

BEFORE THE NATIONAL GREEN TRIBUNAL
PRINCIPAL BENCH, NEW DELHI
ORIGINAL APPLICATION NO. 497 OF 2024

IN THE MATTER OF:-

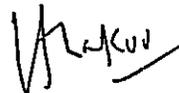
NEWS ITEM TITLED "IMPACT OF PHARMACEUTICAL TOXICITY ON
THE ENVIRONMENT AND ITS REGULATORY ASPECTS" APPEARING
IN CURRENT SCIENCE DATED 25.02.2024

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DATED: 14.08.2024

PLACE: - NEW DELHI



FILED BY :-

(UPENDER THAKUR ADVOCATE
FOR MOEF & CC (RESPONDENT NO. 74

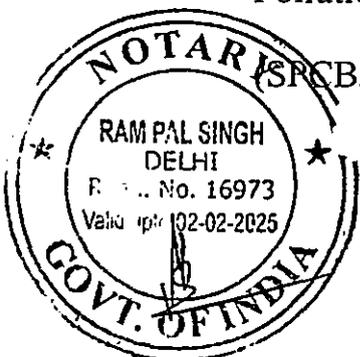
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BEFORE THE NATIONAL GREEN TRIBUNAL**PRINCIPAL BENCH, NEW DELHI****ORIGINAL APPLICATION No. 497 of 2024****IN THE MATTER OF:****NEWS ITEM TITLED "IMPACT OF PHARMACEUTICAL TOXICITY ON THE ENVIRONMENT AND ITS REGULATORY ASPECTS" APPEARING IN CURRENT SCIENCE DATED 25.02.2024.****REPLY AFFIDAVIT ON BEHALF OF RESPONDENT No. 76, THE MINISTRY OF ENVIRONMENT, FORESTS & CLIMATE CHANGE.**

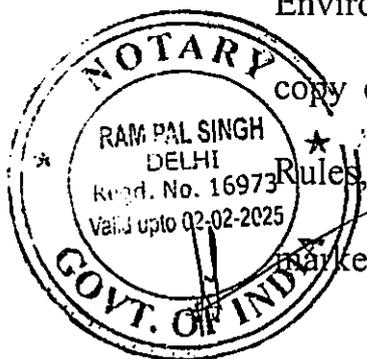
I, Ved Prakash Mishra S/o Shri Ram Sidh Mishra, aged about 49 years working as in the Ministry of Environment, Forest and Climate Change (MoEF&CC), Jor Bagh, New Delhi-110003, do hereby solemnly affirm and declare as under:

1. That I am duly authorized by the Ministry of Environment, Forest and Climate Change (hereby referred as Respondent No. 76) to swear this affidavit and I am conversant with the facts and circumstances of the present case and am thereby competent to depose as under:
2. That the answering Respondent no.76 is engaged in, inter alia, policy formulation for abatement, prevention and control of pollution by prescribing environmental standards which are implemented through the Central Pollution Control Board (CPCB) and State Pollution Control Boards (SPCBs)/ Pollution Control Committees (PCCs).



A handwritten signature in black ink, appearing to read 'Ved Prakash Mishra'.

3. Besides, the State Pollution Control Boards/Pollution Control Committees concerned are mandated and empowered to take all such measures as are deemed necessary or expedient for the purpose of protection and improving the quality of environment as well as prevention, control and abatement of environmental pollution.
4. That the Ministry of Environment, Forest and Climate Change has notified a draft notification in the public domain for seeking suggestions within 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 copy of draft notification GSR 44(E) dated 23.01.2020 is annexed herewith and marked as **ANNEXURE – R-I**.
5. 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 copy of the final standards duly notified under Environment (Protection) Rules, 1986 vide GSR 541(E) dated 06.08.2021 is annexed herewith and marked as **ANNEXURE – R-II**.



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6. That Hon'ble Tribunal vide its order 06.04.2022 passed in O.A. no. 136 of 2020 titled as Veterans Forum for Transparency in Public Life vs. State of Himachal Pradesh & Ors, made an observation that-

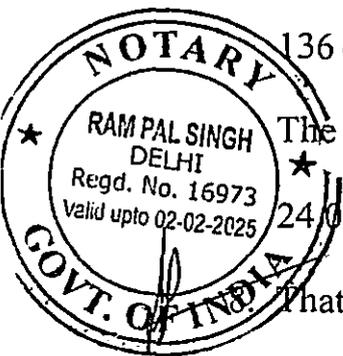
“The MoEF&CC, standards proposed in the draft Notification dated 23.01.2020, which are based on expert studies, be strictly followed by all concerned. It is also necessary to abide by the guidelines of CPCB circulated on 31.1.2022, quoted above in the matter of standards and methodology on the subject. 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.”

A copy of order dated 06.04.2022 is annexed herewith and marked as **ANNEXURE – R-III.**

7. 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 MoEF&CC approached the Hon'ble NGT 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.

The Hon'ble NGT on 23.05.2022 dismissed the same. A copy of order dated 24.05.2022 is annexed herewith and marked as **ANNEXURE – R-IV.**

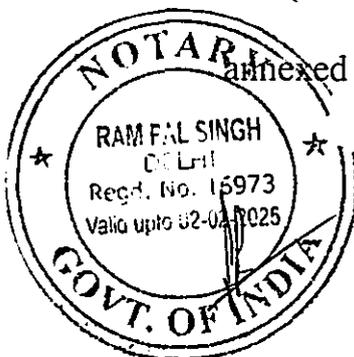
That MoEF&CC had filed an Appeal bearing no. 25732 of 2022 before the Hon'ble Supreme Court against the impugned order dated 06.04.2022 and 23.05.2022 passed by the Hon'ble NGT in O.A no. 136 of 2020. Vide order



[Handwritten Signature]

dated 17.10.2022 the aforesaid orders were stayed by the Hon'ble Supreme Court. A copy of order dated 17.10.2022 is annexed herewith and marked as **ANNEXURE – R-V.**

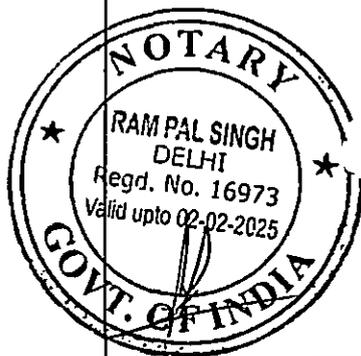
9. That the Ministry of Environment and Forests vide Gazette Notification No. S. O. 630(E) dated 20th July, 1998 notified, the Biomedical Waste (Management and Handling) Rules, 1998. These rules were applicable to all persons who generate, collect, receive, store, transport, treat, dispose, or handle biomedical waste in any form. According to these Rules, every operator of a bio-medical waste facility is required to obtain authorisation in accordance to the procedures specified under the Rules.
10. That the Ministry vide Gazette Notification No. G.S.R 343(E) dated 28th March 2016 has notified the Bio-Medical Waste Management Rules, 2016 in supersession of earlier Rules namely the Bio-Medical Waste (Management & Handling) Rules, 1998 with the objectives to improve segregation, collection, processing, treatment and disposal of bio-medical waste in environmentally sound manner, thereby reducing its impact on the environment. Ministry has issued amendment in the Bio- Medical Waste Management (Amended) Rules, 2018; vide G.S.R. No. 234 (E) dated 16th March 2018. A copy of the Bio-Medical Waste Management Rules, 2016 and (Amended) copy of the Bio-Medical Waste Management Rules 2018 are annexed herewith and marked as **Annexure R-VI & R-VII** respectively.



Singh

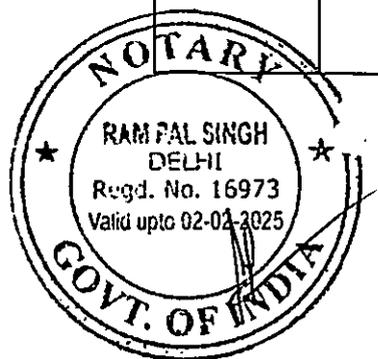
11. That Schedule I of the Bio-Medical Waste Management Rules define three categories of waste that are relevant from perspective of pharmaceutical pollution, a tabular is presented below:

Category as per BMW Rules, 2016	Type of Waste	Type of Bag or Container to be used	Treatment and Disposal options
Yellow	Expired or Discarded Medicines: Pharmaceutical waste like antibiotics, cytotoxic drugs including all items contaminated with cytotoxic drugs along with glass or plastic ampoules, vials etc.	Yellow coloured non-chlorinated plastic bags or containers	Expired cytotoxic drugs and items contaminated with cytotoxic drugs to be returned back to the manufacturer or supplier for incineration at temperature >1200 0C or to common bio-medical waste treatment facility or hazardous waste treatment, storage and disposal facility for incineration at >12000C or Encapsulation or Plasma



[Handwritten signature]

		Pyrolysis at >12000C. All other discarded medicines shall be either sent back to manufacturer or disposed by incineration.
	Chemical Waste: Chemicals used in production of biological and used or discarded disinfectants.	Yellow coloured containers or non-chlorinated plastic bags Disposed of by incineration or Plasma Pyrolysis or Encapsulation in hazardous waste treatment, storage and disposal facility.
	Chemical Liquid Waste : Liquid waste generated due to use of chemicals in production of biological and used or discarded disinfectants, Silver X-ray film developing liquid, discarded Formalin, infected secretions, aspirated body fluids, liquid from laboratories and floor washings, cleaning, house-keeping and disinfecting activities etc.	Separate collection system leading to effluent treatment system After resource recovery, the chemical liquid waste shall be pre-treated before mixing with other wastewater. The combined discharge shall conform to the discharge norms given in Schedule III.



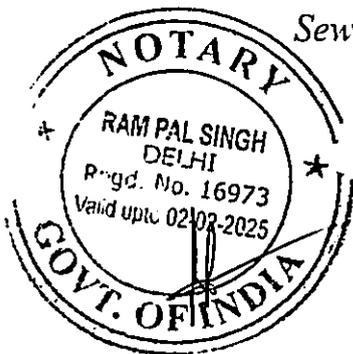
Signature

12. That Schedule II clause 8 of the Bio-Medical Waste Management Rules, 2016 mentions the effluent generated or treated from the HCFs or the CBMWTF should meet the standards for liquid waste before discharge into sewer, which are either connected with sewerage network without terminal sewage treatment plant or not connected to public sewers. The Standards prescribed under BMWM Rules, 2016 as below:

<i>Parameters</i>	<i>Permissible limits</i>
<i>pH</i>	<i>6.5-9.0</i>
<i>Suspended solids</i>	<i>100 mg/l</i>
<i>Oil and grease</i>	<i>10 mg/l</i>
<i>BOD</i>	<i>30 mg/l</i>
<i>COD</i>	<i>250 mg/l</i>
<i>Bio-assay test effluent.</i>	<i>90% survival of fish after 96 hours in 100%</i>

Note:

- i. Above limits are applicable to the occupiers of Health Care Facilities (bedded) which are either connected with sewerage network without terminal sewage treatment plant or not connected to public sewers.*
- ii. For discharge into public sewers with terminal facilities, the general standards as notified under the Environment (Protection) Act, 1986 (29 of 1986) shall be applicable.*
- iii. Health Care Facilities having less than ten beds shall have to install Sewage Treatment Plant by the 31st December, 2019.*



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iv. Non-bedded occupiers shall dispose of infectious liquid wastes only after treatment by disinfection as per Schedule – II (6) of the principal rules.

13. That the SPCBs and the State Health Departments are the nodal agencies to ensure the enforcement and implementation of BMWM Rules 2016 on ground, which include segregation, collection, transportation and scientific disposal of waste.

14. That in view of the foregoing submission, this Hon'ble Tribunal humbly may pleased to pass such order(s) as may deem fit in the circumstances of the case.

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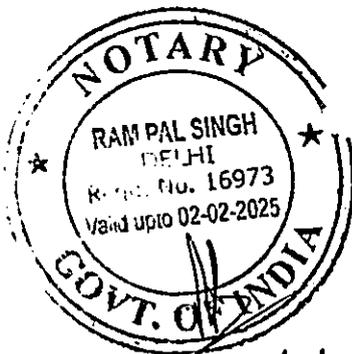
DEPONENT

[Handwritten Signature]
I Verify the Deponent who

VERIFICATON:

14 AUG 2024

Verified at on this day of August, 2024 that the contents of the above affidavit are true and correct to my knowledge and as per official records maintained in the routine course of business. No part of the above affidavit is false and nothing material has been concealed there from.



CERTIFIED THAT THE DEPONENT
Sri/Smt./K...
S/o, W/o
R/o
Id...
Ram Saha Mishra
Upendra Thakur,
5 Ach.

[Handwritten Signature]

DEPONENT

14 AUG 2024

[Handwritten Signature]
Notary Public



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/भाग 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 प्रतिष्ठा, 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-

2

THE GAZETTE OF INDIA : EXTRAORDINARY

[PART II—SEC. 3(i)]

- 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	धोक दवा और निर्माण)फार्मास्युटिकल(क. बहिष्कार मानक	
		ईटीपी का अंतिम बाउंडसेट 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% बहिष्कार में पहले 96 घंटों के बाद मछली की 90% उत्तरजीविता
		II) अवैरिक्त पैरामीटर	
		अमोनिकल नाइट्रोजन	50
		नाइट्रेट नाइट्रोजन	10
		*** बैक्टीरिया	0.05
		*** टॉक्सिन	0.05
		*** ज़ाइलीन	0.06
		***पीथाइलीन 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
सेड	0.1
**** सक्रिय दवा संघटक) एपीआई(0.05
III) साझा बहिष्कार 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 बहिष्कार शोधन संयंत्र) सीईटीपी) के लिए, राज्य बोर्ड साझा बहिष्कार शोधन संयंत्र) सीईटीपी) के डिजाइन और स्थानीय जरूरतों और स्थितियों के अनुसार सामान्य मापदंडों, अमोनियम नाइट्रोजन और डीवी मेटल्स के लिए इनलेट क्वालिटी स्टैंडर्ड्स निर्धारित करेगा।	
टिप्पणी: जेडएसडी= धोक दवा और निर्माण उद्योग में शून्य तत्त्व निस्सारण प्रणाली पर विचार किया जाता है, जब अनिवार्य पैरामीटरों के लिए निर्धारित की गई सीमाओं को पूरा करते हैं। शोधित बहिष्कारों को प्रक्रिया अथवा उपयोगिताओं के प्रयोग में लाया जाएगा। (कूटिंग टॉवरों आदि/बॉयलर) बागवानी / बागवानी में शोधित अवशिष्ट के पुनः उपयोग को धोक दवा और निर्माण उद्योगों में जेडएसडी 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।	
*** वे सीमाएं उन उद्योगों पर लागू होंगी जो बैक्टीरिया, टाल्विन, ज़ाइलीन, मिथाइलीन क्लोराइड, क्लोरोबैक्टीन का उपयोग कर रहे हैं।	
**** एपीआई सीमाएं एंटीबायोटिक दवाओं के अलावा एपीआई बनाने वाली इकाइयों के लिए लागू होंगी।	
घ प्रक्रिया .रिएक्टर बेंटस / टैंक फार्म बेंटस से उत्सर्जन मानक	
पैरामीटर	सांद्रण के लिए सीमित मान (मिलीग्राम/एनएम ³)
क्वोरीन	15
हाइड्रोक्लोरिक एसिड वाष्प	35
अमोनिया	30
बैक्टीरिया	5
टाल्विन	100
ऐसिटोनाईट्राईल	1000
डिक्लोरोमीथेन	200
ज़ाइलीन	100
एसीटोन	2000
ग विलायक का कुल नुकसान, उपयोग किए गए विलायक के 3% से अधिक नहीं होना चाहिए।	
घ. धोक दवा और निर्माण उद्योग में शोधित बहिष्कार में एंटीबायोटिक अवशिष्ट और धोक 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) w/g / l)
i. एमिकासिन	6.40

	ii. एमोबिससिलिन	0.10
	iii. एम्फोटेरिसिन बी	0.01
	iv. एम्पीसिलीन	0.10
	v. एनीड्यूलाफंगिन	0.01
	vi. एविलामाईसिन	3.20
	vii. एजिप्रोमाईसिन	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. सेफाट्रोविसल	0.80
	xv. सेफालोनियम	8.40
	xvi. सेफालोरिडीन	1.60
	xvii. सेफालोथिन	0.80
	xviii. सेफाजोलिन	0.40
	xix. सेफडिनिर	0.10
	xx. सेफेगार्डम	0.20
	xxi. सेफीजाईम	0.02
	xxii. सेफोपेराजोन	0.20
	xxiii. सेफोटेविसम	0.04
	xxiv. सेफोएम्बिसटिन	3.20
	xxv. सेफपिरोम	0.02
	xxvi. सेफपोडोविसन	0.10
	xxvii. सेफडिनोम	0.64
	xxviii. सेफटेरोलिन	0.02
	xxix. सेफटाजिडिम	0.20
	xxx. सेफटीब्यूटेन	0.10
	xxxi. सेफटीग्रोफर	0.02
	xxxii. सेफटोविप्रोल	0.09
	xxxiii. सेफटोलोजेन	0.76
	xxxiv. सेफाट्रियोक्सन	0.01
	xxxv. सेफुरोविसम	0.20
	xxxvi. सेफालेपिसन	0.03
	xxxvii. क्लोरामफेनिकोल	3.20
	xxxviii. गिपटोफ्लोक्सासिन	0.02
	xxxix. क्लेरिप्रोमाईसिन	0.03
	xl. फ्लेब्यूलेनिक एगिड	22.40

	xii. मिलनाफ्लोक्सासिन	0.20
	xiii. निलन्डामाईसिन	0.04
	xiii. फ्लोक्सासिलीन	0.05
	xiv. कोलिस्टिन	0.80
	xiv. डेपटोमाईसिन	0.40
	xvi. डेलमानिड	0.02
	xvii. झोरीपेनेम	0.04
	xviii. डॉक्सिसाइक्लिन	0.80
	xix. एनरामाईसिन	1.92
	i. एनरोफ्लोक्सासिन	0.02
	ii. एस्टापेनेम	0.05
	iii. एरिथ्रोमाईसिन	0.20
	iii. एथामब्युटोल	0.80
	iv. फेरोपेनेम	0.01
	iv. फिडाक्सोमाईसिन	0.01
	vi. फ्लोरफेनिकोल	0.80
	vii. फ्लूकोनेज़ोल	0.10
	viii. फ्लुमेक्विन	0.10
	ix. फॉस्फोमाईसिन	0.80
	ix. फ्यूसीडिक एसिड	0.20
	xi. सेटीफ्लोक्सासिन	0.05
	xii. जेमीफ्लोक्सासिन	0.02
	xiii. जेंटामाईसिन	0.08
	xiv. इनीपेनेम	0.05
	xv. आइसोनियाज़िड	0.05
	xvi. इट्राकोनेज़ोल	0.004
	xvii. फानामाईसिन	0.44
	xviii. लेवोफ्लोक्सासिन	0.10
	ix. लिंकोमाईसिन	0.72
	xx. लाईनज़ोलिड	2.68
	xxi. लोराकार्बेफ	0.80
	xxii. मेसिसिनेम	0.40
	xxiii. मेरोपेनेम	0.02
	xxiv. मेट्रोनिडेज़ोल	0.05
	xxv. माइनोसाइक्लिन	0.40
	xxvi. मॉक्सीफ्लोक्सिन	0.05
	xxvii. म्युरीरोसिन	0.10
	xxviii. नेलीडिक्सिक एसिड	6.40
	xxix. नारासिन	0.20

	lxxx. नियोगाईसिन	0.01
	lxxxi. नेटीलमिसिन	0.20
	lxxxii. निट्रोफ्युरेनटोएन	25.80
	lxxxiii. नॉरफ्लोविसन	0.20
	lxxxiv. ऑफ्लोविसन	0.20
	lxxxv. ऑक्सालिसिन	0.40
	lxxxvi. ऑक्सिटेट्रासाइक्लिन	0.20
	lxxxvii. पेफ्लोविसिन	3.20
	lxxxviii. फेनक्सीमेथिलपेनिसिलिन	0.02
	lxxxix. पिपेरिसिलिन	0.20
	xc. पॉलीमिसिन	0.80
	xci. रेटापाम्युलिन	0.02
	xcii. रिफाम्पिसिन	0.02
	xciii. रॉक्सीप्रोगाईसिन	0.40
	xciv. रोक्नीट्रेजोल	0.40
	xcv. स्पाराफ्लोविसन	0.02
	xcvi. स्पेक्टिनोमाईसिन	12.80
	xcvii. स्त्रिरामाईसिन	0.20
	xcviii. स्ट्रेप्टोमाईसिन	6.40
	xcix. सल्वेपटम	6.40
	c. सल्फाडियाजिन	288.00
	ci. सल्फाडिमिथियोजिन	20.00
	cii. सल्फाहॉविसन	0.24
	ciii. सल्फामेथोक्साजोल	0.24
	civ. टेजोवेक्टम	17.60
	cv. टेटीजोलिड	3.92
	cvi. टेईकोप्लानिन	0.20
	cvi. टेलीप्रोगाईसिन	0.02
	cviii. टेट्रासाइक्लिन	0.40
	cix. थियाफेनीकोल	0.40
	cx. टियाम्युलिन	0.40
	cx. टिकामिसिन	3.20
	cxii. टिगोसाइक्लिन	0.40
	cxlii. टिल्डीपीरोसिन	0.17
	cxiv. टिल्मीकोसिन	0.40
	cxv. टोव्रामाईसिन	0.40
	cxvi. ट्रिगोयोप्रिम	0.20
	cxvii. ट्रोवाफ्लोक्सासिन	0.01
	cxviii. टाइनोसिन	0.33

[भाग II-खण्ड 3(i)]

भारत का राजपत्र : असाधारण

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		cxix. बेकोमाईसिन	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]

जिगमेत टक्का, 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. msceb.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. Cefstaroline	0.02
xxix. Ceflazidime	0.20
xxx. Cefibuten	0.10
xxxi. Cefiofur	0.02
xxxii. Ceflobiprole	0.09
xxxiii. Cefzolozane	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
xlv. Daptomycin	0.40
xlvi. Delamanid	0.02
xlvii. Doripenem	0.04
xlviii. 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.	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.	Lomecarbef	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.i.	Retapamulin	0.02
xc.ii.	Rifampicin	0.02
xc.iii.	Roxithromycin	0.40
xc.iv.	Secnidazole	0.40
xc.v.	Sparfloxacin	0.02
xc.vi.	Spectinomycin	12.80
xc.vii.	Spiramycin	0.20
xc.viii.	Streptomycin	6.40
xc.ix.	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

[भाग II-खण्ड 3(i)]

भारत का राजपत्र : असाधारण

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	cviii.	Tetracycline	0.40
	cix.	Thiamphenicol	0.40
	cx.	Tiamulin	0.40
	cxii.	Ticarcillin	3.20
	cxiii.	Tigecycline	0.40
	cxiiii.	Tildipirosin	0.17
	cxv.	Tilmicosin	0.40
	cxvi.	Tobramycin	0.40
	cxvii.	Trimethoprim	0.20
	cxviii.	Trovaflloxacin	0.01
	cxix.	Tylosin	0.33
	cx.	Vancomycin	3.20
	cx.	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, Jr. 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

सं. 442]
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, माठ दिन की अवधि के भीतर आक्षेप और मुद्दाव 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 मुद्दावों 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-1 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
		टीएमएम	100
		नेल और ग्रीस	10
		अमोनिकल नाइट्रोजन	100
		जैव - परख परीक्षण**	100% में पहले 96 घंटों के बाद 90% मछली की उत्पत्ति
		(ii) अतिरिक्त पैरामीटर###	
		***वेन्जीन	0.1
		***जाइलीन	0.12
		***मीथाइलीन क्लोराइड	0.9
		***क्लोरोवेन्जीन	0.2
पी . के रूप में फॉस्फेट	5		
एम . 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		
एसाधार	26 से कम (भूमि पर केवल वाहन के लिए लागू)		
(iii) सीईटीपी के साथ उद्योग			
<ul style="list-style-type: none"> सीईटीपी के साथ और सीईटीपी के लिए उद्योग हेतु निर्वहन किए गए मानक पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय की अधिमूचना का.आ. 4(अ), तारीख 1 जनवरी, 2016 द्वारा शामिल होंगे। 			

	<ul style="list-style-type: none"> 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। <p>टिप्पण :- पैरा क में मानक सीईटीपी के मिवाय सभी निर्वहन के लिए लागू हैं</p> <p>*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।</p> <p>** जैव परख परीक्षण आई एस. 6582-1971 के अनुसार आयोजित किया जाएगा।</p> <p>“अतिरिक्त पैरा मीटर”के रूप में सूचिवद्ध पैरामीटर प्रक्रिया और उत्पाद पर निर्भर रहते हुए एसपीसीवी द्वारा विहित किए जाएंगे और एसपीसीवी एस द्वारा निर्णय के अनुसार उसकी तत्परता से मानीटरी सामिक/तिमाही रूप से की जाएगी।</p> <p>***ये सीमाएं उन उद्योगों पर लागू होंगी जो वेन्जीन, जाइलीन मिथाइलीन क्लोराइड, क्लोरोवेन्जीन का उपयोग कर रहे हैं।</p>																				
	<p>ख. उत्सर्जन मानक (टैंक फार्म वेंट)</p> <table border="1" data-bbox="555 969 1426 1529"> <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 एमिड वाष्प</td> <td>35</td> </tr> <tr> <td>अमोनिया</td> <td>30</td> </tr> <tr> <td>वेन्जीन</td> <td>5</td> </tr> <tr> <td>टोल्यूनि</td> <td>100</td> </tr> <tr> <td>एमीटोनिट्राइल</td> <td>1000</td> </tr> <tr> <td>डाइक्लोरोमेथेन</td> <td>200</td> </tr> <tr> <td>जाइलीन</td> <td>100</td> </tr> <tr> <td>एमीटोन</td> <td>2000</td> </tr> </tbody> </table> <p>ग. विलायक का कुल मंचयी नुकसान भंडारण सूची से वार्षिक आधार पर विलायक 5% से अधिक नहीं होना चाहिए</p>	पैरामीटर	एकाग्रता के लिए सीमित मूल्य (मिलीग्राम / एनएम 3)	क्लोरीन	15	हाइड्रोक्लोरिक एमिड वाष्प	35	अमोनिया	30	वेन्जीन	5	टोल्यूनि	100	एमीटोनिट्राइल	1000	डाइक्लोरोमेथेन	200	जाइलीन	100	एमीटोन	2000
पैरामीटर	एकाग्रता के लिए सीमित मूल्य (मिलीग्राम / एनएम 3)																				
क्लोरीन	15																				
हाइड्रोक्लोरिक एमिड वाष्प	35																				
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वेन्जीन	5																				
टोल्यूनि	100																				
एमीटोनिट्राइल	1000																				
डाइक्लोरोमेथेन	200																				
जाइलीन	100																				
एमीटोन	2000																				
	<p>घ. थोक दवा के विनिर्माण या फार्मास्युटिकल के प्रतिपादन में लगे उद्योग के लिए उद्योग या सीईटीपी कैटरिंग पर वेकार जल या उसके प्रबंध सुविधा से उत्पन्न होने वाले केमिकल और वायोलोजिकल गाढ़ा कीचड़ या किमी अवशेष, हटाए जाने, खतरनाक और अन्य अपशिष्ट (मैनेजमेंट एंड ट्रांस-वाउंडरी 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।</p>																				

[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 अधिमूचना संख्यांक मा.का.नि. 243(अ) तारीख 31 मार्च, 2021 द्वारा अंतिम रूप में 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	
<ul style="list-style-type: none"> 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.

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

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 (TSS), 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.	Zydu 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 (Sl. 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 HPPCB 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:

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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/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

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, 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.

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

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.
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), Cefprozil (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 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. 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

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

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					

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
xlv.	Daptomycin	0.40
xlvi.	Delamanid	0.02
xlvii.	Doripenem	0.04
xlviii.	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.	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.	Narasín	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.	Polymyxin	0.80

xcviii.	Streptomycin	6.40
xcix.	Sulbactam	6.40
c.	Sulfadiazine	288.00
ci.	Sulfadimethoxine	20.00
cii.	Sulfadoxine	0.24
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
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".

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

"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
		***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	
		<ul style="list-style-type: none"> 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

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.*

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)
	<i>Amoxicillin</i>	0.08
	<i>Cefixime</i>	0.13
	<i>Cefadroxile</i>	0.12
(4)	<i>Fluconazole</i>	0.14
(5)	<i>Levofloxacin</i>	0.16
(6)	<i>Ciprofloxacin</i>	0.15
(7)	<i>Metronidazole</i>	0.12
(8)	<i>Azithromycin</i>	0.03
(9)	<i>Doxycycline</i>	0.03
(10)	<i>Chloramphenicol</i>	0.09

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

- (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-1 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:

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

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	<ul style="list-style-type: none"> • ≈ 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*

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.*

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.

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.

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.

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

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

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

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

“1to14....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.

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

ITEM NO.9

COURT NO.7

SECTION XVII

S U P R E M E C O U R T O F I N D I A
R E C O R D O F P R O C E E D I N G S

CIVIL APPEAL Diary No(s). 25732/2022

(Arising out of impugned final judgment and order dated 06-04-2022 in OA No. 136/2020 & 24-05-2022 in RA No. 14/2022 passed by the National Green Tribunal)

UNION OF INDIA

Petitioner(s)

VERSUS

VETERANS FORUM FOR TRANSPARENCY
IN PUBLIC LIFE & ORS.

Respondent(s)

(IA No.143971/2022-CONDONATION OF DELAY IN FILING and IA No.143972/2022-EXEMPTION FROM FILING C/C OF THE IMPUGNED JUDGMENT)

Date : 17-10-2022 This appeal was called on for hearing today.

CORAM : HON'BLE MR. JUSTICE AJAY RASTOGI
HON'BLE MR. JUSTICE C.T. RAVIKUMARFor Petitioner(s) Ms. Aishwarya Bhati, ASG
Ms. Chitrangda Pashtrawara, Adv.
Mr. Balendu Shekhar, Adv.
Ms. Shagun Thakur, Adv.
Mr. Gurmeet Singh Makker, AOR

For Respondent(s)

UPON hearing the counsel the Court made the following
O R D E R

Delay condoned.

Learned counsel for the appellant submits that after the draft Notification dated 23.01.2022 came in the public domain there was a lot of discussion and the Expert Committee also recommended certain parameters as it is evident from the report dated 09.12.2020 but so far as the Active Pharmaceutical Ingredients (API) and antibiotics residue(AMR) are concerned, the Committee was of the opinion that

looking to the complexity and non-availability of any universally accepted standardized method to test API/AMR, it was proposed to remove the proposed norms of API/AMR from the additional parameter and after active consideration consciously it was not incorporated when the final Notification came to be notified on 06.08.2021.

In the given facts and circumstances, the direction of the Tribunal to continue with the draft Notification so far as API/AMR is concerned, needs to be interfered by this Court.

Delay condoned.

Appeal admitted. Issue notice.

In the meanwhile, there shall be stay of operation of the impugned orders dated 06.04.2022 & 24.05.2022. passed by the National Green Tribunal.

(MONIKA DEY)
COURT MASTER (NSH)

(ASHWANI KUMAR)
ASTT. REGISTRAR-cum-PS

II (I)

प्ररूप 5
(नियम 16 देखें)

विहित प्राधिकारी द्वारा जारी आदेश के विरुद्ध अपील दायर करने के लिए आवेदन

1. अपील हेतु आवेदन करने वाले व्यक्ति का नाम और पता :
2. आदेश की संख्या, तारीख और आदेश पारित करने वाले प्राधिकारी का पता जिसके विरुद्ध अपील की जा रही है (आदेश की प्रमाणित प्रति संलग्न करें)
3. अपील किए जाने का आधार
4. पैरा 2 में निर्दिष्ट ऐसे आदेश से मिन, जिसके विरुद्ध अपील की गई है, संलग्नकों की सूची।

तारीख

हस्ताक्षर

नाम और पता

[फा. सं.3-1/2000-एचएसएमडी]

विश्वनाथ मिन्हा, संयुक्त सचिव

MINISTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE

NOTIFICATION

New Delhi, the 28th March, 2016

G.S.R. 343(E).—Whereas the Bio-Medical Waste (Management and Handling) Rules, 1998 was published *vide* notification number S.O. 630 (E) dated the 20th July, 1998, by the Government of India in the erstwhile Ministry of Environment and Forests, provided a regulatory frame work for management of bio-medical waste generated in the country;

And whereas, to implement these rules more effectively and to improve the collection, segregation, processing, treatment and disposal of these bio-medical wastes in an environmentally sound management thereby, reducing the bio-medical waste generation and its impact on the environment, the Central Government reviewed the existing rules;

And whereas, in exercise of the powers conferred by sections 6, 8 and 25 of the Environment (Protection) Act, 1986 (29 of 1986), the Central Government published the draft rules in the Gazette *vide* number G.S.R. 450 (E), dated the 3rd June, 2015 inviting objections or suggestions from the public within sixty days from the date on which copies of the Gazette containing the said notification were made available to the public;

And whereas, the copies of the Gazette containing the said draft rules were made available to the public on the 3rd June, 2015;

And whereas, the objections or comments received within the specified period from the public in respect of the said draft rules have been duly considered by the Central Government;

Now, therefore, in exercise of the powers conferred by section 6, 8 and 25 of the Environment (Protection) Act, 1986 (29 of 1986), and in supersession of the Bio-Medical Waste (Management and Handling) Rules, 1998, except as respects things done or omitted to be done before such suppression, the Central Government hereby makes the following rules, namely:-

1. **Short title and commencement.**- (1) these rules may be called the Bio-Medical Waste Management Rules, 2016.

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

2. **Application.**-

(1) These rules shall apply to all persons who generate, collect, receive, store, transport, treat, dispose, or handle bio medical waste in any form including hospitals, nursing homes, clinics, dispensaries, veterinary institutions, animal houses, pathological laboratories, blood banks, ayush hospitals, clinical establishments, research or educational institutions, health camps, medical or surgical camps, vaccination camps, blood donation camps, first aid rooms of schools, forensic laboratories and research labs.

(2) These rules shall not apply to.-

(a) radioactive wastes as covered under the provisions of the Atomic Energy Act, 1962(33 of 1962) and the rules made there under;

(b) hazardous chemicals covered under the Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989 made under the Act;

- (c) solid wastes covered under the Municipal Solid Waste (Management and Handling) Rules, 2000 made under the Act;
- (d) the lead acid batteries covered under the Batteries (Management and Handling) Rules, 2001 made under the Act;
- (e) hazardous wastes covered under the Hazardous Wastes (Management, Handling and Transboundary Movement) Rules, 2008 made under the Act;
- (f) waste covered under the e-Waste (Management and Handling) Rules, 2011 made under the Act; and
- (g) hazardous micro organisms, genetically engineered micro organisms and cells covered under the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms, Genetically Engineered Micro organisms or Cells Rules, 1989 made under the Act.
- 3. Definitions.-** In these rules, unless the context otherwise requires, -
- (a) "Act" means the Environment (Protection) Act, 1986 (29 of 1986);
- (b) "animal house" means a place where animals are reared or kept for the purpose of experiments or testing;
- (c) "authorisation" means permission granted by the prescribed authority for the generation, collection, reception, storage, transportation, treatment, processing, disposal or any other form of handling of bio-medical waste in accordance with these rules and guidelines issued by the Central Government or Central Pollution Control Board as the case may be;
- (d) "authorised person" means an occupier or operator authorised by the prescribed authority to generate, collect, receive, store, transport, treat, process, dispose or handle bio-medical waste in accordance with these rules and the guidelines issued by the Central Government or the Central Pollution Control Board, as the case may be;
- (e) "biological" means any preparation made from organisms or micro-organisms or product of metabolism and biochemical reactions intended for use in the diagnosis, immunisation or the treatment of human beings or animals or in research activities pertaining thereto;
- (f) "bio-medical waste" means any waste, which is generated during the diagnosis, treatment or immunisation of human beings or animals or research activities pertaining thereto or in the production or testing of biological or in health camps, including the categories mentioned in Schedule I appended to these rules;
- (g) "bio-medical waste treatment and disposal facility" means any facility wherein treatment, disposal of bio-medical waste or processes incidental to such treatment and disposal is carried out, and includes common bio-medical waste treatment facilities;
- (h) "Form" means the Form appended to these rules;
- (i) "handling" in relation to bio-medical waste includes the generation, sorting, segregation, collection, use, storage, packaging, loading, transportation, unloading, processing, treatment, destruction, conversion, or offering for sale, transfer, disposal of such waste;
- (j) "health care facility" means a place where diagnosis, treatment or immunisation of human beings or animals is provided irrespective of type and size of health treatment system, and research activity pertaining thereto;
- (k) "major accident" means accident occurring while handling of bio-medical waste having potential to affect large masses of public and includes toppling of the truck carrying bio-medical waste, accidental release of bio-medical waste in any water body but exclude accidents like needle prick injuries, mercury spills;
- (l) "management" includes all steps required to ensure that bio- medical waste is managed in such a manner as to protect health and environment against any adverse effects due to handling of such waste;
- (m) "occupier" means a person having administrative control over the institution and the premises generating bio-medical waste, which includes a hospital, nursing home, clinic, dispensary, veterinary institution, animal house, pathological laboratory, blood bank, health care facility and clinical establishment, irrespective of their system of medicine and by whatever name they are called;
- (n) "operator of a common bio-medical waste treatment facility" means a person who owns or controls a Common Bio-medical Waste Treatment Facility (CBMWTF) for the collection, reception, storage, transport, treatment, disposal or any other form of handling of bio-medical waste;
- (o) "prescribed authority" means the State Pollution Control Board in respect of a State and Pollution Control Committees in respect of an Union territory;
- (p) "Schedule" means the Schedule appended to these rules.

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- 4. Duties of the Occupier.-** It shall be the duty of every occupier to-
- (a) take all necessary steps to ensure that bio-medical waste is handled without any adverse effect to human health and the environment and in accordance with these rules;
 - (b) make a provision within the premises for a safe, ventilated and secured location for storage of segregated biomedical waste in colored bags or containers in the manner as specified in Schedule I, to ensure that there shall be no secondary handling, pilferage of recyclables or inadvertent scattering or spillage by animals and the bio-medical waste from such place or premises shall be directly transported in the manner as prescribed in these rules to the common bio-medical waste treatment facility or for the appropriate treatment and disposal, as the case may be, in the manner as prescribed in Schedule I;
 - (c) pre-treat the laboratory waste, microbiological waste, blood samples and blood bags through disinfection or sterilisation on-site in the manner as prescribed by the World Health Organisation (WHO) or National AIDS Control Organisation (NACO) guidelines and then sent to the common bio-medical waste treatment facility for final disposal;
 - (d) phase out use of chlorinated plastic bags, gloves and blood bags within two years from the date of notification of these rules;
 - (e) dispose of solid waste other than bio-medical waste in accordance with the provisions of respective waste management rules made under the relevant laws and amended from time to time;
 - (f) not to give treated bio-medical waste with municipal solid waste;
 - (g) provide training to all its health care workers and others, involved in handling of bio medical waste at the time of induction and thereafter at least once every year and the details of training programmes conducted, number of personnel trained and number of personnel not undergone any training shall be provided in the Annual Report;
 - (h) immunise all its health care workers and others, involved in handling of bio-medical waste for protection against diseases including Hepatitis B and Tetanus that are likely to be transmitted by handling of bio-medical waste, in the manner as prescribed in the National Immunisation Policy or the guidelines of the Ministry of Health and Family Welfare issued from time to time;
 - (i) establish a Bar- Code System for bags or containers containing bio-medical waste to be sent out of the premises or place for any purpose within one year from the date of the notification of these rules;
 - (j) ensure segregation of liquid chemical waste at source and ensure pre-treatment or neutralisation prior to mixing with other effluent generated from health care facilities;
 - (k) ensure treatment and disposal of liquid waste in accordance with the Water (Prevention and Control of Pollution) Act, 1974 (6 of 1974);
 - (l) ensure occupational safety of all its health care workers and others involved in handling of bio-medical waste by providing appropriate and adequate personal protective equipments;
 - (m) conduct health check up at the time of induction and at least once in a year for all its health care workers and others involved in handling of bio- medical waste and maintain the records for the same;
 - (n) maintain and update on day to day basis the bio-medical waste management register and display the monthly record on its website according to the bio-medical waste generated in terms of category and colour coding as specified in Schedule I;
 - (o) report major accidents including accidents caused by fire hazards, blasts during handling of bio-medical waste and the remedial action taken and the records relevant thereto, (including nil report) in Form I to the prescribed authority and also along with the annual report;
 - (p) make available the annual report on its web-site and all the health care facilities shall make own website within two years from the date of notification of these rules;
 - (q) inform the prescribed authority immediately in case the operator of a facility does not collect the bio-medical waste within the intended time or as per the agreed time;
 - (r) establish a system to review and monitor the activities related to bio-medical waste management, either through an existing committee or by forming a new committee and the Committee shall meet once in every six months and the record of the minutes of the meetings of this committee shall be submitted along with the annual report to the prescribed authority and the healthcare establishments having less than thirty beds shall

designate a qualified person to review and monitor the activities relating to bio-medical waste management within that establishment and submit the annual report;

- (s) maintain all record for operation of incineration, hydro or autoclaving etc., for a period of five years;
- (t) existing incinerators to achieve the standards for treatment and disposal of bio-medical waste as specified in Schedule II for retention time in secondary chamber and Dioxin and Furans within two years from the date of this notification.

5. Duties of the operator of a common bio-medical waste treatment and disposal facility.-It shall be the duty of every operator to -

- (a) take all necessary steps to ensure that the bio-medical waste collected from the occupier is transported, handled, stored, treated and disposed of, without any adverse effect to the human health and the environment, in accordance with these rules and guidelines issued by the Central Government or, as the case may be, the central pollution control board from time to time;
- (b) ensure timely collection of bio-medical waste from the occupier as prescribed under these rules;
- (c) establish bar coding and global positioning system for handling of bio- medical waste within one year;
- (d) inform the prescribed authority immediately regarding the occupiers which are not handing over the segregated bio-medical waste in accordance with these rules;
- (e) provide training for all its workers involved in handling of bio-medical waste at the time of induction and at least once a year thereafter;
- (f) assist the occupier in training conducted by them for bio-medical waste management;
- (g) undertake appropriate medical examination at the time of induction and at least once in a year and immunise all its workers involved in handling of bio-medical waste for protection against diseases, including Hepatitis B and Tetanus, that are likely to be transmitted while handling bio-medical waste and maintain the records for the same;
- (h) ensure occupational safety of all its workers involved in handling of bio-medical waste by providing appropriate and adequate personal protective equipment;
- (i) report major accidents including accidents caused by fire hazards, blasts during handling of bio-medical waste and the remedial action taken and the records relevant thereto, (including nil report) in Form I to the prescribed authority and also along with the annual report;
- (j) maintain a log book for each of its treatment equipment according to weight of batch; categories of waste treated; time, date and duration of treatment cycle and total hours of operation;
- (k) allow occupier, who are giving waste for treatment to the operator, to see whether the treatment is carried out as per the rules;
- (l) shall display details of authorisation, treatment, annual report etc on its web-site;
- (m) after ensuring treatment by autoclaving or microwaving followed by mutilation or shredding, whichever is applicable, the recyclables from the treated bio-medical wastes such as plastics and glass, shall be given to recyclers having valid consent or authorisation or registration from the respective State Pollution Control Board or Pollution Control Committee;
- (n) supply non-chlorinated plastic coloured bags to the occupier on chargeable basis, if required;
- (o) common bio-medical waste treatment facility shall ensure collection of biomedical waste on holidays also;
- (p) maintain all record for operation of incineration, hydro or autoclaving for a period of five years; and
- (q) upgrade existing incinerators to achieve the standards for retention time in secondary chamber and Dioxin and Furans within two years from the date of this notification.

6. Duties of authorities.-The Authority specified in column (2) of Schedule-III shall perform the duties as specified in column (3) thereof in accordance with the provisions of these rules.

7. Treatment and disposal.- (1) Bio-medical waste shall be treated and disposed of in accordance with Schedule I, and in compliance with the standards provided in Schedule-II by the health care facilities and common bio-medical waste treatment facility.

(2) Occupier shall hand over segregated waste as per the Schedule-I to common bio-medical waste treatment facility for treatment, processing and final disposal:

Provided that the lab and highly infectious bio-medical waste generated shall be pre-treated by equipment like autoclave or microwave.

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- (3) No occupier shall establish on-site treatment and disposal facility, if a service of common bio-medical waste treatment facility is available at a distance of seventy-five kilometer.
- (4) In cases where service of the common bio-medical waste treatment facility is not available, the Occupiers shall set up requisite biomedical waste treatment equipment like incinerator, autoclave or microwave, shredder prior to commencement of its operation, as per the authorisation given by the prescribed authority.
- (5) Any person including an occupier or operator of a common bio medical waste treatment facility, intending to use new technologies for treatment of bio medical waste other than those listed in Schedule I shall request the Central Government for laying down the standards or operating parameters.
- (6) On receipt of a request referred to in sub-rule (5), the Central Government may determine the standards and operating parameters for new technology which may be published in Gazette by the Central Government.
- (7) Every operator of common bio-medical waste treatment facility shall set up requisite biomedical waste treatment equipments like incinerator, autoclave or microwave, shredder and effluent treatment plant as a part of treatment, prior to commencement of its operation.
- (8) Every occupier shall phase out use of non-chlorinated plastic bags within two years from the date of publication of these rules and after two years from such publication of these rules, the chlorinated plastic bags shall not be used for storing and transporting of bio-medical waste and the occupier or operator of a common bio-medical waste treatment facility shall not dispose of such plastics by incineration and the bags used for storing and transporting biomedical waste shall be in compliance with the Bureau of Indian Standards. Till the Standards are published, the carry bags shall be as per the Plastic Waste Management Rules, 2011.
- (9) After ensuring treatment by autoclaving or microwaving followed by mutilation or shredding, whichever is applicable, the recyclables from the treated bio-medical wastes such as plastics and glass shall be given to such recyclers having valid authorisation or registration from the respective prescribed authority.
- (10) The Occupier or Operator of a common bio-medical waste treatment facility shall maintain a record of recyclable wastes referred to in sub-rule (9) which are auctioned or sold and the same shall be submitted to the prescribed authority as part of its annual report. The record shall be open for inspection by the prescribed authorities.
- (11) The handling and disposal of all the mercury waste and lead waste shall be in accordance with the respective rules and regulations.
8. Segregation, packaging, transportation and storage.-(1) No untreated bio-medical waste shall be mixed with other wastes.
- (2) The bio-medical waste shall be segregated into containers or bags at the point of generation in accordance with Schedule I prior to its storage, transportation, treatment and disposal.
- (3) The containers or bags referred to in sub-rule (2) shall be labeled as specified in Schedule IV.
- (4) Bar code and global positioning system shall be added by the Occupier and common bio-medical waste treatment facility in one year time.
- (5) The operator of common bio-medical waste treatment facility shall transport the bio-medical waste from the premises of an occupier to any off-site bio-medical waste treatment facility only in the vehicles having label as provided in part 'A' of the Schedule IV along with necessary information as specified in part 'B' of the Schedule IV.
- (6) The vehicles used for transportation of bio-medical waste shall comply with the conditions if any stipulated by the State Pollution Control Board or Pollution Control Committee in addition to the requirement contained in the Motor Vehicles Act, 1988 (59 of 1988), if any or the rules made there under for transportation of such infectious waste.
- (7) Untreated human anatomical waste, animal anatomical waste, soiled waste and, biotechnology waste shall not be stored beyond a period of forty –eight hours:

Provided that in case for any reason it becomes necessary to store such waste beyond such a period, the occupier shall take appropriate measures to ensure that the waste does not adversely affect human health and the environment and inform the prescribed authority along with the reasons for doing so.

- (8) Microbiology waste and all other clinical laboratory waste shall be pre-treated by sterilisation to Log 6 or disinfection to Log 4, as per the World Health Organisation guidelines before packing and sending to the common bio-medical waste treatment facility.
9. **Prescribed authority.**-(1) The prescribed authority for implementation of the provisions of these rules shall be the State Pollution Control Boards in respect of States and Pollution Control Committees in respect of Union territories.
- (2) The prescribed authority for enforcement of the provisions of these rules in respect of all health care establishments including hospitals, nursing homes, clinics, dispensaries, veterinary institutions, animal houses, pathological laboratories and blood banks of the Armed Forces under the Ministry of Defence shall be the Director General, Armed Forces Medical Services, who shall function under the supervision and control of the Ministry of Defence.
- (3) The prescribed authorities shall comply with the responsibilities as stipulated in Schedule III of these rules.
10. **Procedure for authorisation.**-Every occupier or operator handling bio-medical waste, irrespective of the quantity shall make an application in Form II to the prescribed authority i.e. State Pollution Control Board and Pollution Control Committee, as the case may be, for grant of authorisation and the prescribed authority shall grant the provisional authorisation in Form III and the validity of such authorisation for bedded health care facility and operator of a common facility shall be synchronised with the validity of the consents.
- (1) The authorisation shall be one time for non-bedded occupiers and the authorisation in such cases shall be deemed to have been granted, if not objected by the prescribed authority within a period of ninety days from the date of receipt of duly completed application along with such necessary documents.
- (2) In case of refusal of renewal, cancellation or suspension of the authorisation by the prescribed authority, the reasons shall be recorded in writing:
- Provided that the prescribed authority shall give an opportunity of being heard to the applicant before such refusal of the authorisation.
- (3) Every application for authorisation shall be disposed of by the prescribed authority within a period of ninety days from the date of receipt of duly completed application along with such necessary documents, failing which it shall be deemed that the authorisation is granted under these rules.
- (4) In case of any change in the bio-medical waste generation, handling, treatment and disposal for which authorisation was earlier granted, the occupier or operator shall intimate to the prescribed authority about the change or variation in the activity and shall submit a fresh application in Form II for modification of the conditions of authorisation.
11. **Advisory Committee.**-(1) Every State Government or Union territory Administration shall constitute an Advisory Committee for the respective State or Union territory under the chairmanship of the respective health secretary to oversee the implementation of the rules in the respective state and to advice any improvements and the Advisory Committee shall include representatives from the Departments of Health, Environment, Urban Development, Animal Husbandry and Veterinary Sciences of that State Government or Union territory Administration, State Pollution Control Board or Pollution Control Committee, urban local bodies or local bodies or Municipal Corporation, representatives from Indian Medical Association, common bio-medical waste treatment facility and non-governmental organisation.
- (2) Notwithstanding anything contained in sub-rule (1), the Ministry of Defence shall constitute the Advisory Committee (Defence) under the chairmanship of Director General of Health Services of Armed Forces consisting of representatives from the Ministry of Defence, Ministry of Environment, Forest and Climate Change, Central Pollution Control Board, Ministry of Health and Family Welfare, Armed Forces Medical College or Command Hospital.
- (3) The Advisory Committee constituted under sub-rule (1) and (2) shall meet at least once in six months and review all matters related to implementation of the provisions of these rules in the State and Armed Forces Health Care Facilities, as the case may be.
- (4) The Ministry of Health and Defence may co-opt representatives from the other Governmental and non-governmental organisations having expertise in the field of bio-medical waste management.
12. **Monitoring of implementation of the rules in health care facilities.**- (1) The Ministry of Environment, Forest and Climate Change shall review the implementation of the rules in the country once in a year through the State Health Secretaries and Chairmen or Member Secretary of State Pollution Control Boards and Central Pollution Control Board and the Ministry may also invite experts in the field of bio-medical waste management, if required.
- (2) The Central Pollution Control Board shall monitor the implementation of these rules in respect of all the Armed Forces health care establishments under the Ministry of Defence.

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- (3) The Central Pollution Control Board along with one or more representatives of the Advisory Committee constituted under sub-rule (2) of rule 11, may inspect any Armed Forces health care establishments after prior intimation to the Director General Armed Forces Medical Services.
 - (4) Every State Government or Union territory Administration shall constitute District Level Monitoring Committee in the districts under the chairmanship of District Collector or District Magistrate or Deputy Commissioner or Additional District Magistrate to monitor the compliance of the provisions of these rules in the health care facilities generating bio-medical waste and in the common bio-medical waste treatment and disposal facilities, where the bio-medical waste is treated and disposed of.
 - (5) The District Level Monitoring Committee constituted under sub-rule (4) shall submit its report once in six months to the State Advisory Committee and a copy thereof shall also be forwarded to State Pollution Control Board or Pollution Control Committee concerned for taking further necessary action.
 - (6) The District Level Monitoring Committee shall comprise of District Medical Officer or District Health Officer, representatives from State Pollution Control Board or Pollution Control Committee, Public Health Engineering Department, local bodies or municipal corporation, Indian Medical Association, common bio-medical waste treatment facility and registered non-governmental organisations working in the field of bio-medical waste management and the Committee may co-opt other members and experts, if necessary and the District Medical Officer shall be the Member Secretary of this Committee.
13. **Annual report.**-(1) Every occupier or operator of common bio-medical waste treatment facility shall submit an annual report to the prescribed authority in Form-IV, on or before the 30th June of every year.
 - (2) The prescribed authority shall compile, review and analyse the information received and send this information to the Central Pollution Control Board on or before the 31st July of every year.
 - (3) The Central Pollution Control Board shall compile, review and analyse the information received and send this information, along with its comments or suggestions or observations to the Ministry of Environment, Forest and Climate Change on or before 31st August every year.
 - (4) The Annual Reports shall also be available online on the websites of Occupiers, State Pollution Control Boards and Central Pollution Control Board.
 14. **Maintenance of records.**-(1) Every authorised person shall maintain records related to the generation, collection, reception, storage, transportation, treatment, disposal or any other form of handling of bio-medical waste, for a period of five years, in accordance with these rules and guidelines issued by the Central Government or the Central Pollution Control Board or the prescribed authority as the case may be.
 - (2) All records shall be subject to inspection and verification by the prescribed authority or the Ministry of Environment, Forest and Climate Change at any time.
 15. **Accident reporting.**-(1) In case of any major accident at any institution or facility or any other site while handling bio-medical waste, the authorised person shall intimate immediately to the prescribed authority about such accident and forward a report within twenty-four hours in writing regarding the remedial steps taken in Form I.
 - (2) Information regarding all other accidents and remedial steps taken shall be provided in the annual report in accordance with rule 13 by the occupier.
 16. **Appeal.**-(1) Any person aggrieved by an order made by the prescribed authority under these rules may, within a period of thirty days from the date on which the order is communicated to him, prefer an appeal in Form V to the Secretary (Environment) of the State Government or Union territory administration .
 - (2) Any person aggrieved by an order of the Director General Armed Forces Medical Services under these rules may, within thirty days from the date on which the order is communicated to him, prefer an appeal in Form V to the Secretary, Ministry of Environment, Forest and Climate Change.
 - (3) The authority referred to in sub-para (1) and (2) as the case may be, may entertain the appeal after the expiry of the said period of thirty days, if it is satisfied that the appellant was prevented by sufficient cause from filing the appeal in time.
 - (4) The appeal shall be disposed of within a period of ninety days from the date of its filing.
 17. **Site for common bio-medical waste treatment and disposal facility.**-(1) Without prejudice to rule 5 of these rules, the department in the business allocation of land assignment shall be responsible for providing suitable site for setting up of common biomedical waste treatment and disposal facility in the State Government or Union territory Administration.

(2) The selection of site for setting up of such facility shall be made in consultation with the prescribed authority, other stakeholders and in accordance with guidelines published by the Ministry of Environment, Forest and Climate Change or Central Pollution Control Board.

18. Liability of the occupier, operator of a facility.- (1) The occupier or an operator of a common bio-medical waste treatment facility shall be liable for all the damages caused to the environment or the public due to improper handling of bio- medical wastes.

(2) The occupier or operator of common bio-medical waste treatment facility shall be liable for action under section 5 and section 15 of the Act, in case of any violation.

SCHEDULE I

[See rules 3 (c), 4(b), 7(1), 7(2), 7(5), 7 (6) and 8(2)]

Part-1

Biomedical wastes categories and their segregation, collection, treatment, processing and disposal options

Category	Type of Waste	Type of Bag or Container to be used	Treatment and Disposal options
(1)	(2)	(3)	(4)
Yellow	(a) Human Anatomical Waste: Human tissues, organs, body parts and fetus below the viability period (as per the Medical Termination of Pregnancy Act 1971, amended from time to time).	Yellow coloured non-chlorinated plastic bags	Incineration or Plasma Pyrolysis or deep burial
	(b) Animal Anatomical Waste : Experimental animal carcasses, body parts, organs, tissues, including the waste generated from animals used in experiments or testing in veterinary hospitals or colleges or animal houses.		
	(c) Soiled Waste: Items contaminated with blood, body fluids like dressings, plaster casts, cotton swabs and bags containing residual or discarded blood and blood components.		Incineration or Plasma Pyrolysis or deep burial In absence of above facilities, autoclaving or micro-waving/ hydroclaving followed by shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent for energy recovery.

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	<p>(d) Expired or Discarded Medicines: Pharmaceutical waste like antibiotics, cytotoxic drugs including all items contaminated with cytotoxic drugs along with glass or plastic ampoules, vials etc.</p>	<p>Yellow coloured non-chlorinated plastic bags or containers</p>	<p>Expired cytotoxic drugs and items contaminated with cytotoxic drugs to be returned back to the manufacturer or supplier for incineration at temperature >1200 °C or to common bio-medical waste treatment facility or hazardous waste treatment, storage and disposal facility for incineration at >1200°C Or Encapsulation or Plasma Pyrolysis at >1200°C.</p> <p>All other discarded medicines shall be either sent back to manufacturer or disposed by incineration.</p>
	<p>(e) Chemical Waste: Chemicals used in production of biological and used or discarded disinfectants.</p>	<p>Yellow coloured containers or non-chlorinated plastic bags</p>	<p>Disposed of by incineration or Plasma Pyrolysis or Encapsulation in hazardous waste treatment, storage and disposal facility.</p>
	<p>(f) Chemical Liquid Waste: Liquid waste generated due to use of chemicals in production of biological and used or discarded disinfectants, Silver X-ray film developing liquid, discarded Formalin, infected secretions, aspirated body fluids, liquid from laboratories and floor washings, cleaning, house-keeping and disinfecting activities etc.</p>	<p>Separate collection system leading to effluent treatment system</p>	<p>After resource recovery, the chemical liquid waste shall be pre-treated before mixing with other wastewater. The combined discharge shall conform to the discharge norms given in Schedule- III.</p>
	<p>(g) Discarded linen, mattresses, beddings contaminated with blood or body fluid.</p>	<p>Non-chlorinated yellow plastic bags or suitable packing material</p>	<p>Non-chlorinated chemical disinfection followed by incineration or Plasma Pyrolysis or for energy recovery.</p> <p>In absence of above facilities, shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent for energy recovery or incineration or Plasma Pyrolysis.</p>
	<p>(h) Microbiology, Biotechnology and other clinical laboratory waste: Blood bags, Laboratory cultures, stocks or specimens of micro-organisms, live or attenuated vaccines, human and animal cell cultures used in research, industrial laboratories, production of</p>	<p>Autoclave safe plastic bags or containers</p>	<p>Pre-treat to sterilize with non-chlorinated chemicals on-site as per National AIDS Control Organisation or World Health Organisation guidelines thereafter for Incineration.</p>

	biological, residual toxins, dishes and devices used for cultures.		
Red	Contaminated Waste (Recyclable) (a) Wastes generated from disposable items such as tubing, bottles, intravenous tubes and sets, catheters, urine bags, syringes (without needles and <i>fixed needle syringes</i>) and vacutainers with their needles cut) and gloves.	Red coloured non-chlorinated plastic bags or containers	Autoclaving or micro-waving/ hydroclaving followed by shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent to registered or authorized recyclers or for energy recovery or plastics to diesel or fuel oil or for road making, whichever is possible. Plastic waste should not be sent to landfill sites.
White (Translucent)	Waste sharps including Metals: Needles, syringes with fixed needles, needles from needle tip cutter or burner, scalpels, blades, or any other contaminated sharp object that may cause puncture and cuts. This includes both used, discarded and contaminated metal sharps	Puncture proof, Leak proof, tamper proof containers	Autoclaving or Dry Heat Sterilization followed by shredding or mutilation or encapsulation in metal container or cement concrete; combination of shredding cum autoclaving; and sent for final disposal to iron foundries (having consent to operate from the State Pollution Control Boards or Pollution Control Committees) or sanitary landfill or designated concrete waste sharp pit.
Blue	(a) Glassware: Broken or discarded and contaminated glass including medicine vials and ampoules except those contaminated with cytotoxic wastes.	Cardboard boxes with blue colored marking	Disinfection (by soaking the washed glass waste after cleaning with detergent and Sodium Hypochlorite treatment) or through autoclaving or microwaving or hydroclaving and then sent for recycling.
	(b) Metallic Body Implants	Cardboard boxes with blue colored marking	

*Disposal by deep burial is permitted only in rural or remote areas where there is no access to common bio-medical waste treatment facility. This will be carried out with prior approval from the prescribed authority and as per the Standards specified in Schedule-III. The deep burial facility shall be located as per the provisions and guidelines issued by Central Pollution Control Board from time to time.

Part -2

- (1) All plastic bags shall be as per BIS standards as and when published, till then the prevailing Plastic Waste Management Rules shall be applicable.
- (2) Chemical treatment using at least 10% Sodium Hypochlorite having 30% residual chlorine for twenty minutes or any other equivalent chemical reagent that should demonstrate $\text{Log}_{10}4$ reduction efficiency for microorganisms as given in Schedule- III.
- (3) Mutilation or shredding must be to an extent to prevent unauthorized reuse.

-
- II (i)
-
- (4) There will be no chemical pretreatment before incineration, except for microbiological, lab and highly infectious waste.
 - (5) Incineration ash (ash from incineration of any bio-medical waste) shall be disposed through hazardous waste treatment, storage and disposal facility, if toxic or hazardous constituents are present beyond the prescribed limits as given in the Hazardous Waste (Management, Handling and Transboundary Movement) Rules, 2008 or as revised from time to time.
 - (6) Dead Fetus below the viability period (as per the Medical Termination of Pregnancy Act 1971, amended from time to time) can be considered as human anatomical waste. Such waste should be handed over to the operator of common bio-medical waste treatment and disposal facility in yellow bag with a copy of the official Medical Termination of Pregnancy certificate from the Obstetrician or the Medical Superintendent of hospital or healthcare establishment.
 - (7) Cytotoxic drug vials shall not be handed over to unauthorised person under any circumstances. These shall be sent back to the manufactures for necessary disposal at a single point. As a second option, these may be sent for incineration at common bio-medical waste treatment and disposal facility or TSDFs or plasma pyrolysis at temperature >1200 °C.
 - (8) Residual or discarded chemical wastes, used or discarded disinfectants and chemical sludge can be disposed at hazardous waste treatment, storage and disposal facility. In such case, the waste should be sent to hazardous waste treatment, storage and disposal facility through operator of common bio-medical waste treatment and disposal facility only.
 - (9) On-site pre-treatment of laboratory waste, microbiological waste, blood samples, blood bags should be disinfected or sterilized as per the Guidelines of World Health Organisation or National AIDS Control Organisation and then given to the common bio-medical waste treatment and disposal facility.
 - (10) Installation of in-house incinerator is not allowed. However in case there is no common biomedical facility nearby, the same may be installed by the occupier after taking authorisation from the State Pollution Control Board.
 - (11) Syringes should be either mutilated or needles should be cut and or stored in tamper proof, leak proof and puncture proof containers for sharps storage. Wherever the occupier is not linked to a disposal facility it shall be the responsibility of the occupier to sterilize and dispose in the manner prescribed.
 - (12) Bio-medical waste generated in households during healthcare activities shall be segregated as per these rules and handed over in separate bags or containers to municipal waste collectors. Urban Local Bodies shall have tie up with the common bio-medical waste treatment and disposal facility to pickup this waste from the Material Recovery Facility (MRF) or from the house hold directly, for final disposal in the manner as prescribed in this Schedule.

SCHEDULE II

[See rule 4(t), 7(1) and 7(6)]

STANDARDS FOR TREATMENT AND DISPOSAL OF BIO-MEDICAL WASTES

1. STANDARDS FOR INCINERATION.-

All incinerators shall meet the following operating and emission standards-

A. Operating Standards

- 1). Combustion efficiency (CE) shall be at least 99.00%.
- 2). The Combustion efficiency is computed as follows:

$$\text{C.E.} = \frac{\% \text{CO}_2}{\% \text{CO}_2 + \% \text{CO}} \times 100$$

- 3). The temperature of the primary chamber shall be a minimum of 800 °C and the secondary chamber shall be minimum of 1050 °C + or - 50 °C.

4). The secondary chamber gas residence time shall be at least two seconds.

B. Emission Standards

Sl. No.	Parameter	Standards	
		(3)	(4)
(1)	(2)	(3)	(4)
		Limiting concentration in mg Nm ³ unless stated	Sampling Duration in minutes, unless stated
1.	Particulate matter	50	30 or 1NM ³ of sample volume, whichever is more
2.	Nitrogen Oxides NO and NO ₂ expressed asNO ₂	400	30 for online sampling or grab sample
3.	HCl	50	30 or 1NM ³ of sample volume, whichever is more
4.	Total Dioxins and Furans	0.1ngTEQ/Nm ³ (at 11% O ₂)	8 hours or 5NM ³ of sample volume, whichever is more
5.	Hg and its compounds	0.05	2 hours or 1NM ³ of sample volume, whichever is more

C. Stack Height: Minimum stack height shall be 30 meters above the ground and shall be attached with the necessary monitoring facilities as per requirement of monitoring of 'general parameters' as notified under the Environment (Protection) Act, 1986 and in accordance with the Central Pollution Control Board Guidelines of Emission Regulation Part-III.

Note:

- (a) The existing incinerators shall comply with the above within a period of two years from the date of the notification.
- (b) The existing incinerators shall comply with the standards for Dioxins and Furans of 0.1ngTEQ/Nm³, as given below within two years from the date of commencement of these rules.
- (c) All upcoming common bio-medical waste treatment facilities having incineration facility or captive incinerator shall comply with standards for Dioxins and Furans.
- (d) The existing secondary combustion chambers of the incinerator and the pollution control devices shall be suitably retrofitted, if necessary, to achieve the emission limits.
- (e) Wastes to be incinerated shall not be chemically treated with any chlorinated disinfectants.
- (f) Ash from incineration of biomedical waste shall be disposed of at common hazardous waste treatment and disposal facility. However, it may be disposed of in municipal landfill, if the toxic metals in incineration ash are within the regulatory quantities as defined under the Hazardous Waste (Management and Handling and Transboundary Movement) Rules, 2008 as amended from time to time.
- (g) Only low Sulphur fuel like Light Diesel Oil or Low Sulphur Heavy Stock or Diesel, Compressed Natural Gas, Liquefied Natural Gas or Liquefied Petroleum Gas shall be used as fuel in the incinerator.
- (h) The occupier or operator of a common bio-medical waste treatment facility shall monitor the stack gaseous emissions (under optimum capacity of the incinerator) once in three months through a laboratory approved under the Environment (Protection) Act, 1986 and record of such analysis results shall be maintained and submitted to the prescribed authority. In case of dioxins and furans, monitoring should be done once in a year.
- (i) The occupier or operator of the common bio-medical waste treatment facility shall install continuous emission monitoring system for the parameters as stipulated by State Pollution Control Board or Pollution Control Committees in authorisation and transmit the data real time to the servers at State Pollution Control Board or Pollution Control Committees and Central Pollution Control Board.
- (j) All monitored values shall be corrected to 11% Oxygen on dry basis.
- (k) Incinerators (combustion chambers) shall be operated with such temperature, retention time and turbulence, as to achieve Total Organic Carbon content in the slag and bottom ashes less than 3% or their loss on ignition shall be less than 5% of the dry weight.

II (i)

(1) The occupier or operator of a common bio-medical waste incinerator shall use combustion gas analyzer to measure CO₂, CO and O₂.

2. Operating and Emission Standards for Disposal by Plasma Pyrolysis or Gasification:

A. Operating Standards:

All the operators of the Plasma Pyrolysis or Gasification shall meet the following operating and emission standards:

- 1) Combustion Efficiency (CE) shall be at least 99.99%.
- 2) The Combustion Efficiency is computed as follows.

$$\frac{\% \text{CO}_2}{(\% \text{CO}_2 + \% \text{CO})} \times 100 \quad \text{C.E} =$$

- 3) The temperature of the combustion chamber after plasma gasification shall be 1050 ± 50 ° C with gas residence time of at least 2(two) second, with minimum 3 % Oxygen in the stack gas.
- 4) The Stack height should be minimum of 30 m above ground level and shall be attached with the necessary monitoring facilities as per requirement of monitoring of 'general parameters' as notified under the Environment (Protection) Act, 1986 and in accordance with the CPCB Guidelines of Emission Regulation Part-III.

B. Air Emission Standards and Air Pollution Control Measures

- (i) Emission standards for incinerator, notified at SI No.1 above in this Schedule, and revised from time to time, shall be applicable for the Plasma Pyrolysis or Gasification also.
- (ii) Suitably designed air pollution control devices shall be installed or retrofitted with the 'Plasma Pyrolysis or Gasification to achieve the above emission limits, if necessary.
- (iii) Wastes to be treated using Plasma Pyrolysis or Gasification shall not be chemically treated with any chlorinated disinfectants and chlorinated plastics shall not be treated in the system.

C. Disposal of Ash Vitrified Material: The ash or vitrified material generated from the 'Plasma Pyrolysis or Gasification shall be disposed off in accordance with the Hazardous Waste (Management, Handling and Transboundary Movement) Rules 2008 and revisions made thereafter in case the constituents exceed the limits prescribed under Schedule II of the said Rules or else in accordance with the provisions of the Environment (Protection) Act, 1986, whichever is applicable.

3. STANDARDS FOR AUTOCLAVING OF BIO-MEDICAL WASTE.-

The autoclave should be dedicated for the purposes of disinfecting and treating bio-medical waste.

- (1) When operating a gravity flow autoclave, medical waste shall be subjected to:
 - (i) a temperature of not less than 121° C and pressure of 15 pounds per square inch (psi) for an autoclave residence time of not less than 60 minutes; or
 - (ii) a temperature of not less than 135° C and a pressure of 31 psi for an autoclave residence time of not less than 45 minutes; or
 - (iii) a temperature of not less than 149° C and a pressure of 52 psi for an autoclave residence time of not less than 30 minutes.
- (2) When operating a vacuum autoclave, medical waste shall be subjected to a minimum of three pre-vacuum pulse to purge the autoclave of all air. The air removed during the pre-vacuum, cycle should be decontaminated by means of HEPA and activated carbon filtration, steam treatment, or any other method to prevent release of pathogen. The waste shall be subjected to the following:
 - (i) a temperature of not less than 121°C and pressure of 15 psi per an autoclave residence time of not less than 45 minutes; or
 - (ii) a temperature of not less than 135°C and a pressure of 31 psi for an autoclave residence time of not less than 30 minutes;
- (3) Medical waste shall not be considered as properly treated unless the time, temperature and pressure indicators indicate that the required time, temperature and pressure were reached during the autoclave process. If for any reasons, time temperature or pressure indicator indicates that the required temperature, pressure or residence time was not

reached, the entire load of medical waste must be autoclaved again until the proper temperature, pressure and residence time were achieved.

(4) **Recording of operational parameters:** Each autoclave shall have graphic or computer recording devices which will automatically and continuously monitor and record dates, time of day, load identification number and operating parameters throughout the entire length of the autoclave cycle.

(5) **Validation test for autoclave:** The validation test shall use four biological indicator strips, one shall be used as a control and left at room temperature, and three shall be placed in the approximate center of three containers with the waste. Personal protective equipment (gloves, face mask and coveralls) shall be used when opening containers for the purpose of placing the biological indicators. At least one of the containers with a biological indicator should be placed in the most difficult location for steam to penetrate, generally the bottom center of the waste pile. The occupier or operator shall conduct this test three consecutive times to define the minimum operating conditions. The temperature, pressure and residence time at which all biological indicator vials or strips for three consecutive tests show complete inactivation of the spores shall define the minimum operating conditions for the autoclave. After determining the minimum temperature, pressure and residence time, the occupier or operator of a common biomedical waste treatment facility shall conduct this test once in three months and records in this regard shall be maintained.

(6) **Routine Test:** A chemical indicator strip or tape that changes colour when a certain temperature is reached can be used to verify that a specific temperature has been achieved. It may be necessary to use more than one strip over the waste package at different locations to ensure that the inner content of the package has been adequately autoclaved. The occupier or operator of a common bio medical waste treatment facility shall conduct this test during autoclaving of each batch and records in this regard shall be maintained.

(7) **Spore testing:** The autoclave should completely and consistently kill the approved biological indicator at the maximum design capacity of each autoclave unit. Biological indicator for autoclave shall be *Geobacillusstearothermophilus* spores using vials or spore Strips; with at least 1×10^6 spores. Under no circumstances will an autoclave have minimum operating parameters less than a residence time of 30 minutes, a temperature less than 121°C or a pressure less than 15 psi. The occupier or operator of a common bio medical waste treatment and disposal facility shall conduct this test at least once in every week and records in this regard shall be maintained.

4. STANDARDS OF MICROWAVING.-

(1) Microwave treatment shall not be used for cytotoxic, hazardous or radioactive wastes, contaminated animal carcasses, body parts and large metal items.

(2) The microwave system shall comply with the efficacy test or routine tests and a performance guarantee may be provided by the supplier before operation of the limit.

(3) The microwave should completely and consistently kill the bacteria and other pathogenic organisms that are ensured by approved biological indicator at the maximum design capacity of each microwave unit. Biological indicators for microwave shall be *Bacillus atrophaeusspores* using vials or spore strips with at least 1×10^4 sporesper detachable strip. The biological indicator shall be placed with waste and exposed to same conditions as the waste during a normal treatment cycle.

5. **STANDARDS FOR DEEP BURIAL.-** (1) A pit or trench should be dug about two meters deep. It should be half filled with waste, then covered with lime within 50 cm of the surface, before filling the rest of the pit with soil.

(2) It must be ensured that animals do not have any access to burial sites. Covers of galvanised iron or wire meshes may be used.

(3) On each occasion, when wastes are added to the pit, a layer of 10 cm of soil shall be added to cover the wastes.

(4) Burial must be performed under close and dedicated supervision.

(5) The deep burial site should be relatively impermeable and no shallow well should be close to the site.

(6) The pits should be distant from habitation, and located so as to ensure that no contamination occurs to surface water or ground water. The area should not be prone to flooding or erosion.

(7) The location of the deep burial site shall be authorised by the prescribed authority.

(8) The institution shall maintain a record of all pits used for deep burial.

(9) The ground water table level should be a minimum of six meters below the lower level of deep burial pit.

6. STANDARDS FOR EFFICACY OF CHEMICAL DISINFECTION

Microbial inactivation efficacy is equated to "Log10 kill" which is defined as the difference between the logarithms of number of test microorganisms before and after chemical treatment. Chemical disinfection methods shall demonstrate a 4 Log10 reduction or greater for *Bacillus Subtilis* (ATCC 19659) in chemical treatment systems.

II (1)

7. STANDARDS FOR DRY HEAT STERILIZATION

Waste sharps can be treated by dry heat sterilization at a temperature not less than 185°C, at least for a residence period of 150 minutes in each cycle, which sterilization period of 90 minutes. There should be automatic recording system to monitor operating parameters.

(i) Validation test for Sharps sterilization unit

Waste sharps sterilization unit should completely and consistently kill the biological indicator *Geobacillus Stearothermophilus* or *Bacillus Atropheauspoers* using vials with at least \log_{10} 6 spores per ml. The test shall be carried out once in three months

(ii) Routine test

A chemical indicator strip or tape that changes colour when a certain temperature is reached can be used to verify that a specific temperature has been achieved. It may be necessary to use more than one strip over the waste to ensure that the inner content of the sharps has been adequately disinfected. This test shall be performed once in week and records in this regard shall be maintained.

8. STANDARDS FOR LIQUID WASTE.-

(1) The effluent generated or treated from the premises of occupier or operator of a common bio medical waste treatment and disposal facility, before discharge into the sewer should conform to the following limits-

PARAMETERS	PERMISSIBLE LIMITS
pH	6.5-9.0
Suspended solids	100 mg/l
Oil and grease	10 mg/l
BOD	30 mg/l
COD	250 mg/l
Bio-assay test	90% survival of fish after 96 hours in 100% effluent.

(2) Sludge from Effluent Treatment Plant shall be given to common bio-medical waste treatment facility for incineration or to hazardous waste treatment, storage and disposal facility for disposal.

Schedule III

[See rule 6 and 9(3)]

List of Prescribed Authorities and the Corresponding Duties

Sl. No. (1)	Authority (2)	Corresponding Duties (3)
1	Ministry of Environment, Forest and Climate Change, Government of India	(i) Making Policies concerning bio-medical waste Management in the Country including notification of Rules and amendments to the Rules as and when required. (ii) Providing financial assistance for training and awareness programmes on bio-medical waste management related activities to for the State Pollution Control Boards or Pollution Control Committees. (iii) Facilitating financial assistance for setting up or up-gradation of common bio-medical waste treatment facilities. (iv) Undertake or support operational research and assessment with reference to risks to environment and health due to bio-medical waste and previously unknown disposables and wastes from new types of equipment. (v) Constitution of Monitoring Committee for implementation of the rules. (vi) Hearing Appeals and give decision made in Form- V against order passed by the prescribed authorities. (vii) Develop Standard manual for Trainers and Training.

		(viii) Notify the standards or operating parameters for new technologies for treatment of bio medical waste other than those listed in Schedule- I.
2	Central or State Ministry of Health and Family Welfare, Central Ministry for Animal Husbandry and Veterinary or State Department of Animal Husbandry and Veterinary.	<p>(i) Grant of license to health care facilities or nursing homes or veterinary establishments with a condition to obtain authorisation from the prescribed authority for bio-medical waste management.</p> <p>(ii) Monitoring, Refusal or Cancellation of license for health care facilities or nursing homes or veterinary establishments for violations of conditions of authorisation or provisions under these Rules.</p> <p>(iii) Publication of list of registered health care facilities with regard to bio-medical waste generation, treatment and disposal.</p> <p>(iv) Undertake or support operational research and assessment with reference to risks to environment and health due to bio-medical waste and previously unknown disposables and wastes from new types of equipment.</p> <p>(v) Coordinate with State Pollution Control Boards for organizing training programmes to staff of health care facilities and municipal workers on bio-medical waste.</p> <p>(vi) Constitution of Expert Committees at National or State level for overall review and promotion of clean or new technologies for bio-medical waste management.</p> <p>(vii) Organizing or Sponsoring of trainings for the regulatory authorities and health care facilities on bio-medical waste management related activities.</p> <p>(viii) Sponsoring of mass awareness campaigns in electronic media and print media.</p>
3	Ministry of Defence	<p>(i) Grant and renewal of authorisation to Armed Forces health care facilities or common bio-medical waste treatment facilities (Rule 9).</p> <p>(ii) Conduct training courses for authorities dealing with management of bio-medical wastes in Armed Forces health care facilities or treatment facilities in association with State Pollution Control Boards or Pollution Control Committees or Central Pollution Control Board or Ministry of Environment, Forest and Climate Change.</p> <p>(iii) Publication of inventory of occupiers and bio-medical waste generation from Armed Forces health care facilities or occupiers</p> <p>(iv) Constitution of Advisory Committee for implementation of the rules.</p> <p>(v) Review of management of bio-medical waste generation in the Armed Forces health care facilities through its Advisory Committee (Rule 11).</p> <p>(vi) Submission of annual report to Central Pollution Control Board within the stipulated time period (Rule 13).</p>
4.	Central Pollution Control Board	<p>(i) Prepare Guidelines on bio-medical waste Management and submit to the Ministry of Environment, Forest and Climate Change.</p> <p>(ii) Co-ordination of activities of State Pollution Control Boards or Pollution Control Committees on bio-medical waste.</p>

II	(I)	
		<ul style="list-style-type: none"> (iii) Conduct training courses for authorities dealing with management of bio-medical waste. (iv) Lay down standards for new technologies for treatment and disposal of bio-medical waste (Rule 7) and prescribe specifications for treatment and disposal of bio-medical wastes (Rule 7). (v) Lay down Criteria for establishing common bio-medical waste treatment facilities in the Country. (vi) Random inspection or monitoring of health care facilities and common bio-medical waste treatment facilities. (vii) Review and analysis of data submitted by the State Pollution Control Boards on bio-medical waste and submission of compiled information in the form of annual report along with its observations to Ministry of Environment, Forest and Climate Change . (viii) Inspection and monitoring of health care facilities operated by the Director General, Armed Forces Medical Services (Rule 9). (ix) Undertake or support research or operational research regarding bio-medical waste.
5.	State Government of Health or Union Territory Government or Administration	<ul style="list-style-type: none"> (i) To ensure implementation of the rule in all health care facilities or occupiers. (ii) Allocation of adequate funds to Government health care facilities for bio-medical waste management. (iii) Procurement and allocation of treatment equipments and make provision for consumables for bio-medical waste management in Government health care facilities. (iv) Constitute State or District Level Advisory Committees under the District Magistrate or Additional District Magistrate to oversee the bio-medical waste management in the Districts. (v) Advise State Pollution Control Boards or Pollution Control Committees on implementation of these Rules. (vi) Implementation of recommendations of the Advisory Committee in all the health care facilities.
6.	State Pollution Control Boards or Pollution Control Committees	<ul style="list-style-type: none"> (i) Inventorisation of Occupiers and data on bio-medical waste generation, treatment & disposal. (ii) Compilation of data and submission of the same in annual report to Central Pollution Control Board within the stipulated time period. (iii) Grant and renewal, suspension or refusal cancellation or of authorisation under these rules (Rule 7, 8 and 10). (iv) Monitoring of compliance of various provisions and conditions of authorisation. (v) Action against health care facilities or common bio-medical waste treatment facilities for violation of these rules (Rule 18). (vi) Organizing training programmes to staff of health care facilities and common bio-medical waste treatment facilities and State Pollution Control Boards or Pollution Control Committees Staff on segregation, collection, storage, transportation, treatment and disposal of bio-medical wastes.

		<ul style="list-style-type: none"> (vii) Undertake or support research or operational research regarding bio-medical waste management. (viii) Any other function under these rules assigned by Ministry of Environment, Forest and Climate Change or Central Pollution Control Board from time to time. (ix) Implementation of recommendations of the Advisory Committee. (x) Publish the list of Registered or Authorised (or give consent) Recyclers. (xi) Undertake and support third party audits of the common bio-medical waste treatment facilities in their State.
7	Municipalities or Corporations, Urban Local Bodies and Gram Panchayats	<ul style="list-style-type: none"> (i) Provide or allocate suitable land for development of common bio-medical waste treatment facilities in their respective jurisdictions as per the guidelines of Central Pollution Control Board. (ii) Collect other solid waste (other than the bio-medical waste) from the health care facilities as per the Municipal Solid Waste (Management and handling) Rules, 2000 or as amended time to time. (iii) Any other function stipulated under these Rules.

SCHEDULE IV

[See rule 8(3) and (5)]

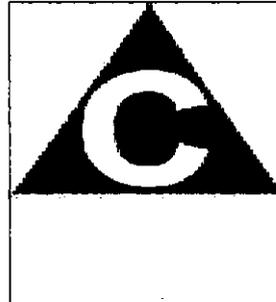
Part A

LABEL FOR BIO-MEDICAL WASTE CONTAINERS or BAGS



HANDLE WITH CARE

CYTOTOXIC HAZARD SYMBOL



HANDLE WITH CARE

Part B

LABEL FOR TRANSPORTING BIO-MEDICAL WASTE BAGS OR CONTAINERS

DayMonth

Year

Date of generation

Waste category Number

Waste quantity.....

Sender's Name and Address

Phone Number

Receiver's Name and Address:

Phone Number

II (i)

Fax Number.....

Fax Number

Contact Person

Contact Person

In case of emergency please contact :

Name and Address :

Phone No.

Note :Label shall be non-washable and prominently visible.

FORM - I

[(See rule 4(o), 5(i) and 15 (2))

ACCIDENT REPORTING

1. Date and time of accident :
2. Type of Accident :
3. Sequence of events leading to accident :
4. Has the Authority been informed immediately :
5. The type of waste involved in accident :
6. Assessment of the effects of the accidents on human health and the environment:
7. Emergency measures taken :
8. Steps taken to alleviate the effects of accidents :
9. Steps taken to prevent the recurrence of such an accident :
10. Does you facility has an Emergency Control policy? If yes give details:

Date :

Signature

Place:

Designation

FORM - II

(See rule10)

APPLICATION FOR AUTHORISATION OR RENEWAL OF AUTHORISATION

(To be submitted by occupier of health care facility or common bio-medical waste treatment facility)

To

The Prescribed Authority
(Name of the State or UT Administration)
Address.

1. Particulars of Applicant:

(i) Name of the Applicant:
(In block letters & in full)

(ii) Name of the health care facility (HCF) or common bio-medical waste treatment facility (CBWTF) :

(iii) Address for correspondence:

(iv) Tele No.. Fax No.:

(v) Email:

(vi) Website Address:

2. Activity for which authorisation is sought:

Activity	Please tick
Generation, segregation	
Collection,	
Storage	
packaging	
Reception	
Transportation	
Treatment or processing or conversion	
Recycling	
Disposal or destruction	
use	
offering for sale, transfer	
Any other form of handling	

3. Application for fresh or renewal of authorisation (please tick whatever is applicable):

(i) Applied for CTO/CTE Yes/No

(ii) In case of renewal previous authorisation number and date:

(iii) Status of Consents:

(a) under the Water (Prevention and Control of Pollution) Act, 1974

(b) under the Air (Prevention and Control of Pollution) Act, 1981:

4. (i) Address of the health care facility (HCF) or common bio-medical waste treatment facility (CBWTF):

(ii) GPS coordinates of health care facility (HCF) or common bio-medical waste treatment facility (CBWTF):

5. Details of health care facility (HCF) or common bio-medical waste treatment facility (CBWTF):

(i) Number of beds of HCF:

(ii) Number of patients treated per month by HCF:

(iii) Number healthcare facilities covered by CBMWTF: _____

(iv) No of beds covered by CBMWTF: _____

(v) Installed treatment and disposal capacity of CBMWTF: _____ Kg per day

(vi) Quantity of biomedical waste treated or disposed by CBMWTF: _____ Kg/ day

(vii) Area or distance covered by CBMWTF: _____

(p. attach map a map with GPS locations of CBMWTF and area of coverage)

(viii) Quantity of Biomedical waste handled, treated or disposed:

Category	Type of Waste	Quantity Generated or Collected, kg/day	Method of Treatment and Disposal (Refer Schedule-1)
(1)	(2)	(3)	(4)
Yellow	(a) Human Anatomical Waste:		
	(b) Animal Anatomical Waste :		
	(c) Soiled Waste:		
	(d) Expired or Discarded Medicines:		
	(e) Chemical Solid Waste:		
	(f) Chemical Liquid Waste :		

II		(i)	
	(g) Discarded linen, mattresses, beddings contaminated with blood or body fluid.		
	(h) Microbiology, Biotechnology and other clinical laboratory waste:		
Red	Contaminated Waste (Recyclable)		
White (Translucent)	Waste sharps including Metals:		
Blue	Glassware:		
	Metallic Body Implants		

6. Brief description of arrangements for handling of biomedical waste (attach details):
 (i) Mode of transportation (if any) of bio-medical waste:
 (ii) Details of treatment equipment (please give details such as the number, type & capacity of each unit)

	No of units	Capacity of each unit
Incinerators :		
Plasma Pyrolysis:		
Autoclaves:		
Microwave:		
Hydroclave:		
Shredder:		
Needle tip cutter or destroyer		
Sharps encapsulation or concrete pit:		
Deep burial pits:		
Chemical disinfection:		
Any other treatment equipment:		

7. Contingency plan of common bio-medical waste treatment facility (CBWTF)(attach documents):

8. Details of directions or notices or legal actions if any during the period of earlier authorisation

9. Declaration

I do hereby declare that the statements made and information given above are true to the best of my knowledge and belief and that I have not concealed any information.

I do also hereby undertake to provide any further information sought by the prescribed authority in relation to these rules and to fulfill any conditions stipulated by the prescribed authority.

Date :

Signature of the Applicant

Place :

Designation of the Applicant

FORM -III

(See rule 10)

AUTHORISATION

(Authorisation for operating a facility for generation, collection, reception, treatment, storage, transport and disposal of biomedical wastes)

1. File number of authorisation and date of issue.....

2. M/s _____ an occupier or operator of the facility located at _____ is hereby granted an authorisation for;

Activity
 Generation, segregation
 Collection,
 Storage
 packaging

Please tick

Reception
 Transportation
 Treatment or processing or conversion
 Recycling
 Disposal or destruction
 use
 offering for sale, transfer
 Any other form of handling

3. M/s _____ is hereby authorized for handling of biomedical waste as per the capacity given below:

- (i) Number of beds of HCF: _____
 (ii) Number healthcare facilities covered by CBMWTF: _____
 (iii) Installed treatment and disposal capacity: _____ Kg per day
 (iv) Area or distance covered by CBMWTF: _____
 (v) Quantity of Biomedical waste handled, treated or disposed:

Type of Waste Category	Quantity permitted for Handling
Yellow	
Red	
White (Translucent)	
Blue	

4. This authorisation shall be in force for a period of Years from the date of issue.

5. This authorisation is subject to the conditions stated below and to such other conditions as may be specified in the rules for the time being in force under the Environment (Protection) Act, 1986.

Date

Signature.....

Place:

Designation

*Terms and conditions of authorisation **

- The authorisation shall comply with the provisions of the Environment (Protection) Act, 1986 and the rules made there under.
- The authorisation or its renewal shall be produced for inspection at the request of an officer authorised by the prescribed authority.
- The person authorized shall not rent, lend, sell, transfer or otherwise transport the biomedical wastes without obtaining prior permission of the prescribed authority.
- Any unauthorised change in personnel, equipment or working conditions as mentioned in the application by the person authorised shall constitute a breach of his authorisation.
- It is the duty of the authorised person to take prior permission of the prescribed authority to close down the facility and such other terms and conditions may be stipulated by the prescribed authority.

Form - IV

(See rule 13)

ANNUAL REPORT

[To be submitted to the prescribed authority on or before 30th June every year for the period from January to December of the preceding year, by the occupier of health care facility (HCF) or common bio-medical waste treatment facility (CBWTF)]

II (1)

Sl. No.	Particulars		
1.	Particulars of the Occupier	:	
	(i) Name of the authorised person (occupier or operator of facility)	:	
	(ii) Name of HCF or CBMWTF	:	
	(iii) Address for Correspondence	:	
	(iv) Address of Facility		
	(v) Tel. No, Fax. No	:	
	(vi) E-mail ID	:	
	(vii) URL of Website		
	(viii) GPS coordinates of HCF or CBMWTF		
	(ix) Ownership of HCF or CBMWTF	:	(State Government or Private or Semi Govt. or any other)
	(x). Status of Authorisation under the Bio-Medical Waste (Management and Handling) Rules	:	Authorisation No.:valid up to
(xi). Status of Consents under Water Act and Air Act	:	Valid up to:	
2.	Type of Health Care Facility	:	
	(i) Bedded Hospital	:	No. of Beds:.....
	(ii) Non-bedded hospital (Clinic or Blood Bank or Clinical Laboratory or Research Institute or Veterinary Hospital or any other)	:	
	(iii) License number and its date of expiry		
3.	Details of CBMWTF	:	
	(i) Number healthcare facilities covered by CBMWTF	:	
	(ii) No of beds covered by CBMWTF	:	
	(iii) Installed treatment and disposal capacity of CBMWTF:	:	_____ Kg per day
	(iv) Quantity of biomedical waste treated or disposed by CBMWTF	:	_____ Kg/day
4.	Quantity of waste generated or disposed in Kg per annum (on monthly average basis)	:	Yellow Category :
			Red Category :
			White:
			Blue Category :
			General Solid waste:
5	Details of the Storage, treatment, transportation, processing and Disposal Facility		
	(i) Details of the on-site storage facility	:	Size :
			Capacity :
Provision of on-site storage : (cold storage or any other provision)			

	disposal facilities		Type of treatment equipment	No of units	Capacity Kg/day	Quantity treated or disposed in kg per annum
			Incinerators Plasma Pyrolysis Autoclaves Microwave Hydroclave Shredder Needle tip cutter or destroyer Sharps encapsulation or concrete pit Deep burial pits: Chemical disinfection: Any other treatment equipment:			
	(iii) Quantity of recyclable wastes sold to authorized recyclers after treatment in kg per annum.	:	Red Category (like plastic, glass etc.)			
	(iv) No of vehicles used for collection and transportation of biomedical waste	:				
	(v) Details of incineration ash and ETP sludge generated and disposed during the treatment of wastes in Kg per annum			Quantity generated	Where disposed	
	(vi) Name of the Common Bio-Medical Waste Treatment Facility Operator through which wastes are disposed of	:	Incineration Ash ETP Sludge			
	(vii) List of member HCF not handed over bio-medical waste.					
6	Do you have bio-medical waste management committee? If yes, attach minutes of the meetings held during the reporting period					
7	Details trainings conducted on BMW					
	(i) Number of trainings conducted on BMW Management.					
	(ii) number of personnel trained					
	(iii) number of personnel trained at the time of induction					
	(iv) number of personnel not undergone any training so far					
	(v) whether standard manual for training is available?					
	(vi) any other information					
8	Details of the accident occurred during the year					

II (i)

	(i) Number of Accidents occurred		
	(ii) Number of the persons affected		
	(iii) Remedial Action taken (Please attach details if any)		
	(iv) Any Fatality occurred, details.		
9.	Are you meeting the standards of air Pollution from the incinerator? How many times in last year could not met the standards?		
	Details of Continuous online emission monitoring systems installed		
10	Liquid waste generated and treatment methods in place. How many times you have not met the standards in a year?		
11	Is the disinfection method or sterilization meeting the log 4 standards? How many times you have not met the standards in a year?		
12	Any other relevant information	:	(Air Pollution Control Devices attached with the Incinerator)

Certified that the above report is for the period from

.....

Name and Signature of the Head of the Institution

Date:

Place

FORM -V

(See rule 16)

Application for filing appeal against order passed by the prescribed authority

1. Name and address of the person applying for appeal :
2. Number, date of order and address of the authority which passed the order, against which appeal is being made (certified copy of order to be attached):
3. Ground on which the appeal is being made:
4. List of enclosures other than the order referred in para 2 against which appeal is being filed:

Signature

Date :

Name and Address.....

[F. No. 3-1/2000-HSMD]

BISHWANATH SINHA, Jt. Secy.

(घ) माझा जैव-चिकित्सा सुविधाओं द्वारा सूचित की गई दुर्घटनाओं की संख्या"

[फा. सं. 3-1/2000-एचएमएमडी]

रीतेश कुमार सिंह, संयुक्त सचिव

टिप्पण : मूल नियम भारत के राजपत्र, असाधारण, भाग , खंड 3, उप-खंड (i) में दिनांक 28 मार्च, 2016 की अधिसूचना सं. मा.का.नि. 343 (अ) के अधीन प्रकाशित किए गए थे।

MINISTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE

NOTIFICATION

New Delhi, the 16th March, 2018

G.S.R. 234 (E).— In exercise of the powers conferred by sub-section (1) and clause (v) of sub-section (2) of section 3 of the Environment (Protection) Act, 1986 (29 of 1986) read with sub-rule (4) of rule 5 of the Environment (Protection) Rules, 1986, the Central Government hereby makes the following rules to amend the Bio-Medical Waste Management Rules, 2016, published in the Gazette of India, Extraordinary, vide G.S.R. 343(E), dated the 28th March, 2016, after having dispensed with the requirement of notice under clause (a) of sub-rule (3) of rule 5 of the said rules in public interest, namely:—

1. (1) These rules may be called the Bio-Medical Waste Management (Amendment) Rules, 2018.
- (2) They shall come into force on the date of their publication in the Official Gazette.
2. In the Bio-Medical Waste Management Rules, 2016 (hereinafter referred to as the principal rules), in rule 2, in sub-rule (2).—
 - (i) in clause (c), for the words, brackets and figures "Municipal Solid Waste (Management and Handling) Rules, 2000", the words and figures "Solid Waste Management Rules, 2016" shall be substituted;
 - (ii) in clause (e), for the words, brackets and figures "Hazardous Wastes (Management, Handling and Transboundary Movement) Rules, 2008", the words, brackets and figures "Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016", shall be substituted; and
 - (iii) in clause (f), for the words, brackets and figures "E-Waste (Management and Handling) Rules, 2011", the words, brackets and figures "E-Waste (Management) Rules, 2016", shall be substituted.
3. In the principal rules, in rule 4.—
 - (i) in clause (c), for the portion beginning with "or National and ending with final disposal", the following shall be substituted, namely:—

"(c) guidelines on Safe management of wastes from health care activities and WHO Blue Book, 2014 and then sent to the Common bio-medical waste treatment facility for final disposal;"
 - (ii) for clause (d), the following clause shall be substituted, namely:—

"(d) phase out use of chlorinated plastic bags (excluding blood bags) and gloves by the 27th March, 2019;"
 - (iii) in clause (i), for the words "place for any purpose within one year from the date of the notification of these rules", the words and figures "for the further treatment and disposal in accordance with the guidelines issued by the Central Pollution Control Board by 27th March, 2019" shall be substituted;
 - (iv) for clause (p), the following clause shall be substituted, namely:—

"(p) all the health care facilities (any number of beds) shall make available the annual report on its web-site within a period of two years from the date of publication of Bio-Medical Waste Management (Amendment) Rules, 2018;"
4. In the principal rules, in rule (5), in clause (c), for the words "within one year", the words, letters and figures "in accordance with the guidelines issued by the Central Pollution Control Board by 27th March, 2019" shall be substituted.
5. In the principal rules, in rule 7, in clause (8).—

- II (i)
-
- (a) for the words "phase out use of non-chlorinated plastic bags", the words "phase out use of chlorinated plastic bags" shall be substituted;
- (b) for the words and figures "the Plastic Waste Management Rules, 2011", the words and figures "the Plastic Waste Management Rules, 2016" shall be substituted.
6. In the principal rules, in rule 13, in sub-rule (2), for the words "Central Pollution Control Board on or before", the words, figures, brackets and letter "Central Pollution Control Board in Form IVA before" shall be substituted.
7. In the Schedule I to the principal rules,-
- (a) in the Table under part 1-
- (i) against the category yellow,-
- (A) in item (g) under column (2), after the words "body fluid", the words ", routine mask and gown" shall be inserted;
- (B) against item (h), for the entry under column (3), the following entry shall be substituted, namely:-
"Autoclave or Microwave or Hydroclave safe plastic bags or containers";
- (C) against item (h), in the entry under column (4), for the portion beginning with "as per National AIDS Control Organisation", and ending with "for incineration", the following shall be substituted, namely:-
"as per World Health Organisation guidelines on Safe management of wastes from health care activities and WHO Blue Book, 2014 and thereafter sent for incineration";
- (ii) against the category blue-
- (A) against item (a), for the entry under column (3), the following item shall be substituted, namely:-
"(a) Puncture proof and leak proof boxes or containers with blue colored marking";
- (B) against item (b) for the entry under column (3), the following item shall be substituted, namely:-
"(b) Puncture proof and leak proof boxes or containers with blue colored marking";
- (iii) in the Note, for the word and figures "Schedule - III", the word and figures "Schedule - II" shall be substituted;
- (b) in Part - 2, in item (2), for the figures "10 %", the figures "1% to 2%" shall be substituted;
8. In Schedule II to the principal rules,-
- (i) in serial number 1, in the Table under Part B relating to "Emission Standards", in column heading under (3), for the letters and figure "mgNm³" the letters and figure "mg/Nm³" shall be substituted;
- (ii) in serial number 8, in item (1), the following Note shall be inserted, namely:-
"Note-
1. Above limits are applicable to the occupiers of Health Care Facilities (bedded) which are either connected with sewerage network without terminal sewage treatment plant or not connected to public sewers.
 2. For discharge into public sewers with terminal facilities, the general standards as notified under the Environment (Protection) Act, 1986 (29 of 1986) shall be applicable.
 3. Health Care Facilities having less than ten beds shall have to install Sewage Treatment Plant by the 31st December, 2019.
 4. Non-bedded occupiers shall dispose infectious liquid wastes only after treatment by disinfection as per Schedule - II (6) of the principal rules."
9. In Schedule - III to the principal rules,-
- (i) against serial number 3, in item (i) under column (3), for the brackets, word and figure "(Rule 9)", the brackets, word and figure "(Rule 10)" shall be substituted;
- (ii) against serial number 4, in item (viii) under column (3), for the brackets, word and figure "(Rule 9)", the brackets, word and figure "(Rule 12)" shall be substituted.

10. In the principal rules, after Form IV, the following Form shall be inserted, namely:-

Form IVA

[See rule 13(2)]

Format for Submission of the Annual Report Information on Bio-medical Waste Management (to be submitted by the State Pollution Control Boards or Pollution Control Committees and Director General Armed Forces Medical Services to Central Pollution Control Board on or before 31st July of every year for the period from January to December of the preceding calendar year)

Part-1 (Summary of Information)

- | | | | |
|--------|--|-------|----------------|
| (1) | Name of the Organisation | : | |
| (2) | Name of the Nodal Officer with contact telephone number and e-mail | : | |
| (3) | Total no. of Health Care Facilities / Occupiers | : | |
| (i) | Bedded Hospitals and Nursing Homes (bedded) | : | |
| (ii) | Clinics, dispensaries | : | |
| (iii) | Veterinary institutions | : | |
| (iv) | Animal houses | : | |
| (v) | Pathological laboratories | : | |
| (vi) | Blood banks | : | |
| (vii) | Clinical establishment | : | |
| (viii) | Research Institutions | : | |
| (ix) | AYUSH | : | |
| (4) | Total no. of beds | : | |
| (5) | Status of authorisation | : | |
| (i) | Total number of Occupiers applied for authorisation | : | |
| (ii) | Total number of Occupiers granted authorisation | : | |
| (iii) | Total number of application under consideration | : | |
| (iv) | Total number of applications rejected | : | |
| (v) | Total number of Occupiers in operation without applying for authorisation | : | |
| (6) | Quantity of Bio-medical Waste Generation (in kg/day) | : | |
| | (please enclose District Wise Bio-medical Waste Generation as per Part-2) | | |
| (i) | Bio-medical waste generation by bedded hospitals(in kg/day) | : | |
| (ii) | Bio-medical waste generation by non-bedded hospitals (in kg/day) | : | |
| (iii) | Any other | : | |
| | | Total | : _____ Kg/day |
| (7) | Bio-medical waste treatment and disposal | | |
| (a) | By Captive bio-medical waste treatment and disposal by Health Care Facilities (please enclose details as per Part-3) | | |
| (i) | Number of Health Care Facilities having captive treatment and Disposal facilities : | | |
| (ii) | Total bio-medical waste treated and disposed by captive treatment facilities in kg/day : | | |
| (b) | Bio-medical waste treatment and disposal by Common Bio Medical Waste Treatment Facilities (please enclose details as per Part 4) | | |
| (i) | Number of Common Bio Medical Waste Treatment Facilities in Operation | : | |
| (ii) | Number of Common Bio Medical Waste Treatment Facilities under construction : | | |

Medical Waste Treatment Facilities with contact person name and telephone number			by Common Bio-Medical Waste Treatment Facilities	being covered		collected from member Health Care Facilities (in Kg/day)	Equipment	Numbers	Total installed capacity (kg/day)	kg/day	(ties)
							Incinerator				Incineration Ash:
							Plasma Pyrolysis				Quantity: Disposed by:
							Autoclave Hydroclave				Sharps:
							Microwave				Quantity Disposed by:
							Shredder				Plastics
							Sharps encapsulation or concrete pit				Quantity: Disposed by:
							Deep burial pits				
							Any other equipment				
							Effluent Treatment Plant				ETP Sludge: Quantity: Disposed by:
							Sub-total				

- (a) Total Number of transportation vehicles used for collection of Bio-medical Waste on daily basis by the Common Bio-Medical Waste Treatment Facilities:
- (b) List of Health Care Facilities not having membership with the Common Bio-Medical Waste Treatment Facilities and neither having captive treatment facilities:
- (c) Number of trainings organised by the Common Bio-Medical Waste Treatment Facility operators:
- (d) Number of Accidents reported by the Common Bio Medical Waste Treatment Facilities:".

[F. No. 3-1/2000-HSMD]
RITESH KUMAR SINGH, Jt. Secy.

Note: The principal rules were published in the Gazette of India, Extraordinary, PART II-Section 3-Sub-section (i), vide G.S.R. 343(E), dated the 28th March, 2016.

"(त), सभी विस्तरयुक्त स्वास्थ्य केन्द्रों के मामले में, (चाहे विस्तरों की संख्या कितनी भी हो), जैव-चिकित्सा अपशिष्ट प्रबंधन (संशोधन) नियम, 2018 के प्रकाशन की तिथि से दो वर्षों की अवधि के अंदर अपनी वेबसाइट पर वार्षिक रिपोर्ट उपलब्ध कराएंगे।"

3. उक्त नियमों की अनुसूची-II में, क्रम सं. 8 के मामले, मद सं. (1) में, टिप्पण में, खंड-3 के लिए, निम्नलिखित खंड प्रतिस्थापित किया जाएगा, अर्थात्:-

"3. दस विस्तरों से कम वाले स्वास्थ्य केन्द्रों को 31 दिसम्बर, 2019 की तारीख तक द्रव अपशिष्ट पदार्थ के लिए आउटपुट खाब मानक का अनुपालन करना होगा।"

4. उक्त नियमों की अनुसूची-III में,-

(i) क्र. सं. 3 के मामले, स्तंभ (3) में, मद सं. (vi) के पश्चात्, निम्नलिखित मद अंतर्लिखित की जाएगी, अर्थात्:-

"(vii) महानिदेशक, मशम्र बल चिकित्सा सेवा द्वारा प्रचालित चिकित्सा निरीक्षण (एमआई) कक्ष, जहाजों पर रोगी कक्ष या पनडुव्वी, स्टेशन चिकित्सा केन्द्र तथा अग्रिम स्थानों में स्थित क्षेत्र अस्पताल का निरीक्षण और निगरानी।"

(ii) क्र.सं. 4 के मामले, स्तंभ (3) में, मद सं. (viii) के लिए, निम्नलिखित मद अंतर्विष्ट की जाएगी, अर्थात्:-

"(vii) महानिदेशक, मशम्र बल चिकित्सा सेवा द्वारा प्रचालित चिकित्सा निरीक्षण (एमआई) कक्षों, जहाजों पर रोगी कक्ष या पनडुव्वी, स्टेशन चिकित्सा केन्द्रों तथा अग्रिम स्थानों में स्थित क्षेत्र अस्पतालों को छोड़कर अन्य स्वास्थ्य केन्द्रों का निरीक्षण और निगरानी (नियम-9)।"

[फा.सं.3-1/2000-एचएमएमडी]

गिनेश कुमार सिंह, संयुक्त सचिव

टिप्पण : मूल नियम भारत के राजपत्र, असाधारण, भाग-II, खंड 3, उप-खंड (i) में अधिसूचना सं. मा.का.नि. 343 (अ) तारीख 28 मार्च, 2016 द्वारा प्रकाशित किए गए थे और पश्चान्वर्ती अधिसूचना सं. मा.का.नि. 234 (अ) तारीख 16 मार्च, 2018 द्वारा संशोधित किए गए थे।

NOTIFICATION

New Delhi, the 19th February, 2019

G.S.R. 129(E).—In exercise of the powers conferred by Sections 6.8 and 25 of the Environment (Protection) Act, 1986 (29 of 1986) read with sub-rule (4) of rule 5 of the Environment (Protection) Rules, 1986, the Central Government, after having dispensed with the requirement of notice under clause(a) of sub-rule (3) of rule 5 of the said rule in public interest, hereby makes the following rules further to amend the Bio-Medical Waste Management Rules, 2016, namely:-

1. (1) These rules may be called the Bio-Medical Waste Management (Amendment) Rules, 2019.
- (2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Bio-Medical Waste Management Rules, 2016 (herein after referred to as the said rules), in rule 4,-
- (i) For clause (n), the following clause, shall be substituted, namely:-
- “(n) .in case of all bedded health care units, maintain and update on day to day basis the bio-medical waste management register and display the monthly record on its website according to the bio-medical waste generated in terms of category and colour coding as specified in Schedule I:”;
- (ii) For clause (p), the following clause shall be substituted, namely:-
- “(p) ,in case of all bedded health care facilities (any number of beds), make available the annual report on its web-site within a period of two years from the date of publication of the Bio-Medical Waste Management (Amendment) Rules, 2018:”.
3. In Schedule II to the said rules, against serial number 8, in item (1), in the Note, for clause 3, the following clause shall be substituted, namely: -
- “3. *Health Care Facilities having less than ten beds shall have to comply with the output discharge standard for liquid waste by 31st December, 2019.*”
4. In Schedule III to the said rules, -
- (i) Against serial number 3, in column (3), after item (vi), the following item shall be inserted, namely: -
- “(vii) Inspection and monitoring of Medical Inspection (MI) rooms, sick bays onboard ships or submarines, station medical centres and field hospitals in forward locations operated by the Director General, Armed Force Medical Services.”;
- (ii) Against serial number 4, in column (3), for item (viii), the following item shall be is substituted, namely: -
- “(viii) Inspection and monitoring of health care facilities other than Medical Inspection (MI) rooms, sick bays on board ships or submarines, station medical centres and field hospitals in forward locations operated by the Director General, Armed Forces Medical Services (Rule-9).”.

[F. No. 3-1/2000-HSMD]
RITESH KUMAR SINGH, Jt. Secy.

Note : The Principal rules were published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R. 343(E), dated the 28th March, 2016 and subsequently amended vide number G.S.R. 234(E), dated the 16th March, 2018.

टिप्पण : मूल नियम भारत के राजपत्र, अमाधारण, भाग- , खंड 3, उप-खंड (i) में अधिमूचना सं. सा.का.नि. 343 (अ) तारीख, 28 मार्च, 2016 द्वारा प्रकाशित किए गए थे और नत्पश्चात इनमें अधिमूचना सं. सा.का.नि. 234 (अ) तारीख 16 मार्च, 2018 और सं. सा.का.नि. 129 (अ) 19 फरवरी, 2019 द्वारा संशोधन किए गए थे।

New Delhi, the 10th May, 2019

G.S.R. 360(E).—In exercise of the powers conferred by Sections 6, 8 and 25 of the Environment (Protection) Act, 1986 (29 of 1986) read with sub-rule (4) of rule 5 of the Environment (Protection) Rules, 1986, the Central Government, after having dispensed with the requirement of notice under clause (a) of sub-rule (3) of rule 5 of the said rule in public interest, hereby makes the following rules further to amend the Bio-Medical Waste Management Rules, 2016, namely:—

1. (1) These rules may be called the Bio-Medical Waste Management (Second Amendment) Rules, 2019.

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

2. In the Bio-Medical Waste Management Rules, 2016 (hereinafter referred to as the said rules), in rule 4, in clause (d), the following Explanation shall be inserted, namely:—

“Explanation.— For removal of doubts, it is hereby clarified that the expression “Chlorinated plastic bags” shall not include urine bags, effluent bags, abdominal bags and chest drainage bags.”.

3. In Schedule III to the said rules, against serial number 3, in column (3), in item (viii), for the brackets and letters “(viii)”, the brackets and letters “(vii)” shall be substituted.

[F. No. 3-1/2000-HSMD]

ARVIND KUMAR NAUTIYAL, Jt. Secy.

Note: The principal rules were published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), *vide* number G.S.R. 343(E), dated the 28th March, 2016 and subsequently amended *vide* number G.S.R. 234(E), dated the 16th March, 2018 and number G.S.R. 129(E), dated the 19th February, 2019.