possibility of environmental pollution that may be caused by the pharmaceutical industry (under inspection) owing to mixing of the industrial effluent/any process effluent or leachate from the process / storage area containing minute concentration of Pharmaceutical ingredients with rain water / storm water.
24. In case, the pharmaceutical unit discharges its treated effluent to the inland surface water, river, stream or drain, the monitoring of the water body shall be conducted along with the monitoring of treated effluent. In case of discharge to rivers, streams, drains etc. upstream and downstream monitoring shall be conducted along with the monitoring of treated effluent.

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The monitoring of water body shall be done for prescribed parameters including pharmaceuticals and heavy metals.

25. Monitoring of the water body (to which the treated effluent is discharged) shall also be conducted w.r.t. pharmaceutical parameters. For the purpose of baseline concentration for reference / comparison, water samples from another location(s) as per discretion of the monitoring officials shall also be taken so that it may be ascertained whether the pharmaceutical unit (under inspection) is causing any water pollution.
26. Half yearly monitoring of water bodies, if any within the 500 m radius of pharmaceutical units shall be conducted to assess any pharmaceutical contamination/Anti-Microbial Resistance due to continuous discharge of industrial effluent with minor concentration of pharmaceutical ingredients in the water body. If it is observed that the monitored water body (within the 500 m radius of pharmaceutical units) is polluted with pharmaceutical ingredient (s); then further monitoring of water bodies situated beyond 500 m shall be done to assess the extent of pollution. For the purpose of baseline concentration for reference / comparison, fresh water samples from other locations as per discretion of the monitoring officials may be taken.
27. In case, the pharmaceutical unit uses its treated effluent in irrigation / gardening; groundwater monitoring w.r.t. pharmaceutical parameters shall be conducted by SPCBs / PCCs along with the monitoring of treated effluent. For the purpose of baseline concentration for reference / comparison, groundwater samples from another location(s) as per discretion of the monitoring officials shall also be taken so that it may be ascertained whether the pharmaceutical unit (under inspection) is causing any groundwater pollution.
28. In every case, irrespective of mode of discharge of the treated effluent, the inspections shall also involve ground water monitoring w.r.t. pharmaceutical parameters around 500 m of the pharmaceutical unit. If it is observed that the groundwater (within the 500 m radius of pharmaceutical units) is polluted with pharmaceuticals, then further monitoring of groundwater beyond 500 m shall be done to assess the extent of pollution. For the purpose of baseline concentration for reference / comparison, ground water samples from another location(s) as per discretion of the monitoring officials shall also be collected so that it may be ascertained whether the pharmaceutical unit (under inspection) is responsible for ground water pollution (if any).
29. In every case, irrespective of mode of discharge of the treated effluent, the inspections shall also involve water monitoring w.r.t. pharmaceutical parameters around 500m of the pharmaceutical unit. If it is observed that the water (within the 500 m radius of pharmaceutical units) is polluted with pharmaceutical, then further monitoring of soil beyond 500 m shall be done to assess the extent of pollution. For the purpose of baseline concentration for reference/ comparison, water samples from another location(s) as per discretion of the

monitoring officials shall also be taken so that it may be ascertained whether the pharmaceutical unit (under inspection) is causing any water pollution.

30. In case the pharmaceutical industry is situated within a notified industrial cluster, the monitoring officials may at their discretion decide the distance from where water, and ground water have to be taken for the purpose of baseline concentration for reference / comparison.
31. SPCBs and PCCs shall conduct effluent monitoring of Common Effluent Treatment Plants and Sewage Treatment Plants under their jurisdiction w.r.t. pharmaceutical parameters. The treated effluent from Common Effluent Treatment Plants and Sewage Treatment Plants shall not contain any pharmaceutical ingredients so that to resist from Anti-microbial resistance in environment. The monitoring has to be done regularly at least on half yearly basis.
32. SPCBs and PCCs shall conduct regular inspections of Hazardous Waste Disposal / Treatment facilities as well as Municipal Waste dumping sites within their jurisdiction. The inspections have to be done at least on half yearly basis. The monitoring shall involve ground water as well as soil sampling around 500m. of Hazardous waste disposal facility and Municipal Waste dumping sites w.r.t. pharmaceutical parameters. If it is observed that the groundwater and / or soil (within the 500 m radius of pharmaceutical/Bulk drug manufacturing units) is polluted with pharmaceutical ingredients (s), then further monitoring of groundwater and / or soil beyond 500 m shall be done to assess the extent of pollution. For the purpose of baseline concentration for reference and comparison, ground water samples and soil samples from another location(s) as per discretion of the monitoring officials shall be taken.
33. In case, SPCBs / PCCs observe that any Pharmaceutical/Bulk drug Manufacturing Industry, Common Effluent Treatment Plant, Sewage Treatment Plant, Municipal Waste dumping site or Hazardous Waste Disposal/Treatment facility has caused grave injury to the environment because of discharge of effluent / leachate contaminated with pharmaceutical ingredients or improper disposal of hazardous / other wastes containing pharmaceutical ingredients, action on the defaulter under extant laws shall immediately be taken.
34. The decision whether the pollution of environment and development of anti-microbial resistant in the water bodies has been caused by the pharmaceutical industries or bulk drug manufacturing units run off or by Common Effluent Treatment Plant, Sewage Treatment Plant, Municipal Waste dumping site or Hazardous Waste Disposal/Treatment shall be taken based upon the observed facts, evidences and scientific rationale.
35. SPCBs / PCCs may direct the pharmaceutical industries in their jurisdiction to recycle and reuse the treated effluent to the maximum possible extent.

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36. SPCBs / PCCs shall ensure that no pharmaceutical unit shall manufacture or formulate the pharmaceutical products other than the consented products.
37. SPCBs / PCCs jointly with CPCB shall carry out monitoring of water bodies during pre and post monsoon seasons so as to assess the impact of the Anti-microbial resistance/pharmaceutical run off into the water bodies because of industrial discharge.
38. For conducting the above stated inspections / monitoring; SPCBs, PCCs at their discretion may engage any Government organization or Government approved organization having adequate expertise in monitoring of Anti-microbial resistance in water bodies.
39. The analysis of effluent / ground water / soil samples for the pharmaceutical parameters and other than pharmaceuticals parameters shall be carried out in the laboratories of SPCBs / PCCs or in the laboratories recognised by Ministry of Environment, Forests and Climate Change and accredited by National Accreditation Board for Testing and Calibration Laboratories (NABL)."

11. The said guidelines have been circulated by CPCB to all the State PCBs/PCCs vide letter dated 31.01.2022.

Action taken report of the State PCB

12. The State PCB in its action taken report filed on 26.03.2022 has stated that the Notification dated 06.08.2021 issued by the MoEF&CC does not cover antibiotic residue standards. Regulatory action has also been taken against CETP against which proceedings are pending in the High Court. Monitoring has been intensified.

Surviving issue for resolution, Finding and directions

13. Thus, the question which survives for consideration by this Tribunal is the remedial action against discharge of toxic pollution from the antibiotic residue by the pharmaceutical units, apart from other pollution.

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OA 801/2018

14. As regards pollution other than that generated by the pharma units, we reiterate our earlier direction of taking remedial action as per law by closure of polluting units till compliance and fixing accountability for past violations, following due process. OA 801/2018 will stand disposed of accordingly with liberty to the aggrieved party to take remedy in accordance with law, if any grievance survives.

OA 136/2020

15. As regards the issue of pharma industries, we have noted the draft Notification dated 23.01.2020 as well as final Notification dated 06.08.2021 and also the stand of the parties that the standards proposed in the draft notification have yet to be finalized, except and to the extent of those mentioned in the Notification dated 06.08.2021. Draft standards were formulated and notified on 23.1.2020 i.e. more than two years ago, based on study by the experts. Regulatory mechanism is such important issues cannot remain in abeyance for indefinite period on the ground that the MoEF&CC is unable to finalise the draft standards even after two years. In view of serious consequences of unregulated discharge of API residue to the detriment of environment and public health, we consider it appropriate to direct under Section 15(1) of the NGT Act that pending finalisation by the MoEF&CC, standards proposed in the draft Notification dated 23.01.2020, which are based on expert studies, be strictly followed by all concerned. It is also necessary to abide by the guidelines of CPCB circulated on 31.1.2022, quoted above in the matter of standards and methodology on the subject. The State PCB may take further action accordingly to prevent and remedy the situation of unregulated discharge of harmful pollutants of pharma industries in the rivers.

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16. CPCB may coordinate with the State PCBs to strengthen monitoring of API and assess Predicted No-Effect Concentration (PNEC) values. ETPs and CETPs may be upgraded to control the discharge of active ingredient. Ambient monitoring of recipient aquatic resources like rivers, lakes, ground water and other environmental entities be monitored, if necessary, with the assistance of institutions of repute. CPCB and PCBs may intensify monitoring of micro pollutants by regular vigilance.

OA 136/2020 will stand disposed of accordingly, with liberty to the aggrieved parties to take remedies against any surviving grievance as per law.

Adarsh Kumar Goel, CP

Sudhir Agarwal, JM

Arun Kumar Tyagi, JM

Prof. A. Senthil Vel, EM

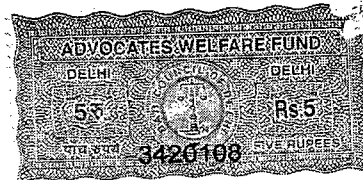
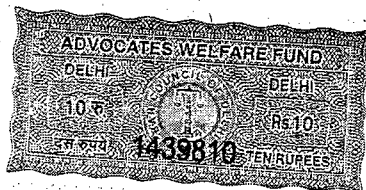
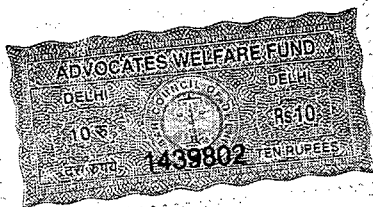
Dr. Vijay Kulkarni, EM

Dr. Afroz Ahmad, EM

April 06, 2022
Original Application No. 801/2018
Original Application No. 136/2020
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BEFORE THE HON'BLE NATIONAL GREEN TRIBUNAL, PRINCIPAL BENCH, NEW DELHI
REVIEW APPLICATION NO.....OF 2022

IN

ORIGINAL APPLICATION NO.136 OF 2020

IN THE MATTER OF:-

Veterans Forum for Transparency
in Public Life

...Applicant

-Versus-

...Respondents

State of Himachal Pradesh & Ors.

AND IN THE MATTER OF:

Ministry of Environment Forest &
Climate Change

...Review Applicant

KNOW ALL to whom these present shall come that I, Ved Prakash Mishra S/o. Sh. Ram Sidh Mishra Age about 48 years, working as Director (MoEF&CC) office at Ministry of Environment Forest and Climate Change, Indira Paryavaran Bhawan, Jor Bagh, New Delhi-110003.the above named do hereby appoint:

Balendu Shekhar Advocate Office LB-17, 5 Gauri Sadan, Hailey Road, New Delhi-110001, Mob. No. 9999666769 Email:- officeofbalendu@gmail.com Enrolment No. D/208/2002

(herein after called the advocate/s) to be my/our Advocate in the above noted case authorise him:-

1. To act, appear and plead in the above-noted case in this Court or in any other Court in which the same may be tried or heard and also in the appellate Court including High Court subject to payment of fees separately for each Court by me/us.
2. To sign, file, verify and present pleadings, appeals, cross-objections or petitions for executions review revision, withdrawal, compromise or other petitions or affidavits or other documents as may be deemed necessary or proper for the prosecution of the said case in all its stages subject to payment of fees for each stage.
3. To file and take back documents, to admit and/or deny the documents of opposite party.
4. To withdraw or compromise the said case or submit to arbitration any differences or disputes that may arise touching or in any manner relating to the said case.
5. To take execution proceedings.
6. To deposit, draw and receive monthly cheques, cash and grant receipts thereof and to do all other acts and things which may be necessary to be done for the progress and in the course of the prosecution of the said case.
7. To appoint and instruct any other Legal Practitioner authorizing him to exercise the power and authority hereby conferred upon the Advocate whenever he may think fit to do so and to sign the power of attorney on our behalf.
8. And I/We the undersigned do hereby agree to rectify and confirm all acts done by the Advocate or his substitute in the matter as my/our own acts, as if done by me/us to all intents and proposes.
9. And I/We undertake that I/We or my/our duly authorised agent would appear in Court on all hearings and will inform the Advocate for appearance when the case is called.
10. And I/We the undersigned do hereby agree not to hold the advocate or his substitute responsible for the result of the said case. 11. The adjournment costs whenever ordered by the Court shall be of the Advocate which he shall receive and retain for himself.
12. And I/We the undersigned to hereby agree that in the event of the whole or part of the fee agreed by me/us to be paid to the advocate remaining unpaid he shall be entitled to withdraw from the prosecution of the said case until the same is paid up. The fee settled is only for the above case and above Court. I/we hereby agree that once fee is paid, I/We will not be entitled for the refund of the same in any case whatsoever and if the case prolongs for more than 3 years the original fee shall be paid again by me/us.

IN WITNESS WHEREOF I/We do hereunto set my/our hand to these presents the contents of which have been understood by me/us on this. 29/5/2022 day of May 2022

Accepted subject to the terms of the fees

Balendu Shekhar
Advocate *D/208/02*

Ved Prakash Mishra
Prakash

Client
VED PRAKASH MISHRA
निदेशक/Director
पर्यावरण, वन एवं जलवायु परिवर्तन मंत्रालय
Mo Environment, Forest and Climate Change
भारत सरकार, नई दिल्ली
Govt of India, New Delhi

Client

IN THE SUPREME COURT OF INDIA
CIVIL APPELLATE JURISDICTION
CIVIL APPEAL NO _____ OF 2022

IN THE MATTER OF:-

Union of India

...Appellant

-Versus-

Veterans Forum for Transparency in Public
Lifethrough its General Secretary&Ors. ...Respondents

AN APPLICATION FOR CONDONATION OF DELAY

TO,

**THE HON'BLE CHIEF JUSTICE OF INDIA
AND HIS COMPANION JUDGES OF
THE HON'BLE SUPREME COURT OF INDIA.**

**THE HUMBLE PETITION OF THE
APPELLANT ABOVE NAMED**

MOST RESPECTFULLY SHOWETH:-

1. The Appellant have filed the present Civil appeal feeling aggrieved by the final impugned orders dated 06.04.2022 in O.A. No. 136 of 2020 and order dated 24.05.2022 in Review Application No. 14 of 2022 in O.A. No. 136 of 2020 passed by the Hon'ble National Green Tribunal, New Delhi. The said direction of the Hon'ble Tribunal is erroneous and bad in law is

causing great prejudice to the Appellant thus liable to be set aside in the interest of justice.

2. The contents of the petition may be read as part and parcel of the present application and the same are not being repeated here for the sake of brevity.
3. That there is a delay in preferring the aforesaid petition. It is submitted that the above said delay is not intentional but on account of the departmental administrative procedure involved in filing the Civil Appeal. It is submitted that unlike the private litigant the matter relating to the Govt. are required to be considered at various levels and then only a decision is taken to file the Civil Appeal. The process of referring the particular files from one department to another is a time consuming process and thus lead to delay.
4. The there is a delay in filing the present Civil Appeal, which has occurred in the following circumstances: -

S. No.	Date	Events

1.	10.04.2022	The Hon'ble NGT disposed the O.A. No.136 of 2020 vide judgment dated 06.04.2022
2.	12.04.2022	As the submissions made by MoEFCC have not taken on record by the Hon'ble NGT. Therefore, it was proposed to file a review petition before Hon'ble NGT.
3.	19.04.2022	As per direction received from Additional Secretary, MoEF & CC, opinion was sought from Ld. ASG.
4.	04.05.2022	Ld ASG gave opinion that, it is a fit case to file a Review Petition against

		the order dated 06.04.2022 passed by the Hon'ble NGT, in OA no. 136 of 2020 being Veterans Forum for Transparency in Public Life vs State of Himachal Pradesh and Ors.
5.	05.05.2022	A review application was drafted and placed on filed for approval from compete.
6.	10.05.2022	The Review application was filed.
7.	24.05.2022	The Review Application was dismissed by the Hon'ble NGT with observation that <i>"The issue in question was</i>

		<i>duly considered and rehearing cannot be allowed in the guise of a review application. Jurisdiction of this Tribunal is not dependent on MoEF & CC's decision alone."</i>
8.	31.05.2022 to 30.06.2022	As Per the direction received from the Additional Secretary , MoEF&CC a self-contained note was put up to Secretary, MoEF&CC for considering various factors and grounds to file appeal and thereafter it was decided to challenge order dated

		06.04.2022
9.	30.06.2022	Hon'ble Minister, MoEF&CC directed that the Appeal should be filed.
10.	01.07.2022	File was submitted for seeking opinion from Ministry of Law and Justice for filing the appeal before the Hon'ble Supreme Court against the order dated 06.04.2022 and 24.05.2022 passed by the Hon'ble Tribunal in O.A. no. 136 of 2020.
11.	04.07.2022	File was sent to CAS, Supreme Court from MOLJ for seeking opinion

		in matter from Ld. ASG.
12.	05.07.2022	File was sent to Ld. ASG for seeking opinion.
13.	18.07.2022	File was received in CAS, Supreme Court by Ld ASG, giving opinion that the case is fit for filing Civil Appeal.
14.	19.07.2022	A panel counsel was appointed to draft the civil appeal.
15.	02.08.2022	That a draft copy was sent to the department for approval.
16.	06.08.2022	Department after making the necessary changes in the Draft Civil Appeal sent the Draft to the panel counsel for making necessary changes and

		accompanying Application
17.	10.08.2022	That the panel counsel sent the draft civil appeal and the accompanying Application to the department, accordingly the same was approved.
18.	17.08.2022	That the Department sent the approved and finalised draft civil for filing in CAS, Supreme Court.
19.		Hence the Civil Appeal.

5. That, the delay of days in filing present Civil Appeal beyond the stipulated time frame of 90 days for filing the Civil Appeal have been caused all because of reason mentioned above Para No.3. That, the Appellant is a Government Body and decision for filing any Civil Appeal is required to be done as per norms and practice.

6. That, the delay is not intentional and the delay may be condoned in the interest of justice.

P R A Y E R

It is, therefore, prayed that this Hon'ble Court may graciously be pleased to:

- A] Condone the delay of days in filing the Civil Appeal of the final impugned orders dated 06.04.2022 in O.A. No. 136 of 2020 passed by the Hon'ble National Green Tribunal, New Delhi;
- B] and/or to pass such other order/orders as it may deem fit and proper in the interest of justice.

DROWN BY:

BALENDU SHEKHAA

Date of Filing: 08.2022

 Filed by:
18/01/22
[G.S. MAKKER]
Counsel for the Appellant

IN THE SUPREME COURT OF INDIA
CIVIL APPELLATE JURISDICTION
CIVIL APPEAL NO _____ OF 2022

IN THE MATTER OF:-

Union of India

...Appellant

-Versus-

Veterans Forum for Transparency in Public
Life through its General Secretary & Ors.

...Respondents

APPLICATION FOR EXEMPTION FROM FILING
CERTIFIED COPY OF THE IMPUGNED ORDER

To

THE HON'BLE CHIEF JUSTICE OF INDIA

AND HIS COMPANION JUDGES OF THE

SUPREME COURT OF INDIA.

The humble petition of the
Petitioner above named,

MOST RESPECTFULLY SHOWETH:

1. That the applicant above named is filling the present Civil Appeal being aggrieved by the final impugned orders dated 06.04.2022 in O.A. No. 136 of 2020 and order dated 24.05.2022 in Review Application No. 14 of 2022 in O.A. No.

136 of 2020 passed by the Hon'ble National Green Tribunal,
New Delhi

2. The contents of the accompanying petition may be read as part and parcel of the present application and the same are not being repeated here for the sake of brevity. Appellant crave leave of this Hon'ble Court to refer and rely upon the same at the time of hearing of this application.
3. That the Appellant are filing the above mentioned Civil Appeal with an ordinary/true typed copy of the final impugned orders dated 06.04.2022 in O.A. No. 136 of 2020 and order dated 24.05.2022 in Review Application No. 14 of 2022 in O.A. No. 136 of 2020 passed by the Hon'ble National Green Tribunal, New Delhi and accept its true and correct ordinary copy of the same. That the Appellant undertakes to file the certified copy of the impugned judgment as soon as it is received.
4. That it would be in the interest of justice if this Hon'ble Court is pleased to exempt the petitioner from filing the

certified copy of the impugned Judgment and order accept its true and correct ordinary copy of the same.

P R A Y E R

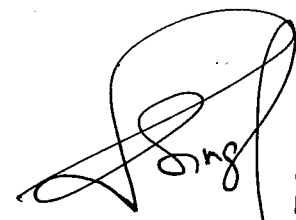
It is, therefore, prayed that this Hon'ble Court may graciously be pleased to:

- A] Exempt the Appellant from filing the certified copy of the final impugned orders dated 06.04.2022 in O.A. No. 136 of 2020 and order dated 24.05.2022 in Review Application No. 14 of 2022 in O.A. No. 136 of 2020 passed by the Hon'ble National Green Tribunal, New Delhi;
- B] and or to pass such other order/orders as it may deem fit and proper in the interest of justice.

DROWN BY:

BALENDU SHEKHAR

Filed by:

18/08/2022

[G.S. MAKKER]
Counsel for the Appellant

Date of Filing: 08.2022