

BEFORE THE NATIONAL GREEN TRIBUNAL,
PRINCIPAL BENCH, AT NEW DELHI
ORIGINAL APPLICATION NO. 136 OF 2020

IN THE MATTER OF:-

VETERANS FORUM FOR TRANSPARENCY IN PUBLIC LIFE.

APPLICANT

VERSUS

HIMACHAL PRADESH POLLUTION CONTROL BOARD & ORS

RESPONDENTS

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APPLICANT

WING COMMANDER (RETD.)

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WRITTEN SUBMISSION BY THE APPLICANT

SIR,

MOST RESPECTFULLY SHEWETH:-

1. That, during last hearing Hon'ble Tribunal was pleased to pass the following direction;

“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 violation 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 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 river in question- Sirsa and Sutlej, 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 system. 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 dated 18.9.2020 filed by CPCB in OA 95/2018, Aryavart Foundation v.

**M/s Vapi Green Enviro Ltd & Ors, and the
direction of the Tribunal dated 05.02.2021.**

2. That in pursuance of the direction of Hon'ble Tribunal, the respondent No 2 and Committee consisting of the representative of State PCB, MoEF&CC, CPCB and DC Solan have submitted their Affidavit. However, Affidavit from CPCB is awaited.
3. That respondent No 2 in its Affidavit (Para 8, pg 3, internal) has submitted that;

“That prior to filing of OA 136/2020 the issue of existence of antibiotics residual was never raised by any party and as there are no standard in existence, hence same could not have been monitored by the State Board. This being a relatively new concept for which no research study, expertise or standards are available, particularly with the State Board, there is a need to depend on the CPCB and MoEF&CC which have adequate expertise and appropriate infrastructure to notify any such norms.”

- a. Therefore, it is an admitted fact by respondent No 2, that they lack expertise and infrastructure to lay down standard for pharmaceutical industrial effluent, especially of API's.

- b. That MoEF&CC on 06.08.2021, has notified standards in the gazette for Bulk Drugs and Formulation (Pharmaceutical) Industry wherein limits for antibiotics residue are not notified. Further, the said gazette notification vide Para (ii) has prescribed that State Pollution Board shall prescribe additional parameters as given at para A (ii) of the notification as per needs and discharge potential of member industries and specify the frequency of monitoring considering environment conditions.
- c. **That it is humbly submitted that it is intra contrary at the part of MoEF&CC and a peculiar situation has now arisen where implementing agency is repeatedly expressing its inability/weakness to execute the task of setting such standard for pharmaceutical effluent and the same time MoEF&CC is ordering to do so.**
- d. That it is humbly submitted that preparing/drafting of such standards is a subject matter of national concern. For the State Boards, who has admitted its inability due to inadequate domain knowledge and expertise, to lay down any such standard will have undetermined impact across the Country. State PCB's has the legal competence to lay down standards, but does not have the expertise and resources to lay down the norms. It is therefore logical that MoEF&CC or CPCB should lay down standards for antibiotics residue for

pharma units, so that there exists uniformity in the same and all the State Boards are able to implement them effectively.

4. That the report of committee consisting of the representative of MoEF&CC, CPCB, HPPCB and DC Solan, has submitted two important submission for the consideration to the Hon'ble Tribunal, those are as following:-

- a. Vide para 3.3.1, it has been submitted that an additional CETP of 3 MLD is being established at village Kenduwal, Baddi based on adsorption process and subsequent ultra-filtration technology. Adsorption is the process of adhesion of atoms, ions, or molecule from gas, liquid or dissolved solid to a surface. The process creates a film of the adsorbate on the surface of adsorbant, which in further process of ultra filtration, film of adsorbate is removed.
- b. **That in this regard it is submitted that there no such proven technology of ETP/STP exists which can neutralise/segregate/ remove API.**
- c. API's are the challenge to treat with conventional waste water technology (STP/ETP) because they are chemically stable, often recalcitrant and non-biodegradable. In many cases, conventional on site pharmaceutical ETP's are either ineffective at

treating API's or unable to treat API's to the level required to minimize environmental impact. There is significant concentration of antibiotics and other drugs which can kill microorganism involved in biological treatment, therefore, biological treatment is not effective in the removal of API's from pharmaceutical waste water. **Following are some important points to be taken into consideration in context of conventional ETP:-**

- i. In line with current regulation, the existing ETPs are designed to meet the requirements for BOD, COD, and TDS, but there is no specific consideration with regards to API content or antibiotics residues. Therefore, it is difficult to determine the removal efficiency of APIs in the existing treatment technologies as there are no standard yet and these compounds are not regularly monitored.
- ii. In some cases, it has also been observed that traces of pharmaceutical residues reappear in the treated water samples from Waste Water Treatment Plant. This establishes to the failure of existing facilities in complete removal of APIs.
- iii. The existing treatment strategies are not only ineffective to treat APIs completely, but can also produce other problems such as formation of

unknown pharmaceutical metabolites
and resistant bacteria.

- d. As per the waste management protocol, effluent is supposed to be treated, and water and minerals recovered and reused. The end product- which cannot be recovered- is treated and made chemically inert before being safely disposed in a secured landfill. In common parlance, this process of recycling and reuse of waste water – intensive industries is known as Zero Liquid Discharge (ZLD).
- e. That idea as it may sound, and despite widespread awareness and Hon'ble Tribunal guideline for adoption of ZLD, its use has been limited to units of major multinational companies like Uniliver, and Procter & Gamble.
- f. Many pharmaceutical companies, especially in India, are considering ways to minimize their liquid discharge. Therefore, some have adopted a Zero Liquid Discharge (ZLD) program for their treatment facility. ZLD is a closed loop cycle that minimizes or eliminates discharge of any liquid effluent by recycling and treating all waste water.



5. That Hon'ble Tribunal in the matter of OA 348/2017 (Shailesh Singh v. M/S Al- Dua Food Processing Pvt Ltd & Ors was pleased to observe the following;

“6. We may add that no industry can be permitted to dispose treated effluent on land for irrigation, plantation of horticulture/gardening by prescribing standards applicable without assessment of adequate availability of land and impacts of such disposal on agricultural/crops/plants and the recipient ground water. Impact of precipitation levels also needs consideration while granting such approvals. ZLD needs to be considered with respect to use of effluents in the industrial processes not in terms of its disposal on land or farm. Therefore, the CPCB needs to look into this aspect with the help of experts and issue appropriate guidelines in this regard. This aspect may also be covered in the report to be submitted in the present case.”

6. That in pursuance of the said observation of Hon'ble Tribunal, CPCB has submitted detailed guideline, copy of which is annexed herewith as **ANNEXURE-A**.
7. That the Pharmaceutical industry manufactures thousands of drugs or active pharmaceutical ingredients (APIs) for a range

of treatment application including cancer therapy, antidepressants, steroids, antibiotics etc. Increase in global demand for drugs has made pharmaceutical industry one of the major 26 polluters of solid waste and trade effluents into the environment. While the extent of pharmaceutical pollution on humans, animals and the environment is the topic of ongoing research, antibiotics API's have been linked to the growing problem of antimicrobials resistance (AMR) and rise of antibiotics resistant superbug.

8. Pharmaceutical industry can be divided into two stages as per their manufacturing process.

a. Active Pharmaceutical Ingredients (bulk active drugs)-

A typical drug manufacturing unit involves a series of reaction, separation and purification steps to make the desired end product. The bulk drug or active pharmaceutical ingredient (API) then goes for formulation.

b. Finished Dosages Form (Formulation)- Formulation means a medicine in the form of tablets, capsules, liquid, ointment, injection, processed out of or containing one or more bulk drugs.

9. That pharmaceutical wastewater contains a high level of pollutants because of the presence of non-biodegradable

organic matter such as antibiotics, other prescription drugs, non-prescription drugs, animal and plant steroids, reproductive hormones, betalactamides, anti-inflammatories, analgesics, lipid regulators, anti-depressants, cytostatic agents, personal care products, detergent metabolites, flame retardants, product of oil use and combustion, and other broadly uses chemicals, i.e., spent solvents, reaction residues, used filter media, heavy metals (such as lead, mercury, cadmium, nickel and chromium), and other pollutants.

10. That pharmaceutical sector falls within the category of high polluting industries. This sector generates strong wastewater having high chemical oxygen demand (COD) which require proper disposal. Moreover, it also produces hazardous waste which requires effective treatment. As purity of the final product is very important, pharmaceutical industry requires very high grade purity water apart from other raw materials for its manufacturing process. The rejects (both un-reacted and converted portion of raw materials) contribute to major pollution load to pharmaceutical ETP.
11. That a typical pharmaceutical industry involves several batch reactors to get the required product and each reaction yield different kinds of pollutants depending on particular reactants and processes. There are number of streams with different characteristics from different sections of plant which may

require segregation and corresponding treatment instead of conventional and of pipe treatment system for combined effluent.

Prayer

In view of the above submissions that the Hon'ble Tribunal may be pleased to:-

- A. direct respondent No 4, CPCB to submit industrial effluent of pharmaceutical industry guideline in view of order of the Tribunal in the matter OA 348/2017 (Supra).
- B. direct respondent No 4, CPCB to lay down standard for pharmaceutical residue presence in the industrial effluent of pharmaceutical industry.
- C. Or pass any other further order as the Hon'ble Tribunal may deems fit and proper to protect the environment as well as river/water bodies, in the interest of justice.



APPLICANT

WING COMMANDER (RETD)

DR. BISHWANATH PRASAD SINGH

Place:- New Delhi

Dated:- 12 Nov 2021

**Guidelines
for
Utilisation of Treated Effluent in Irrigation**



**CENTRAL POLLUTION CONTROL BOARD
(Ministry of Environment, Forest & Climate Change)
'Parivesh Bhawan', East Arjun Nagar,
Delhi- 110 032**

September 2019

Guidelines for Utilisation of Treated Effluent in Irrigation

1.0 Background

The Hon'ble National Green Tribunal (NGT), Principal Bench, New Delhi, vide order dated 24.05.2019 in the matter of O.A. No. 348/2017, Shailesh Singh Vs Al-Dua Food Processing Pvt. Ltd., issued the following directions to CPCB:

"..We may add that no industry can be permitted to dispose treated effluents on land for irrigation, plantation or horticulture/gardening by prescribing standards applicable without assessment of adequate availability of land and impacts of such disposal on agricultural / crops /plants and the recipient ground water. Impact of precipitation levels also needs consideration while granting such approvals. ZLD needs to be considered with respect to use of effluents in the industrial processes not in terms of its disposal on land or farm. Therefore, the CPCB needs to look into this aspect with the help of experts and issue appropriate guidelines in this regard. This aspect may also be covered in the report to be submitted in the present case..."

CPCB, constituted an Expert Group, comprising of members from Indian Institute of Technology (IIT), Delhi, National Environmental Engineering Research Institute (NEERI), Delhi and Central Pollution Control Board (CPCB), Delhi, to lay down guidelines as directed by the Hon'ble NGT. The Expert Group in its two meetings held on 7.8.2019 and 23.09.2019, discussed the issues thoroughly and finalised the "Guidelines for Utilisation of Treated Effluent in Irrigation" as given in the following paragraphs/sections.

2.0 Introduction

Zero Liquid Discharge (ZLD) implies that the industries are not discharging any effluent, either on the land or in the water body or at any other place i.e. recycling the same in the process entirely without releasing any effluent.

ZLD accomplishment may need physical & chemical treatment, followed by biological system to remove organic load. The treated effluents can be then subjected for concentration and evaporation. The concentration method quite often involves the adoption of Reverse Osmosis (RO) and Nano Filtration (NF) methods. The evaporation methods involve drying/evaporation of effluent in multi effect evaporators (MEE).

Adopting ZLD practices may not be feasible in many cases in view of techno-economical reasons. However, the industries should still to be encouraged for

recycling and reuse of waste water as far as practicable in order to minimize the fresh water consumption and discharge of waste water into the environment. The treated waste water of an industry may also be utilised for irrigation. This type of utilisation/application is considered an efficient approach for managing/conserving water resources, compensating water shortages caused by seasonality or the irregular availability of water sources for irrigation throughout the year.

The possible risks of wastewater usage in agriculture may range from changes to physico-chemical and micro-biological properties of soils to impact on human health. In unfavorable economic conditions, the search for alternative irrigation sources, such as the use of untreated or inadequately treated wastewater may result in risk factors. Thus, it is necessary to ensure the beneficial aspects of this practice before application of treated wastewater in irrigation.

3.0 Guidelines for Utilisation of Effluent in Irrigation

- (i) The industry should engage an agricultural scientist or tie-up with an agricultural university or institute for advice on the utilization or the rate of application of the effluent for irrigation considering the agro-climatic conditions.
- (ii) As seasons and the sowing periods of the crops put restrictions on the utilisation of effluent for irrigation, the industry should prepare a comprehensive Irrigation Management Plan (IMP), which should include the following, in consultation with the agricultural scientist or agriculture university/institute and submit to SPCBs/PCCs which should verify the same while issuing Consent to the industry:
 - a. Areas to be covered under irrigation.
 - b. Survey/plot (khasra) numbers of land and their area covered in the scheme.
 - c. Written agreement with the farmers to bring their land under the scheme.
 - d. The quantity of effluent to be used in different periods of the year and crop-wise.
 - e. The treated effluent distribution system and arrangement for low/no demand period.
 - f. Agronomic plan for effective utilisation of land.
- iii. The treated effluent should meet the norms prescribed for irrigation under Environment (Protection) Rules, 1986/Consent. The effluent should also conform to Total Dissolved Solid (TDS)- 2100 mg/l and Sodium Adsorption Ratio (SAR)- preferably less than 18 but not more than 26, depending on soil/crop type, besides meeting any other parameters suggested by agricultural scientist or agricultural university/institute in the IMP.

- iv. Meeting the prescribed norms shall not be the only criteria for use of treated waste water in irrigation, the requirement of water for irrigation will also be a limiting condition and this depends upon various factors, as follow:
 - a. **Crop:** This is the main subject determining the water requirement, such as, paddy crops (in general) need more water than trees.
 - b. **Climate:** In tropical and subtropical climate especially in arid regions, irrigation frequency is higher. However, in slightly moist conditions the frequency decreases.
 - c. **Irrigation type:** There are various irrigation types, namely, flood irrigation, sprinkler, rain gun, drip irrigation, etc., which influences the water requirement for irrigation.
 - d. **Soil condition:** The various soil types, such as loam, clay, sandy, clay loam, sandy loam etc., determine the crop types and also alters the irrigation system thus determining the water requirement.
 - e. **Soil permeability:** The soil permeability, which is also known as water conductivity of the soil, determines the water retention capacity. This determines the cultivable crops, which in turn determines the water requirement for irrigation.
 - f. **Total Salt Concentration:** Total salt concentration (for all practical purposes, the total dissolved solids) is one of the most important agricultural water quality parameters. The plant growth, crop yield and quality of produce are affected by the total dissolved salts in the irrigation water.
- v. The command area for effluent utilisation should be as near as feasible to the industry in order to facilitate easy monitoring and effective control. The industry should construct a distribution network of impervious conduits to cover the irrigated area.
- vi. The industry should construct impervious lined storage tank of minimum 15 days capacity for storage of treated effluent during low/no demand, based on the Irrigation Management Plan.
- vii. The treated effluent should be analysed regularly, say after every 15 days. The effluent samples should be taken at the point from where the effluent is discharged for irrigation.
- viii. The physico-chemical characteristics of the soil under irrigation with treated effluent, should be monitored twice in a year to assess conditions in summer and post monsoon seasons, in order to determine the deterioration of soil quality.

- ix. Similarly, the groundwater quality should also be monitored twice in a year. Samples should be collected from the first water bearing strata from existing hand pumps or by installing the same for sampling purpose only. The sampling points should be uniformly spread in the command area and near effluent storage area.
- x. The industry should carry out the analysis of various prescribed effluent/soil/ground water quality parameters from the NABL/EPA/SPCBs/PCCs recognised/accredited laboratories.
- xi. Reports regarding compliance of effluent quality standards and status of soil and ground water quality shall be submitted to SPCBs/PCCs twice in a year, in first week of January and July.
- xii. In case of observation of any deterioration of the soil and groundwater quality parameters in the assessment by agricultural scientist or agricultural university/institute, the application of effluent should be stopped immediately and the industry should inform the SPCB, accordingly. The industry shall be solely responsible for reclaiming the soil and water quality at their cost in the affected area.
