BEFORE THE HON'BLE NATIONAL GREEN TRIBUNAL

PRINCIPAL BENCH, NEW DELHI

Original Application No. 497/2024

IN THE MATTER OF: -

News item titled "Impact of Pharmaceutical toxicity on the environment and its regulatory aspects" appearing in current science dated 25.02.2024

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Filed by Adv. Mohit Singhal
(On behalf of Central Pollution Control Board)

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Date: - 16.08.2024
Place: Delhi

NOTARY PUBLIC R.L. Chaudhary N.C.T. of Delhi Regd. No. 1513 GOVT. OF INDIA

BEFORE HON'BLE NATIONAL GREEN TRIBUNAL,
PRINCIPAL BENCH, AT NEW DELHI
Original Application No. 497 OF 2024

Suo-moto 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 on behalf of the Respondent No.73 i.e, Central Pollution Control Board (CPCB)

1. That, Hon'ble NGT vide order dated 06.05.2024 has sought the reply of this answering respondent in the instant matter. Thereby, the reply is made in succeeding paragraphs on behalf of this answering respondent.

2. That, it is submitted that the Central Pollution Control Board (CPCB) is a statutory Board constituted under Section 3 of The Water (Prevention and Control of Pollution) Act, 1974 and it performs the functions under The Water (Prevention and Control of Pollution) Act, 1974, The Air (Prevention and Control of Pollution) Act, 1981 and The Environment (Protection) Act, 1986.

3. That, it is respectfully submitted that the residue of antibiotic and Active Pharmaceutical Ingredient (API) is considered as one of the potential source of antimicrobial resistance(AMR) in the environment and monitoring of the same is in primary stage. The United States Environment Protection Authority ('USEPA') analysis method is available for measuring level of antibiotic residue in effluent. (**Annexure R1**).

4. It is humbly submitted that the operation of the Order dated 06.04.2022 passed by Hon'ble NGT in the O.A. no. 136 of 2020 regarding notification of standard w.r.t antibiotic residue (draft notification no. G.S.R. 44(E) dated 23.01.2020 – placed as **Annexure R2**) has been stayed vide Order dated 17.10.2022 of Hon'ble Supreme Court

in Civil Appeal No. 8056-8057 of 2022 (Civil Appeal Diary No. 25732/2022 - **Annexure R3**).

5. That, it is humbly submitted that as per direction given by the Hon'ble NGT vide its order dated 23.06.2021 in O.A. No 136 of 2020 titled "*Veterans Forum for Transparency in Public Life vs. State of Himachal Pradesh & Ors*", CPCB has developed "Guidelines on Monitoring mechanism for API residue" **(Annexure R4)** which has been circulated to all SPCBs/PCCs vide letter dated 31.01.2022 for regular surveillance and monitoring of manufacturing units and CETPs by SPCBs.

6. That, the MoEF&CC has notified the effluent and emission standards for Bulk Drug and Formulation (Pharmaceutical) Industry vide G.S.R. 541(E) dated 6th August, 2021 **(Annexure R5).** The Notification stipulates that:

i. 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 formulations of pharmaceuticals, has been classified as Hazardous Waste as per the provisions of the Hazardous Waste and Other Wastes (Management and Transboundary Movement) Rules, 2016 and shall be managed in environmentally sound manner in accordance with these rules.

NOTARY PUBLIC R.L. Chaudhary N.C.T. of Delhi Regd. No. 1513 GOVT. OF INDIA

ii. "State Pollution Control Board shall prescribe additional relevant parameters as given in para A (ii) of notification vide GSR 541(E) dated 6th August, 2021 as per needs and discharge potential of member industries and specify the frequency of monitoring considering the receiving environment conditions."

7. That, it is respectfully submitted that to reduce antibiotic residue from effluent sources, it is prudent for a pharmaceutical industry to adopt the principles of reduce, recycle and reuse of treated effluent to maximum extent or to attain Zero Liquid Discharge (ZLD) to minimize risk of subject residues.

8. That, it is submitted that the Trace Organics Laboratory at Head Office of CPCB has validated method for 21 most consumable API/Pharmaceuticals Compounds out of 121 antibiotics sold in India with Limit of quantification (LOQ) by using LC/MS/MS (USEPA Method 1694) **(Annexure R1)**.

9. That the expired or Discarded Medicines shall be treated and disposed off in accordance with Schedule I, and in compliance with the standards prescribed in Schedule-II of the Bio-medical Waste Management Rules, 2016 (BMW Rules), as amended time to time **(Annexure R6)**.

10. That the Date-expired products generated from production/formulation of drugs/pharmaceutical and health care product is categorized as hazardous waste as category 28.5 of Schedule I of Hazardous & Other Wastes (Management and Trans-boundary Movement) Rules, 2016, as amended time to time **(Annexure R7).** As per the Rules, the handling, generation, collection, storage, packaging, transportation, use, treatment, processing, co-processing, utilisation, offering for sale, transfer or disposal of the hazardous waste shall be carried out only after obtaining authorisation from the concerned State Pollution Control Board / Pollution Control Committee and in accordance with the provisions and procedures laid down under the said Rules.

11. That, the answering respondent craves leave of the Hon'ble Tribunal for filing additional reply, in future, if required.

12. That, the answering respondent shall abide by any order or direction passed by this Hon'ble Tribunal in the instant matter.

NOTARY PUBLIC
R.L. Chaudhary
N.C.T. of Delhi
Regd. No. 1513
GOVT. OF INDIA

(Dinabandhu Gouda)
Scientist 'F'
Central Pollution Control Board

BEFORE HON'BLE NATIONAL GREEN TRIBUNAL,

PRINCIPAL BENCH, AT NEW DELHI

OA No. 497 OF 2024

In Matter of: -

Suo-moto 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

AFFIDAVIT

I, Dinabandhu Gouda S/o Late Brundaban Gouda, working as Scientist 'F' in Central Pollution Control Board, office at Parivesh Bhawan, East Arjun Nagar, Vishwas Nagar, Near Karkardooma Court, Delhi- 110032, do hereby solemnly affirm and declare as under:

1. That I, in capacity of Scientist 'F' of CPCB, have made myself acquainted with the facts and circumstances of the instant case due to the official capacity as mentioned above and on the basis of available records, I am well versed with the facts and circumstances of the matter and as such competent & authorized to affirm this reply on behalf of Respondent No. 3.

2. That, I have read and understood the averments made by Applicants in synopsis, list of dates, grounds and annexures enclosed with the Original Application and at the outset it is respectfully submitted that all averments/contentions/submissions made in the present Application are denied unless specifically admitted by the answering respondent and are also borne out of available record of the case.

NOTARY PUBLIC
R.L. Chaudhary
N.C.T. of Delhi
Regd. No. 1513
GOVT. OF INDIA

DEPONENT

दीनबन्धु गोडा /Dinabandhu Gouda
प्रभागीय प्रमुख, आई.पी.सी.-I/Divisional Head, IPC-I
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पर्यावरण, वन एवं जलवायु परिवर्तन मंत्रालय, भारत सरकार
M/o Envt. Forest & Climate Change, Govt. of India
परिवेश भवन, पूर्वी अर्जुन नगर, दिल्ली-110032
Parivesh Bhawan, East Arjun Nagar, Delhi-110032

VERIFICATION

Verified at NEW DELHI on this 16 AUG 2024 ..... day of August, 2024 that the contents of the above reply affidavit are correct and true on the basis of the record of the case as maintained in the day-to-day affairs of the CPCB. Nothing has been concealed therefrom or mis-stated.

NOTARY PUBLIC
R.L. Chaudhary
N.C.T. of Delhi
Regd. No. 1513
GOVT. OF INDIA

DEPONENT

दीनबन्धु गोडा /Dinabandhu Gouda
प्रभागीय प्रमुख, आई.पी.सी.-I/Divisional Head, IPC-I
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ATTESTED
NOTARY PUBLIC
GOVT. OF INDIA
16 AUG 2024

Method 1694: Pharmaceuticals and Personal Care Products in Water, Soil, Sediment, and Biosolids by HPLC/MS/MS

December 2007

U.S. Environmental Protection Agency
Office of Water
Office of Science and Technology
Engineering and Analysis Division (4303T)
1200 Pennsylvania Avenue, NW
Washington, DC 20460

EPA-821-R-08-002
December 2007

Introduction

EPA Method 1694 determines pharmaceuticals and personal care products (PPCPs) in environmental samples by high performance liquid chromatography combined with tandem mass spectrometry (HPLC/MS/MS) using isotope dilution and internal standard quantitation techniques. This method has been developed for use with aqueous, solid, and biosolids matrices.

Disclaimer

This method has been reviewed by the Engineering and Analytical Support Branch of the Engineering and Analysis Division (EAD) in OST. The method is available for general use, but has not been published in 40 CFR Part 136. Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

Contacts

Questions concerning this method or its application should be addressed to:

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Method 1694
Pharmaceuticals and Personal Care Products in Water, Soil, Sediment, and Biosolids by HPLC/MS/MS

1.0 Scope and Application

1.1 Method 1694 is for determination of pharmaceuticals and personal care products (PPCPs) in multi-media environmental samples by high performance liquid chromatography combined with tandem mass spectrometry (HPLC/MS/MS).

1.2 This method was developed for use in Clean Water Act (CWA) programs; other applications are possible. It is based on existing EPA methods (Reference 1) and procedures developed at Axys Analytical Services (Reference 2) as well as previous work on pharmaceuticals and personal care products (Reference 3).

1.3 The target analytes and their corresponding Chemical Abstracts Service Registry Numbers (CASRNs) are listed in Table 1.

1.4 The detection limits and quantitation levels in this method are usually dependent on the level of interferences rather than instrumental limitations. The method detection limits (MDLs; 40 CFR 136, appendix B) and minimum levels of quantitation (MLs; 68 FR 11790) in Tables 3, 5, 7, and 9 are the levels at which the analytes can be determined in the absence of interferences.

1.5 This method is restricted to use by or under the supervision of analysts experienced in LC/MS/MS or under the close supervision of such qualified persons. Each laboratory that uses this method must demonstrate the ability to generate acceptable results using the procedure in Section 9.2.

1.6 This method is performance-based which means that you may modify the method to improve performance (e.g., to overcome interferences or improve the accuracy or precision of the results) provided that you meet all performance requirements in this method. These requirements for establishing equivalency of a modification are in Section 9.1.2. For Clean Water Act (CWA) uses, additional flexibility is described at 40 CFR 136.6. Modifications that are not within the scope of Part 136.6, or in Section 9 of this method may require prior review and approval.

1.7 Some of the compounds in this method are controlled substances. Laboratories performing this method should have all appropriate licenses and certifications and obtain all needed standards and chemicals from licensed sources. For some of the compounds in this method it may be necessary for laboratories to obtain a DEA license.

2.0 Summary of Method

The target analytes in this method are divided into four groups (1 through 4). Each group represents an LC/MS/MS run, as detailed in Tables 2 to 9 in Section 23. Tables 2 and 3 are specific to Group 1. Tables 4 and 5 are specific to Group 2. Tables 6 and 7 are specific to Group 3. Tables 8 and 9 are specific to Group 4.

Groups 1, 2, and 3 are extracted under acidic (pH 2) conditions. Groups 1 and 2 are run in the positive electrospray ionization (ESI+) mode and Group 3 is run in the negative electrospray ionization (ESI-) mode. Group 4 is extracted under basic (pH 10) conditions and is run in the ESI+ mode. Group 3 is specific to the tetracyclines.

The general steps in this method are summarized in Section 2.1 to 2.7. A flow chart that summarizes procedures for sample preparation, cleanup, and analysis is shown in Figure 1.

2.1 Aqueous samples absent visible particles and filtrate from samples with visible particles – The pH of a 1-L sample aliquot is adjusted to 2 with acid. The pH of a second 1-L aliquot of sample is adjusted with 10 with base. Stable, isotopically labeled analogs of the analytes of interest are spiked into their respective acid or base fraction. The acid fraction is stabilized with tetrasodium ethylenediamine-tetraacetate dihydrate (NA4EDTA.2H2O•2H_2O).

2.2 Solid and semi-solid samples, including biosolids and visible particles from aqueous samples – A phosphate buffer and an ammonium hydroxide solution are used to adjust the pH, respectively, of up to 1 g each of dry solids from a solid sample, or 1 g each of dry solids filtered from an aqueous sample. The labeled compounds are spiked into their respective acid and base fractions. The acid fraction is ultrasonically extracted three times with a phosphate buffer/acetonitrile solution and the base fraction is ultrasonically extracted three times with a ammonium hydroxide/acetonitrile solution. The solutions are concentrated to remove the acetonitrile and diluted with reagent water. The acid fraction is stabilized with NA4EDTA.2H2O•2H_2O.

2.3 Sample cleanup – The acid and base fraction solutions are separately cleaned up using solid-phase extraction (SPE) with hydrophilic-lipophillic balance (HLB) cartridges. After cleanup, the fractions are exchanged to methanol, labeled injection internal standards are added, and the final volume is adjusted to 4 mL with the LC elution solvent.

2.4 Determination by LC/MS/MS – The acid extract is analyzed in two positive electrospray ionization (ESI+) LC/MS/MS runs and one negative electrospray ionization (ESI-) run, each specific to a subset of the analytes of interest. The base extract is analyzed in a single ESI+ run. The analytes are separated by the LC and detected by a tandem (1000 resolution) mass spectrometer. A daughter m/z for each compound is monitored throughout a pre-determined retention time window.

2.5 An individual compound is identified by comparing the LC retention time and presence of the daughter m/z with the corresponding retention time and daughter m/z of an authentic standard.

2.6 Quantitative analysis is performed in one of two ways, using selected ion current profile (SICP) areas:

2.6.1 For a compound for which a labeled analog is available, the concentration is determined using the isotope dilution technique and a multipoint calibration of all the target analytes. Isotope dilution provides automatic correction of the target analyte concentrations.

2.6.2 For a compound for which a labeled analog is not available, the concentration is determined using the internal standard technique and a multipoint calibration of all the target analytes. The labeled compounds are used to recovery correct results of those analytes quantitated by the internal standard technique.

2.6.3 Additional labeled compounds may be incorporated into this method, at the user's discretion to determine the concentration of the native compound using the isotope dilution technique provided that all performance requirements in this method are met. Requirements for establishing equivalency are given in Section 9.1.2, and additionally for CWA uses, at 40 CFR 136.6.

2.7 The quality of the analysis is assured through reproducible calibration and testing of the extraction, cleanup, and LC/MS/MS systems.

3.0 Definitions and Units of Measure

Definitions and units of measure are given in the glossary at the end of this method.

4.0 Interferences

4.1 Solvents, reagents, glassware, and other sample processing hardware may yield artifacts, elevated baselines, matrix enhancement or matrix suppression causing misinterpretation of chromatograms. Specific selection of reagents and purification of solvents by distillation in all-glass systems may be required. Where possible, reagents are cleaned by extraction or solvent rinse.

4.2 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.

4.2.1 Glassware should be rinsed with solvent and washed with a detergent solution as soon after use as is practical. Sonication of glassware containing a detergent solution for approximately 30 seconds may aid in cleaning. Glassware with removable parts, particularly separatory funnels with fluoropolymer stopcocks, must be disassembled prior to detergent washing.

4.2.2 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.

4.2.3 Baking of glassware in a kiln or other high temperature furnace (300 – 500 EC) may be useful after particularly dirty samples are encountered. The kiln or furnace should be vented to prevent laboratory contamination by vapors. Baking should be minimized, as repeated baking of glassware may cause active sites on the glass surface that may irreversibly adsorb the compounds of interest. Volumetric ware should not be baked at high temperature.

4.2.4 After drying and cooling, glassware should be sealed and stored in a clean environment to prevent any accumulation of dust or other contaminants. Store inverted or capped with solvent rinsed aluminum foil.

4.3 All materials used in the analysis must be demonstrated to be free from interferences by running reference matrix method blanks (Section 9.5) initially and with each sample batch (samples started through the extraction process on a given 12-hour shift, to a maximum of 20 samples).

4.3.1 The reference matrix must simulate, as closely as possible, the sample matrix under test. Ideally, the reference matrix should not contain the analytes of interest in detectable amounts, but should contain potential interferents in the concentrations expected to be found in the samples to be analyzed.

4.3.2 When a reference matrix that simulates the sample matrix under test is not available, reagent water (Section 7.6.1) can be used to simulate water samples; playground sand (Section 7.6.2) can be used to simulate soils; and peat moss (Section 7.6.3) can be used to simulate biosolids.

4.4 Interferences co-extracted from samples will vary considerably from source to source, depending on the diversity of the site being sampled. Interfering compounds may be present at concentrations several orders of magnitude higher than the analytes of interest. Because low levels of PPCPs are measured by this method, elimination of interferences is essential. The cleanup steps given in Section 13 can be used to reduce or eliminate these interferences and thereby permit reliable determination of the PPCPs at the levels shown in Tables 3, 5, 7, and 9.

4.5 It may be useful to number reusable glassware is to associate that glassware with the processing of a particular sample. This will assist the laboratory in tracking possible sources of contamination for individual samples, identifying glassware associated with highly contaminated samples that may require extra cleaning, and determining when glassware should be discarded.

4.6 Contamination from personal care products used by laboratory staff that are also target analytes is possible. Target analytes also include commonly used medications. Therefore, it is important to take precautions to avoid contamination of the samples, for example wearing of protective gloves and clothing (see Section 5).

5.0 Safety

The target analytes in this method have many beneficial uses as pharmaceuticals or over-the-counter products. While their safety is less of a concern than for many environmental contaminants, laboratory staff should avoid direct contact with samples and pure standards. General guidelines are provided below.

5.1 The toxicity or carcinogenicity of each chemical used in this 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. It is recommended that the laboratory purchase dilute standard solutions of the analytes in this method. However, if primary solutions are prepared, they should be prepared in a hood, and a NIOSH/MESA approved toxic gas respirator may be necessary when high concentrations are handled

5.2 This method does not address all safety issues associated with its use. The laboratory is responsible for maintaining a current awareness file of OSHA regulations regarding the safe handling of the chemicals specified in this method. A reference file of material safety data sheets (MSDSs) should also be made available to all personnel involved in these analyses. It is also suggested that the laboratory perform personal hygiene monitoring of each analyst who uses this method and that the results of this monitoring be made available to the analyst. Additional information on laboratory safety can be found in References 4 – 7. The references and bibliography at the end of Reference 6 are particularly comprehensive in dealing with the general subject of laboratory safety.

5.3 The pure PPCPs and samples suspected to contain high concentrations of these compounds should be handled with care.

5.3.1 Facility – When finely divided samples (dusts, soils, dry chemicals) are handled, all operations (including removal of samples from sample containers, weighing, transferring, and mixing) should be performed in a glove box demonstrated to be leak tight or in a fume hood demonstrated to have adequate air flow. Gross losses to the laboratory ventilation system must not be allowed. Handling of the dilute solutions normally used in analytical and animal work presents no inhalation hazards except in the case of an accident.

5.3.2 Protective equipment – 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.

5.3.3 Training – Workers must be trained in the proper method of removing contaminated gloves and clothing without contacting the exterior surfaces.

5.3.4 Personal hygiene – 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).

5.3.5 Confinement – Isolated work areas posted with signs, segregated glassware and tools, and plastic absorbent paper on bench tops will aid in confining contamination.

5.3.6 Waste handling – Good technique includes minimizing contaminated waste. Plastic bag liners should be used in waste cans. Janitors and other personnel should be trained in the safe handling of waste. See Section 20 for additional information on waste handling and disposal.

5.4 Biosolids 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 biosolids samples.

6.0 Equipment and Supplies

Note: *Brand names, suppliers, and part numbers are cited for illustration purposes only. No endorsement is implied. Equivalent performance may be achieved using equipment and materials other than those specified here. Demonstration of equivalent performance that meets the requirements of this method is the responsibility of the laboratory.*

6.1 Sample bottles and caps

6.1.1 Liquid samples (waters, sludges and similar materials containing 5 percent solids or less) – Sample bottle, amber glass, 1 L minimum, with screw cap.

6.1.2 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.

6.1.3 If amber bottles are not available, samples must be protected from light.

6.1.4 Bottle caps – Threaded to fit sample bottles. Caps must be lined with fluoropolymer.

6.1.5 Cleaning – Bottles are washed with detergent and water, then solvent rinsed before use. Liners are washed with detergent and water and rinsed with reagent water before use.

6.2 Compositing equipment – Automatic or manual compositing system incorporating glass containers cleaned per bottle cleaning procedure above. Only glass or fluoropolymer tubing must be used. If the sampler uses a peristaltic pump, a minimum length of compressible silicone rubber tubing may be used in the pump only. Before use, the tubing

must be thoroughly rinsed with methanol, followed by repeated rinsing with reagent water to minimize sample contamination. An integrating flow meter is used to collect proportional composite samples.

6.3 Equipment for sample preparation

6.3.1 Laboratory fume hood of sufficient size to contain the sample preparation equipment listed below.

6.3.2 Glove box (optional)

6.3.3 Tissue homogenizer – VirTis Model 45 Macro homogenizer (American Scientific Products H-3515, or equivalent) with stainless steel Macro-shaft and Turbo-shear blade.

6.3.4 Vortex mixer

6.3.5 Ultrasonic mixer

6.3.6 Oven – Capable of maintaining a temperature of 110∀5 °C

6.3.7 Desiccator

6.3.8 Balance, analytical – Capable of weighing 0.1 mg

6.3.9 Balance, top loading – Capable of weighing 10 mg

6.4 Apparatus for measuring pH

6.4.1 pH meter, with combination glass electrode

6.4.2 pH paper, wide range (Hydrion Papers, or equivalent)

6.5 Apparatus for ultrasonic and solid-phase extraction

6.5.1 Sonic disrupter – 375 watt with pulsing capability and ½ or ¾ in. disrupter horn (Ultrasonics, Inc., Model 375, or equivalent)

6.5.2 Sonabox (or equivalent), for use with disrupter.

6.5.3 Vac-Elute Manifold (Analytichem International, or equivalent)

6.5.4 Vacuum trap: Made from 500-mL sidearm flask fitted with single-hole rubber stopper and glass tubing.

6.5.5 Vacuum source – Capable of maintaining 25 in. Hg, equipped with shutoff valve and vacuum gauge.

6.5.6 Rack for holding 50-mL volumetric flasks in the manifold.

6.5.7 SPE cartridge – Hydrophilic-Lipophilic-Balance (HLB) 60 mg, Waters Oasis, 20 cc/1 g LP, 60 µm, or equivalent, calibrated per the procedure in Section 10.6.

6.6 Filtration apparatus

6.6.1 Vacuum filtration apparatus – 1-L , including glass funnel, frit support, clamp, adapter, stopper, filtration flask, and vacuum tubing. For wastewater samples, the apparatus should accept 90- or 144-mm disks.

6.6.2 Glass-fiber filter – Whatman GMF 150 (or equivalent), 1 micron pore size, to fit the vacuum filtration apparatus.

6.6.3 Pressure filtration apparatus – Millipore YT30 142 HW, or equivalent.

6.6.4 Whatman GF/A (1.6 µm), or equivalent, differing diameters, to fit the pressure filtration apparatus.

6.6.5 Millipore, 0.2 µm, or equivalent to fit the pressure filtration apparatus.

6.7 Centrifuge – Capable of rotating 500-mL centrifuge bottles or 50-mL centrifuge tubes at 5,000 rpm minimum, equipped with 500-mL centrifuge bottles (glass or polypropylene bottles) with screw-caps, and 50-mL centrifuge tubes with screw-caps, to fit centrifuge.

6.8 Pipet apparatus and pipets

6.8.1 Pipetter – variable volume

6.8.2 Pipet tips, disposable polypropylene, sizes from 1-10 µL to 5 mL

6.8.3 Disposable, Pasteur, 150-mm long x 5-mm ID (Fisher Scientific 13-678-6A, or equivalent)

6.8.4 Disposable, serological, 50-mL (8- to 10- mm ID)

6.9 Rotary evaporator – Buchi/Brinkman-American Scientific No. E5045-10, or equivalent, equipped with a variable temperature water bath and a vacuum source with shutoff valve at the evaporator and vacuum gauge. A recirculating water pump and chiller are recommended, as use of tap water for cooling the evaporator wastes large volumes of water and can lead to inconsistent performance as water temperatures and pressures vary.

6.9.1 Round-bottom flask – 100-mL and 500-mL or larger, with ground-glass fitting compatible with the rotary evaporator

6.9.2 Boiling chips

6.9.2.1 Glass or silicon carbide – Approximately 10/40 mesh, extracted with methylene chloride and baked at 450 EC for one hour minimum

6.9.2.2 Fluoropolymer (optional) – Extracted with methylene chloride

6.10 Water bath – Heated, with concentric ring cover, capable of maintaining a temperature within ∀ 2 EC, installed in a fume hood.

6.11 Nitrogen evaporation apparatus – Equipped with water bath controlled in the range of 30 – 60 EC (N-Evap, Organomation Associates, Inc., South Berlin, MA, or equivalent), installed in a fume hood.

6.12 Amber glass vials, 2- to 5-mL with fluoropolymer-lined screw-cap

6.13 Clear glass vials, 0.3-mL, conical, with fluoropolymer-lined screw or crimp cap

6.14 HPLC/MS/MS System

6.14.1 HPLC system with high pressure inlet, multi-segment gradient capability, and post-column pump for admission of calibrant. The system must be able to produce the LC separations for the analytical runs detailed in Tables 3, 5, 7, and 9 under the instrument conditions detailed in Tables 2, 4, 6, and 8, and must meet other HPLC requirements in this method (Waters 2690, 2795, or equivalent).

6.14.2 LC columns

6.14.2.1 C_{18} – 10.0 cm, 2.1 mm i.d., 3.5 :m particle size (Waters Xtera C18MS, or equivalent)

6.14.2.2 Hydrophilic – 10 cm. 2.1 mm i.d., 3.0 µm particle size (Waters Atlantis HILIC, or equivalent)

6.14.2.3 Alternative columns other than described above have not been tested and are not allowed for this method. EPA may establish criteria for equivalency in later versions of this method.

6.14.3 MS/MS system

6.14.3.1 Tandem MS with the necessary pumps, collision cell, makeup gases, high vacuum system, and capability for positive and negative ion electrospray ionization (ESI) of the effluent from the HPLC. (Waters Quattro Ultima triple quadrupole MS, or equivalent). The system must be able to produce parent-daughter transitions for the groups of compounds in the acid and base fractions of the PPCPs for the analytical runs detailed in Tables 3, 5, 7, and 9.

6.14.3.2 Instrument control and data system – Interfaced to the HPLC and MS/MS to control the LC gradient and other LC and MS/MS operating conditions, and to acquire, store, and reduce LC/MS/MS data. The data system must be able to identify a compound by retention time and parent-daughter m/zs, and quantify the compound using linear or

quadratic multi-point relative responses and response factors by isotope dilution and internal standard techniques.

6.15 Miscellaneous labware – Beakers, 400- to 500-mL; Erlenmeyer flasks; volumetric flasks; pipets; syringes; stainless steel spatulas; etc.

7.0 Reagents and Standards

Note: All r*eagents are ACS Reagent Grade unless specified otherwise.*

7.1 pH adjustment and solution stabilization

7.1.1 Potassium hydroxide – Dissolve 20 g reagent grade KOH in 100 mL reagent water.

7.1.2 Sulfuric acid – Reagent grade (specific gravity 1.84)

7.1.3 Hydrochloric acid – Reagent grade, 6N

7.1.4 Phosphoric acid (H_3PO_4) – Reagent grade (85%), Fisher, or equivalent

7.1.5 Sodium chloride – Reagent grade, prepare at 5% (w/v) solution in reagent water

7.1.6 Ammonium hydroxide (NH_4OH) – Reagent grade, Anachemia, or equivalent

7.1.7 Sodium dihydrogen phosphate monohydrate – Reagent grade, J.T. Baker, or equivalent

7.1.8 Oxalic acid, anhydrous

7.2 Prepurified nitrogen

7.3 Solvents, reagents, and solutions

7.3.1 Acetic acid, acetone, acetonitrile ammonium acetate, formic acid, methanol, methylene chloride, HPLC water, ammonium formate.

7.3.2 Solvents and purchased solutions should be lot-certified to be free of interferences. If necessary, solvents should be analyzed by this method to demonstrate that they are interference free.

7.4 Buffer and elution solutions

7.4.1 Phosphate buffer (sodium phosphate monohydrate/phosphoric acid) – 0.14 M $NaH_2PO_4.H_2O$ /85% H_3PO_4 (1.93 g $NaH_2PO_4.H_2O$ in 99 mL of reagent water + 1 mL of 85% H_3PO_4)

7.4.2 Tetrasodium ethylenediamine tetraacetate hydrate ($Na_4EDTA \bullet 2H_2O$ ~+99.5%

titration), Sigma, used as received

7.4.3 Formic acid solutions – Alfa Aesar, >99 percent purity

7.4.3.1 2% v/v in methanol

7.4.3.2 0.1% v/v in methanol

7.4.3.3 Formic acid/ammonium formate (0.1%) in water – dissolve 4 mL of formic acid and 4 g of ammonium formate in 4.0 L of HPLC water. Mix thoroughly and sonicate for 5 min.

7.4.3.4 Formic acid (0.1%) in methanol:water (75:25) – add 4 mL of formic acid to 3.0 L methanol premixed with 1.0 L HPLC-grade water. Mix thoroughly and sonicate for 5 min.

7.4.4 Acetonitrile:methanol (1:1) – mix 500 mL methanol and 500 mL of acetonitrile. Sonicate for 5 min.

7.4.5 Oxalic acid solution (5 mM) – dissolve 0.45 g anhydrous oxalic acid in 1.0 L of HPLC water. Mix thoroughly and sonicate for 5 min.

7.4.6 Oxalic acid/acetonitrile/methanol (5 mM) – dissolve 0.45 g anhydrous oxalic acid in 500 mL acetonitrile premixed with 500 mL methanol. Mix thoroughly and sonicate for 5 min.

7.4.7 Acetonitrile/water (90%) – Add 400 mL HPLC-grade water to 3600 mL of acetonitrile. Mix thoroughly and sonicate for 5 min.

7.4.8 Ammonium acetate/acetic acid, 1 mM (0.1%) in water – Add 4 g NH_4OAC and 4 mL acetic acid to 4.0 L of HPLC-grade water. Mix thoroughly and sonicate for 5 min.

7.5 Sodium iodide/cesium iodide mass calibration solution – 2 mg/mL NaI and 50 µg/mL CsI in (1:1) isopropyl alcohol:water (Waters 700000889, or equivalent) or other based on manufacture's specifications.

7.6 Reference matrices – Matrices in which the PPCPs and interfering compounds are not detected by this method

7.6.1 Reagent water – Bottled water purchased locally, or prepared by passage through activated carbon

7.6.2 High-solids reference matrix – Playground sand or similar material.

7.6.2.1 Playground sand is used to simulate the base fraction of solids in this method, including biosolids (see Section 7.6.3.1 for simulation of the biosolids acid fraction) – Place 1 g of sand in a 50-mL centrifuge tube. Add 15 mL of reagent water and adjust the pH to 10 ± 0.5 with NH_4OH.

Add 20 mL of acetonitrile and sonicate for 20 minutes. Discard the aqueous phase.

7.6.2.2 Extract with a second 20-mL portion of acetonitrile. Decant and discard the acetonitrile. The sand is now ready for spiking (Section 11.5.4).

7.6.3 Biosolids (sludge) reference matrix – Dry peat moss, purchase from local garden center. Note: Store peat moss in closed container to prevent further drying. Sand may be used for the acid fraction if QC acceptance criteria (Section 9) are met.

7.6.3.1 Peat moss is used to simulate the acid fraction of biosolids in this method (see Section 7.6.2.1 for information on the biosolids base fraction) – Place 1 g of peat moss in a 50-mL centrifuge tube. Add 15 mL of phosphate buffer (Section 7.4.1) and vortex to mix. Extract with 20 mL of acetonitrile and discard the aqueous phase.

7.6.3.2 Extract with a second 20-mL portion of acetonitrile. Decant and discard the acetonitrile. The peat moss is now ready for spiking (Section 11.4.3).

7.6.4 Other matrices – Other reference matrices of interest may be used if the results from the tests given in Section 9.2 demonstrate acceptable performance. Ideally, the matrix should be free of the analytes of interest, but in no case must the background level of the analytes in the reference matrix exceed the minimum levels in Tables 3, 5, 7, and 9. If low background levels of the analytes of interest are present in the reference matrix, the spike level of the analytes used in Section 9.2 should be increased to provide a spike-to-background ratio of approximately 5 (Reference 8).

7.7 Standard solutions – Prepare from materials of known purity and composition or purchase as solutions or mixtures with certification to their purity, concentration, and authenticity. If the chemical purity is 98 % or greater, the weight may be used without correction to calculate the concentration of the standard. Observe the safety precautions in Section 5.

7.7.1 Preparation and storage of solutions - For preparation of stock solutions from neat materials, dissolve an appropriate amount of assayed reference material in solvent. For example, weigh 10 to 20 mg of Ampicillin to three significant figures in a 10-mL ground-glass-stoppered volumetric flask and fill to the mark with methanol. After the compound is completely dissolved, transfer the solution to a clean 15-mL vial with fluoropolymer-lined cap. When not being used, store standard solutions in the dark at less than -10 ºC in screw-capped vials with fluoropolymer-lined caps or under a non-reactive gas (e.g., nitrogen) in a flame-sealed glass ampul. Place a mark on the vial or ampul at the level of the solution so that solvent loss by evaporation can be detected. Replace the solution if solvent loss has occurred.

7.7.2 Native (unlabeled; authentic) compound spiking solution – Separately prepare Group 1 to Group 4 native compounds at the concentrations shown in column 3 of Table 10 in methanol, or purchase prepared solutions. If additional native compounds are to be determined, include these compounds in this stock solution.

Stock solutions should be prepared at a frequency necessary to preclude degradation from affecting the analysis. For example, it may be necessary to prepare the tetracycline compounds weekly if concentrations drop more than 30 % of their original concentration. Stock solutions should also be checked for signs of degradation prior to preparation of calibration or performance test standards.

7.7.3 Labeled compound spiking solution – Prepare Group 1 to Group 4 labeled compounds at the concentrations shown in column 3 of Table 10 in methanol, or purchase prepared solutions. If additional labeled compounds are to be used, include these compounds in this solution. Note: The Group 2, acid extracted positive ESI (tetracyclines) contains the same labeled compounds as for Group 1 and 3, acid extracted positive and negative ESI, yet the only labeled compounds used in determination of the Group 2 are Thiabendazole-d6 and 13C3-Atrazine. This minimizes the work required to prepare solutions. Some of those surrogates are used to quantify the Group 1 and 2 and some Group 3 in separate runs of the same extract. This is not a requirement.

7.7.4 Labeled injection internal standard spiking solutions – For the labeled injection internal standards for Groups 1 and 2, prepare ^{13}C-Atrazine in methanol at the concentration shown column 3 of Table 10. For the labeled injection internal standard for Group 3, prepare $^{13}C_6$-2,4,5-Trichlorophenoxyacetic acid (TCPAA) in methanol at the concentration shown in column 3 of Table 10. For the labeled injection internal standards for Group 4, prepare $^{13}C_3$-Atrazine and Continine-d3 in methanol at the concentrations shown in column 3 of Table 10. If additional labeled injection internal standards are to be used, include these compounds in these solutions.

7.7.5 Calibration standards – Combine and dilute the solutions in Sections 7.7.1 and 7.7.2 to produce the calibration solutions in Table 11 or purchase prepared standards for the CS-1 to CS-5 set of calibration solutions. These solutions permit the relative response (labeled to native) and response factor to be determined as a function of concentration. The CS-3 standard is used for calibration verification (VER).

7.8 QC Check Sample – A QC Check Sample should be obtained from a source independent of the calibration standards. Ideally, this check sample would be a Standard Reference Material (SRM) from the National Institute of Standards and Technology (NIST) containing the compounds of interest in known concentrations in a sample matrix similar to the matrix of interest. If no SRM is available, a certified reference material (CRM) may be used or a QC check sample may be prepared from materials from a source or lot of standards separate from those used for calibration and spiked into a clean reference matrix.

7.9 Stability of solutions – standard solutions used for quantitative purposes (Sections 7.7.2 - 7.7.5) should be assayed periodically (e.g., every 6 months) against SRMs from NIST (if available), or against certified reference materials from a source that will attest to the authenticity and concentration, to assure that the composition and concentrations have not changed.

8.0 Sample Collection, Preservation, Storage, and Holding Times

8.1 Collect samples in amber glass containers following conventional sampling practices (Reference 9).

8.2 Aqueous samples

8.2.1 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.

8.2.2 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. Ascorbic acid has also been used by a number of other groups as a preservative for a number of pharmaceuticals however it has not been tested for all of the pharmaceuticals covered under this method (Reference 10).

8.2.3 Maintain aqueous samples in the dark at <6 EC from the time of collection until receipt at the laboratory (see 40 CFR 136.6(e), Table II). If the sample will be frozen, allow room for expansion.

8.3 Solid, mixed-phase, and semi-solid samples, including biosolids

8.3.1 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.

8.3.2 Maintain solid, semi-solid, and mixed-phase samples in the dark at <6 EC from the time of collection until receipt at the laboratory. Store solid, semi-solid, and mixed-phase samples in the dark at less than -10 EC.

8.4 Store sample extracts in the dark at less than -10 EC until analyzed. Analyze extracts within 40 days of extraction.

8.5 Holding times

EPA has not conducted formal holding time studies for these analytes to date. Use the information below as guidance. Exceeding these default holding times does not invalidate the sample results.

8.5.1 Aqueous samples – Anecdotal evidence suggests that some may degrade rapidly in aqueous samples. Therefore, begin sample extraction within 7 days of collection (within 48 hours is strongly encouraged). Extracts should be analyzed within 40 days of extraction. Freezing of aqueous samples is encouraged to minimize degradation, in which case, samples should be extracted within 48 hours of removal from the freezer.

8.5.2 Biosolid, solid, mixed-phase, and semi-solid samples – Anecdotal evidence suggests that some may degrade rapidly in these samples. Therefore, begin sample extraction within 7 days of collection (within 48 hours is strongly encouraged). Extracts should be analyzed within 40 days of extraction. Freezing of biosolids, mixed phase and semisolid samples is encouraged to minimize degradation, in which case, samples should be extracted within 48 hours of removal from the freezer..

8.5.3 If extraction within 48 hours is not practical, samples should be frozen to increase the holding time to seven days.

8.5.4 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 aqueous samples are stored frozen, extraction should begin within 48 hours of removal from the freezer.

9.0 Quality Assurance/Quality Control

9.1 Each laboratory that uses this method is required to operate a formal quality assurance program (Reference 11). The minimum requirements of this program consist of an initial demonstration of laboratory capability, analysis of samples spiked with labeled compounds to evaluate and document data quality, and analysis of standards and blanks as tests of continued performance. Laboratory performance is compared to established performance criteria to determine if the results of analyses meet the performance characteristics of the method.

If the method is to be applied to sample matrix other than water (e.g., soil, sediment, filter cake, compost) the most appropriate alternate reference matrix (Sections 7.6.1 – 7.6.4) is substituted for the reagent water matrix (Section 7.6.1) in all performance tests.

9.1.1 The laboratory must make an initial demonstration of the ability to generate acceptable precision and recovery with this method. This demonstration is given in Section 9.2.

9.1.2 In recognition of advances that are occurring in analytical technology, and to overcome matrix interferences, the laboratory is permitted certain options to improve separations or lower the costs of measurements. These options include alternate extraction, concentration, and cleanup procedures, and changes in columns and detectors (see also 40 CFR 136.6). Alternate determinative techniques, such as the substitution of spectroscopic or immunoassay techniques, and changes that degrade method performance, are not allowed. If an analytical technique other than the techniques specified in this method is used, that technique must have a specificity equal to or greater than the specificity of the techniques in this method for the analytes of interest.

9.1.2.1 Each time a modification is made to this method, the laboratory is

required to repeat the procedure in Section 9.2. If the detection limit of the method will be affected by the change, the laboratory is required to demonstrate that the MDLs (40 CFR Part 136, Appendix B) are lower than one-third the regulatory compliance level or the MDLs in this method, whichever are greater. If calibration will be affected by the change, the instrument must be recalibrated per Section 10. Once the modification is demonstrated to produce results equivalent or superior to results produced by this method as written, that modification may be used routinely thereafter, so long as the other requirements in this method are met (e.g., labeled compound recovery).

9.1.2.2 The laboratory is required to maintain records of modifications made to this method. These records include the following, at a minimum:

9.1.2.2.1 The names, titles, addresses, and telephone numbers of the analyst(s) that performed the analyses and modification, and of the quality control officer that witnessed and will verify the analyses and modifications.

9.1.2.2.2 A list of compounds (s) measured, by name and CAS Registry number.

9.1.2.2.3 A narrative stating reason(s) for the modifications.

9.1.2.2.4 Results from all quality control (QC) tests comparing the modified method to this method, including:

a) Calibration (Section 10).
b) Calibration verification (Section 15.2).
c) Initial precision and recovery (Section 9.2).
d) Labeled compound recovery (Section 9.3).
e) Analysis of blanks (Section 9.5).
f) Accuracy assessment (Section 9.4).

9.1.2.2.5 Data that will allow an independent reviewer to validate each determination by tracing the instrument output (peak height, area, or other signal) to the final result. These data are to include:

a) Sample numbers and other identifiers.
b) Extraction dates.
c) Analysis dates and times.
d) Analysis sequence/run chronology.
e) Sample weight or volume (Section 11).
f) Sample or extract volume prior to each cleanup step (Section 12).
g) Extract volume after each cleanup step (Section 12).
h) Final extract volume prior to injection (Section 12).
i) Injection volume (Sections 10.2.1 and 14.2).

j) Dilution data, differentiating between dilution of a sample or extract (Section 17.5).
k) Instrument and operating conditions.
l) Column (dimensions, material, particle size, etc).
m) Operating conditions (flow rates, elution solvents, gradient, flow rates).
n) Detector (type, operating conditions, etc).
o) Chromatograms, printer tapes, and other recordings of raw data.
p) Quantitation reports, data system outputs, and other data to link the raw data to the results reported.

9.1.3 Analyses of method blanks are required to demonstrate freedom from contamination (Section 4.3). The procedures and criteria for analysis of a method blank are given in Sections 9.5 and 15.4.

9.1.4 The laboratory must spike all samples with labeled compounds to monitor method performance. This test is described in Section 9.3. When results of these spikes indicate atypical method performance for samples, the samples are diluted to bring method performance within acceptable limits. Procedures for dilution are given in Section 17.5.

9.1.5 The laboratory must, on an ongoing basis, demonstrate through calibration verification and the analysis of the ongoing precision and recovery standard (OPR) and blanks that the analytical system is in control. These procedures are given in Sections 15.1 through 15.4.

9.1.6 The laboratory should maintain records to define the quality of data generated. Development of accuracy statements is described in Section 9.4.

9.2 Initial precision and recovery (IPR) – To establish the ability to generate acceptable precision and recovery, the laboratory must perform the following operations.

9.2.1 For aqueous samples containing less than 1% solids, analyze four 1-L aliquots of reagent water (7.6.1) each for the acid and base fractions according to the procedures in Sections 11 through 18. For an alternate sample matrix, four aliquots each for the acid and base fractions of the alternate reference matrix (Sections 7.6.2-7.6.4) are used. All sample processing steps that are to be used for processing samples, including preparation (Section 11), extraction (Section 12), and cleanup (Section 13), must be included in this test.

9.2.2 Using results of the set of four analyses, compute the average percent recovery (X) of the concentration of each compound in each extract and the relative standard deviation (RSD) of the concentration for each compound, by isotope dilution for compounds with a labeled analog, and by internal standard for compounds without a labeled analog and for the labeled compounds.

9.2.3 For each native and labeled compound, compare RSD and X with the corresponding limits for initial precision and recovery in Table 12. If RSD and X

for all compounds meet the acceptance criteria, system performance is acceptable and analysis of blanks and samples may begin. If, however, any individual RSD exceeds the precision limit or any individual X falls outside the range for recovery, system performance is unacceptable for that compound. Correct the problem and repeat the test (Section 9.2).

9.3 To assess method performance on the sample matrix, the laboratory must spike all samples with the Labeled spiking solution (Section 7.7.3).

9.3.1 Analyze each sample according to the procedures in Sections 11 through 18.

9.3.2 Compute the percent recovery of the labeled compounds using the internal standard method (Sections 10.4 and 7.2).

9.3.3 The recovery of each labeled compound must be within the limits in Table 12. If the recovery of any compound falls outside of these limits, method performance is unacceptable for that compound in that sample. Additional cleanup procedures must then be employed to attempt to bring the recovery within the normal range. If the recovery cannot be brought within the normal range after all cleanup procedures have been employed, water samples are diluted and smaller amounts of soils, sludges, sediments, and other matrices are analyzed per Section 18.

9.4 Recovery of labeled compounds from samples should be assessed and recorded.

9.4.1 After the analysis of 30 samples of a given matrix type (water, soil, sludge, pulp, etc.) for which the labeled compounds pass the tests in Section 9.3, compute the average percent recovery (R) and the standard deviation of the percent recovery (S_R) for the labeled compounds only. Express the assessment as a percent recovery interval from R ! $2S_R$ to R + $2S_R$ for each matrix. For example, if R = 90% and S_R = 10% for 30 analyses of biosolids, the recovery interval is expressed as 70 to 110%.

9.4.2 Update the accuracy assessment for each labeled compound in each matrix on a regular basis (e.g., after each 5-10 new measurements).

9.5 Method blanks – A reference matrix method blank is analyzed with each sample batch (Section 4.3) to demonstrate freedom from contamination. The matrix for the method blank must be similar to the sample matrix for the batch, e.g., a 1-L reagent water blank (Section 7.6.1), high-solids reference matrix blank (Section 7.6.2), biosolids reference matrix blank (Section 7.6.3) or alternate reference matrix blank (Section 7.6.4).

9.5.1 Process the method blank(s) along with the IPR or batch of samples according to the procedures in Sections 11 through 18. Analyze the blank immediately after analysis of the OPR (Section 15.4) to demonstrate freedom from contamination.

9.5.2 If any compound of interest (Table 1) is found in the blank at greater than the minimum level (Tables 3, 5, 7, or 9) or one-third the regulatory compliance limit, whichever is greater; or if any potentially interfering compound is found in the blank above the minimum level for each native compound in Tables 3, 5, 7, or 9

(assuming a response factor of 1 relative to the quantitation reference in Tables 3, 5, 7, or 9 for a potentially interfering compound; i.e., a compound not listed in this method), analysis of samples must be halted until the sample batch is re-extracted and the extracts re-analyzed, and the blank associated with the sample batch shows no evidence of contamination at these levels. All samples must be associated with an uncontaminated method blank before the results for those samples may be reported or used for permitting or regulatory compliance purposes.

9.6 QC Check Sample – If available, analyze the QC Check Sample (Section 7.8) periodically to assure the accuracy of calibration standards and the overall reliability of the analytical process. It is suggested that the QC Check Sample be analyzed at least quarterly.

9.7 The specifications contained in this method can be met if the apparatus used is calibrated properly and then maintained in a calibrated state. The standards used for calibration (Section 10), calibration verification (Section 15.2), and for initial (Section 9.2) and ongoing (Section 15.4) precision and recovery should be identical, so that the most precise results will be obtained. A LCMSMS instrument will provide the most reproducible results if dedicated to the settings and conditions required for determination of PPCPs by this method.

9.8 Depending on specific program requirements, field replicates may be collected to determine the precision of the sampling technique, and spiked samples may be required to determine the accuracy of the analysis when the internal standard method is used.

10.0 Calibration and Standardization

10.1 Establish the LC/MS/MS operating conditions for the Group 1 through Group 4 compounds, as suggested in Tables 2, 4, 6, and 8, to meet the retention times in Tables 3, 5, 7, and 9, respectively. The LC conditions may be optimized for compound separation and sensitivity. Once optimized, the same conditions must be used for the analysis of all standards, blanks, IPR and OPR standards, and samples.

10.2 Retention time calibration for the native and labeled compounds

10.2.1 Inject the volume of CS-3 calibration standard (Section 7.7.5 and Table 11) listed in Table 2, 4, 6, or 8, or other volume appropriate to system optimization. Establish the beginning and ending retention times for the parent-daughter descriptors in Tables 3, 5, 7, and 9. Descriptors other than those listed may be used provided the MLs in those tables are met. Store the retention time (RT) for each compound in the data system.

10.2.2 The absolute retention time of last-eluted compound in each of the four Groups must be equal to or greater than its retention time in Tables 3, 5, 7, or 9; otherwise, the LC operating conditions must be adjusted and this test repeated until this minimum retention time criterion is met.

10.3 Mass spectrometer calibration and optimization

10.3.1 Mass calibration – The mass spectrometer must undergo mass calibration according to manufacture's specifications to ensure accurate assignments of m/z's by the instrument. This mass calibration must be performed at least annually to maintain instrument sensitivity and stability. It must be repeated after performing major maintenance on the mass spectrometer.

In the absence of vendor-specific instructions and acceptance criteria, the following procedure may be used.

10.3.1.1 Introduce the NaCsI calibration solution (Section 7.5) to the MS at the flow rate necessary to produce a stable aerosol spray (e.g., 10 µL/min).

10.3.1.2 Scan the MS/MS over the mass range from 20 to 3000 Daltons. Adjust the source parameters to optimize peak intensity and shape across the mass range. The exact m/z's for NaCsI calibration are:

Calibration Masses (Daltons)	
22.9898	1521.9321
132.9054	1671.8264
172.8840	1821.7206
322.7782	1971.6149
472.6725	2121.5091
622.5667	2271.4033
772.4610	2421.2976
922.3552	2571.1918
1072.2494	2721.0861
1222.1437	2870.9803
1372.0379	

10.3.1.3 Mass calibration is judged on the basis of the presence or absence of the exact calibration masses, e.g., a limit of the number of masses that are "missed." Absent vendor-specific instructions, all of the masses from 22.9898 to 1971.6149 must be present. If peaks above 1971 are missing or not correctly identified, adjust the MS/MS and repeat the test. Only after the MS/MS is properly calibrated may standards, blanks, and samples be analyzed.

10.3.2 Mass spectrometer optimization – Prior to measurements of a given analyte Group (Table 2, 4, 6, or 8), the mass spectrometer must be separately optimized for that Group.

10.3.2.1 Using the post-column pump (Section 6.14.1), infuse the CS-3 calibration solution (Table 11 a, b, or c) for the Group of interest.

10.3.2.2 Optimize sensitivity to the daughter m/z's for the high mass compounds in each Group (Table 3, 5, 7, or 9).

10.3.2.3 After MS calibration and optimization and LC/MS/MS calibration (Sections 10.4 and 10.5), MS and LC/MS/MS conditions may not be altered without verifying calibration (Section 15.2).

10.4 Calibration by isotope dilution – Isotope dilution is used for calibration of each native compound for which a labeled analog is available. The reference compound for each native compound is its labeled analog, as listed in Tables 3, 5, 7, and 9. A 5-point calibration encompassing the concentration range is prepared for each native compound. The calibration solutions are listed in Table 11.

10.4.1 To calibrate the analytical system by isotope dilution, inject calibration standards CS-1 through CS-5 (Section 7.7.5 and Table 11). Use the volume shown in identical to the volume chosen in Section 10.2.1, the procedure in Section 14, and the optimized operating conditions from Sections 10.1 - 10.3.

10.4.2 For the compounds determined by isotope dilution, the relative response (RR) (labeled to native) vs. concentration in the calibration solutions (Table 11) is computed over the calibration range according to the procedures below. Determine the response of each compound relative to its labeled analog using the area responses of the daughter m/zs specified in Tables 3, 5, 7, and 9. Use the labeled compounds listed in the tables as the quantitation reference and the daughter m/zs of these labeled compounds for quantitation. The area of the daughter m/z for the native compound is divided by the area of the daughter m/z of the labeled quantitation reference compound.

Note: *Other quantitation references and procedures may be used provided that the results produced are as accurate as results produced by the quantitation references and procedures described in this method.*

10.4.3 Calibrate the native compounds with a labeled analog using the following equation:

$$RR = \frac{A_n\ C_l}{A_l\ C_n}$$

Where:

A_n = The area of the daughter m/z for the native compound

A_l = The area of the daughter m/z for the labeled compound.

C_l = The concentration of the labeled compound in the calibration standard (Table 11) (ng/mL).

C_n = The concentration of the native compound in the calibration standard (Table 11) (ng/mL).

10.4.4 Compute the average (mean) RR, and the standard deviation and relative standard deviation (RSD) of the 5 RRs.

10.4.5 Linearity – If the RR for any compound is constant (less than 20% RSD), the average RR may be used for that compound; otherwise, the complete calibration curve for that compound must be used over the calibration range.

10.5 Calibration by internal standard – Internal standard calibration is applied to determination of the native compounds for which a labeled compound is not available, and to determination of the labeled compounds for performance tests and intra-laboratory statistics (Sections 9.4 and 15.4.4). The reference compound for each native compound is listed in Table 3, 5, 7, or 9. For the labeled compounds, calibration is performed at a single concentration using data from the 5 points in the calibration (Section 10.4).

10.5.1 Response factors – Internal standard calibration requires the determination of response factors (RF) defined by the following equation:

$$RF = \frac{A_n\ C_{is}}{A_{is}\ C_n}$$

Where:

A_n = The area of the daughter m/z for the native compound
A_{is} = The area of the daughter m/z for the internal standard.
C_{is} = The concentration of the internal standard (Table 11) (ng/mL).
C_n = The concentration of the native compound in the calibration standard (Table 11) (ng/mL).

10.5.2 To calibrate the analytical system for compounds that do not have a labeled analog, and for the labeled compounds, use the data from the 5-point calibration (Section 10.4 and Table 11).

10.5.3 Compute and store the response factor (RF) for all native compounds that do not have a labeled analog. Use the labeled compounds and daughter m/zs listed in Tables 3, 5, 7, and 9 as the quantitation references.

10.5.4 Compute and store the response factor (RF) for the labeled compounds using the labeled injection internal standard as the quantitation reference, as given in Tables 3, 5, 7, and 9.

10.5.5 Linearity – If the RF for any native compound without a labeled analog or for any labeled compound is constant (less than 35% RSD), the average RF may be used for that compound; otherwise, the complete calibration curve for that compound must be used over the calibration range.

10.6 SPE cartridge performance check

In order to be used for extraction of aqueous samples or cleanup of solid-sample extracts, the performance of the HLB SPE cartridges must be checked at least once for each manufacturer's lot of cartridges. This performance check is accomplished by processing a spiked reagent water sample through the extraction procedure is Section 12 and analyzing the extract. Separate checks are performed for the acid and base fractions. Labeled compounds are not added to these check samples before extraction because the

recovery correction inherent in isotope dilution will mask problems with the cartridges. Cartridge performance is acceptable if the recoveries of the native analytes are within the QC acceptance criteria for the OPR in Table 12. Perform this cartridge check as outlined below. Note – This performance check is performed when a new lot number of cartridges is purchased.

10.6.1 Acid fraction – Acidify a 1.0-L aliquot of reagent water to pH 2.0 ± 0.5. Add 500 mg Na_4EDTA (Section 7.4.2) and spike with the Group 1, 2, and 3 native compounds (Section 7.7.2 and Table 10). Do not spike the labeled compounds. Process the solution through the SPE HLB procedure for the acid fraction in Section 12. After processing, spike the solution with the Group 1, 2, and 3 labeled compounds (Section 7.7.3 and Table 10) and complete the analysis per Sections 12 - 15. Recovery of the native compounds must be within the QC acceptance crieria for the OPR in Table 12. If the compounds are not recovered in this range, adjust the elution volumes or reject the cartridge batch.

10.6.2 Base fraction – Adjust the pH a 1.0-L aliquot of reagent water to pH 10.0 ± 0.5 and spike with the Group 4 native compounds (Section 7.7.2 and Table 10). Do not spike the labeled compounds. Process the solution through the SPE HLB procedure for the base fraction in Section 12. After processing, spike the extract with the Group 4 labeled compounds (Section 7.7.3 and Table 10) and complete the analysis per Sections 12 - 15. Recovery of the native compounds must be within the QC acceptance criteria for the OPR in Table 12. If the compounds are not recovered in this range, adjust the elution volumes or reject the cartridge batch.

11.0 Sample Preparation

Sample preparation involves modifying the physical form of the sample so that the analytes can be extracted efficiently. In general, the samples must be in a liquid form or in the form of finely divided solids in order for efficient extraction to take place. Table 13 lists the phases and suggested quantities for extraction of various sample matrices. For samples known or expected to contain high levels of the analytes, the smallest sample size representative of the entire sample should be used (see Section 18).

Biosolids and solid samples are prepared per Section 11.4, extracted per Sections 12.3 and 12.4, and cleaned up using SPE HLB cleanup in Sections 12.1 and 12.2.

Aqueous samples - Because the analytes may be bound to suspended particles, the preparation of aqueous samples is depends on the presence of visible particles. Aqueous samples absent visible particles are prepared per Section 11.3 and processed using SPE HLB cleanup in Sections 12.1 and 12.2.

Aqueous samples with visible particles - If visible particles can be seen in aqueous samples they should be filtered and the solids and aqueous portions of these samples should be extracted and combined prior to clean up as follows. Filtration of particles - assemble a clean filtration apparatus (Section 6.6). Apply vacuum to the apparatus, and pour the entire contents of the

sample bottle through the filter, swirling the sample remaining in the bottle to suspend any particles. Rinse the sample bottle twice with approximately 5 mL portions of reagent water to transfer any remaining particles onto the filter. Rinse any particles off the sides of the filtration apparatus with small quantities of reagent water. Weigh the empty sample bottle to ±1 g. Determine the weight of the sample by difference. Save the bottle for further use. Prepare and extract the filtrate using the procedure in Section 11.3. Prepare and extract the filter containing the particles using the same procedure for biosolids and solid samples in Section 11.4, Sections 12.3 and 12.4, and Sections 12.1 and 12.2. These extracts should be combined prior to analysis (Section 14) or results of separate analysis combined. It should be noted that the judgment of the analyst must be used to determine the need to analyze samples with visible particles that compose less than 1 % of the sample weight per Section 11.1.

Procedures for grinding, homogenization, and blending of various sample phases are given in Section 11.5.

Note: *Each sample batch (Section 4.3) is accompanied by a blank and an OPR. If the acid fraction (Groups 1, 2, and 3) only is to be analyzed then 1 acid blank and OPR must be used. If both the acid (Groups 1, 2, and 3) and base (Group 4) fractions are to be analyzed, 1 acid blank and OPR as well as 1 base blank and OPR must accompany the batch. If the base fraction (Group 4) only is to be analyzed, a base blank and OPR must accompany the base batch.*

11.1 Determination of solids content

The solids content of the bulk sample is determined from a subsample that is used only for the solids determination. Separate procedures are used for the solids determination, based on the sample matrix, as described below.

11.1.1 Aqueous liquids and multi-phase samples consisting of mainly an aqueous phase.

11.1.1.1 Dry a GF/A filter (Section 6.6.4) and weigh to three significant figures. Mix the bulk sample in the original container (e.g., cap the bottle and shake) and take a 10.0 ∀ 0.2 mL aliquot. Filter that aliquot through the filter. Dry the filter in an oven for a minimum of 12 hours at 110 ∀ 5 EC and cool in a dessicator.

11.1.1.2 Weigh the filter and calculate percent solids as follows:

$$\% \text{ Solids} = \frac{\text{Weight of sample aliquot after drying (g) - weight of filter (g)}}{10 \text{ g}} x\, 100$$

11.1.2 Non-aqueous liquids, solids, semi-solid samples, and multi-phase samples in which the main phase is not aqueous

11.1.2.1 Weigh 5 to 10 g of the bulk sample to three significant figures in a tared beaker, weighing pan, or other suitable container. Dry for a minimum of 12 hours at 110 ∀ 5 EC, and cool in a dessicator.

11.1.2.2 Weigh the dried aliquot and calculate percent solids as follows:

$$\% \text{ Solids} = \frac{\text{Weight of sample aliquot after drying (g)}}{\text{Weight of sample aliquot before drying (g)}} \; x \; 100$$

11.2 Estimation of particle size

Extraction of a sample matrix is affected by the size of particles in the sample. Ideally, the particles should be 1 mm or less. The particle size can be estimated using the sample aliquot filtered or dried in Sections 11.1.1 or 11.1.2. Spread the aliquot on a piece of filter paper or aluminum foil in a fume hood or glove box. Visually estimate the size of the particles in the sample. If the size of the largest particles is greater than 1 mm, use one of the procedures in Section 11.5 to reduce the particle size to 1 mm or less prior to extraction. If the largest particles are 1 mm or less, proceed with sample preparation, using the procedures in Section 11.4

11.3 Preparation of aqueous samples absent visible particles and corresponding QC samples.

Two separate sample aliquots are required to analyze all of the target analytes in this procedure: one aliquot is adjusted to pH 2 ± 0.5 (Section 11.3.3.1) and the other aliquot is adjusted to pH 10 ± 0.5 (Section 11.3.4.1). Following this pH adjustment, both aliquots are filtered separately, and the two filtrates are extracted using the SPE HLB cartridge per Section 12.

11.3.1 Mark the original level of the sample on each of the two sample bottles. Designate one bottle for the acid fraction and the other for the base fraction. Weigh each sample plus bottle to the nearest 1 g. If only one sample bottle was provided, and both the acid and base fractions are to be analyzed, split the sample in half and place each new aliquot in a separate clean container.

11.3.2 For each sample batch (Section 4.3) to be extracted during the same 12-hour shift, transfer four 1-L aliquots of reagent water to clean sample bottles or flasks. Two of these aliquots will serve as method blanks (one for the acid fraction and one for the base fraction) and the other two aliquots will be used to prepare the OPR samples (one acid and one base). (If both acid and base fractions are not required, prepare only the reference matrix aliquots appropriate for the fraction of interest.)

11.3.3 Acid fraction - typically 500 mL to 1 L

11.3.3.1 Acidify the filtrate for the acid fraction to pH 2.0 ± 0.5 with HCl while swirling or stirring the water. Re-adjust the pH as necessary to achieve pH 2.0 ± 0.5. Maintain the pH above 1.95 to preclude deuterium-hydrogen exchange on the deuterium-labeled compounds.

11.3.3.2 Spike the acid fraction (Group 1, 2, and 3) native compounds (Section 7.7.2 and Table 10) into the reagent water aliquot that will serve as the acid fraction OPR. Acidify the OPR aliquot and the

blank aliquot in the same manner as the acid fraction of the field sample (11.3.3.1).

11.3.3.3 Spike the acid fraction (Group 1, 2, and 3) labeled compounds (Section 7.7.3 and Table 10) into the acid fractions of the samples and QC aliquots.

11.3.3.4 Add 500 mg NA4EDTA.2H2O (Section 7.4.2) to each of the acid fraction samples and QC aliquots. Cap the bottles and mix by shaking. Allow the sample and QC aliquots to equilibrate for 1 to 2 hours, with occasional shaking. Proceed to Section 12 for sample extraction.

11.3.4 Base fraction – typically 500 mL to 1 L

11.3.4.1 Adjust the pH of the second of the two sample bottles to pH 10.0 ± 0.5 with NH_4OH while swirling or stirring the water. Re-adjust the pH as necessary to achieve pH 10.0 ± 0.5.

11.3.4.2 Spike the base fraction (Group 4) native compounds (Section 7.7.2 and Table 10) into the reagent water aliquot that will serve as the base fraction OPR. Adjust the pH of the OPR aliquot and the blank aliquot in the same manner as the base fraction of the field sample (11.3.4.1).

11.3.4.3 Spike the base fraction (Group 4) labeled compounds (Section 7.7.3 and Table 10) into the base fractions of the samples and QC aliquots.

11.3.4.4 Cap the bottles and mix by shaking. Allow the sample and aliquots to equilibrate for 1 to 2 hours, with occasional shaking. Proceed to Section 12 for sample extraction.

11.4 Preparation of solid samples and samples from filtered particles and corresponding QC samples.

Filtered solids from aqueous samples are treated as solid matrices, regardless of whether they are pourable liquids or solid materials. Two separate aliquots are required to analyze all of the target analytes in this procedure. If the particle size estimated in Section 11.2 exceeds 1 mm, use one of the six size-reduction procedures in Section 11.5 first. Following addition of buffer solutions, one aliquot is adjusted to pH 2 ± 0.5 and the other aliquot is adjusted to pH 11 ± 0.5. Following pH adjustment, each aliquot is extracted separately per Section 12.

11.4.1 Homogenize the sample in its original container, by shaking samples that are pourable liquids, or by stirring solids in their original container with a clean spatula, glass stirring rod, or other suitable implement.

11.4.2 Using the percent solids data collected in Section 11.1, collect two aliquots of the well-mixed sample sufficient to provide 1.0 g of dry solids, but do not exceed a maximum of 5 g wet weight. For biosolids, do not exceed 0.25 g of wet solids. Place the two sample aliquots in separate clean 50-mL disposable centrifuge tubes. Designate one of the samples as the acid fraction, the other the base fraction.

11.4.3 For each sample batch (Section 4.3) to be extracted during the same 12-hour shift, transfer two 1-g aliquots of peat moss (Section 7.6.3) to clean sample bottles or flasks. These two peat moss aliquots will be used for the method blank and the OPR sample for the acid fraction. Transfer two 1-g aliquots of clean sand (Section 7.6.2) to clean sample bottles or flasks. These two clean sand aliquots will be used for the method blank and the OPR sample for the base fraction. (If both acid and base fractions are not required, prepare only the reference matrix aliquots appropriate for the fraction of interest.)

11.4.4 Acid fraction

11.4.4.1 Add 15 mL of pH 2 phosphate buffer (Section 7.4.1) to the sample, blank, and OPR. Vortex each for 5 min. Check and adjust the pH to 2.0 ± 0.5 with buffer, vortexing the mixture after each addition. Maintain the pH above 1.95 to preclude deuterium-hydrogen exchange on the deuterium-labeled compounds.

11.4.4.2 Spike the acid fraction (Group 1, 2, and 3) native compounds (Section 7.7.2 and Table 10) into the peat moss aliquot that will serve as the acid fraction OPR. Acidify the OPR aliquot and the blank aliquot in the same manner as the acid fraction of the field sample (11.4.4.1).

11.4.4.3 Spike the acid fraction (Group 1, 2, and 3) labeled compounds (Section 7.7.3 and Table 10) into the acid fractions of the samples and QC aliquots.

11.4.4.4 Vortex the samples and QC aliquots. Proceed to Section 12.3 for extraction of the solids acid fraction.

11.4.5 Base fraction

11.4.5.1 Add 15 mL of reagent water to the sample, blank, and OPR. Vortex each for 5 min. Adjust the pH of the sample, blank, and OPR aliquots to 10.0 ± 0.5 by adding NH_4OH solution dropwise. Vortex for 5 min. Check and adjust the pH to 10.0 ± 0.5 with NH_4OH solution, vortexing the mixture after each addition.

11.4.5.2 Spike the base fraction (Group 4) native compounds (Section 7.7.2 and Table 10) into one of the QC aliquots. This aliquot will serve as the OPR. The other will serve as the blank.

11.4.5.3 Spike the base fraction (Group 4) labeled compounds (Section 7.7.3 and Table 10) into the samples and QC aliquots.

11.4.5.4 Vortex the samples and QC aliquots. Proceed to Section 12.4 for extraction of the solids base fraction.

11.5 Sample grinding, homogenization, or blending

Samples with particle sizes greater than 1 mm (as determined in Section 11.2) are subjected to grinding, homogenization, or blending. The method of reducing particle size to less than 1 mm is matrix-dependent. In general, hard particles can be reduced by grinding with a mortar and pestle. Softer particles can be reduced by grinding in a Wiley mill or meat grinder, by homogenization, or in a blender.

11.5.1 Each size-reducing preparation procedure on each matrix must be verified by running the tests in Section 9.2 before the procedure is employed routinely.

11.5.2 The grinding, homogenization, or blending procedures must be carried out in a glove box or fume hood to prevent particles from contaminating the work environment.

11.5.3 Grinding – Amorphous and other solids can be ground in a Wiley mill or heavy duty meat grinder. In some cases, reducing the temperature of the sample to freezing or to dry ice or liquid nitrogen temperatures can aid in the grinding process. Grind the sample aliquots in a clean grinder. Do not allow the sample temperature to exceed 50 EC. Also grind the blank and OPR reference matrix aliquots using a clean grinder.

11.5.4 Homogenization or blending – Particles that are not ground effectively, or particles greater than 1 mm in size after grinding, can often be reduced in size by high speed homogenization or blending. Homogenize and/or blend the particles or filter for the sample, blank, and OPR aliquots.

11.5.5 After size reduction, return to Section 11.4 for preparation of the sample and QC aliquots.

12.0 Extraction and Concentration

This method employs solid-phase extraction (SPE) procedures to extract the target analytes from aqueous samples. Solid samples are extracted using ultrasonic extraction with acetonitrile. The extracts from solid samples contain significant amount of coextracted interferences which can be removed through the use of the same SPE procedure employed for the aqueous samples.

12.1 Extraction of aqueous samples absent visible particles, and cleanup of extracts from filtered solids, solids and biosolids samples.

Extraction of both the acid and base fractions of aqueous samples involve many of the same

steps, beginning with the conditioning of the SPE cartridges.

12.1.1 Assemble the SPE extraction apparatus and attach the SPE HLB cartridges (Section 6.5.7).

12.1.2 Condition an SPE HLB cartridge by eluting it with 20 mL of methanol, and 6 mL of reagent water. Discard these eluants. When extracting the base fraction of a sample, the conditioning steps stop here. Do not let the cartridge go dry at any point during the conditioning process.

12.1.3 When extracting the acid fraction of a sample, complete the cartridge conditioning step by eluting the cartridge with 6 mL reagent water at pH 2.0 ± 0.5. Discard this eluant.

12.1.4 Using the SPE cartridge appropriate for the sample fraction (acid or base), load the sample prepared as described in Sections 11.3.3.4 or 11.3.4.4 onto the cartridge at a flow rate of 5-10 mL/min. Extraction of a 1-L aqueous sample will take 100-200 minutes, thus use of a multi-position extraction manifold is desirable.

12.1.5 Once the entire sample has passed through the cartridge, wash the acid fraction cartridge with 10 mL of reagent water to remove the EDTA. Do not wash the cartridge for the base fraction.

12.1.6 Dry the cartridges for either fraction under vacuum for approximately 5 min.

12.2 Cartridge elution

12.2.1 Acid fraction

12.2.1.1 Elute the analytes with 12 mL methanol. Initiate the elution by vacuum and complete the elution by gravity. Collect the eluant in a clean centrifuge tube.

12.2.1.2 If triclocarban and triclosan are analytes of interest, elute these two analytes with 6 mL of acetone:methanol (1:1). Combine with the methanol eluant.

12.2.1.3 Proceed with concentration of the extract (Section 12.5).

12.2.2 Base fraction

12.2.2.1 Elute the analytes with 6 mL methanol followed by 9 mL of 2% formic acid solution (Section 7.4.3.1). Initiate the elution by vacuum and complete the elution by gravity. Collect the eluant in a clean centrifuge tube.

12.2.2.2 Proceed with concentration of the extract (Section 12.5).

12.3 Acid extraction of solid samples

12.3.1 Add 20 mL acetonitrile to the solid sample and the QC aliquots, sonicate for 30 min, and centrifuge for approximately 5 min at approximately 3000 rpm.

12.3.2 Decant the extracts (supernatants) of the sample and the QC aliquots into separate, clean 250-mL round-bottom flasks.

12.3.3 Add 15 mL of phosphate buffer (Section 7.4.1) to the sample and the QC aliquots. Adjust to pH 2.0 ± 0.5 with HCl. Vortex to resuspend the solids. Check and adjust the pH to 2.0 ± 0.5 with buffer, vortexing the mixture after the addition.

12.3.4 Perform a second extraction by repeating Sections 12.3.1 and 12.3.2, adding the extracts to their respective flasks.

12.3.5 For the third extraction, add 15 mL of acetonitrile only to each of the tubes. Sonicate and centrifuge the tubes, and decant the supernatants into their respective round-bottom flasks.

12.3.6 If particles are visible in the extract, filter through a 110-mm or larger GF/A filter. Using squeeze bottles, rinse the filter three times with reagent water, followed by three rinses with acetonitrile.

12.3.7 Proceed with concentration of the acid extract (Section 12.6) followed by SPE in 12.1 and 12.2.

12.4 Base extraction of solid samples

12.4.1 Add 20 mL acetonitrile to the solid sample and QC aliquots, sonicate for 30 min, and centrifuge for approximately 5 min at approximately 3000 rpm.

12.4.2 Decant the extracts (supernatants) of the sample and QC aliquots into separate, clean 250-mL round-bottom flasks.

12.4.3 Add 15 mL of reagent water to the sample and QC aliquots. Add NH_4OH dropwise to the sample and QC aliquots to pH 10.0 ± 0.5. Vortex to resuspend the solids. Check and adjust the pH to 10.0 ± 0.5 with NH_4OH, vortexing the mixture after the addition.

12.4.4 Perform a second extraction by repeating Sections 12.4.1 and 12.4.2, adding the extracts to their respective flasks.

12.4.5 For the third extraction, add 15 mL of acetonitrile only to the centrifuge tubes. Sonicate and centrifuge the tubes, and decant the supernatants into the round-bottom flasks.

12.4.6 If particles are visible in the extract, filter through a 110-mm or larger GF/A filter. Using squeeze bottles, rinse the filter three times with reagent water, followed by three rinses with acetonitrile.

12.4.7 Proceed with concentration of the base extract (Section 12.6) followed by SPE in Section 12.1 and 12.2.

12.5 Concentration of aqueous sample extracts

Extracts from the acid and base fractions of aqueous samples are concentrated separately to near dryness and the solvent exchanged to methanol, as described below. This same procedure is used to concentration the extracts of solid samples after they have been subjected to the SPE HLB cleanup procedure in Sections 12.1 - 12.2.

12.5.1 Concentrate the extract to near dryness under a gentle stream of nitrogen in a water bath held at 50 ± 5 °C.

12.5.2 Add 3 mL of methanol to the concentrated acid and base extracts, including the blank and OPR aliquots.

12.5.3 Spike the acid extracts with the labeled injection acid internal standards and the base extracts with the labeled injection base internal standard (Table 10).

12.5.4 Bring the acid and base extracts to a final volume of 4.0 ± 0.1 mL with 0.1% formic acid solution (Section 7.4.3.2). Vortex to mix.

12.5.5 If visible particles are present in the extract, or if the extract is cloudy, filter through a 0.2-µm filter (Section 6.6.5.

12.5.6 Transfer 1 mL of each extract to an LC/MS/MS autosampler vial for analysis. Store the remaining 3 mL of extract as backup in a refrigerator. (Other proportions of the extract may be used as long as sensitivity is not compromised).

12.5.7 Proceed to Section 14 for analysis.

12.6 Concentration of the solid sample extracts

Extracts from the acid and base fractions of solid samples are concentrated separately prior to cleanup and the extracts are reconstituted into aqueous solutions that are processed through the aqueous sample SPE HLB extraction procedures (Sections 12.1 - 12.2) as a cleanup step.

12.6.1 Concentrate the extracts from the acid and base fractions of the solid samples and QC aliquots separately, to a final volume of 20 - 30 mL by rotary evaporation at 50 °C. Do not allow the extracts to go dry.

12.6.2 Immediately after concentration, add 200 mL of reagent water and 500 mg of NA4EDTA.2H2O to the acid fraction extract. Swirl to mix.

12.6.3 Immediately after concentration, add 200 mL of reagent water to the base fraction extract. Check that the pH is 10.0 ± 0.5. If necessary, adjust dropwise with

NH_4OH solution. Swirl to mix.

12.6.4 Proceed to Section 13 for cleanup of the extracts of all solid samples and associated QC aliquots.

13.0 Extract Cleanup

As noted in Section 12.6, the extracts from all solid samples are subjected to cleanup using the same SPE procedure used to extract aqueous samples. In essence, the solvent extract is reconstituted with reagent water and the pH adjusted to that appropriate for the analytes of interest. The reconstituted sample is processed through the same SPE procedure and the final extract is concentrated and prepared for instrumental analysis. Because the volume of the reconstituted solid sample extract is about 200 mL, the SPE cleanup will take significantly less time than the extraction of a 1-L water sample. Therefore, it is not recommended that aqueous sample extractions and cleanup of solid sample extracts be performed simultaneously on the same extraction manifold.

13.1 The acid fraction extract of each solid sample in Section 12.6.2 is processed through the SPE procedure, beginning at Section 12.1.1 and proceeding through Section 12.2.1.3. Process the associated QC aliquots (blank and OPR) through the cleanup procedure as well.

13.2 The base fraction extract of each solid sample in Section 12.6.3 is processed through the SPE procedure, beginning at Section 12.1.1 and proceeding through Section 12.1.6, and 12.2.2.1 through 12.2.2.2, but omitting Sections 12.1.3 and 12.1.5. Process the associated QC aliquots (blank and OPR) through the cleanup procedure as well.

13.3 After completing the SPE cleanup, concentrate the acid and base extracts of solid samples and QC aliquots separately per Section 12.5 and proceed to Section 14 for analysis.

14.0 LC/MS/MS Analysis

14.1 Establish the same operating conditions established and optimized in Section 10.1 - 10.3 for the calibration appropriate to the fraction and Group to be analyzed. Analysis is performed using positive electrospray ionization (ESI+) for the acid fraction Group 1 and 2 analytes and the base fraction Group 4 analytes. Analysis is performed by ESI– for the acid fraction Group 3 analytes. Retention times (RTs), parent-daughter transitions, quantitation references, method detection limits, and minimum levels of quantitation for Groups 1, 2, 3, and 4 are given in Tables 3, 5, 7, and 9, respectively.

14.2 Inject the volume of the concentrated extract specific to the Group into the LC/MS/MS instrument. The volume injected must be identical to the volume chosen in Section 10.2.1 and used for calibration in Section 10.3.1.

14.2.1 Start the gradient according to the program appropriate for the Group (see Table 2, 4, 6, or 8 for recommended conditions). Start data collection prior to elution of the first analyte.

14.2.2 Monitor the daughter m/z's for each analyte throughout its retention time window. Where known, monitor m/z's associated with interferents expected to be present.

14.2.3 Stop data collection after elution of the last analyte in each Group. Return the gradient to the initial mixture for analysis of the next sample extract or standard.

15.0 System and Laboratory Performance

15.1 At the beginning of each 12-hour shift during which analyses are performed, LC/MS/MS system performance and calibration are verified for all native and labeled compounds. For these tests, analysis of the CS-3 calibration verification (VER) standard (Section 7.7.5 and Table 11) must be used to verify all performance criteria. Adjustment and/or recalibration (Section 10) must be performed until all performance criteria are met. Only after all performance criteria are met may samples, blanks, IPRs, and OPRs be analyzed.

15.2 Calibration verification

15.2.1 Inject the VER (CS-3) calibration standard (Table 10) for the Group being analyzed using the procedure in Section 14.

15.2.2 The LC peak representing each native and labeled compound in the VER standard must be present with a S/N of at least 10; otherwise, the LC/MS/MS system must be adjusted and the verification test repeated.

15.2.3 Compute the concentration of the native compounds that have labeled analogs by isotope dilution and the concentration of the native compounds that do not have labeled analogs and of the labeled compounds by the internal standard technique. These concentrations are computed based on the calibration data in Section 10.

15.2.4 For each compound, compare the concentration with the calibration verification limit in Table 12. If all compounds meet the acceptance criteria, calibration has been verified and analysis of standards and sample extracts may proceed. If, however, any compound fails its respective limit, the measurement system is not performing properly. In this event, prepare a fresh calibration standard or correct the problem and repeat the verification (Section 15.2) tests, or recalibrate (Section 10).

15.3 Retention time

15.3.1 The retention times of the native and labeled compounds in the verification test (Section 15.2) must be within ± 15 seconds of the respective retention times in the most recent calibration verification standard.

15.3.2 If the retention time of any compound is not within the limits specified, the LC is not performing properly. In this event, adjust the LC operating conditions and

repeat the verification test (Section 15.3) or recalibrate (Section 10), or replace the LC column and either verify calibration or recalibrate.

15.4 Ongoing precision and recovery

15.4.1 Analyze the extracts of both the acid and base fractions of the ongoing precision and recovery (OPR) aliquots prior to analysis of samples from the same batch.

15.4.2 Compute the percent recovery of each native compound with a labeled analog by isotope dilution (Section 10.4). Compute the percent recovery of each native compound without a labeled analog and of each labeled compound by the internal standard method (Section 10.5).

15.4.3 For the native and labeled compounds, compare the recovery to the OPR limits given in Table 12. If all compounds meet the acceptance criteria, system performance is acceptable and analysis of blanks and samples may proceed. If, however, any individual concentration falls outside of the range given, the extraction/concentration processes are not being performed properly for that compound. In this event, correct the problem, re-prepare, extract, and clean up the sample batch and repeat the ongoing precision and recovery test (Section 15.4).

15.4.4 If desired, add results that pass the specifications in Section 15.4.3 to initial and previous ongoing data for each compound in each matrix. Update QC charts to form a graphic representation of continued laboratory performance. Develop a statement of laboratory accuracy for each compound in each matrix type by calculating the average percent recovery (R) and the standard deviation of percent recovery (S_R). Express the accuracy as a recovery interval from R ! $2S_R$ to R + $2S_R$. For example, if R = 95% and S_R = 5%, the accuracy is 85 to 105%.

15.5 Blank – Analyze the method blank extracted with each sample batch immediately following analysis of the OPR aliquot to demonstrate that there is no contamination or carryover from the OPR analysis. If native compounds will be carried from the OPR into the method blank, analyze one or more aliquots of solvent between the OPR and the method blank. Results of analysis of the method blank must meet the specifications in Section 9.5.2 before sample analysis may begin.

16.0 Qualitative Determination

A native or labeled compound is identified in a standard, blank, or sample when the criteria in Sections 16.1 through 16.2 are met.

16.1 The signal-to-noise ratio (S/N) at the LC peak maximum for each native compound at its daughter m/z must be greater than or equal to 2.5 for each compound detected in a sample extract, and greater than or equal to 10 in CALs and VER samples for parent to daughter transition except S/N of 3 in CS-1.

16.2 The retention time of the peak for a native compound must be within ± 15 seconds of its RT in the most recent CS-3 standard (Table 11).

16.3 Because of compound RT overlap and the potential for interfering substances, it is possible that all of the identification criteria (Sections 16.1 - 16.2) may not be met. If identification is ambiguous, an experienced spectrometrist (Section 1.5) must determine the presence or absence of the compound.

16.4 If the criteria for identification in Sections 16.1 - 16.2 are not met, the compound has not been identified and the result for that compound may not be reported or used for permitting or regulatory compliance purposes. If interferences preclude identification, a new aliquot of sample must be analyzed. Refer to Section 18 for guidance.

17.0 Quantitative Determination

17.1 Isotope dilution quantitation

17.1.1 By adding a known amount of a labeled compound to every sample prior to extraction, correction for recovery of the native analog of that compound can be made because the native compound and its labeled analog exhibit similar effects upon extraction, concentration, and chromatography. Relative responses (RRs) are used in conjunction with the calibration data in Section 10.4 to determine the concentration in the final extract, as long as labeled compound spiking levels are constant.

17.1.2 Compute the concentration of each compound in the extract using the RR from the calibration data (Section 10.4) and following equation:

$$C_{ex}\ (ng/mL) = \frac{A_n\ C_l}{A_l\ RR}$$

Where:

C_{ex} = Concentration of the compound in the extract , and the other terms are as defined in Section 10.4.3

17.2 Internal standard quantitation and labeled compound recovery

17.2.1 Compute the concentration of each native compound that does not have labeled analog and each labeled compound using the RF from the calibration data (Section 10.5) and the following equation:

$$C_{ex}\ (ng/mL) = \frac{A_s\ C_{is}}{A_{is}\ RF}$$

Where:

C_{ex} = Concentration of the compound in the extract, and the other terms are as defined in Section 10.5.1

17.2.2 Using the concentration in the extract determined above, compute the percent recovery of the labeled compounds using the following equation:

$$\text{Recovery}\ (\%) = \frac{\textit{Concentration found}\ (ng/mL)}{\textit{Concentration spiked}\ (ng/mL)}\ x\ 100$$

17.3 The concentration of a native compound in the solid phase of the sample is computed using the concentration of the compound in the extract and the weight of the solids, as follows:

$$\textit{Concentration in solid sample}\ (ng/kg) = \frac{C_{ex}\,V_{ex}}{W_s}$$

Where:
C_{ex} = Concentration of the compound in the extract.
V_{ex} = Extract volume in mL.
W_s = Sample weight (dry weight) in kg.

If desired, divide the concentration by 1000 to convert ng/kg to µg/kg.

17.4 The concentration of a native compound in the aqueous phase of the sample is computed using the concentration of the compound in the extract and the volume of water extracted, as follows:

$$\textit{Concentration in aqueous phase (ng/L)} = 1000 \times \frac{(C_{ex} \times V_{ex})}{V_s}$$

Where:
C_{ex} = Concentration of the compound in the extract.
V_{ex} = Extract volume in mL.
V_s = Sample volume in liters.

17.5 If the SICP area at the daughter quantitation m/z for any compound exceeds the calibration range of the system, dilute the sample extract by the factor necessary to bring the concentration within the calibration range, adjust the concentration of the labeled injection internal standard to the original concentration in the extract, and analyze an aliquot of this diluted extract. If the compound cannot be measured reliably by isotope dilution, dilute and analyze an aqueous sample or analyze a smaller portion of a solid, or other sample. Adjust the compound concentration, detection limit, and minimum level of quantitation to account for the dilution.

17.6 Reporting of results

17.6.1 Reporting units and levels

17.6.1.1 Aqueous samples – Report results in ng/L (parts-per-trillion).

17.6.1.2 Samples containing solids (aqueous samples containing visible particles, solids, soils, sediments, filter cake, compost) – Report results in µg/kg (parts-per-billion) based on the dry weight of the sample.

Report the percent solids so that the result may be converted to aqueous units.

17.6.2 Reporting level

17.6.2.1 Report the result for each compound in each sample, blank, or standard (VER, IPR, OPR) at or above the minimum level of quantitation (ML; Table 3, 5, 7, or 9) to 3 significant figures. Report the result below the ML in each sample as <ML (where ML is the concentration at the ML) or as required by the regulatory authority or permit.

17.6.2.2 Blanks – Report the result for each compound below the ML but above the MDL to 2 significant figures. Report results below the MDL as <MDL (where MDL is the concentration at the MDL) or as required by the regulatory authority or permit. In addition to reporting results for the samples and blank(s) separately, the concentration of each compound in a method blank or field blank associated with the sample may be subtracted from the results for that sample, or must be subtracted if requested or required by a regulatory authority or in a permit.

17.6.2.3 Results for a compound in a sample that has been diluted are reported at the least dilute level at which the area at the quantitation m/z is within the calibration range (Section 17.5).

17.6.2.4 For a compound having a labeled analog, report results at the least dilute level at which the area at the quantitation m/z is within the calibration range (Section 17.5) and the labeled compound recovery is within the normal range for the method (Section 9.3 and Table 12).

17.6.2.5 Results from tests performed with an analytical system that is not in control must not be reported or otherwise used for permitting or regulatory compliance purposes, but do not relieve a discharger or permittee of reporting timely results.

18.0 Analysis of Complex Samples

18.1 Some samples may contain high levels (>1 μg/L; >1 mg/kg) of the compounds of interest, interfering compounds, and/or polymeric materials. The concentration of analytes and/or interferences in some extracts may overload the LC column and/or mass spectrometer.

18.2 Analyze a smaller aliquot of the sample (Section 17.5) when the interferences preclude analysis of the full sample volume or amount. If a smaller aliquot of a solid, biosolid, or mixed-phase sample is analyzed, attempt to assure that the smaller aliquot is representative.

18.3 Perform integration of peak areas and calculate concentrations manually when interferences preclude computerized calculations.

18.4 Signal suppression – Coextracted interferences in the sample may suppress signals for the compounds of interest. To detect signal suppression, the labeled injection internal standard(s) must be monitored in the analysis. If the signal for the labeled injection internal standard is suppressed by more than 30%, as compared to the average signal for the labeled injection internal standard in the 5-point calibration, the sample must be further cleaned up and reanalyzed. If the sample cannot be cleaned up further, the sample or extract must be diluted, and a diluted sample or extract must be analyzed (Section 17.5).

18.5 Recovery of labeled compounds – For most samples, recoveries of the labeled compounds will be similar to those from reagent water or from the alternate matrix (Section 7.6 and Table 12).

18.5.1 If the recovery of any of the labeled compounds is outside of the normal range (Table 12), a diluted sample must be analyzed (Section 17.5).

18.5.2 If the recovery of any of the labeled compounds in the diluted sample is outside of normal range, the calibration verification standard (Section 7.7.5 and Table 11) must be analyzed and calibration verified (Section 15.2).

18.5.3 If the calibration cannot be verified, a new calibration must be performed and the original sample extract reanalyzed.

18.5.4 If calibration is verified and the diluted sample does not meet the limits for labeled compound recovery, this method does not apply to the sample being analyzed and the result may not be reported or used for permitting or regulatory compliance purposes. In this case, alternate extraction and cleanup procedures in this method or an alternate LC column must be employed to resolve the interference. If all cleanup procedures in this method and an alternate LC column have been employed and labeled compound recovery remains outside of the normal range, extraction and/or cleanup procedures that are beyond this scope of this method will be required to analyze the sample.

19.0 Pollution Prevention

19.1 Pollution prevention encompasses any technique 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.

19.2 The compounds in this method are used in extremely small amounts and pose little threat to the environment when managed properly. Standards should be prepared in volumes

consistent with laboratory use to minimize the disposal of excess volumes of expired standards.

19.3 For information about pollution prevention that may be applied to laboratories and research institutions, consult *Less is Better: Laboratory Chemical Management for Waste Reduction*, available from the American Chemical Society's Department of Governmental Relations and Science Policy, 1155 16th Street NW, Washington DC 20036, 202/872-4477.

20.0 Waste Management

20.1 The laboratory is responsible for complying with all Federal, State, and local regulations governing waste management, particularly the hazardous waste identification rules and land disposal restrictions, and to protect the air, water, and land by minimizing and controlling all releases from fume hoods and bench operations. Compliance is also required with any sewage discharge permits and regulations. An overview of requirements can be found in *Environmental Management Guide for Small Laboratories* (EPA 233-B-98-001).

20.2 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.

20.3 The compounds in this method decompose above 500 EC. 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.

20.4 For further information on waste management, consult *The Waste Management Manual for Laboratory Personnel* and *Less is Better-Laboratory Chemical Management for Waste Reduction*, available from the American Chemical Society's Department of Government Relations and Science Policy, 1155 16th Street N.W., Washington, D.C. 20036.

21.0 Method Performance

Method 1694 was validated and preliminary data were collected in a single laboratory (Reference 2). Performance data are given in Table 14.

22.0 References

1 EPA Methods 610, 1668A, and 8321A

2 "Analytical Procedure for the Analysis of Pharmaceutical Compounds in Solid and Aqueous Samples by LC-MS/MS," Axys Analytical Services proprietary.

3 Previous work on pharmaceuticals and personal-care products

3a Castiglioni at al., A Multiresidue Analytical Method Using Solid-Phase Extraction and High-Pressure Liquid Chromatography Tandem Mass Spectrometry to Measure Pharmaceuticals of Different Therapeutic Classes in Urban Wastewaters. J. Chromatogr.A 1092 (2005), 206-215.

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3c Michele E. Lindsey, Michael Meyer, and E.M.Thurman, Analysis of Trace Levels of Sulfonamide and Tetracycline Antimicrobials in Groundwater and Surface Water Using Solid-Phase Extraction and Liquid Chromatography/Mass Spectrometry, Anal. Chem. 2001, 73, 4640-4646.

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4 "Working with Carcinogens," Department of Health, Education, & Welfare, Public Health Service, Centers for Disease Control, NIOSH, Publication 77-206, August 1977, NTIS PB-277256.

5 "OSHA Safety and Health Standards, General Industry," OSHA 2206, 29 *CFR* 1910.

6 "Safety in Academic Chemistry Laboratories," ACS Committee on Chemical Safety, 1979.

7 "Standard methods for the Examination of Water and Wastewater," 18th edition and later revisions, American Public Health Association, 1015 15th St, N.W., Washington, DC 20005, 1-35: Section 1090 (Safety), 1992.

8 Provost, L.P., and Elder, R.S., "Interpretation of Percent Recovery Data," *American Laboratory*, 15: 56-83, 1983.

9 "Standard Practice for Sampling Water," ASTM Annual Book of Standards, ASTM, 1916 Race Street, Philadelphia, PA 19103-1187, 1980.

10 A) Paul E. Stackelberg, Jacob Gibs, Edward T. Furlong, Michael T. Meyer, Steven D. Zaugg, R. Lee Lippincott. Science of the Total Environment 377 (2007) 255–272. B) Zhengqi Ye and Howard S. Weinberg and Michael T. Meyer. Anal. Chem., 79 (3), 1135 - 1144, 2007.

11 "Handbook of Analytical Quality Control in Water and Wastewater Laboratories,"

USEPA EMSL, Cincinnati, OH 45268, EPA-600/4-79-019, March 1979.

23.0 Tables and Flowchart

Table 1. Names and CAS Registry numbers for pharmaceuticals and personal-care products (PPCPs) determined by isotope dilution and internal standard HPLC/MS/MS

Compound	CAS Registry	Labeled analog	CAS Registry
Acetaminophen	103-90-2	$^{13}C_2$-^{15}N-Acetaminophen	
Albuterol	18559-94-9	Albuterol-d_3	
Ampicillin	69-53-4		
Anhydrochlortetracycline (ACTC)	4497-08-9		
Anhydrotetracycline (ATC)	4496-85-9		
Azithromycin	83905-01-5		
Caffeine	58-08-2	$^{13}C_3$-Caffeine	
Carbadox	6804-07-5		
Carbamazepine	298-46-4		
Cefotaxime	63527-52-6		
Chlortetracycline (CTC)	57-62-5		
Cimetidine	51481-61-9		
Ciprofloxacin	85721-33-1	$^{13}C_3$-^{15}N-Ciprofloxacin	
Clarithromycin	81103-11-9		
Clinafloxacin	105956-97-6		
Cloxacillin	61-72-3		
Codeine	76-57-3		
Cotinine	486-56-6	Cotinine-d_3	
Dehydronifedipine	67035-22-7		
Demeclocycline	127-33-3		
Digoxigenin	1672-46-4		
Digoxin	20830-75-5		
Diltiazem	42399-41-7		
1,7-Dimethylxanthine	611-59-6		
Diphenhydramine	58-73-1		
Doxycycline	564-25-0		
Enrofloxacin	93106-60-6		
4-Epianhydrochlortetracycline (EACTC)	158018-53-2		
4-Epianhydrotetracycline (EATC)	4465-65-0		
4-Epichlortetracycline (ECTC)	14297-93-9		
4-Epioxytetracycline (EOTC)	14206-58-7		
4-Epitetracycline (ETC)	23313-80-6		
Erythromycin	114-07-8		
Erythromycin anhydrate	59319-72-1	$^{13}C_2$-Erythromycin anhydrate	
Flumequine	42835-25-6		
Fluoxetine	54910-89-3	Fluoxetine-d_5	
Gemfibrozil	25812-30-0	Gemfibrozil-d_6	

Compound	CAS Registry	Labeled analog	CAS Registry
Ibuprofen	15687-27-1	$^{13}C_3$-Ibuprofen	
Isochlortetracycline (ICTC)	514-53-4		
Lincomycin	154-21-2		
Lomefloxacin	98079-51-7		
Metformin	657-24-9	Metformin-d_6	
Miconazole	22916-47-8		
Minocycline	10118-91-8		
Naproxen	22204-53-1	^{13}C-Naproxen-d_3	
Norfloxacin	70458-96-7		
Norgestimate	35189-28-7		
Ofloxacin	82419-36-1		
Ormetoprim	6981-18-6		
Oxacillin	66-79-5		
Oxolinic acid	14698-29-4		
Oxytetracycline (OTC)	79-57-2		
Penicillin V	87-08-1		
Penicillin G	61-33-6		
Ranitidine	66357-35-5		
Roxithromycin	80214-83-1		
Sarafloxacin	98105-99-8		
Sulfachloropyridazine	80-32-0		
Sulfadiazine	68-35-9		
Sulfadimethoxine	122-11-2		
Sulfamerazine	127-79-7		
Sulfamethazine	57-68-1	$^{13}C_6$-Sulfamethazine	
Sulfamethizole	144-82-1		
Sulfamethoxazole	723-46-6	$^{13}C_6$-Sulfamethoxazole	
Sulfanilamide	63-74-1		
Sulfathiazole	72-14-0		
Tetracycline (TC)	60-54-8		
Thiabendazole	148-79-8	Thiabendazole-d_6	
Triclocarban	101-20-2	$^{13}C_6$-Triclocarban	
Triclosan	3380-34-5	$^{13}C_{12}$-Triclosan	
Trimethoprim	738-70-5	$^{13}C_3$-Trimethoprim	
Tylosin	1401-69-0		
Virginiamycin	11006-76-1		
Warfarin	81-81-2	Warfarin-d_5	
Other standards			
Unlabeled compound spiked into sample and used for recovery correction			
Meclocycline			
Labeled injection internal standard spiked into sample extract prior to injection into LC/MS/MS			
		$^{13}C_3$-Atrazine	
		$^{13}C_6$-2,4,5-Trichlorophenoxyacetic acid ($^{13}C_6$-TCPAA)	

Table 2. Group 1 – Acidic extraction, positive electrospray ionization (ESI+) instrument conditions

Instrument	Waters 2690 HPLC or Waters 2795 HPLC, Micromass Quattro Ultima MS/MS
LC Column	Waters Xtera C18, 10.0 cm, 2.1 mm i.d., 3.5 µm particle size
Ionization	Positive Ion Electrospray
Acquisition	MRM mode, unit resolution
Injection Volume	15 µL

LC Gradient Program		**LC Flow Rate (mL/min)**	**Gradient**	**General LC Conditions**	
Time (min)	**Flow Mixture[1]**			Column Temp	40 °C
0.0	95% Solvent A 5% Solvent B	0.150	1	Flow Rate	0.15 – 0.30 mL/min
4.0	95% Solvent A 5% Solvent B	0.250	6	Max Pressure	345 Bar
22.5	12% Solvent A 88% Solvent B	0.300	6	Autosampler tray temperature	4ºC
23.0	100% Solvent B	0.300	6	**MS Conditions**	
26.0	100% Solvent B	0.300	6	Source Temp	140°C
26.5	95% Solvent A 5% Solvent B	0.150	6	Desolvation Temp	350°C
33.0	95% Solvent A 5% Solvent B	0.150	6	Cone / Desolvation Gas Rate	80 L/hr / 400 L/hr

[1] Solvent A = 0.3% Formic Acid and 0.1% Ammonium Formate in HPLC water
Solvent B = 1:1 Acetonitrile:Methanol

Table 3. Group 1 acidic extraction, positive electrospray ionization (ESI+) compound retention times (RTs), parent-daughter transitions, quantitation references, method detection limits, and minimum levels of quantitation.

Analyte	RT (min)	Parent-daughter m/zs	Quantitation reference	Detection limits and minimum levels					
				Water (ng/L)		Other (µg/kg)		Extract (ng/ΦL)	
				MDL	ML	MDL	ML	MDL	ML
Group 1	**Analytes Extracted Under Acidic Conditions and Analyzed Using Positive Electrospray Ionization (+) ESI**								
Native compounds									
Sulfanilamide	2.5	190.0 - 155.8	$^{13}C_6$-Sulfamethazine	8.9	50	48	200	2.2	12.5
Cotinine	2.8	177.0 - 98.0	Cotinine-d_3	3.4	5	1.1	5	0.9	1.25
Acetaminophen	4.6	152.2 - 110.0	$^{13}C_2$-^{15}N-Acetaminophen	27	200	35	200	6.7	50
Sulfadiazine	6.0	251.2 - 156.1	$^{13}C_6$-Sulfamethazine	0.4	5	2.7	10	0.1	1.25
1,7-Dimethylxanthine	6.9	181.2 - 124.0	$^{13}C_3$-Caffeine	120	500	270	1000	30	125
Sulfathiazole	7.7	256.3 - 156.0	$^{13}C_6$-Sulfamethoxazole	0.5	5	1.9	50	0.1	1.25
Codeine	8.3	300.0 - 152.0	$^{13}C_3$-Trimethoprim	1.5	10	3.4	10	0.4	2.5
Sulfamerazine	8.7	265.0 - 156.0	$^{13}C_6$-Sulfamethazine	0.3	2	1.4	5	0.1	0.5
Lincomycin	9.3	407.5 - 126.0	$^{13}C_3$-Trimethoprim	0.8	10	4.7	10	0.2	2.5
Caffeine	9.3	195.0 - 138.0	$^{13}C_3$ Caffeine	15	50	5.4	50	3.6	12.5
Sulfamethizole	10.0	271.0 - 156.0	$^{13}C_6$-Sulfamethoxazole	0.4	2	0.88	5	0.1	0.5
Trimethoprim	10.0	291.0 - 230.0	$^{13}C_3$-Trimethoprim	1.1	5	3.3	10	0.3	1.25
Thiabendazole	10.0	202.1 - 175.1	Thiabendazole-d_6	0.7	5	2.1	10	0.2	1.25
Sulfamethazine	10.1	279.0 - 156.0	$^{13}C_6$-Sulfamethazine	0.6	2	0.83	5	0.2	0.5
Cefotaxime	10.2	456.4 - 396.1	$^{13}C_3$-Trimethoprim	10	20	18	50	2.5	5
Carbadox	10.5	263.2 - 231.2	$^{13}C_3$-Trimethoprim	2.3	5	2.1	10	0.6	1.25
Ormetoprim	10.5	275.3 - 259.1	$^{13}C_3$-Trimethoprim	0.3	2	0.50	2	0.1	0.5
Norfloxacin	10.7	320.0 - 302.0	$^{13}C_3$ ^{15}N-Ciprofloxacin	28	50	15	50	7.0	12.5
Sulfachloropyridazine	10.8	285.0 - 156.0	$^{13}C_6$-Sulfamethazine	1.2	5	1.9	5	0.3	1.25
Ofloxacin	10.8	362.2 - 318.0	$^{13}C_3$ ^{15}N-Ciprofloxacin	1.8	5	3.4	10	0.4	1.25
Ciprofloxacin	10.9	332.2 - 314.2	$^{13}C_3$ ^{15}N-Ciprofloxacin	5.1	20	8.1	20	1.3	5
Sulfamethoxazole	11.2	254.0 - 156.0	$^{13}C_6$-Sulfamethoxazole	0.4	2	1.2	5	0.1	0.5
Lomefloxacin	11.2	352.2 - 308.1	$^{13}C_3$ ^{15}N-Ciprofloxacin	4.9	10	4.4	10	1.2	2.5
Enrofloxacin	11.5	360.0 - 316.0	$^{13}C_3$ ^{15}N-Ciprofloxacin	5.2	10	3.1	10	1.3	2.5
Sarafloxacin	11.9	386.0 - 299.0	$^{13}C_3$ ^{15}N-Ciprofloxacin	170	200	--	200	42	12.5
Clinafloxacin	12.1	366.3 - 348.1	$^{13}C_3$ ^{15}N-Ciprofloxacin	6.9	20	14	50	1.7	5

Analyte	RT (min)	Parent-daughter m/zs	Quantitation reference	Detection limits and minimum levels					
				Water (ng/L)		Other (ng/g)		Extract (ng/ΦL)	
				MDL	ML	MDL	ML	MDL	ML
Digoxigenin	12.6	391.2 - 355.2	$^{13}C_3$-Trimethoprim	5.7	20	9.4	20	1.4	5
Oxolinic acid	13.1	261.8 - 243.8	$^{13}C_3$-Trimethoprim	0.6	2	0.62	2	0.2	0.5
Sulfadimethoxine	13.2	311.0 - 156.0	$^{13}C_6$-Sulfamethoxazole	0.1	1	0.55	2	0.03	0.25
Diphenhydramine	14.5	256.8 - 168.1	$^{13}C_3$-Trimethoprim	0.4	2	0.66	2	0.1	0.5
Penicillin G	14.6	367.5 - 160.2	$^{13}C_3$-Trimethoprim	2.4	10	13	50	0.6	2.5
Azithromycin	14.8	749.9 - 591.6	$^{13}C_3$-Trimethoprim	1.3	5	1.6	5	0.3	1.25
Flumeqine	15.2	262.0 - 173.7	$^{13}C_3$-Trimethoprim	2.7	5	1.4	5	0.7	1.25
Ampicillin	15.3	350.3 - 160.2	$^{13}C_3$-Trimethoprim	--	5	--	5	--	1.25
Diltiazem	15.3	415.5 - 178.0	$^{13}C_3$-Trimethoprim	0.6	2	0.30	2	0.2	0.25
Carbamazepine	15.3	237.4 - 194.2	$^{13}C_3$-Trimethoprim	1.4	5	1.6	5	0.4	1.25
Penicillin V	15.4	383.4 - 160.2	$^{13}C_3$-Trimethoprim	4.4	20	19	50	1.1	5
Erythromycin	15.9	734.4 - 158.0	$^{13}C_2$-Erythromycin	--	1	--	2	--	0.25
Tylosin	16.3	916.0 - 772.0	$^{13}C_2$-Erythromycin anhydrate	13	50	8.1	50	3.2	5
Oxacillin	16.4	434.3 - 160.1	$^{13}C_3$-Trimethoprim	3.3	10	9.4	20	0.8	2.5
Dehydronifedipine	16.5	345.5 - 284.1	$^{13}C_3$-Trimethoprim	0.6	2	0.41	2	0.2	0.5
Digoxin	16.6	803.1 - 283.0	$^{13}C_3$-Trimethoprim	--	50	--	100	--	12.5
Fluoxetine	16.9	310.3 - 148.0	Fluoxetine-d_5	3.7	10	2.8	10	0.9	1.25
Cloxcillin	16.9	469.1 - 160.1	$^{13}C_3$-Trimethoprim	4.3	10	9.2	20	0.1	2.5
Virginiamycin	17.3	508.0 - 355.0	$^{13}C_3$-Trimethoprim	3.6	10	3.4	10	0.9	2.5
Clarithromycin	17.5	748.9 - 158.2	$^{13}C_2$-Erythromycin anhydrate	1.0	5	1.2	5	0.3	1.25
Erythromycin anhydrate	17.7	716.4 - 158.0	$^{13}C_2$-Erythromycin anhydrate	0.4	2	0.46	2	0.1	0.25
Roxithromycin	17.8	837.0 - 679.0	$^{13}C_2$-Erythromycin anhydrate	0.2	1	0.22	1	0.05	0.25
Miconazole	20.1	417.0 - 161.0	$^{13}C_3$-Trimethoprim	1.3	5	0.90	5	0.3	1.25
Norgestimate	21.7	370.5 - 124.0	$^{13}C_3$-Trimethoprim	2.5	10	1.4	10	0.6	2.5
Labeled compounds spiked into each sample									
Cotinine-d_3	2.8	180.0 - 79.9	$^{13}C_3$ Atrazine						
$^{13}C_2$-^{15}N-Acetaminophen	4.5	155.2 - 111.0	$^{13}C_3$ Atrazine						
$^{13}C_3$ Caffeine	9.3	198.0 - 140.0	$^{13}C_3$ Atrazine						
Thiabendazole-d_6	9.8	208.1 - 180.1	$^{13}C_3$ Atrazine						
$^{13}C_3$-Trimethoprim	10.0	294.0 - 233.0	$^{13}C_3$ Atrazine						
$^{13}C_6$ Sulfamethazine	10.1	285.1 - 162.0	$^{13}C_3$ Atrazine						
$^{13}C_3$ ^{15}N-Ciprofloxacin	10.9	336.1 - 318.0	$^{13}C_3$ Atrazine						
$^{13}C_6$-Sulfamethoxazole	11.2	260.0 - 162.0	$^{13}C_3$ Atrazine						
$^{13}C_2$-Erythromycin	15.9	736.4 - 160.0	$^{13}C_3$ Atrazine						

Analyte	RT (min)	Parent-daughter m/zs	Quantitation reference	Detection limits and minimum levels					
				Water (ng/L)		Other (Φg/g)		Extract (ng/ΦL)	
				MDL	ML	MDL	ML	MDL	ML
Fluoxetine-d_5	16.8	315.3 - 153.0	$^{13}C_3$ Atrazine						
$^{13}C_2$-Erythromycin anhydrate	17.7	718.4 - 160.0	$^{13}C_3$ Atrazine						
Injection internal standard									
$^{13}C_3$ Atrazine	15.9	219.5 - 176.9 (134.0)	External standard						

Table 4. Group 2 – Acidic extraction positive electrospray ionization (ESI+) instrument conditions

Instrument	Waters 2690 HPLC or Waters 2795 HPLC, Micromass Quattro Ultima MS/MS
LC Column	Waters Xtera C18, 10.0 cm, 2.1 mm i.d., 3.5 µm particle size
Ionization	Positive Ion Electrospray
Acquisition	MRM mode, unit resolution
Injection Volume	5 µL

LC Gradient Program		**LC Flow Rate (mL/min)**	**Gradient**	**General LC Conditions**	
Time (min)	**Flow Mixture[1]**			Column Temp	40 °C
0.0	10% Solvent A 90% Solvent B	0.20	1	Flow Rate	0.20 – 0.23 mL/min
1.0	10% Solvent A 90% Solvent B	0.20	6	Max Pressure	345 Bar
18.0	40% Solvent A 60% Solvent B	0.23	6	Autosampler tray temperature	4ºC
20.0	90% Solvent A 10% Solvent B	0.23	6	**MS Conditions**	
24.0	90% Solvent A 10% Solvent B	0.23	6	Source Temp	120°C
24.3	10% Solvent A 90% Solvent B	0.20	6	Desolvation Temp	400°C
28	10% Solvent A 90% Solvent B	0.20	6	Cone / Desolvation Gas Rate	70 L/hr / 450 L/hr

[1] Solvent A = 1:1 acetonitrile:methanol, with 5 mM Oxalic Acid
Solvent B = HPLC H_2O, with 5 mM Oxalic Acid

Table 5. Group 2 acidic extraction positive electrospray ionization (ESI+) compound retention times (RTs), parent-daughter transitions, quantitation references, method detection limits, and minimum levels of quantitation.

Analyte	RT (min)	Parent-daughter m/zs	Quantitation reference	Detection limits and minimum levels					
				Water (ng/L)		Other (ng/g)		Extract (ng/μL)	
				MDL	ML	MDL	ML	MDL	ML
Group 2	**Analytes Extracted Under Acidic Conditions and Analyzed Using Positive Electrospray Ionization (+) ESI.**								
Native compounds									
Minocycline	5.1	458.0 - 441.0	Thiabendazole-d_6	51	200	--	200	13	50
Epitetracycline	8.1	445.2 - 410.2	Thiabendazole-d_6	3.6	20	8.6	20	0.9	5
Epioxytetracycline (EOTC)	8.6	461.2 - 426.2	Thiabendazole-d_6	4.1	20	18	50	1.0	5
Oxytetracycline (OTC)	9.4	461.2 - 426.2	Thiabendazole-d_6	2.1	20	2.2	20	0.5	5
Tetracycline (TC)	9.9	445.2 - 410.2	Thiabendazole-d_6	1.9	20	2.8	20	0.5	5
Demeclocycline	11.7	465.0 - 430.0	Thiabendazole-d_6	6.6	50	7.9	50	1.7	12.5
Isochlortetracycline (ICTC) [1]	11.9	479.0 - 462.2	Thiabendazole-d_6	1.7	20	3.5	20	0.4	5
Epichlortetracycline (ECTC) [1]	12.0	479.0 - 444.0	Thiabendazole-d_6	7.7	50	26	100	1.9	12.5
Chlortetracycline (CTC)	14.1	479.0 - 444.0	Thiabendazole-d_6	1.2	20	2.3	20	0.3	5
Doxycycline	16.7	445.2 - 428.2	Thiabendazole-d_6	2.8	20	2.3	20	0.7	5
Epianhydrotetracycline (EATC)	17.0	426.8 - 409.8	Thiabendazole-d_6	7.7	50	14	50	1.9	12.5
Anhydrotetracycline (ATC)	18.8	426.8 - 409.8	Thiabendazole-d_6	4.6	50	7.1	50	1.2	12.5
Epianhydrochlortetracycline (EACTC)	20.7	461.2 - 444.0	Thiabendazole-d_6	28	200	23	200	7.0	50
Anhdrochlortetracycline (ACTC)	22.1	461.2 - 444.0	Thiabendazole-d_6	5.2	50	11	50	1.3	12.5
Labeled compound spiked into each sample									
Thiabendazole-d_6	7.0	208.1 - 180.1	$^{13}C_3$ Atrazine						
Injection internal standard									
$^{13}C_3$ Atrazine	10.5	219.5 - 176.9 (134.0)	External standard						

1. Isochlortetracycline (ICTC) is reported as the sum ICTC + ECTC due to a common transition ion.

Table 6. Group 3 – Acidic extraction negative electrospray ionization (ESI-) instrument conditions

Instrument	Waters 2690 HPLC or Waters 2795 HPLC, Micromass Quattro Ultima MS/MS
LC Column	Waters Xtera C18MS, 10.0 cm, 2.1 mm i.d., 3.5 µm particle size
Ionization	Negative Ion Electrospray
Acquisition	MRM mode, unit resolution
Injection Volume	15 µL

LC Gradient Program		**LC Flow Rate (mL/min)**	**Gradient**	**General LC Conditions**	
Time (min)	**Flow Mixture[1]**			**Column Temp**	**40°C**
0.0	60% Solvent A, 40% Solvent B	0.2	1	Flow Rate	0.200 mL/min
0.5	60% Solvent A, 40% Solvent B	0.2	6	Max Pressure	345 Bar
7.0	100% Solvent B	0.2	6	Autosampler tray temperature	4ºC
12.5	100%Solvent B	0.2	6	**MS Conditions**	
12.7	60% Solvent A, 40% Solvent B	0.2	6	Source Temp	100°C
16.0	60% Solvent A, 40% Solvent B	0.2	1	Desolvation Temp	350°C
				Cone / Desolvation Gas Rate	50L/hr / 300 L/hr

1. Solvent A = 0.1% Ammonium Acetate and 0.1% Acetic Acid in HPLC water
   Solvent B = 1:1 MethanolAcetonitrile

Table 7. Group 3 acidic extraction negative electrospray ionization (ESI-) compound retention times (RTs), parent-daughter transitions, quantitation references, method detection limits, and minimum levels of quantitation

Analyte	RT (min)	Parent- daughter m/zs	Quantitation reference	Detection limits and minimum levels					
				Water (ng/L)		Other (Φg/g)		Extract (ng/ΦL)	
				MDL	ML	MDL	ML	MDL	ML
Group 3	**Analytes Extracted Under Acidic Conditions and Analyzed Using Negative Electrospray Ionization (-) ESI.**								
Native compounds									
Naproxen	6.7	228.9 - 168.6	^{13}C-Naproxen-d_3	3.9	10	6.1	20	1.0	2.5
Warfarin	7.1	307.0 - 117.0	Warfarin-d_5	0.9	5	1.6	5	0.2	1.25
Ibuprofen	8.4	205.1 - 161.1	$^{13}C_3$-Ibuprofen	6.0	50	11	50	1.5	12.5
Gemfibrozil	9.5	249.0 - 121.0	Gemfibrozil-d_6	0.8	5	1.2	5	0.2	1.25
Triclocarban	9.6	312.9 - 159.7	$^{13}C_6$-Triclocarban	2.1	10	2.7	10	0.5	2.5
Triclosan	9.7	286.8 - 35.0	$^{13}C_{12}$-Triclosan	92	200	56	200	23	50
Labeled compounds spiked into samples									
^{13}C-Naproxen-d_3	6.6	232.9 - 168.6	$^{13}C_6$-TCPAA						
Warfarin-d_5	7.0	312.0 - 161.0	$^{13}C_6$-TCPAA						
$^{13}C_3$-Ibuprofen	8.5	208.2 - 163.1	$^{13}C_6$-TCPAA						
Gemfibrozil-d_6	9.5	255.0 - 121.0	$^{13}C_6$-TCPAA						
$^{13}C_6$-Triclocarban	9.6	318.9 - 159.7	$^{13}C_6$-TCPAA						
$^{13}C_{12}$-Triclosan	9.7	298.8 - 35.0	$^{13}C_6$-TCPAA						
Injection Internal Standard									
$^{13}C_6$-TCPAA	4.9	258.8 - 200.7	External standard						

Table 8. Group 4 – Basic extraction positive electrospray ionization (ESI+) instrument conditions

Instrument	Waters 2690 HPLC or Waters 2795 HPLC, Micromass Quattro Ultima MS/MS
LC Column	Waters Atlantis HILIC, 10 cm, 2.1 mm i.d., 3.0 µm particle size
Ionization	Positive Ion Electrospray
Acquisition	MRM mode, unit resolution
Purge Solvent	100% CH_3CN (changed from H_2O)
Injection Volume	2.0 µL

LC Gradient Program		**LC Flow Rate (mL/min)**	**Gradient**	**General LC Conditions**	
Time (min)	**Flow Mixture[1]**			**Column Temp**	**40 °C**
0.0	2% Solvent A 98% Solvent B	0.25	1	Flow Rate	0.25 mL/min
5.0	30% Solvent A 70% Solvent B	0.25	6	Max Pressure	345 Bar
12.0	30% Solvent A 70% Solvent B	0.25	6	Autosampler tray temperature	4ºC
12.5	2% Solvent A 98% Solvent B	0.25	6	**MS Conditions**	
16.0	2% Solvent A 98% Solvent B	0.25	6	Source Temp	120°C
				Desolvation Temp	350°C
				Cone / Desolvation Gas Rate	70L/hr / 400 L/hr

1. Solvent A = 0.1% Acetic Acid/Ammonium Acetate Buffer
   Solvent B = Acetonitrile

Table 9. Group 4 basic extraction positive electrospray ionization (ESI+) compound retention times (RTs), parent-daughter transitions, quantitation references, method detection limits, and minimum levels of quantitation

Analyte	RT (min)	Parent-daughter m/zs	Quantitation reference	Detection limits and minimum levels					
				Water (ng/L)		Other (ng/g)		Extract (ng/ΦL)	
				MDL	ML	MDL	ML	MDL	ML
Group 4	**Analytes Extracted Under Basic Conditions and Analyzed Using Positive Electrospray Ionization (+) ESI**								
Native compounds									
Cimetidine	6.9	253.1 - 159.0	Albuterol-d_3	0.6	2	0.78	2	0.2	0.5
Albuterol	9.4	240.0 - 148.0	Albuterol-d_3	0.9	2	0.39	2	0.2	0.5
Ranitidine	10.3	315.0 - 175.9	Albuterol-d_3	0.7	2	1.1	2	0.2	0.5
Metformin	11.0	131.1 - 60.1	Metformin-d_6	23	100	38	100	5.8	25
Labeled compounds spiked into samples									
Albuterol-d_3	9.4	243.0 - 151.0	Cotinine-d_3						
Metformin-d_6	11.0	285.1 - 162.0	Cotinine-d_3						
Injection internal standard									
Cotinine-d_3	5.9	180.0 - 79.9	External standard						
13C3-Atrazine	2.0	219.5 - 176.9 (134.0)	External Standard						

Table 10. Nominal concentrations of native compounds, labelled compounds, and instrument internal standard solutions [1]

Compound Name	**Spiking solution concentration (µg/mL)**	**Typical amount spiked into sample (ng)**
Native compound spike solutions for acid extracted analytes (Groups 1 and 3)		**(Typical spiking volume into sample: 30 µL)**
Acetaminophen	100	3000
Azithromycin	2.5	75
Caffeine	25	750
Carbodox	2.5	75
Carbamazapine	2.5	75
Cefotaxime	10	300
Clarithromycin	2.5	75
Cloxacillin	5	150
Codeine	5	150
Cotinine	2.5	75
Dehydronifedipine (Oxidized Nifedipine)	1	30
Diphenhydramine	1	30
Diltiazem	0.5	15
Digoxin	25	750
Digoxigenin	10	300
Erythromycin	0.5	15
Flumequine	2.5	75
Fluoxetine	2.5	75
Lincomycin	5	150
Miconazole	2.5	75
Norgestimate	5	150
Ormetoprim	1	30
Oxacillin	5	150
Oxolinic acid	1	30
Penicillin G	5	150
Penicillin V	5	150
Roxithromycin	0.5	15
Sulfachloropyridazine	2.5	75
Sulfadiazine	2.5	75
Sulfadimethoxine	0.5	15
Sulfamerazine	1	30
Sulfamethazine	1	30
Sulfamethizole	1	30
Sulfamethoxazole	1	30
Sulfanilamide	25	750

Compound Name	Spiking solution concentration (μg/mL)	Typical amount spiked into sample (ng)
Sulfathiazole	2.5	75
Thiabendazole	2.5	75
Trimethoprim	2.5	75
Tylosin	10	300
Virginiamycin	5	150
1,7-Dimethylxanthine	250	7500
Ampicillin	2.5	75
Ciprofloxacin	8.75	263
Clinafloxacin	10	300
Enrofloxacin	5	150
Lomefloxacin	5	150
Norfloxacin	25	750
Ofloxacin	2.5	75
Sarafloxacin	22.8	684
Gemfibrozil	2.5	75
Ibuprofen	25	750
Naproxen	5	150
Triclocarban	5	150
Triclosan	100	3000
Warfarin	2.5	75
Native compound spike solutions for tetracyclines (Group 2)		**(Typical spiking volume into sample: 200 µL)**
Tetracycline (TC)	0.5	100
Oxytetracycline (OTC)	0.5	100
Doxycycline	0.5	100
Chlortetracycline (CTC)	0.5	100
Anhydrochlortetracycline (ACTC)	1.25	250
Anhydrotetracycline (ATC)	1.25	250
4-Epianhydrochlortetracycline (EACTC)	5	1000
4-Epianhydrotetracycline (EATC)	1.25	250
4-Epichlortetracycline (ECTC)	1.25	250
4-Epioxytetracycline (EOTC)	0.5	100
4-Epitetracycline (ETC)	0.5	100
Isochlortetracycline (ICTC)	0.5	100
Demeclocycline	1.25	250
Minocycline	5	1000
Native compound spike solutions for base extracted analytes (Group 4)		**(Typical spiking volume into sample: 15 µL)**
Albuterol	1	15
Cimetidine	2	30

Compound Name	Spiking solution concentration (µg/mL)	Typical amount spiked into sample (ng)
Metformin	100	1500
Ranitidine	2	30
Labeled compound solutions for acid extracted analytes (Groups 1, 2 and 3)		**(Typical spiking volume into sample: 100 µL)**
Meclocycline	8	800
d_{10}-Carbamazepine-10,11-epoxide	2	200
d_3-Cotinine	2	200
d_5-Fluoxetine	1	100
d_6-Gemfibrozil	1	100
$^{13}C_2$, ^{15}N-Acetaminophen	4	400
$^{13}C_6$-Sulfamethoxazole	1	100
^{13}C, d_3-Naproxen	3	300
$^{13}C_6$-Triclocarban	0.5	50
$^{13}C_3$-Trimethoprim	1	100
d_6-Thiabendazole	1	100
$^{13}C_3$-Caffeine	3	300
$^{13}C_2$-Erythromycin	1	100
$^{13}C_{12}$-Triclosan	4	400
d_5-Warfarin	1	100
$^{13}C_6$-Sulfamethazine	1	100
$^{13}C_3$, ^{15}N-Ciprofloxacin	4	400
$^{13}C_3$-Ibuprofen	4	400
Labeled compound solutions for base extracted analytes (Group 4)		**(Typical spiking volume into sample: 100 µL)**
d_3-Albuterol	1	100
d_6-Metformin	4	400
Instrument internal standard solutions for acid extracted analytes (Groups 1, 2 and 3)		**(Typical spiking volume into extract: 80 µL)**
$^{13}C_3$-Atrazine	2.5	200
$^{13}C_6$-2,4,5-Trichlorophenoxyacetic acid	2.5	200
Instrument internal standard solutions for base extracted analytes (Group 4)		**(Typical spiking volume into extract: 100 µL)**
$^{13}C_3$-Atrazine	2	200
d_3-Cotinine	2	200

1. See Sections 7.8 – 7.9 for solution details

Tables 11a-c. Concentrations of calibration solutions (ng/mL)

Table 11a Concentrations of calibration standards for Group 1 and Group 3 compounds (ng/mL) (Acid extraction, positive and negative ESI). CS=calibration standard.

Compound	CS-1	CS-2	CS-3 (VER)	CS-4	CS-5
Acetaminophen	50	150	750	2500	10000
Azithromycin	1.25	3.75	18.7	62.5	250
Caffeine	12.5	37.5	187.	625	2500
Carbadox	1.25	3.75	18.7	62.5	250
Carbamazapine	1.25	3.75	18.7	62.5	250
Cefotaxime	5	15	75	250	1000
Clarithromycin	1.25	3.75	18.7	62.5	250
Cloxacillin	2.5	7.5	37.5	125	500
Codeine	2.5	7.5	37.5	125	500
Cotinine	1.25	3.75	18.7	62.5	250
Dehydronifedipine (Oxidized Nifedipine)	0.5	1.5	7.5	25	100
Diphenhydramine	0.5	1.5	7.5	25	100
Diltiazem	0.25	0.75	3.75	12.5	50
Digoxin	12.5	37.5	187	625	2500
Digoxigenin	5	15	75	250	1000
Erythromycin	0.25	0.75	3.75	12.5	50
Erythromycin anhydrate	0.25	0.75	3.75	12.5	50
Flumequine	1.25	3.75	18.7	62.5	250
Fluoxetine	1.25	3.75	18.7	62.5	250
Lincomycin	2.5	7.5	37.5	125	500
Miconazole	1.25	3.75	18.7	62.5	250
Norgestimate	2.5	7.5	37.5	125	500
Ormetoprim	0.5	1.5	7.5	25	100
Oxacillin	2.5	7.5	37.5	125	500
Oxolinic acid	0.5	1.5	7.5	25	100
Penicillin G	2.5	7.5	37.5	125	500
Penicillin V	5	15	75	250	1000
Roxithromycin	0.25	0.75	3.75	12.5	50
Sulfachloropyridazine	1.25	3.75	18.7	62.5	250
Sulfadiazine	1.25	3.75	18.7	62.5	250
Sulfadimethoxine	0.25	0.75	3.75	12.5	50
Sulfamerazine	0.5	1.5	7.5	25	100
Sulfamethazine	0.5	1.5	7.5	25	100
Sulfamethizole	0.5	1.5	7.5	25	100
Sulfamethoxazole	0.5	1.5	7.5	25	100
Sulfanilamide	12.5	37.5	187.5	625	2500

Compound	CS-1	CS-2	CS-3 (VER)	CS-4	CS-5
Sulfathiazole	1.25	3.75	18.7	62.5	250
Thiabendazole	1.25	3.75	18.7	62.5	250
Trimethoprim	1.25	3.75	18.7	62.5	250
Tylosin	5	15	75	250	1000
Virginiamycin	2.5	7.5	37.5	125	500
1,7-Dimethylxanthine	125	375	1870	6250	25000
Ampicillin	1.25	3.75	18.7	62.5	250
Ciprofloxacin	4.4	13.1	65.6	218.	875
Clinafloxacin	5	15	75	250	1000
Enrofloxacin	2.5	7.5	37.5	125	500
Lomefloxacin	2.5	7.5	37.5	125	500
Norfloxacin	12.5	37.5	187	625	2500
Ofloxacin	1.25	3.75	18.7	62.5	250
Sarafloxacin	11.4	34.2	171	570	2280
Gemfibrozil	1.25	3.75	18.7	62.5	250
Ibuprofen	12.5	37.5	187	625	2500
Naproxen	2.5	7.5	37.5	125	500
Triclocarban	2.5	7.5	37.5	125	500
Triclosan	50	150	750	2500	10000
Warfarin	1.25	3.75	18.7	62.5	250
Labeled compounds					
d_3-Cotinine	50	50	50	50	50
d_5-Fluoxetine	25	25	25	25	25
d_6-Gemfibrozil	25	25	25	25	25
$^{13}C_2$, ^{15}N-Acetaminophen	100	100	100	100	100
$^{13}C_6$-Sulfamethoxazole	25	25	25	25	25
^{13}C-d_3-Naproxen	75	75	75	75	75
$^{13}C_6$-Triclocarban	12.5	12.5	12.5	12.5	12.5
$^{13}C_3$-Trimethoprim	25	25	25	25	25
d_6-Thiabendazole	25	25	25	25	25
$^{13}C_3$-Caffeine	75	75	75	75	75
$^{13}C_2$-Erythromycin	25	25	25	25	25
$^{13}C_{12}$-Triclosan	90	90	90	90	90
d_5-Warfarin	25	25	25	25	25
$^{13}C_6$-Sulfamethazine	25	25	25	25	25
$^{13}C_3$, ^{15}N-Ciprofloxacin	100	100	100	100	100
$^{13}C_3$-Ibuprofen	100	100	100	100	100

Compound	CS-1	CS-2	CS-3 (VER)	CS-4	CS-5
Instrument internal standards					
$^{13}C_3$-Atrazine	50	50	50	50	50
$^{13}C_6$-2,4,5-Trichlorophenoxyacetic acid	50	50	50	50	50

Table 11b Concentrations of calibration standards for Group 2 compounds (ng/mL) (Acid extraction, positive ESI). CS=calibration standard.

Compound name	CS-1	CS-2	CS-3 (VER)	CS-4	CS-5
Tetracycline (TC)	5	12.5	25	50	150
Oxytetracycline (OTC)	5	12.5	25	50	150
Doxycycline	5	12.5	25	50	150
Chlortetracycline (CTC)	5	12.5	25	50	150
Anhydrochlortetracycline (ACTC)	12.5	31.25	62.5	125	375
Anhydrotetracycline (ATC)	12.5	31.25	62.5	125	375
4-Epianhydrochlortetracycline (EACTC)	50	125	250	500	1500
4-Epianhydrotetracycline (EATC)	12.5	31.2	62.5	125	375
4-Epichlortetracycline (ECTC)	12.5	31.2	62.5	125	375
4-Epioxytetracycline (EOTC)	5	12.5	25	50	150
4-Epitetracycline (ETC)	5	12.5	25	50	150
Isochlortetracycline (ICTC)	5	12.5	25	50	150
Demeclocycline	12.5	31.2	62.5	125	375
Minocycline	50	125	250	500	1500
Labeled compounds					
d_3-Cotinine	50	50	50	50	50
d_5-Fluoxetine	25	25	25	25	25
d_6-Gemfibrozil	25	25	25	25	25
$^{13}C_2$, ^{15}N-Acetaminophen	100	100	100	100	100
$^{13}C_6$-Sulfamethoxazole	25	25	25	25	25
^{13}C, d_3-Naproxen	75	75	75	75	75
$^{13}C_6$-Triclocarban	12.5	12.5	12.5	12.5	12.5
$^{13}C_3$-Trimethoprim	25	25	25	25	25
d_6-Thiabendazole[1]	25	25	25	25	25
$^{13}C_3$-Caffeine	75	75	75	75	75
$^{13}C_2$-Erythromycin	25	25	25	25	25
$^{13}C_{12}$-Triclosan	90	90	90	90	90
d_5-Warfarin	25	25	25	25	25
$^{13}C_6$-Sulfamethazine	25	25	25	25	25
$^{13}C_3$, ^{15}N-Ciprofloxacin	100	100	100	100	100
$^{13}C_3$-Ibuprofen	100	100	100	100	100
Instrument internal standards					

Compound name	CS-1	CS-2	CS-3 (VER)	CS-4	CS-5
$^{13}C_3$-Atrazine[1]	50	50	50	50	50
$^{13}C_6$-2,4,5-Trichlorophenoxyacetic acid	50	50	50	50	50

1. Note: The Group 2, acid extracted positive ESI (tetracyclines) contains the same labeled compounds as for Group 1 and 3, acid extracted positive and negative ESI, yet the only labeled compounds used in determination of the Group 2 are Thiabendazole-d6 and 13C3-Atrazine. This minimizes the work required to prepare solutions. Some of those surrogates are used to quantify the Group 1 and 2 and some Group 3 in separate runs of the same extract. This is not a requirement.

Table 11c Concentrations of calibration standards for Group 4 (ng/mL) compounds (Base extraction, positive ESI). CS=calibration standard.

Compound name	CS-1	CS-2	CS-3 (VER)	CS-4	CS-5
Albuterol	0.25	0.75	3.75	12.5	50
Cimetidine	0.5	1.5	7.5	25	100
Metformin	25	75	375	1250	5000
Ranitidine	0.5	1.5	7.5	25	100
Labeled compounds					
d_3-Albuterol	25	25	25	25	25
d_6-Metformin	100	100	100	100	100
Instrument internal standards					
$^{13}C_3$-Atrazine	50	50	50	50	50
d_3-Cotinine	50	50	50	50	50

Table 12. QC acceptance criteria for PPCPs in VER, IPR, OPR, and samples.

Compound	VER (%)	IPR RSD (%)	IPR X (%)	OPR (%)	Labeled compound recovery in samples (%)
Acetaminophen	70 - 130	30	55 - 108	50 - 120	
Albuterol	70 - 130	30	55 - 120	50 - 133	
Ampicillin	70 - 130	70	6 - 180	5 - 200	
Anhydrochlortetracycline (ACTC)	70 - 130	30	55 - 121	50 - 135	
Anhydrotetracycline (ATC)	70 - 130	30	8 - 127	7 - 141	
Azithromycin	70 - 130	30	36 - 108	33 - 120	
Caffeine	70 - 130	30	55 - 111	50 - 124	
Carbadox	70 - 130	30	36 - 130	33 - 144	
Carbamazepine	70 - 130	30	23 - 123	21 - 137	
Cefotaxime	70 - 130	36	9 - 168	8 - 186	
Chlortetracycline (CTC)	70 - 130	31	49 - 155	45 - 172	
Cimetidine	70 - 130	47	6 - 108	5 - 120	
Ciprofloxacin	70 - 130	30	55 - 108	50 - 120	
Clarithromycin	70 - 130	30	8 - 139	8 - 154	
Clinafloxacin	70 - 130	37	6 - 180	5 - 200	
Cloxacillin	70 - 130	30	6 - 180	5 - 200	
Codiene	70 - 130	30	37 - 116	34 - 129	
Cotinine	70 - 130	30	55 - 112	50 - 124	
Dehydronifedipine	70 - 130	30	47 - 108	42 - 120	
Demeclocycline	70 - 130	30	6 - 180	5 - 200	
Digoxigenin	70 - 130	30	8 - 165	8 - 183	
Digoxin	70 - 130	45	6 - 133	5 - 148	
Diltiazem	70 - 130	48	13 - 108	11 - 120	
1,7-Dimethylxanthine	70 - 130	30	55 - 124	50 - 138	
Diphenhydramine	70 - 130	30	53 - 108	48 - 120	
Doxycycline	70 - 130	30	24 - 149	22 - 166	
Enrofloxacin	70 - 130	30	55 - 113	50 - 125	
4-Epianhydrochlortetracycline (EACTC)	70 - 130	30	20 - 108	18 - 120	
4-Epianhydrotetracycline (EATC)	70 - 130	30	6 - 180	5 - 200	
4-Epichlortetracycline (ECTC)	70 - 130	30	55 - 135	50 - 150	
4-Epioxytetracycline (EOTC)	70 - 130	30	55 - 127	50 - 142	
4-Epitetracycline (ETC)	70 - 130	30	55 - 156	50 - 173	
Erythromycin hydrate	70 - 130	30	55 - 142	50 - 158	
Flumequine	70 - 130	30	39 - 180	36 - 200	
Fluoxetine	70 - 130	30	54 - 112	49 - 125	
Gemfibrozil	70 - 130	30	55 - 108	50 - 120	
Ibuprofen	70 - 130	30	55 - 108	50 - 120	
Isochlortetracycline (ICTC)	70 - 130	30	6 - 180	5 - 200	
Lincomycin	70 - 130	60	6 - 108	5 - 120	
Lomefloxacin	70 - 130	33	19 - 180	17 - 200	
Metformin	70 - 130	30	55 - 134	50 - 149	
Miconazole	70 - 130	30	29 - 108	27 - 120	
Minocycline	70 - 130	30	6 - 159	5 - 176	

		IPR			
Naproxen	70 - 130	30	55 - 108	50 - 120	
Norfloxacin	70 - 130	30	55 - 121	50 - 135	
Norgestimate	70 - 130	30	39 - 108	36 - 120	
Ofloxacin	70 - 130	30	55 - 180	50 - 200	
Ormetoprim	70 - 130	30	55 - 108	50 - 120	
Oxacillin	70 - 130	30	6 - 180	5 - 200	
Oxolinic acid	70 - 130	30	46 - 112	42 - 124	
Oxytetracycline (OTC)	70 - 130	30	55 - 165	50 - 183	
Penicillin V	70 - 130	30	6 - 180	5 - 200	
Penicillin G	70 - 130	30	6 - 180	5 - 200	
Ranitidine	70 - 130	41	26 - 144	24 - 160	
Roxithromycin	70 - 130	30	42 - 108	38 - 120	
Sarafloxacin	70 - 130	32	18 - 180	17 - 200	
Sulfachloropyridazine	70 - 130	30	55 - 180	50 - 200	
Sulfadiazine	70 - 130	30	6 - 180	5 - 200	
Sulfadimethoxine	70 - 130	30	55 - 108	50 - 120	
Sulfamerazine	70 - 130	30	55 - 133	50 - 148	
Sulfamethazine	70 - 130	30	55 - 128	50 - 142	
Sulfamethizole	70 - 130	30	55 - 108	50 - 120	
Sulfamethoxazole	70 - 130	30	55 - 108	50 - 120	
Sulfanilamide	70 - 130	71	6 - 170	5 - 189	
Sulfathiazole	70 - 130	30	45 - 108	41 - 120	
Tetracycline (TC)	70 - 130	30	55 - 139	50 - 155	
Thiabendazole	70 - 130	30	55 - 108	50 - 120	
Triclocarban	70 - 130	30	55 - 108	50 - 120	
Triclosan	70 - 130	30	55 - 108	50 - 120	
Trimethoprim	70 - 130	30	55 - 114	50 - 126	
Tylosin	70 - 130	30	17 - 134	16 - 149	
Virginiamycin	70 - 130	33	6 - 170	5 - 189	
Warfarin	70 - 130	30	55 - 108	50 - 120	
$^{13}C_2$-^{15}N-Acetaminophen	70 - 130	30	6 - 180	5 - 200	19 – 200
Albuterol-d3	70 - 130	30	38 - 109	35 - 121	39 – 141
$^{13}C_3$-Caffeine	70 - 130	46	6 - 180	5 - 200	31 – 200
$^{13}C_3$-^{15}N-Ciprofloxacin	70 - 130	34	6 - 180	5 - 200	37 – 181
Cotinine-d3	70 - 130	84	6 - 108	5 - 120	5 – 145
$^{13}C_2$-Erythromycin hydrate	70 - 130	30	55 - 108	50 - 120	23 – 120
Fluoxetine-d5	70 - 130	30	55 - 113	50 - 126	40 – 148
Gemfibrozil-d6	70 - 130	30	42 - 110	38 - 122	21 – 123
$^{13}C_3$-Ibuprofen	70 - 130	30	31 - 109	28 - 122	29 – 127
Metformin-d6	70 - 130	30	6 - 127	5 - 141	5 – 200
^{13}C-Naproxen-d3	70 - 130	30	37 - 118	34 - 131	14 – 132
$^{13}C_6$-Sulfamethazine	70 - 130	30	6 - 141	5 - 157	12 – 120
$^{13}C_6$-Sulfamethoxazole	70 - 130	30	55 - 131	50 - 146	40 – 129
Thiabendazole-d6 (A Pos)	70 - 130	30	55 - 132	50 - 146	32 – 140
Thiabendazole-d6 (TCY)	70 - 130	30	55 - 108	50 - 120	30 – 132
$^{13}C_6$-Triclocarban	70 - 130	30	6 - 155	5 - 172	5 – 147

		IPR			
$^{13}C_{12}$-Triclosan	70 - 130	30	6 - 151	5 - 168	5 – 153
$^{13}C_{3}$-Trimethoprim	70 - 130	30	55 - 162	50 - 180	50 – 172
Warfarin-d5	70 - 130	30	55 - 159	50 - 177	50 – 200

Table 13. Suggested sample quantities to be extracted for various matrices [1]

Sample matrix[2]	Example	Percent solids	Phase	Quantity extracted
Single-phase				
Aqueous	Drinking water	No visible particles	Aqueous	1000 mL
	Groundwater			
	Treated wastewater			
Solid	Dry soil	>20	Solid	1 g
	Filter cake			
	Compost			
Multi-phase				
Liquid/Solid				
Aqueous/solid[2]	Wet soil	1 - 30	Aqueous and solid	1 g
	Untreated effluent	1 - 5		
	Municipal sludge	1 - 30		0.25 g

1. The quantity of sample to be extracted is adjusted to provide 1 g of solids (dry weight). One liter of aqueous samples containing 0.1% solids will contain 1 gram of solids. For aqueous samples containing greater than 0.1% solids, a lesser volume is used so that 1 gram of solids (dry weight) will be prepared.
2. 1 g of solids (0.25 g for biosolids), or 5 g wet weight if solids content is <20%.

Table 14. Performance Data from single laboratory validation.

Analyte	Solid-Based on 5 samples			Reagent Water-Based on 5 samples			Biosolids-Based on 6 samples		
	Solids Average Recovery	Solids Standard Deviation	Solids Relative Standard Deviation	Water Average Recovery	Water Standard Deviation	Water Relative Standard Deviation	Biosolids Average Recovery	Biosolids Standard Deviation	Biosolids Relative Standard Deviation
Group 3 acidic extraction ESI-									
Warfarin	90.76	5.96	6.57	86.52	3.59	4.15	119.64	13.67	11.42
Ibuprofen	103.16	3.63	3.52	97.43	3.70	3.80	93.82	7.96	8.48
Gemfibrozil	97.94	2.84	2.90	98.11	2.45	2.50	78.35	21.19	27.05
Naproxen	96.57	6.23	6.45	95.41	5.03	5.27	99.94	10.10	10.10
Triclocarban	100.60	2.36	2.34	106.09	4.81	4.53	265.00	190.08	71.73
Triclosan	97.52	6.78	6.95	93.14	3.35	3.60	359.73	500.34	139.09
d5-Warfarin	113.44	8.21	7.23	143.13	8.22	5.74	145.03	23.97	16.52
13C3-Ibuprofen	59.25	2.34	3.95	90.20	8.04	8.91	74.30	21.35	28.74
d6-Gemfibrozil	65.37	2.85	4.36	94.94	3.16	3.33	65.80	28.35	43.09
13C-d3-Naproxen	65.52	5.45	8.31	98.95	3.99	4.03	55.18	20.45	37.06
13C6-Triclocarban	20.36	1.38	6.78	100.55	3.10	3.09	54.18	36.10	66.62
13C12-Triclosan	42.75	3.75	8.77	108.28	5.80	5.36	71.62	34.48	48.15
Group 1 acidic extraction ESI+									
Acetaminophen	104.50	3.53	3.38	100.85	1.17	1.16	94.25	4.97	5.27
Azithromycin	66.08	11.99	18.15	60.95	6.80	11.15	86.53	25.39	29.34
Caffeine	96.41	10.08	10.45	99.14	6.38	6.44	86.08	5.95	6.91
Carbadox	107.42	3.78	3.52	69.50	7.48	10.76	52.91	13.50	25.52
Carbamazepine	98.84	6.85	6.93	59.14	4.92	8.32	91.50	19.27	21.06
Cefotaxime	122.83	4.32	3.52	71.75	23.92	33.33	173.69	15.86	9.13
Ciprofloxacin	95.76	3.54	3.70	99.66	2.20	2.21	73.93	69.08	93.44
Clarithromycin	54.67	4.07	7.44	106.90	2.64	2.47	69.53	12.17	17.50
Clinafloxacin	172.32	31.99	18.57	76.12	5.13	6.74	171.73	24.34	14.17
Cloxacillin	261.54	15.78	6.03	60.77	3.90	6.42	166.24	11.42	6.87
Codeine	97.65	1.79	1.83	64.66	5.36	8.29	141.78	11.87	8.38
Cotinine	96.04	3.79	3.94	102.27	9.75	9.53	92.34	4.56	4.94
Dehydronifedipine	84.14	6.80	8.09	66.50	7.17	10.78	126.82	13.52	10.66
Diphenhydramine	66.76	2.94	4.40	68.99	8.42	12.20	103.43	20.40	19.73
Diltiazem	66.96	3.47	5.19	55.23	20.89	37.83	160.04	114.83	71.75
Digoxin	92.33	13.28	14.39	52.22	18.64	35.69	22.60	18.11	80.13
Digoxigenin	126.01	1.96	1.55	64.36	8.55	13.28	79.57	11.63	14.61
Enrofloxacin	97.44	11.24	11.54	96.37	7.08	7.34	108.72	6.71	6.17
Erythromycin-H2O	136.67	3.12	2.28	113.95	3.09	2.71	100.45	7.46	7.42
Flumequine	151.31	7.43	4.91	91.15	4.08	4.48	92.35	14.79	16.02
Fluoxetine	88.09	16.86	19.14	85.89	4.27	4.97	100.48	19.64	19.55
Lincomycin	55.95	15.38	27.49	17.70	1.70	9.58	198.99	13.38	6.72
Lomefloxacin	179.94	32.28	17.94	106.07	6.19	5.83	79.59	9.63	12.10
Miconazole	51.31	4.73	9.23	73.81	6.50	8.81	55.79	17.71	31.74
Norfloxacin	101.34	6.89	6.80	114.79	5.07	4.41	63.02	7.17	11.37
Norgestimate	58.06	3.52	6.06	48.26	3.61	7.48	49.20	7.61	15.47

Ofloxacin	166.98	26.78	16.04	127.81	12.16	9.51	78.44	34.96	44.57
Ormetoprim	64.83	2.86	4.41	66.94	3.44	5.14	78.76	5.96	7.56
Oxacillin	168.38	15.50	9.20	60.02	6.22	10.36	163.73	11.69	7.14
Oxolinic Acid	96.72	2.48	2.56	69.17	6.30	9.10	108.07	12.09	11.19
Penicillin G	214.04	14.66	6.85	58.83	6.77	11.51	99.09	14.24	14.37
Penicillin V	195.93	9.43	4.81	61.80	7.81	12.63	157.80	9.85	6.24
Roxithromycin	61.28	3.61	5.89	85.57	2.23	2.60	83.70	19.61	23.42
Sarafloxacin	146.84	25.89	17.63	87.70	4.25	4.84	108.36	8.57	7.91
Sulfachloropyridazine	158.30	8.72	5.51	115.36	3.88	3.36	90.24	9.86	10.92
Sulfadiazine	158.51	17.49	11.03	80.11	2.33	2.91	107.55	12.80	11.90
Sulfadimethoxine	78.65	3.44	4.37	87.00	2.95	3.39	67.87	9.14	13.46
Sulfamerazine	115.08	13.12	11.40	90.48	1.01	1.12	136.01	9.46	6.96
Sulfamethazine	119.60	5.59	4.67	100.67	6.19	6.15	103.35	11.96	11.57
Sulfamethizole	75.61	8.69	11.49	93.86	4.52	4.82	70.14	3.00	4.28
Sulfamethoxazole	103.21	2.97	2.88	88.17	3.63	4.12	102.56	12.66	12.34
Sulfanilamide	99.94	29.94	29.96	20.71	0.95	4.59	130.84	8.89	6.79
Sulfathiazole	59.06	3.39	5.74	76.73	3.22	4.20	92.10	8.07	8.76
Thiabendazole	106.47	1.44	1.35	99.83	1.92	1.93	81.89	6.03	7.36
Trimethoprim	103.24	3.23	3.13	80.82	5.65	6.99	98.81	5.35	5.42
Tylosin	60.99	9.93	16.28	103.48	9.59	9.27	47.80	14.56	30.46
Virginiamycin	116.39	10.65	9.15	43.62	15.26	34.99	172.33	42.36	24.58
1,7 DimethylXanthine	100.64	16.81	16.70	95.73	7.16	7.48	137.15	38.02	27.72
13C2-15N-Acetaminophen	258.79	19.66	7.60	112.20	4.48	3.99	137.17	28.54	20.80
13C3-Caffeine	203.04	50.76	25.00	115.82	7.57	6.54	119.47	9.50	7.95
d3-Cotinine	28.08	9.20	32.76	3.20	0.35	10.92	68.57	19.19	27.99
13C3-N15-Ciprofloxacin	66.74	18.81	28.19	144.50	16.99	11.75	132.12	13.74	10.40
13C2-Erythromycin-H2O	97.49	7.73	7.93	86.25	2.83	3.28	54.62	13.12	24.03
d5-Fluoxetine	92.68	8.40	9.07	103.69	6.05	5.84	94.67	35.78	37.79
13C6-Sulfamethazine	54.80	7.77	14.17	105.70	11.12	10.52	50.78	7.28	14.35
13C6-Sulfamethoxazole	85.21	9.29	10.90	111.77	9.32	8.34	72.67	10.63	14.63
d6-Thiabendazole	92.75	8.63	9.30	117.76	4.64	3.94	66.75	5.19	7.78
13C3-Trimethoprim	121.40	12.12	9.98	144.35	9.96	6.90	94.08	12.15	12.91
Group 4 basic extraction ESI+									
Albuterol	100.43	7.12	7.09	90.04	14.09	15.65	96.58	1.88	1.95
Cimetidine	37.37	10.69	28.60	64.93	12.83	19.75	52.77	14.30	27.09
Metformin	115.61	9.40	8.13	103.72	13.16	12.69	89.06	3.32	3.72
Ranitidine	79.99	13.90	17.37	103.66	22.67	21.87	71.15	7.22	10.15
d3-Albuterol	91.52	8.47	9.25	63.83	2.41	3.78	105.42	19.25	18.26
d6-Metformin	94.38	13.05	13.83	51.66	6.86	13.28	161.13	67.48	41.88
Group 2 acidic extraction ESI+									
Chlortetracycline	121.24	6.98	5.75	95.24	22.32	23.44	114.43	45.67	39.91
4-Epichlortetracycline	112.41	8.71	7.75	96.83	15.65	16.16	95.59	32.60	34.11
Anhydrochlortetracycline	92.62	10.43	11.27	102.22	11.51	11.26	50.40	21.73	43.12
4-Epianhydrochlortetracycline	53.57	1.87	3.49	82.28	13.31	16.18	33.88	8.30	24.49
Isochlortetracycline	65.88	5.01	7.61	149.37	16.06	10.75	91.65	25.51	27.83
Demeclocycline	54.53	1.96	3.59	136.58	3.18	2.33	76.03	31.01	40.79
Doxycycline	67.83	2.96	4.36	119.65	1.01	0.85	87.03	34.42	39.55

Oxytetracycline	112.85	3.12	2.77	148.84	5.76	3.87	74.46	16.46	22.10
4-Epioxytetracycline	119.40	6.94	5.81	122.38	6.25	5.11	83.55	18.09	21.65
Tetracycline	93.41	3.95	4.23	124.79	4.69	3.76	77.98	19.24	24.68
4-Epitetracycline	138.95	3.42	2.46	102.11	4.02	3.94	97.37	37.03	38.03
4-Epianhydrotetracycline	70.11	6.87	9.80	170.82	22.25	13.02	67.87	23.27	34.29
Anhydrotetracycline	50.21	4.13	8.23	98.14	2.50	2.55	86.20	34.27	39.76
d6-Thiabendazole	77.07	4.76	6.18	64.80	3.21	4.95	89.82	15.10	16.81

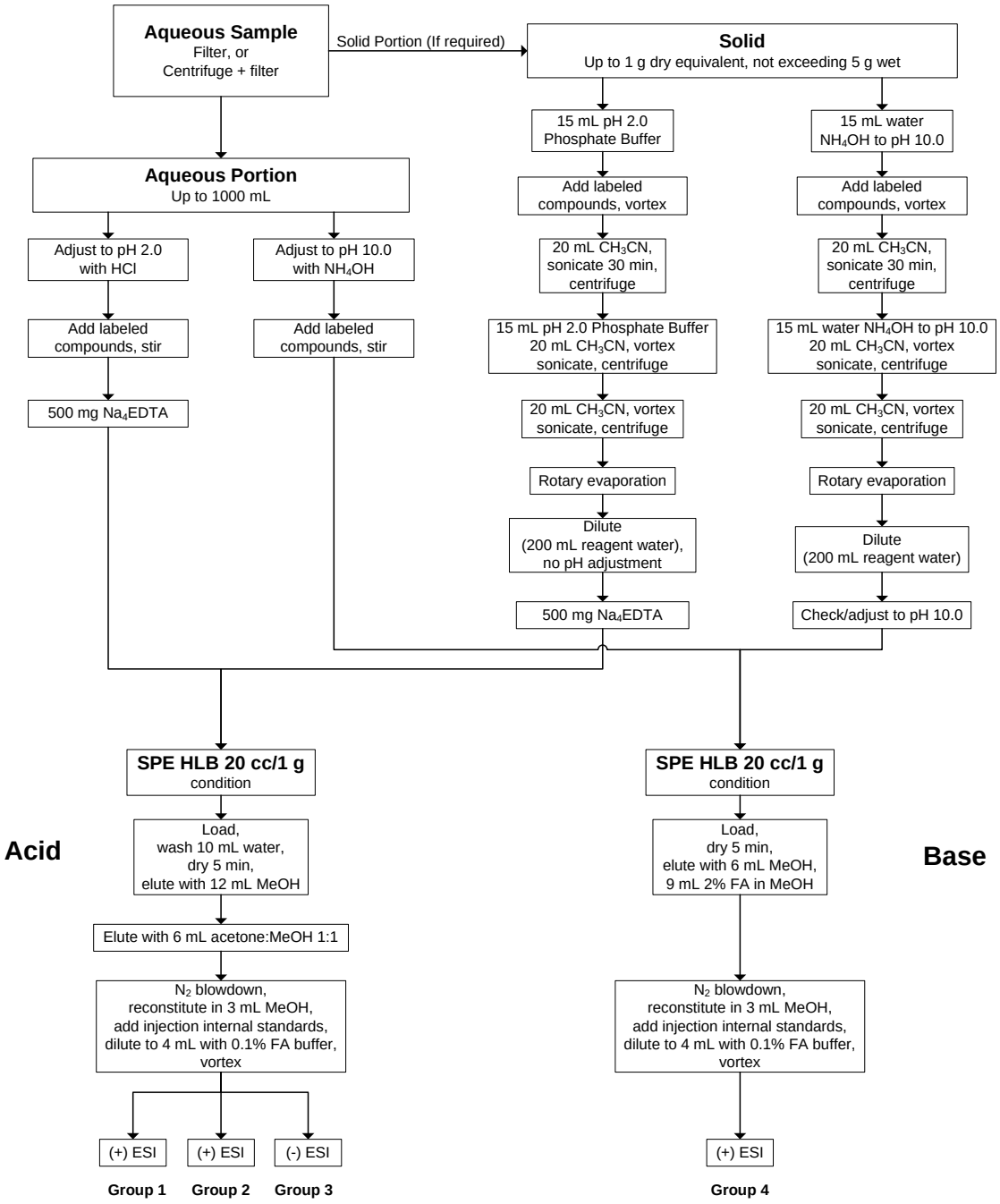

Figure 1 Flow chart for determination of pharmaceuticals and personal-care products by LC/MS/MS

24.0 Glossary

These definitions and purposes are specific to this method but have been conformed to common usage to the extent possible.

24.1 Units of weight and measure and their abbreviations

24.1.1 Symbols

EC	degrees Celsius
ΦL	microliter
Φm	micrometer
<	less than
>	greater than
%	percent

24.1.2 Abbreviations (in alphabetical order)

cm	centimeter
g	gram
h	hour
ID	inside diameter
in.	inch
L	liter
M	Molecular ion
m	mass or meter
mg	milligram
min	minute
mL	milliliter
mm	millimeter
m/z	mass-to-charge ratio
N	normal; gram molecular weight of solute divided by hydrogen equivalent of solute, per liter of solution
OD	outside diameter
pg	picogram
ppb	part-per-billion
ppm	part-per-million
ppq	part-per-quadrillion
ppt	part-per-trillion
psig	pounds-per-square inch gauge
v/v	volume per unit volume
w/v	weight per unit volume

24.2 Definitions and acronyms (in alphabetical order)

Analyte – A pharmaceutical or personal-care product tested for by this method. The analytes are listed in Table 1.

Calibration standard (CAL) – A solution prepared from a secondary standard and/or stock solution and used to calibrate the response of the HPLC/MSMS

instrument.

Calibration verification standard (VER) – The mid-point calibration standard (CS-4) that is used to verify calibration. See Table 4.

CS-1, CS-2, CS-3, CS-4, CS-5, CS-6 – See Calibration standards and Table 4.

Field blank – An aliquot of reagent water or other reference matrix that is placed in a sample container in the field, and treated as a sample in all respects, including exposure to sampling site conditions, storage, preservation, and all analytical procedures. The purpose of the field blank is to determine if the field or sample transporting procedures and environments have contaminated the sample.

GPC – Gel permeation chromatograph or gel permeation chromatography

HPLC – High performance liquid chromatograph or high performance liquid chromatography

Labeled injection internal standard – A labeled spiked into the concentrated extract immediately prior to injection of an aliquot of the extract into the LC/MS/MS.

Internal standard – a labeled compound used as a reference for quantitation of other labeled compounds and for quantitation of a native compound other than the compound of which it is a labeled analog. See Internal standard quantitation.

Internal standard quantitation – A means of determining the concentration of (1) a naturally occurring (native) compound by reference to a compound other than its labeled analog and (2) a labeled compound by reference to another labeled compound.

IPR – Initial precision and recovery; four aliquots of a reference matrix spiked with the analytes of interest and labeled compounds and analyzed to establish the ability of the laboratory to generate acceptable precision and recovery. An IPR is performed prior to the first time this method is used and any time the method or instrumentation is modified.

Isotope dilution quantitation – A means of determining a naturally occurring (native) compound by reference to the same compound in which one or more atoms has been isotopically enriched. In this method, labeled are enriched with deuterium to produce ^{2}H labeled analogs or carbon-13 to produce ^{13}C-labeled analogs. The labeled analogs are spiked into each sample to allow identification and correction of the concentration of the native compounds in the analytical process.

Labeled compound – A molecule in which one or more of the atoms is isotopically entriched, thereby increasing the mass of the molecule

Laboratory blank – See method blank

Laboratory control sample (LCS) – See Ongoing precision and recovery standard (OPR)

Laboratory reagent blank – See method blank

May – This action, activity, or procedural step is neither required nor prohibited.

May not – This action, activity, or procedural step is prohibited.

Method blank – An aliquot of reagent water that is treated exactly as a sample including exposure to all glassware, equipment, solvents, reagents, internal standards, and surrogates that are used with samples. The method blank is used to determine if analytes or interferences are present in the laboratory environment, the reagents, or the apparatus.

Method detection limit (MDL) – The lowest concentration at which an analyte can be detected under routine operating conditions (see 40 CFR 136, appendix B). MDLs are listed in Table 3, 5, 7, and 9.

Minimum level (ML) – The greater of a multiple of the MDL or the lowest calibration point (see 68 FR 11790, March 12, 2003.) MLs are listed in Tables 3, 5, 7, and 9.

MS – Mass spectrometer or mass spectrometry

Must – This action, activity, or procedural step is required.

Native compound – A molecule in which the atoms all have naturally occuring isotopic abundances

OPR – Ongoing precision and recovery standard (OPR); a method blank spiked with known quantities of analytes. Also known as a “laboratory control sample” (LCS). The OPR is analyzed exactly like a sample. Its purpose is to assure that the results produced by the laboratory remain within the limits specified in this method for precision and recovery.

Preparation blank – See method blank

Quality control check sample (QCS) – A sample containing all or a subset of the analytes at known concentrations. The QCS is obtained from a source external to the laboratory or is prepared from a source of standards different from the source of calibration standards. It is used to check laboratory performance with test materials prepared external to the normal preparation process.

Reagent water – water demonstrated to be free from the analytes of interest and potentially interfering substances at the method detection limit for the analyte.

Relative standard deviation (RSD) – The standard deviation times 100 divided by the mean. Also termed "coefficient of variation."

RF – Response factor. See Section 10.5

RR – Relative response. See Section 10.4

RSD – See relative standard deviation

Signal-to-noise ratio (S/N) – The height of the signal as measured from the mean (average) of the noise to the peak maximum divided by the width of the noise.

Should – Although this action, activity, or procedural step is suggested and not required, you may be asked to explain why you changed or omitted this action, activity, or procedural step.

SICP – Selected ion current profile; the line described by the signal at an exact m/z.

SPE – Solid-phase extraction; an extraction technique in which an analyte is extracted from an aqueous solution by passage over or through a material capable of reversibly adsorbing the analyte. Also termed liquid-solid extraction.

Stock solution – A solution containing an analyte that is prepared using a reference material traceable to EPA, the National Institute of Science and Technology (NIST), or a source that will attest to the purity and authenticity of the reference material.

VER – See Calibration verification.

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पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय

अधिसूचना

नई दिल्ली, 23 जनवरी, 2020

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

ऐसा कोई व्यक्ति, जो प्रारूप अधिसूचना में अंतर्विष्ट प्रस्तावों पर कोई आपत्ति या सुझाव देने में हितबद्ध है, इस प्रकार ऊपर विनिर्दिष्ट की गई अवधि के भीतर, केन्द्रीय सरकार द्वारा विचार किए जाने के लिए, आपत्ति या सुझाव सचिव, पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय, इंदिरा पर्यावरण भवन, जोर बाग रोड, नई दिल्ली - 110003 को या ई-मेल पते अर्थात 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 एतद्द्वारा निम्नलिखित नियम बनाती है, अर्थात्-

1 **संक्षिप्त शीर्षक और प्रारम्भ**—(1) इन नियमों को पर्यावरण (संरक्षण) संशोधन नियम, 2019 कहा जाएगा। (2) ये आधिकारिक राजपत्र में उनके अंतिम प्रकाशन की तारीख से लागू होंगे।

2. पर्यावरण (संरक्षण) अधिनियम, 1986 में, अनुसूची-I में क्रम संख्या 73 और उससे संबंधित प्रविष्टियों के लिए निम्नलिखित क्रम संख्या और प्रविष्टियां प्रतिस्थापित की जाएगी अर्थात:-

क्रम सं.	उद्योग	पैरामीटर	मानक
1	2	3	4
*73	थोक दवा और निर्माण)फार्मास्युटिकल(	**क. बहिस्राव मानक**	
			ईटीपी का अंतिम आउटलेट सांद्रण के लिए सीमित मान) पीएच और जैव परख को छोड़कर मिलीग्राम / एल में(
		I) अनिवार्य पैरामीटर	
		पीएच	6.0 -8.5
		बीओडी) 3 दिन 27 डिग्री सेल्सियस(	30
		सीओडी	250
		टीएसएस	100
		टीडीएस	2100
		तेल और चिकनाई (ग्रीज)	10
		जैव - परख परीक्षण**	100% बहिस्राव में पहले 96 घंटों के बाद मछली की 90% उत्तरजीविता
		ii) अतिरिक्त पैरामीटर	
		अमोनिकल नाइट्रोजन	50
		नाइट्रेट नाइट्रोजन	10
		*** *बेंजीन*	*0.05*
		*** *टाल्विन*	*0.05*
		*** *ज़ाइलीन*	*0.06*
		***मीथाइलीन क्लोराइड*	*0.9*
		फॉस्फेट पी के रूप में	5
		क्लोराइड	1000
		सल्फेट SO_4 के रूप में	1000
		फ्लोराइड	2
		एस के रूप में सल्फाइड	2
		फेनोलिक यौगिक	1
		कुल अवशिष्ट क्लोरीन	1
		जस्ता	5
		लोहा	3
		तांबा	3
		कुल क्रोमियम	2
		हेक्सावलेंट क्रोमियम) Cr^{6+})	0.1

साइनाइड	0.1
आर्सेनिक	0.2
पारा	0.01
लेड	0.1
**** सक्रिय दवा संघटक) एपीआई(	*0.05*

iii) साझा बहिस्राव 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 बहिस्राव शोधन संयंत्र) सीईटीपी) के लिए, राज्य बोर्ड साझा बहिस्राव शोधन संयंत्र) सीईटीपी) के डिजाइन और स्थानीय जरूरतों और स्थितियों के अनुसार सामान्य मापदंडों, अमोनियम नाइट्रोजन और हैवी मेटल्स के लिए इनलेट क्वालिटी स्टैंडर्ड्स निर्धारित करेगा।

टिप्पणी:

जेडएलडी= *थोक दवा और निर्माण* उद्योग में शून्य तरल निस्सारण प्रणाली पर विचार किया जाता है, जब अनिवार्य पैरामीटरों के लिए निर्धारित की गई सीमाओं को पूरा करते है। शोधित बहिस्रावों को प्रक्रिया अथवा उपयोगिताओं के प्रयोग में लाया जाएगा। (कूलिंग टॉवरो आदि/बॉयलर) बागवानी / बागवानी में शोधित अपशिष्ट के पुन :उपयोग को थोक दवा और निर्माण उद्योगों में जेडएलडी नहीं माना जाएगा।

** **जैव परख परीक्षण** आईएस :6582-1971 के अनुसार आयोजित किया जाएगा

*अतिरिक्त पैरामीटर *के रूप में सूचीबद्ध **पैरामीटर** प्रक्रिया और उत्पाद के आधार पर निर्धारित किए जाएंगे।

*** ये *सीमाएं उन उद्योगों पर लागू होंगी जो बेंजीन,* टाल्विन, ज़ाइलीन, मिथाइलीन क्लोराइड, क्लोरोबेंजीन *का उपयोग कर रहे हैं*।

*** * एपीआई सीमाएं एंटीबायोटिक दवाओं के अलावा एपीआई बनाने वाली इकाइयों के लिए लागू होगी।

ख प्रक्रिया .रिएक्टर वेंटस / टैंक फार्म वेंटस से उत्सर्जन मानक

पैरामीटर	**सांद्रण के लिए सीमित मान)मिलीग्राम/एनएम ³)**
क्लोरीन	15
हाइड्रोक्लोरिक एसिड वाष्प	35
अमोनिया	30
बेंजीन	5
टाल्विन	100
ऐसिटोनाईट्राईल	1000
डिकलोरोमीथेन	200
ज़ाइलीन	100
एसीटोन	2000

ग विलायक का कुल .नुकसान, उपभोग किए गए विलायक के 3% से अधिक नहीं होना चाहिए।

घ. थोक दवा और निर्माण उद्योग में शोधित बहिस्राव में एंटोबायोटिक अवशिष्ट और थोक दवा और निर्माण इकाइयों की सदस्यता सहित सीईटीपी।

पृथक एंटीबायोटिक अवशिष्ट नीचे तालिका में दिए गए मानों के बराबर या उससे कम होंगे।

पैरामीटर	**सांद्रण के लिए सीमित मान) u/g / l)**
i.एमिकासिन	6.40

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

		xli. क्लिनाफ्लोक्सासिन	0.20
		xlii. क्लिन्डामाईसिन	0.04
		xliii. क्लोक्सासिलीन	0.05
		xliv. कोलिस्टिन	0.80
		xlv. डेपटोमाईसिन	0.40
		xlvi. डेलमानिड	0.02
		xlvii. डोरीपेनेम	0.04
		xlviii. डॉक्सीसाइक्लिन	0.80
		xlix. एनरामाईसिन	1.92
		l. एनरोफ्लोक्ससिन	0.02
		li. एरटापेनेम	0.05
		lii. एरिथ्रोमाईसिन	0.20
		liii. एथामब्युटोल	0.80
		liv. फेरोपेनेम	0.01
		lv. फिडाएक्सोमाईसिन	0.01
		lvi. फ्लोरफेनिकोल	0.80
		lvii. फ्लूकोनेज़ोल	0.10
		lviii. फ्लुमेक्विन	0.10
		lix. फॉस्फोमाईसिन	0.80
		lx. फ्युसीडिक एसिड	0.20
		lxi. सेटीफ्लोक्सासिन	0.05
		lxii. जेमीफलोक्सासिन	0.02
		lxiii. जेंटामाईसिन	0.08
		lxiv. इनीपेनेम	0.05
		lxv. आइसोनियाजिड	0.05
		lxvi. इट्राकोनेजोल	0.004
		lxvii. कानामाईसिन	0.44
		lxviii. लेवोफ्लोक्सासिन	0.10
		lxix. लिंकोमाईसिन	0.72
		lxx. लाईनज़ोलिड	2.68
		lxxi. लोराकारबेफ	0.80
		lxxii. मेसिलिनेम	0.40
		lxxiii. मेरोपेनेम	0.02
		lxxiv. मेट्रोनिडेजोल	0.05
		lxxv. माइनोसाइक्लिन	0.40
		lxxvi. मॉक्सीफ्लोक्सिन	0.05
		lxxvii. म्युरीरोसिन	0.10
		lxxviii. नेलीडिक्सिक एसिड	6.40
		lxxix. नारासिन	0.20

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

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

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

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

जिगमेत टक्पा, संयुक्त सचिव

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

MINISTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE

NOTIFICATION

New Delhi, the 23rd January, 2020

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

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

Draft Notification

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

1. **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.

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

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 1st 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.	Narasin	0.20
		lxxx.	Neomycin	0.01
		lxxxi.	Netilmicin	0.20
		lxxxii.	Nitrofurantoin	25.60
		lxxxiii.	Norfloxacin	0.20
		lxxxiv.	Ofloxacin	0.20
		lxxxv.	Oxacillin	0.40
		lxxxvi.	Oxytetracycline	0.20
		lxxxvii.	Pefloxacin	3.20
		lxxxviii.	Phenoxymethylpenicillin	0.02
		lxxxix.	Piperacillin	0.20
		xc.	Polymixin	0.80
		xci.	Retapamulin	0.02
		xcii.	Rifampicin	0.02
		xciii.	Roxithromycin	0.40
		xciv.	Secnidazole	0.40
		xcv.	Sparfloxacin	0.02
		xcvi.	Spectinomycin	12.80
		xcvii.	Spiramycin	0.20
		xcviii.	Streptomycin	6.40
		xcix.	Sulbactam	6.40
		c.	Sulfadiazine	288.00
		ci.	Sulfadimethoxine	20.00
		cii.	Sulfadoxine	0.24
		ciii.	Sulfamethoxazole	0.24
		civ.	Tazobactam	17.60
		cv.	Tedizolid	3.92
		cvi.	Teicoplanin	0.20
		cvii.	Telithromycin	0.02

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

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

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

JIGMET TAKPA, Jt. Secy.

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

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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
RECORD OF PROCEEDINGS

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. RAVIKUMAR

For 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 sandardized 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

केन्द्रीय प्रदूषण नियंत्रण बोर्ड
CENTRAL POLLUTION CONTROL BOARD
पर्यावरण, वन एवं जलवायु परिवर्तन मंत्रालय भारत सरकार
MINISTRY OF ENVIRONMENT, FOREST & CLIMATE CHANGE GOVT. OF INDIA

SPEED POST

B-29016/04/06/IPC-I

January 31, 2022

To

All SPCBs/PCCs (Listed)

Sub. : Guidelines on Monitoring Mechanism for API residue -reg

Sir,

As directed by Hon'ble NGT on 23.06.2021 in the matter of O.A no 136/2020 Veterans forum for Transparency in Public life Vs. state of Himacahl Pradesh & Ors. the following:

"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 vs M/s Vapi Green Enviro Ltd. & Ors. and the directions of the Tribunal dated 05.02.2021."

On further hearing on this matter, the Hon'ble NGT order on 21.01.2022 has passed the order as follows *"CPCB may circulate monitoring mechanism to the State PCBs on API, as directed earlier and file the action taken report before the next date."*

Central Pollution Control Board has prepared the above stated "Guidelines on Monitoring Mechanism for API residue" and same is attached herewith for your kind perusal and necessary action please.

Yours faithfully,

31/1/22

(Dinabandhu Gouda)

Additional Director & DH-IPC-I

Encl.: As above

Copy to:

1. D.H - LAW
2. D.H -Trace Organic Lab
3. DH WQM-I
4. All RDs by email : for necessary follow up with SPCBs please

31/1/22

(Dinabandhu Gouda)

List of State Pollution Control Boards/Committees

1. The Member Secretary
   Andhra Pradesh State Pollution Control Board
   D.No. 33-26-14 D/2, Near Sunrise Hospital,
   Pushpa Hotel Centre, Chalmvari Street,
   Kasturibaipet, Vijayawada- 520010
   Andhra Pradesh

2. The Member Secretary
   Arunachal Pradesh State Pollution Control Board
   'Paryavaran Bhavan', Yupla Road,
   PappuNallah,
   Naharlagun – 791110
   Arunachal Pradesh

3. The Member Secretary
   Assam State Pollution Control Board
   Bamunimaidan,
   Guwahati – 781021
   Assam

4. The Member Secretary
   Bihar State Pollution Control Board
   Parivesh Bhawan, Plot No.N-B/2,
   Patliputra Industrial Area
   Patna-800023

5. The Member Secretary
   Chhattisgarh Environment Conservation Board
   5, 32 Bungalows, Bhilai,
   Chhattisgarh 490009
   Chhattisgarh

6. The Member Secretary
   Goa State Pollution Control Board
   Dempo Tower, EDC Plaza, 1st floor
   Patto Plaza, Panaji,
   Goa – 403001

7. The Member Secretary
   Gujarat State Pollution Control Board
   Sector 10-A, Gandhi Nagar – 382043
   Gujarat

8. The Member Secretary
   Haryana State Pollution Control Board
   C-11, Sector 6, Panchkula,
   Haryana 134109

9. The Member Secretary
Himachal Pradesh State Pollution Control Board
ParyavaranBhavan, Phase III,
New Shimla – 171009
Himachal Pradesh

10. The Member Secretary
J&K State Pollution Control Board,
Parivesh Bhawan, Forest Complex
Gladni, Narwal, Transport Nagar,
Jammu-180004
Jammu and Kashmir

11. The Member Secretary
Jharkhand State Pollution Control Board
T.A Building, HEC Campus, P.O. Dhurwa
Ranchi – 834004
Jharkhand

12. The Member Secretary
Karnataka State Pollution Control Board
ParisaraBhavan, 4th& 5th floors, Church Street,
Bangalore – 560 001
Karnataka

13. The Member Secretary
Kerala State Pollution Control Board
Head Office, Pattom. P. O
Thiruvananthapuram-695004
Kerala

14. The Member Secretary
Maharashtra State Pollution Control Board
Kalpataru Point, 3rd& 4th floors
Sion Matunga Scheme Road No. 6
Opp. Cine Planet, Sion Circle, Sion (E),
Mumbai 400 022
Maharashtra

15. The Member Secretary
Madhya Pradesh State Pollution Control Board
ParyavaranParisar, E-5 Arera Colony
Bhopal – 462016
Madhya Pradesh

16. The Member Secretary
Manipur State Pollution Control Board
Lamphelpat, Imphal
West D.C. Office Complex – 795004
Manipur

17. The Member Secretary
Meghalaya State Pollution Control Board
Arden, Lumpyngngad,
Shillong – 793014
Meghalaya

18. The Member Secretary
Mizoram State Pollution Control Board
New Secretariat Complex,
Khatla, Thlanmual Peng, Aizwal
Mizoram- 796001

19. The Member Secretary
Nagaland State Pollution Control Board
Signal Point, Dimapur,
Nagaland – 797112
Nagaland

20. The Member Secretary
Odisha State Pollution Control Board
Paribesh Bhawan A-118, Nilakanta Nagar,
Unit –VIII, Bhubaneshwar – 751012.
Odisha

21. The Member Secretary
Punjab State Pollution Control Board
Nabha Road, ITI Rd, Adarsh Nagar,
Prem Nagar,
Patiala - 147001.
Punjab

22. The Member Secretary
Rajasthan State Pollution Control Board
A-4 Institutional Area, Jhalana Doongri
Jaipur – 302004.
Rajasthan

23. The Member Secretary
Sikkim State Pollution Control Board
State land Use & Environment Cell
Govt. of Sikkim, Deorali,
Gangtok, **Sikkim**

24. The Member Secretary
Tamil Nadu State Pollution Control Board
No. 76, Mount Salai, Guindy,
Chennai - 600032.
Tamil Nadu

25. The Member Secretary
Telangana State Pollution Control Board
Paryavaran Bhavan
A-3, Industrial Estate, Sanath Nagar,
Hyderabad – 500 018.
Telangana

26. The Member Secretary
Tripura State Pollution Control Board
Parivesh Bhawan, Pt. Nehru Complex,
Gorkhabasti P.O., Kunjaban, Agartala,
West Tripura - 799 006.
Tripura

27. The Member Secretary
Uttarakhand Pollution Control Board
94, Haridwar Rd, Saket Colony,
Dharampure, Dehradun,
Uttarakhand- 248001

28. The Member Secretary
Uttar Pradesh State Pollution Control Board
Building.No. TC-12V
VibhutiKhand, Gomti Nagar,
Lucknow– 226010.
Uttar Pradesh

29. The Member Secretary
West Bengal State Pollution Control Board
Paribesh Bhavan
Building, No.10-A, Block –LA, Sector 3,
Salt Lake City,
Kolkata – 700 091.
West Bengal

30. The Member Secretary
Andaman & Nicobar Islands Pollution Control Committee
Department of Science & Technology
Dollyganj Van Sadan, Haddo P.O.,
Port Blair-744102
Andaman & Nicobar

31. The Member Secretary
Chandigarh Pollution Control Committee
Paryavaran Bhawan
Madhya Marg, Sector - 19 B,
Chandigarh – 160019.
Chandigarh

32. The Member Secretary
Daman, Diu & Dadra Nagar Haveli Pollution Control Committee
Office of the Deputy Conservator of Forests
Moti Daman,
Daman – 396220.
Daman & Diu

33. The Member Secretary
Delhi Pollution Control Committee
4th floor, ISBT Building,
Kashmeri Gate,
Delhi - 110006.

34. The Member Secretary
Lakshadweep Pollution Control Committee
Lakshadeweep Administration
Department of Science, Technology & Environment
Kavarati – 682555.
Lakshadweep

35. The Member Secretary
Puducherry Pollution Control Committee
Department of Science, Technology & Environment
Housing Board Complex,
3rd floor, Anna Nagar, **Pondichery** – 600 005

Guidelines on Monitoring Mechanism for API residue

Background

Hon'ble National Green Tribunal Principal Bench, New Delhi in the matter of Original Application No. 136/2020 sought report from Ministry of Environment, Forests and Climate Change and Central Pollution Control Board with reference to the prayer of the applicant (Dr. Bishwanath Prasad Singh, Wing Commander (Retd.)), to prevent pollution of rivers Sirsa and Satluj by taking remedial action against discharge of waste from CETP at Baddi and from Acme Life Sciences, Nalagarh and Helio Pharmaceuticals at Solan.

The prayer was that pharmaceutical units at Barotiwala and Nalagarh are not connected to the CETP are discharging their effluents directly into the rivers. The effluent that discharged in to the rivers consists pharmaceutical ingredients even after treatment in ETP/STPs as the ETP/STPs are not specialized for the purpose/ for removal of pharmaceutical active ingredients. The CETPs are also not designed to neutralize Active Pharmaceutical Ingredient (API). The applicant stated that the presence of Ciprofloxacin in the concentration of 296.1 ug/l in the effluent discharge of M/s Acme Life Sciences was found on chemical analysis. 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.

Hon'ble National Green Tribunal passed the order in the aforesaid matter on 23.06.2021. S No. 12. of the said order reads as follows:

"In view of the above, 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 vs M/s Vapi Green Enviro Ltd. & Ors. and the directions of the Tribunal dated 05.02.2021."

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 accidently 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)
(1)	Amoxicillin	0.08
(2)	Cefixime	0.13
(3)	Cefadroxile	0.12

(4)	Fluconazole	0.14
(5)	Levofloxacin	0.16
(6)	Ciprofloxacin	0.15
(7)	Metronidazole	0.12
(8)	Azithromycin	0.03
(9)	Doxycyline	0.03
(10)	Chloramphenicol	0.09
(11)	Norfloxacin	0.045
(12)	Ofloxacin	0.03
(13)	Ampicillin	0.045
(14)	Nalidixic Acid	0.045
(15)	Spiramycin	0.051
(16)	Roxithromycin	0.026
(17)	Lincomycin	0.028
(18)	Enrofloxacin	0.022
(19)	Cloxacillin	0.088
(20)	Diclofenac	0.14
(21)	Mefenamic Acid	0.14

Guidelines for Sampling:

Sample Collection and locations:

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

a) Samples for Baseline and Trend stations shall be collected from well-mixed section of the river or main stem 30 cm below the water surface using a weighted bottle.

b) Samples for Impact stations shall be collected 30 cm below the water surface from the point of interest, such as bathing Ghats, downstream of point discharges, water supply intakes and other sources.

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

a) Reservoir water quality has temporal, spatial as well as depth variation. The water is generally not well-mixed and sampling from a single depth may inadequately represent the overall water quality. It is, therefore necessary to ensure that sampling stations are truly representative of the water body.

b) It is necessary to conduct preliminary survey to determine whether and where differences in water quality occur before deciding on the number of stations to establish. The most important feature of water in reservoir is vertical stratification which results in water quality variation along the depth. The vertical stratification at a sampling station can be detected by taking a temperature reading at 1 m below the surface and another at 1 m above the bottom. If there is a significant difference (more than 3 °C) between the two readings, there is a "thermocline" (a layer where the temperature changes rapidly with depth) and the reservoir is stratified. In stratified reservoirs, more than one sample is necessary to describe water quality.

c) For reservoirs of 10 m depth or more, it is essential that the position of the thermocline is first assessed by means of regularly-spaced temperature readings through the water column (e.g. metre intervals). Samples should then be taken according to the position and extent (in depth) of the thermocline. As a general guide, the minimum samples should consist of 1 m below the water surface, just above the determined depth of the thermocline, just below the determined depth of the thermocline, and 1 m above the bottom sediment (or closer if possible without disturbing the sediment). If the thermocline extends through several meters depth, additional samples are necessary from within the thermocline in order to characterise fully the water quality variations with depth.

d) In general, if the water depth at the sampling site is less than 10 m, the minimum sampling programme should consist of a sample taken 1 m below the water surface and another sample taken at 1 m above the bottom sediment.

e) Access to reservoir sampling stations is usually by boat and returning to precisely to the same locations for subsequent samples can be extremely difficult unless GPS is used or alternatively poles may be installed for the purpose.

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

(a) Open dug wells, which are not in use or have been abandoned, shall not be considered as water quality monitoring station. However, such well could be considered for water level monitoring. The ground water quality monitoring agencies should close down the unused open dug wells if they are potential source of microbiological contaminations in the areas without affecting the water level monitoring programme by replacing the abandoned dug wells with piezometers.

(b) Weighted sample bottle to collect sample from an open well about 30 cm below the surface of water may be used. The plastic bucket, which is likely to skim the surface layer only, shall not be used.

(c) Samples from the production tube wells shall be collected after running the well for about five minutes.

(d) Non-production piezometers shall be purged using a submersible pump. The purged water volume shall equal 4 to 5 times the standing water volume, before sample is collected.

(e) For bacteriological samples, when collected from tube wells or hand pump, the spout or outlet of the pump shall be sterilized under flame by spirit lamp before collection of sample in container.

Sample preservation and transportation:

(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 litter of water.
15. Solid, mixed-phase, and semi-solid samples, including bio solids: Collect samples as grab samples using wide-mouth jars. Collect a sufficient amount of wet material to produce a minimum of 10 g of solids. If the sample will not be extracted within 48 hours of collection, the laboratory should adjust the pH of aqueous samples to 5.0 to 9.0 with a sodium hydroxide or sulfuric acid solution. Record the volume of acid or base used. If extraction of samples within 48 hours is not practical, then samples should be frozen to increase the holding time to seven days. If aqueous samples are stored frozen, extraction should begin within 48 hours of removal from the freezer.

Requirements for The Analysis of Antibiotics

S. No.	Requirements	Quantity	Size	Remarks
Requirement of Space				
01	Room with AC and Exhaust	04	• ≈ 625.0 Square Feet (Instrument Room) • ≈ 400.0 Square Feet (Process Room) • ≈ 400.0 Square Feet (Sample Storage Room) • ≈ 400.0 Square Feet (Chemical and CRM Storage Room)	
Requirement of Instruments and Equipment				
02	LC-MS/MS (Tandem Mass)	01		For Qualitative & Quantitative Analysis
03	Solid Phase Extraction System	01	12 or 24 port	For Extraction & Cleanup
04	Ultra Sonicator	01		For sonication of mobile phase and cleaning of HPLC parts
05	MiniVap or Turbovap Concentrator	01	06-10 port	For Concentration
06	Rotatory Evaporator	01		For Concentration
07	Millipore Filtration Assembly	01		For Filtration of sample And Mobile phase

08	MQ Water Assembly	01		For MQ Water
09	Deep Freezer	01		CRM Storage
10	Vici cooler	01		Sample Storage
11	UPS 20KVA	01	20 KVA	Only for LC-MS/MS
12	UPS 10KVA	01	120 KVA	For others equipment
Miscellaneous Requirement				
Chemicals and Glassware/100 Sample (Approx.)				
13	Methanol	1.5L		LC-MS/MS Grade
14	Acetonitrile	1.5L		LC-MS/MS Grade
15	HPLC Water	3.0L		LC-MS/MS Grade
16	Formic Acid	5.0ml		LC-MS/MS Grade
17	Ammonium Acetate	5.0gm		LC-MS/MS Grade
18	Ammonia Liquid	5.0ml		LC-MS/MS Grade
19	Orthophosphoric Acid	100.0ml		AR-Grade
20	Sulphuric Acid	20.0ml		AR-Grade
21	pH paper	150 strip		
22	Filter Paper GF/A	200	0.45µm / 47mm	
23	Filter Paper GF/A	10	0.25 µm / 47mm	
24	Syringe Filter	100	0.25 µm nylon	
25	HLB Cartridge	100	60 mg / 20cc	
26	Micropipette	01	100-1000µl (Variable)	
27	Micropipette	01	10µl (Fixed)	
28	Micropipette	01	25µl (Fixed)	
29	Micropipette	01	50µl (Fixed)	
30	Micropipette tip		As per requirements	
31	Sample Storage Vial	100		
32	Reference Standards for Antibiotics		As per requirements	
(1) Others				

33	Argon Gas Cylinder with Regulator	01	Approx. one cylinder for 500 sample	For LC-MS/MS
34	Nitrogen Gas Cylinder with regulator	01	Approx. one cylinder (47L) for 06 sample	For Sample Preparation
Requirement of Manpower				
35	Manpower	01		1.For Instrument operation, calibration & Analysis.
36	Manpower	02		2.For Sampling, processing including extraction, clean up, & sample preparation.

16.

I) Pollution Prevention: comprises techniques that reduces or eliminates the quantity or toxicity of waste at the point of generation. Many opportunities for pollution prevention exist in laboratory operation. EPA has established a preferred hierarchy of environmental management techniques that places pollution prevention as the management option of first choice. Whenever feasible, laboratory personnel should use pollution prevention techniques to address waste generation. When wastes cannot be reduced at the source, the Agency recommends recycling as the next best option.

II) Waste Management: Samples at pH<2, or pH >12 are hazardous and must be neutralized before being poured down a drain, or must be handled as hazardous waste.

III) Low-level waste such as absorbent paper, tissues, animal remains, and plastic gloves may be burned in an appropriate incinerator. Gross quantities (milligrams) should be packaged securely and disposed of through commercial or governmental channels that are capable of handling toxic wastes.

Duties of SPCBs/PCCs and frequency of monitoring

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

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.

FORM - I

SAMPLE IDENTIFICATION FOR SURFACE WATER SAMPLES

Sample Code :		
Observer :	Agency:	Project:
Date :	Station Name and Code :	
Time :	Latitude :	Longitude :
Depth of Sample:	River :	Division :

Parameter Code	Container				Preservation			
	Glass	PVC	PE	Teflon	None	Cool	Acid	Other
(1) General								
(2) Bacteriology								
(3) BOD								
(4) COD, NH_3, NO_3								
(5) Toxic Metals								
(6) Trace Organics								

Source of Water				
O River	O Main Current	O Bridge	O Water	O Fresh
O Drain	O Right Bank	O Boat	O Sediment	O Brackish
O Canal	O Left Bank	O Wading	O Susp. Matter	O Salt
O Reservoir	O other	O other	O Biota	O Effluent
Sample Types	O Grab	O Time Comp.	O Flow Comp.	O Depth-integ O Width-integ
Sample Device	Weighted Bottle	Pump	Depth Sampler	

Field Determination						
Temperture:	pH		EC	µmhos/cm	DO	mg/L
Odour code	[1] Odour free	[6] Septic	Colour code	[1] Light brown	[6] Dark green	
	[2] Rotten eggs	[7] Aromatic		[2] Brown	[7] Light black	
	[3] Burnt sugar	[8] Chlorinous		[3] Dark brown	[8] Black	
	[4] Soapy	[9] Alcoholic		[4] Light green	[9] Clear	
	[5] Fishy	[10] Unpleasant		[5] Green	[10] Other (Specify)	

Remarks				
Weather	O Sunny	O Cloudy	O Rainy	O Windly
Water vel.(m/sec)	O High (>0.5)	O Medium (0.1-0.5)	O Low (<0.1)	O Standing
Water Use	O None		O Cultivation / Irrigation	
	O Bathing & Washing		O Cattle washing	
	O Melon / vegetable farming		O Industrial / Organised water supply	

SAMPLE FORMAT

FORM-II

SAMPLE IDENTIFICATION FOR GROUND WATER SAMPLES

Sample Code											
Observer		Agency				Project					
Date Time	Station Address and Code Location: Village: Tehsil: District: State					Latitude: Longitude:					
Source of Sample	Open dug well / Dug cum bore well		Hand pump			Tube Well/ bore well			Piezometer		
Parameter Code	Container				Preservation						
	Glass	PVC	PE	Teflon	None	Cool	Acid	Other			
(1) General											
(2) Bacteriology											
(3) BOD											
(4) COD											
(5) Toxic Metals											
(6) Trace Organics											

Field Determination

Temp °C	pH	EC	micromhos/cm
Odor code	(1) Odor free (2) Rotten eggs (3) Burnt sugar (4) Soapy (5) Fishy (6) Septic (7) Aromatic (8) Chlorinous (9) Alcoholic (10) Unpleasant	Color code	(1) Light brown (2) Brown (3) Dark brown (4) Light green (5) Green (6) Dark green (7) Clear (8) Other(specify)

Hydro geological Information

Well Data			
Diameter	Q		cm
Total Depth	D		m bgl
Static Water Level (Avg.)	SWL		M bgl
Aquifer Characteristics			
Use of the well/tubewell/bore well			
Depth of Slot pipes			M bgl
Land use in surrounding area			

If the tubewell/bore well/piezometer is purged, complete below

Field Flow Measurement			
Static Water Level	SWL		mbgl
Actual pump setting depth			M
Purging duration			min
Pump discharge	Q		L/min
Volume purged	V		L

SAMPLE FORMAT

FORM-III

Sample Record for Analysis

Date / time received at lab	Date / time collected	Lab. ID No	Station Name and Code	Tehsil/ District	Project	Collecting agency / collector	Preservation	Parameter Code
1	2	3	4	5	6	7	8	9

Sample receipt register

Note:

- Column (3) gives the laboratory sample assigned to the sample as it is received in the laboratory. Note that the numbering has two parts separated by hyphen. The first part is assigned in a sequential manner as samples are received from various stations. If two samples are collected at the same time from a station for different sets of analysis, the first part of the number is the same. The second part corresponds to the parameter code as given in the sample.
- Column (4) gives the station code conventionally followed by the monitoring agency.
- Column (6) gives the project under which the sample is collected.
- Column (9) corresponds to the parameter(s) code given in the sample identification form.
- The result of the analysis of all the samples having the same first part of the code would be entered in the data entry system as one sample having the same station code and time of sample collection.

SAMPLE FORMAT

रजिस्ट्री सं. डी.एल.- 33004/99 REGD. No. D. L.-33004/99

भारत का राजपत्र
The Gazette of India

सी.जी.-डी.एल.-अ.-06082021-228807
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असाधारण
EXTRAORDINARY

भाग II—खण्ड 3—उप-खण्ड (i)
PART II—Section 3—Sub-section (i)

प्राधिकार से प्रकाशित
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पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय

अधिसूचना

नई दिल्ली, 6 अगस्त, 2021

सा.का.नि. 541(अ).—जहां, कतिपय प्रारूप नियम अर्थात् पर्यावरण (संरक्षण) संशोधन नियम, 2020 भारत सरकार के पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय में अधिसूचना संख्या सा.का.नि. 44(अ), तारीख 23 जनवरी, 2020 की अधिसूचना द्वारा पर्यावरण (संरक्षण) नियम, 1986, के नियम 5 के उपनियम (3) के अधीन यथा अपेक्षानुसार भारत के राजपत्र, असाधारण में प्रकाशित किए गए थे, जिसमे सभी व्यक्तियों से जिनके उसके द्वारा प्रभावित होने की संभावना है उस तारीख से जिसको उक्त अधिसूचना में अंतर्विष्ट राजपत्र की प्रतियां जनता को उपलब्ध करा दी गई थी, साठ दिन की अवधि के भीतर आक्षेप और सुझाव आमंत्रित किए गए थे;

और पूर्वोक्त अधिसूचना में अंतर्विष्ट राजपत्र की प्रतियां 23 जनवरी, 2020 को जनता को उपलब्ध करा दी गई थीं;

और, पूर्वोक्त अधिसूचना के प्रतिउत्तर में सभी व्यक्तियों और पणधारियों से प्राप्त आक्षेपों और सुझावों को केंद्रीय सरकार द्वारा सम्यक रुप से विचार किया गया;

अत:, अब, केंद्रीय सरकार, पर्यावरण (संरक्षण) नियम, 1986 के नियम 5 के उपनियम (3) के साथ पठित पर्यावरण (संरक्षण) अधिनियम, 1986 का 29 की धारा 6 और धारा 25 द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए पर्यावरण (संरक्षण) नियम, 1986 का और संशोधन करने के लिए निम्नलिखित नियम बनाती है, अर्थात्: -

1. **संक्षिप्त नाम और प्रारंभ**- (1) इन नियमों का संक्षिप्त नाम पर्यावरण (संरक्षण) दूसरा संशोधन नियम, 2021 है।

(2) ये राजपत्र में उनके प्रकाशन की तारीख से एक वर्ष के पश्चात् प्रवृत्त होंगे।

2. पर्यावरण (संरक्षण) नियम, 1986 की अनुसूची-I में क्रमांक 73 और उससे संबंधित प्रविष्टियों के स्थान पर निम्नलिखित क्रमांक और प्रविष्टियां रखी जाएंगी, अर्थात्:-

क्र. सं.	उद्योग	पैरामीटर	मानक
1	2	3	4
"73।	थोक दवा और निर्माण (फार्मास्युटिकल)	**क. बहिःस्राव मानक***	
			एकाग्रता के लिए सीमित मूल्य (पीएच और जैव परख को छोड़कर मिलीग्राम / एल में)
		(i) **अनिवार्य पैरामीटर**	
		पीएच	6.0 -8.5
		बीओडी (3 दिन 27 डिग्री सेल्सियस)	30
		सीओडी	250
		टीएसएस	100
		तेल और ग्रीस	10
		अमोनिकल नाइट्रोजन	100
		जैव - परख परीक्षण**	100% में पहले 96 घंटों के बाद 90% मछली की उत्तरजीविता
		(ii) अतिरिक्त पैरामीटर##	
		***बेन्जीन	0.1
		***जाइलीन	0.12
		***मीथाइलीन क्लोराइड	0.9
		***क्लोरोबेन्जीन	0.2
		पी . के रूप में फॉस्फेट	5
		एस . के रूप में सल्फाइड	2
		फेनोलिक यौगिक	1
		जस्ता	5
		लोहा	3
		कुल क्रोमियम	2
		हेक्सावलेंट क्रोमियम (क्रो6+)	0.1
		साइनाइड (एचसीएन के रुप में)	0.1
		आर्सेनिक	0.2
		मर्करी	0.01
		लेड	0.1
		एसएआर	26 से कम (भूमि पर केवल वाहन के लिए लागू)
		(iii) सीईटीपी के साथ उद्योग	
		• सीईटीपी के साथ और सीईटीपी के लिए उद्योग हेतु निर्वहन किए गए मानक पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय की अधिसूचना का.आ. 4(अ), तारीख 1 जनवरी, 2016 द्वारा शासित होंगे।	

- राज्य प्रदूषण नियंत्रण बोर्ड अतिरिक्त सुसंगत पैरामीटर को विहित करेगा जैसा कि उद्योगों के सदस्य के आवश्यकता और निर्वहन के अनुसार इस अधिसूचना के पैरा क (ii) में दिया गया है और पर्यावरण शर्तों को प्राप्त करने के विचार की निगरानी को तत्परता से विनिर्दिष्ट करता हो।

टिप्पण :- पैरा क में मानक सीईटीपी के सिवाय सभी निर्वहन के लिए लागू हैं

*सीईटीपी के लिए उद्योग निर्वहन को लागू नहीं किया जाता है और भूमि तथा सतह जल निकाय के सभी निर्वहन को लागू होगा जिसके अंतर्गत उद्यान और सिंचाईं प्रयोजन के लिए जल निस्तारण का प्रयोग किया जाना सम्मिलित है।

** जैव परख परीक्षण आई एस. 6582-1971 के अनुसार आयोजित किया जाएगा।

"अतिरिक्त पैरा मीटर"के रुप में सूचिबद्ध पैरामीटर प्रक्रिया और उत्पाद पर निर्भर रहते हुए एसपीसीवी द्वारा विहित किए जाएंगे और एसपीसीवी एस द्वारा निर्णय के अनुसार उसकी तत्परता से मानीटरी मासिक/तिमाही रुप से की जाएगी।

***ये सीमाएं उन उद्योगों पर लागू होंगी जो बेन्जीन, जाइलीन मिथाइलीन क्लोराइड, क्लोरोबेन्जीन का उपयोग कर रहे हैं।

ख. उत्सर्जन मानक

(टैंक फार्म वेंट)

पैरामीटर	एकाग्रता के लिए सीमित मूल्य (मिलीग्राम / एनएम 3)
क्लोरीन	15
हाइड्रोक्लोरिक एसिड वाष्प	35
अमोनिया	**30**
बेंजीन	5
टोल्यूनि	100
एसीटोनिट्राइल	1000
डाइक्लोरोमेथेन	200
जाइलीन	100
एसीटोन	2000

ग. विलायक का कुल संचयी नुकसान भंडारण सूची से वार्षिक आधार पर विलायक 5% से अधिक नहीं होना चाहिए

घ.थोक दवा के विनिर्माण या फार्मास्युटिकल के प्रतिपादन में लगे उद्योग के लिए उद्योग या सीईटीपी कैटरिंग पर बेकार जल या उसके प्रबंध सुविधा से उत्पन्न होने वाले केमिकल और बायोलोजिकल गाढ़ा कीचड़ या किसी अवशेष, हटाए जाने, खतरनाक और अन्य अपशिष्ट (मैनेजमेंट एंड ट्रांस-बाउंडरी मूवमेंट) नियम 2016 के नियम 3 के उपनियम (1) के खंड 17 के उपबंध के अनुसार खतरनाक अपशिष्ट के रुप में वर्गीकृत किया जाएगा और उसमें किए गए उपबंध के अधीन होगा।

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

नरेश पाल गंगवार, संयुक्त सचिव

टिप्पण : मूल नियम भारत के राजपत्र, असाधारण, भाग II, खंड 3, उप-खंड (i) में संख्यांक का. आ. 844(अ) तारीख 19 नवंबर, 1986 में प्रकाशित किए गए थे और अंतिम बार अधिसूचना संख्यांक सा.का.नि. 243(अ) तारीख 31 मार्च, 2021 द्वारा अंतिम रुप से संशोधित किया गया था ।

MINISTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE

NOTIFICATION

New Delhi, the 6th August, 2021

G.S.R. 541(E).—Whereas, certain draft rules, namely the Environment (Protection) Amendment Rules, 2020 were published in the Gazette of India, Extraordinary, as required under sub-rule (3) of rule 5 of the Environment (Protection) Rules,1986, *vide* notification of the Government of India in the Ministry of Environment, Forest and Climate Change *vide* number G.S.R. 44 (E), dated the 23rd January, 2020, inviting objections and suggestions from all persons likely to be affected thereby within a period of sixty days from the date on which copies of the Gazette containing the said notification were made available to the public;

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

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

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

1. **Short title and commencement**. - (1) These rules may be called the Environment (Protection) Second Amendment Rules, 2021.

(2) They shall come into force after one year from the date of publication of this notification in the Official Gazette.

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

S.No.	Industry	Parameters	Standard
1	2	3	4
"73.	**Bulk Drug and Formulation (Pharmaceutical)**	A. **EFFLUENT STANDARDS***	
			Limiting value for concentration (in mg/l except for pH and Bio assay)
		(i) Compulsory Parameters	
		pH	6.0 -8.5
		BOD (3 days 27°C)	30
		COD	250
		TSS	100
		Oil & Grease	10
		Ammonical Nitrogen	100
		Bio - Assay Test**	90% Survival of Fish after first 96 hours in 100% effluent

		(ii) Additional Parameters##	
		****Benzene*	*0.1*
		****Xylene*	*0.12*
		****Methylene Chloride*	*0.9*
		****Chlorobenzene*	0.*2*
		Phosphates as P	5
		Sulphides as S	2
		Phenolic Compounds	1
		Zinc	5
		Copper	3
		Total Chromium	2
		Hexavalent Chromium (Cr^{6+})	0.1
		Cyanide (as HCN)	0.1
		Arsenic	0.2
		Mercury	0.01
		Lead	0.1
		SAR	Less than 26 (applicable only for discharge on land)
		(iii) Industry connected with CETP	
		• The discharge norms for industry connected with CETP and of CETP shall be governed by Ministry of Environment, Forest & Climate Change notification S.O. 4 (E), dated the 1st January, 2016. • State Pollution Control Board shall prescribe additional relevant parameters as given at para A (ii) of this notification as per needs and discharge potential of member industries and specify the frequency of monitoring considering the receiving environment conditions.	
		Note: The standards in para A is applicable to all discharges except to CETP. *Not applicable to industry discharging to CETP, and shall be applicable to all discharge to land and surface water bodies including use of treated wastewater for horticulture or irrigation purpose. ** The Bio assay test shall be conducted as per IS : 6582-1971 ## Parameters listed as **"Additional Parameters"** shall be prescribed by SPCB depending on the process and product and its monitoring frequency shall be monthly/quarterly as decided by SPCBs ****Limits shall be applicable to industries those are using Benzene, Xylene, Methylene Chloride, Chlorobenzene.*	

B. **EMISSION STANDARDS**

(Tank farm Vents)

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

C. *The total cumulative losses of solvent should not be more than 5% of the solvent on annual basis from storage inventory*

D. Chemical and Biological sludge or any residue, reject, concentrate generated from wastewater treatment or its management facility at Industry or CETP catering to industries engaged in manufacturing of bulk drug or formulation of Pharmaceuticals, shall be classified as Hazardous Waste as per the provision of clause 17 of sub-rule (i) of rule 3 of the Hazardous and Other Wastes (Management and Trans-boundary Movement) Rules, 2016 and shall be subject to the provision made therein.

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

NARESH PAL GANGWAR, Jt. Secy.

Note : The principle rules were published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) *vide* number S.O. 844(E), dated the 19th November, 1986 and lastly amended *vide* notification G.S.R. 243(E), dated the 31st March, 2021.

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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 भिन्न, जिसके विरुद्ध अपील की गई है, संलग्नकों की सूची।

तारीख

हस्ताक्षर .....

नाम और पता .....

.....

[फा. सं.3-1/2000-एचएसएमडी]

विश्वनाथ सिन्हा, 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.

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, hydroor 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.

(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.

(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 (e), 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.

	(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.	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 ^{0}C or to common bio-medical waste treatment facility or hazardous waste treatment, storage and disposal facility for incineration at >1200^{0}C Or Encapsulation or Plasma Pyrolysis at >1200^{0}C. All other discarded medicines shall be either sent back to manufacturer or disposed by incineration.
	(e) 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.
	(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.	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.
	(g) Discarded linen, mattresses, beddings contaminated with blood or body fluid.	Non-chlorinated yellow plastic bags or suitable packing material	Non- chlorinated chemical disinfection followed by incineration or Plazma Pyrolysis or for energy recovery. 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 Plazma Pyrolysis.
	(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	Autoclave safe plastic bags or containers	Pre-treat to sterilize with non-chlorinated chemicals on-site as per National AIDS Control Organisation or World Health Organisation guidelines thereafter for Incineration.

	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 *fixed needle syringes*) and vaccutainers 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 minutesor any other equivalent chemical reagent that should demonstrate $Log_{10}4$ reduction efficiency for microorganisms as given in Schedule- III.

(3) Mutilation or shredding must be to an extent to prevent unauthorized reuse.

(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 pyrolys is at temperature >1200 ^{0}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-MEDICALWASTES

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:

$$C.E. = \frac{\%CO_2}{\%CO_2 + \%\ CO} \times 100$$

3). The temperature of the primary chamber shall be a minimum of 800 ^{0}C and the secondary chamber shall be minimum of 1050^{0}C + or - 50^{0}C.

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

B. Emission Standards

Sl. No.	Parameter	Standards	
(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% O2)	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/Nm^3, 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.

(l) The occupier or operator of a common bio-medical waste incinerator shall use combustion gas analyzer to measure CO_2, CO and O_2.

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

A. Operating Standards:

All the operators of the Plasma Pyrolysis or Gasification **s**hall 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.

$$C.E = \frac{\%\ CO_2}{(\%\ CO_2 + \%\ CO)} \times 100$$

3) The temperature of the combustion chamber after plasma gasification shall be 1050 ± 50 ^{o} 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 Sl 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 $1X10^6$ spores. Under no circumstances will an autoclave have minimum operating parameters less than a residence time of 30 minutes, a temperature less than 121^o 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 1×10^4sporesper 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.

7. STANDARDS FOR DRY HEAT STERILIZATION

Waste sharps can be treated by dry heat sterilization at a temperature not less than 185^0C, 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 Shaprs sterilization unit

Waste shaprs sterilization unit should completely and consistently kill the biological indicator GeobacillusStearothermophillus or Bacillus Atropheausspoers 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.	(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. (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. (iii) Publication of list of registered health care facilities with regard to bio-medical waste generation, treatment and disposal. (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) Coordinate with State Pollution Control Boards for organizing training programmes to staff of health care facilities and municipal workers on bio-medical waste. (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. (vii) Organizing or Sponsoring of trainings for the regulatory authorities and health care facilities on bio-medical waste management related activities. (viii) Sponsoring of mass awareness campaigns in electronic media and print media.
3	Ministry of Defence	(i) Grant and renewal of authorisation to Armed Forces health care facilities or common bio-medical waste treatment facilities (Rule 9). (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. (iii) Publication of inventory of occupiers and bio-medical waste generation from Armed Forces health care facilities or occupiers (iv) Constitution of Advisory Committee for implementation of the rules. (v) Review of management of bio-medical waste generation in the Armed Forces health care facilities through its Advisory Committee (Rule 11). (vi) Submission of annual report to Central Pollution Control Board within the stipulated time period (Rule 13).
4.	Central Pollution Control Board	(i) Prepare Guidelines on bio-medical waste Management and submit to the Ministry of Environment, Forest and Climate Change. (ii) Co-ordination of activities of State Pollution Control Boards or Pollution Control Committees on bio-medical waste.

		(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	(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	(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.

		(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	(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

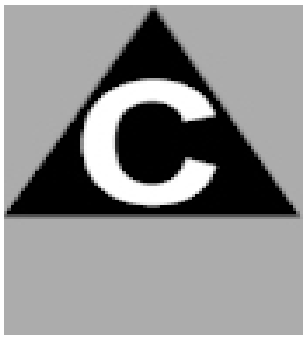
[See rule 8(3) and (5)]

Part A

LABEL FOR BIO-MEDICAL WASTE CONTAINERS or BAGS

HANDLE WITH CARE

CYTOTOXIC HAZARDSYMBOL



HANDLE WITH CARE

Part B

LABEL FOR TRANSPORTING BIO-MEDICAL WASTE BAGS OR CONTAINERS

Day .....Month .....

Year .....

Date of generation .....

Waste category Number .....

Waste quantity……

Sender's Name and Address

Phone Number .....

Receiver's Name and Address:

Phone Number .....

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:_____

(pl. 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-I)
(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 :		

	(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	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. 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 **

1. The authorisation shall comply with the provisions of the Environment (Protection) Act, 1986 and the rules made there under.

2. The authorisation or its renewal shall be produced for inspection at the request of an officer authorised by the prescribed authority.

3. The person authorized shall not rent, lend, sell, transfer or otherwise transport the biomedical wastes without obtaining prior permission of the prescribed authority.

4. 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.

5. 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)]

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 treatedor 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 Incineration Ash ETP Sludge
	(vi) Name of the Common Bio-Medical Waste Treatment Facility Operator through which wastes are disposed of	:	
	(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		

	(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.

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पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय

अधिसूचना

नई दिल्ली, 4 अप्रैल, 2016

सा. का.नि. 395(अ).—भारत सरकार द्वारा प्रारूप नियम अर्थात्, परिसंकटमय और अन्य अपशिष्ट (प्रबंधन और सीमापारीय संचलन) नियम 2015 का और संशोधन करने के लिए भारत सरकार के तत्कालीन पर्यावरण और वन मंत्रालय की अधिसूचना सं. का.आ.582 (अ) तारीख 24 जुलाई, 2015 द्वारा उन सभी व्यक्तियों से, जिनके उससे प्रभावित होने की संभावना थी, उस तारीख से जिसको उस राजपत्र की प्रतियां, जिसमें यह अधिसूचना अंतर्विष्ट है, उपलब्ध करा दी जाती हैं, साठ दिन की अवधि के भीतर आक्षेप और सुझाव आमंत्रित करते हुए एक प्रारूप अधिसूचना प्रकाशित की गई थी ;

और जनता को उक्त अधिसूचना को अंतर्विष्ट करने वाले राजपत्र की प्रतियां 24 जुलाई, 2015 को उपलब्ध करा दी गईं थी;

और केन्द्रीय सरकार द्वारा उक्त प्रारूप नियमों के संबंध में विनिर्दिष्ट अवधि के भीतर जनता से प्राप्त आक्षेपों और सुझावों पर सम्यक्त: विचार कर लिया गया है;

अत: अब केन्द्रीय सरकार, पर्यावरण संरक्षण अधिनियम, 1986 (1986 का 29) की धारा 6, धारा 8 और धारा 25 द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए, परिसंकटमय अपशिष्ट (प्रबंधन, प्रहस्तन और सीमापारीय संचलन) नियम, 2008 को सिवाय उन बातों के अधिक्रांत करते हुए जिन्हे ऐसे अधिक्रमण से पूर्व किया गया है या करने का लोप किया गया है, निम्नलिखित नियम बनाती है, अर्थात:-

अध्याय I

प्रारम्भिक

1. संक्षिप्त नाम और प्रारंभ – (1) इन नियमों का संक्षिप्त नाम परिसंकटमय और अन्य अपशिष्ट (प्रबंध और सीमापार संचलन) नियम, 2016 है |

(2) ये राजपत्र में उनके प्रकाशन की तारीख से प्रवृत्त होंगे |

2. **लागू होना-** ये नियम अनुसूचियों में यथा विनिर्दिष्ट परिसंकटमय और अन्य अपशिष्टों के प्रबंधन को लागू होंगे किन्तु निम्नलिखित पर लागू नहीं होंगे –

(क) जल (प्रदूषण निवारण और नियंत्रण) अधिनियम, 1974 (1974 का 6) और वायु (प्रदूषण निवारण और नियंत्रण) अधिनियम, 1985 (1985 का 14) और इसके अधीन बनाए गए और समय-समय पर यथासंशोधित नियमों के उपबंधों के अधीन आने वाले अपशिष्ट जल या निशेषित गैस;

(ख) वाणिज्यिक पोत परिवहन अधिनयम, 1958 (1958 का 44) और इसके अधीन बनाए गए और समय-समय पर यथासंशोधित नियमों के उपबधों के अधीन आने वाले सुसंगत बेस रेखा के पांच किलोमीटर से परे पोतों के प्रचालन से निकलने वाला अपशिष्ट;

(ग) परमाणु ऊर्जा अधिनियम, 1962 (1962 का 33) और इसके अधीन बनाए गए और समय-समय पर यथासंशोधित नियमों के उपबंधों के अधीन आने वाले रेडियोंधर्मी अपशिष्ट;

(घ) अधिनियम के अधीन बनाए गए और समय-समय पर यथासंशोधित जैव-चिकित्सीय अपशिष्ट (प्रबंध और प्रहस्तन), नियम, 1998 के अधीन आने वाले जैव चिकित्सीय अपशिष्ट; और

(ञ) अधिनियम के अधीन बनाए गए और समय-समय पर यथासंशोधित नगरपालिका ठोस अपशिष्ट (प्रबंध और प्रहस्तन) नियम, 2000 के अधीन आने वाले अपशिष्ट |

3. **परिभाषाएं** – (1) इन नियमों में जब तक कि संदर्भ से अन्यथा अपेक्षित न हो;

1. "अधिनियम'' से पर्यावरण (संरक्षण) अधिनियम, 1986 (1986 का 29) अभिप्रेत है ;

2. "वास्तविक प्रयोक्ता" से ऐसा अधिभोगी अभिप्रेत है जो पुन: उपयोग, पुन:चक्रण, पुन:प्राप्ति, पूर्व-प्रसंस्करण, सह-प्रसंस्करण सहित उपयोग हेतु परिसंकटमय और अन्य अपशिष्ट को अधिप्रापित और प्रसंस्कृत करता है;

3. "प्राधिकार'' से नियम 6 के उपनियम (2) के अधीन मंजूर परिसंकटमय अपशिष्टों के सृजन, प्रहस्तन, संग्रहण, ग्रहण, शोधन, परिवहन, भंडारण, पुन:उपयोग पुनर्चक्रीकरण, पूर्व-प्रसंस्करण, सह-प्रसंस्करण सहित उपयोग और निपटान के लिए अनुज्ञा अभिप्रेत है |

4. "बेसिल अभिसमय'' से परिसंकटमय अपशिष्टों के सीमापार संचलन और उनके निपटान के नियंत्रण पर संयुक्त राष्ट्र पर्यावरण कार्यक्रम अभिसमय अभिप्रेत है ;

5. "अबाध शोधन, भंडारण ओर निपटान सुविधा" से ऐसी सुविधा अभिप्रेत है जिसका विकास परिसंकटमय और अन्य अपशिष्टों के शोधन, भंडारण और विनिर्माण प्रसंस्करण, शोधन, पैकेज, भंडारण, परिवहन, उपयोग, संग्रहण, नष्ट करने, परिवर्तन, बिक्री हेतु देने, हस्तांतरण के दौरान उत्पन्न अपशिष्टों के निपटान के लिए किसी अधिभोगी के परिसर के अंदर किया गया हो;

6. "केन्द्रीय प्रदूषण नियंत्रण बोर्ड' से जल (प्रदूषण निवारण और नियंत्रण) अधिनियम, 1974 (1974 का 6) की धारा 3 की उपधारा (1) के अधीन गठित केन्द्रीय प्रदूषण नियंत्रण बोर्ड अभिप्रेत है;

7. "साझा शोधन, भंडारण और निपटान सुविधा" से ऐसी साझा सुविधा अभिप्रेत है जिसे व्यक्तिगत रूप से या राज्य सरकार या किसी सुविधा के अधिभोगी प्रचालक द्वारा संयुक्त रूप से या अधिभोगियों के सहयोग से अभिनिर्धारण किया गया हो जिसका उपयोग परिसंकटमय और अन्य अपशिष्टों के शोधन, भंडारण और निपटान के लिए अनेक अधिभोगियों या वास्तविक उपयोकर्ताओं द्वारा साझा सुविधा के रूप में उपयोग किया जाएगा;

8. "पुन: प्रसंस्करण" से अभिप्रेत ऊर्जा या संसाधन या दोनों की पुन: प्राप्ति और प्रतिस्थान के माध्यक से पारंपरिक इंधनों या कच्ची सामग्रियों या दोनों के प्रयोग में परिणामी कमी के उद्देश्य से विनिर्माण प्रक्रियाओं में अपशिष्ट सामग्रियों का प्रयोग है;

9. "गहन देखभाल उपकरण" से जीवन रक्षक उपकरण अभिप्रेत है और इसमें स्वास्थ्य एवं परिवार कल्याण मंत्रालय द्वारा समय-समय पर यथानिर्दिष्ट उपकरण शामिल है;

10. "निपटान'' से ऐसा कोई प्रचालन अभिप्रेत है जो पुन:प्रयोग, पुनर्चक्रीकरण, पुन: प्राप्ति या पुन:उपयोग सह-प्रसंस्करण सहित उपयोग की ओर नहीं ले जाता है और इसके अन्तर्गत अर्जित कचरे में भौतिक रसायन, जैविक उपचार, भस्मीकरण सुरक्षित खत्ता-स्थल में और निपटान सम्मिलित हैं;

11. "निर्यात" से इसके व्याकरणिक रूप भेदों और सहजातीय पदों में भारत से भारत के बाहर किसी स्थान को ले जाना अभिप्रेत है ;

12. "निर्यातक' से परिसंकटमय या अन्य अपशिष्ट का निर्यात करने वाले देश सहित ऐसे निर्यातक देश की अधिकारिता के अधीन कोई व्यक्ति या अधिभोगी अभिप्रेत है जो परिसंकटमय या अन्य अपशिष्टों का निर्यात करता है;

13. "परिसंकटमय और अन्य अपशिष्टों का पर्यावरणीय दृष्टि से अनुकूल प्रबंध" से यह सुनिश्चित करने के लिए अपेक्षित सभी उपाय करना अभिप्रेत है कि परिसंकटमय और अन्य अपशिष्टों का प्रबंध ऐसी रीति से हो जो ऐसे अपशिष्ट के परिणामस्वरूप प्रतिकूल प्रभावों के विरुद्ध स्वास्थ्य और पर्यावरण को संरक्षित करेगा;

14. "पर्यावरणीय दृष्टि से अनुकूल प्रौद्योगिकियां" से केन्द्रीय सरकार द्वारा समय समय पर अनुमोदित कोई प्रौद्योगिकी अभिप्रेत है;

15. "सुविधा" से ऐसा कोई स्थापन अभिप्रेत है जिसमें परिसंकटमय और/या अन्य अपशिष्टों के उत्पादन, प्रहस्तन, संग्रहण, प्रवेश, शोधन, भंडारण, पुन:प्रयोग, पुनर्चक्रीकरण, पुन: प्राप्ति , पूर्व-प्रसंस्करण, सह-प्रसंस्करण, उपयोग और निपटान के आनुषंगिक प्रक्रियाएं चलाई जाती हैं;

16. "प्ररूप" से इन नियमों से उपाबद्ध प्ररूप अभिप्रेत है ;

17. "परिसंकटमय अपशिष्ट" से कोई ऐसा अपशिष्ट अभिप्रेत है जो अपने भौतिक, रासायनिक, जैविक, प्रतिक्रियात्मक, विषाक्त, ज्वलनशील, विस्फोटक या क्षयकारी जैसे लक्षणों के कारण स्वास्थ्य या पर्यावरण को चाहे अकेले या अन्य अपशिष्टों या पदार्थों के सम्पर्क से खतरा कारित करता है या खतरा कारित करने की संभावना है और इसमें निम्नलिखित सम्मिलित होगा-

(i) अनुसूची 1 के स्तंभ 3 के अधीन विनिर्दिष्ट अपशिष्ट;

(ii) अनुसूची 2 के वर्ग क और वर्ग ख में या अनुसूची-।। के वर्ग ग में यथाविनिर्दिष्ट किन्हीं लक्षणों के अपशिष्ट संघटकों के लिए विनिर्दिष्ट संकेन्द्रण सीमाओं के समान या उससे अधिक रखने वाले अपशिष्ट; और

(iii) ऐसे अपशिष्टों के आयात या निर्यात की बाबत अनुसूची-।।। के भाग क में विनिर्दिष्ट अपशिष्ट या भाग क में विनिर्दिष्ट के सिवाए अपशिष्ट यदि उसमें अनुसूची-।।। के भाग ग में विनिर्दिष्ट कोई परिसंकटमय लक्षण है;

18. "आयात" से इसके व्याकरणीय रूपभेदों और सहजातीय पदों के अनुसार भारत में भारत के बाहर के स्थान से लाया जाना अभिप्रेत है;

19. "आयातक" से कोई व्यक्ति या अधिभोगी अभिप्रेत है जो परिसंकटमय और अन्य अपशिष्ट का आयात करता है;

20. "माल सूची" से इन नियमों के उपबंधों के अनुसार भेजने वाले द्वारा तैयार किया गया और हस्ताक्षरित परिवहन दस्तावेज अभिप्रेत है;

21. किसी कारखाना या परिसर के संबंध में "अधिभोगी" से ऐसा व्यक्ति अभिप्रेत है जिसका कारखाना या परिसर के क्रियाकलाप पर नियंत्रण है और इसके अन्तर्गत परिसंकटमय या अन्य अपशिष्ट के कब्जे में कोई परिसंकटमय या अन्य अपशिष्ट है;

22. "व्ययन सुविधा का प्रचालक" से ऐसा व्यक्ति अभिप्रेत है जो परिसंकटमय और अन्य अपशिष्टों के संग्रहण, ग्रहण, शोधन, भंडारण और व्ययन की सुविधा पर स्वामित्व रखता है या प्रचालित करता है ;

23. "अन्य अपशिष्ट" से आयात या निर्यात के लिए अनुसूची 3 के भाग ख और भाग ग में विनिर्दिष्ट अपशिष्ट अभिप्रेत है और इसमें देश में स्वदेशी रूप से उत्पादित ऐसे सभी अपशिष्ट शामिल हैं;

24. "पूर्व-प्रसंस्करण" से अपशिष्ट को सह-प्रसंस्करण या पुन: चक्रीकरण या आगे किसी अन्य प्रसंस्करण के लिए उपयुक्त बनाने हेतु अपशिष्ट का शोधन करना अभिप्रेत है;

25. "पुन:चक्रीकरण" से मूल प्रयोजन या अन्य प्रयोजनों के लिए पर्यावरणीय अनुकूल रीति से परिसंकटमय या अन्य अपशिष्टों का पुन: उद्धार और पुन: प्रसंस्करण अभिप्रेत है;

26. "पुन:उपयोग" से इसके मूल उपयोग या अन्य उपयोग के प्रयोजन के लिए परिसंकटमय या अन्य अपशिष्ट का उपयोग अभिप्रेत है;

27. "पुन:प्राप्ति" से पुन:चक्रीकरण से कोई ऐसा परिचालन या कार्यकलाप अभिप्रेत है जिसमें विनिर्दिष्ट सामग्रियों की पुन: प्राप्ति की जाती है;

28. "अनुसूची" से इन नियमों से उपाबद्ध अनुसूची अभिप्रेत है;

29. संघ राज्य क्षेत्र के संबंध में "राज्य सरकार" से संविधान के अनुच्छेद 239 के अधीन नियुक्त उसका प्रशासक अभिप्रेत है;

30. "राज्य प्रदूषण नियंत्रण बोर्ड" से जल (प्रदूषण निवारण और नियंत्रण) अधिनियम, 1974 (1974 का 6) की धारा 4 के अधीन गठित राज्य प्रदूषण नियंत्रण बोर्ड अभिप्रेत है और इसके अन्तर्गत संघ राज्य क्षेत्र प्रदूषण नियंत्रण समिति के अधीन गठित भी है ;

31. "भंडारण" से अस्थायी अवधि के लिए किसी परिसंकटमय या अन्य अपशिष्ट का भंडारण अभिप्रेत है जिसके अन्त में ऐसे अपशिष्ट का प्रसंस्करण या निपटान किया जाता है;

32. "सीमापार संचलन" से एक देश की अधिकारिता के अधीन क्षेत्र से या दूसरे देश की अधिकारिता के अधीन क्षेत्र के माध्यम से या किसी देश की अधिकारिता के अधीन न आने वाले क्षेत्र के माध्यम से परिसंकटमय और अन्य अपशिष्टों का कोई संचलन अभिप्रेत है, परन्तु यह कि संचलन में कम से कम कोई दो देश अन्तर्वलित हों;

33. "परिवहन" से वायु, रेल, सड़क या जल द्वारा परिसंकटमय या अन्य अपशिष्टों का अपतट संचलन अभिप्रेत है;

34. "परिवाहक" से वायु, रेल, सड़क या जल द्वारा परिसंकटमय या अन्य अपशिष्ट का अपतट परिवहन में लगा व्यक्ति अभिप्रेत है;

35. "शोधन" से किसी परिसंकटमय या अन्य अपशिष्ट के भौतिक, रासायनिक या जैविक लक्षणों या संरचना को परिवर्तित करने के लिए ढंग, तकनीक या प्रक्रिया अभिप्रेत है जिससे कि नुकसान कारित करने की इसकी क्षमता को कम किया जा सके;

36. "'प्रयुक्त तेल' से निम्नलिखित कोई तेल अभिप्रेत है-

(i) प्रयुक्त इंजन तेल, गियर तेल, हाइड्रोलिक तेल, टरबाइन तेल, कम्प्रेशर तेल, औद्योगिक गियर तेल, ताप अन्तरण तेल, ट्रांसफार्मर तेल और उनके टेंक के तल के मलबे सहित कच्चा तेल या स्पेन्ट तेल सहित सिन्थेटिक मिश्रित तेल से व्युत्पन्न; और

(ii) पुन:संस्करण के लिए उपयुक्त यदि यह अनुसूची V के भाग क में निर्धारित विनिर्देश को पूरा करता है किन्तु इसमें अपशिष्ट तेल सम्मिलित नहीं है;

37. "उपयोग" से एक संसाधन के रूप में परिसंकटमय या अन्य अपशिष्ट का उपयोग अभिप्रेत है;

38. "अपशिष्ट" से ऐसी सामग्री अभिप्रेत है जो उत्पाद या उपोत्पाद नहीं है जिनका उत्पादन, परिवर्तन या उपभोग के प्रयोजन के लिए सृजनकर्ता के लिए आगे कोई उपयोग नहीं है।

स्पष्टीकरण – इस खंड के प्रयोजनों के लिए –

(i) अपशिष्ट में ऐसी सामग्री सम्मिलित है जिसका सृजन कच्ची सामग्री के उत्कर्षण के दौरान, कच्ची सामग्री से मध्यवर्ती और अन्तिम उत्पाद के प्रसंस्करण, अंतिम उत्पाद के उपभोग और अन्य मानवीय क्रियाकलापों के माध्यम से किया जा सकेगा और प्रक्रिया के भाग के रूप में सृजन के स्थान पर पुन:चक्रीत या पुन:उपयोगी अवशिष्टों को अपवर्जित करता है |

(ii) उपोत्पाद से ऐसी सामग्री अभिप्रेत है जो उत्पादन प्रक्रिया द्वारा एकमात्र या पृथकत: उत्पादित नहीं किया गया है किन्तु प्रक्रिया में उत्पादित किया गया है और इस प्रकार उपयोग किया गया है |

39. "अपशिष्ट तेल" से ऐसा कोई तेल अभिप्रेत है जिसमें कच्चा तेल, मिश्रण, टेंक सतह कचरा और पैट्रोलियम परिष्करणी संस्थापनों या पोतों से सृजित तरल तेल और ऊर्जा पुन: प्राप्ति के लिए भट्टी में ईंधन के रूप में उपयोग किया जा सकता है यदि यह इस प्रकार या प्रसंस्करण के पश्चात अनुसूची 5 के भाग ख में अधिकथित विनिर्देशों को पूरा करता है |

(2) इन नियमों में प्रयुक्त शब्द और पद जो यहां परिभाषित नहीं है किन्तु अधिनियम में परिभाषित हैं का वही अर्थ होगा जो उनका अधिनियम में है।

अध्याय ॥

परिसंकटमय और अन्य अपशिष्टों के प्रबंधन की प्रक्रिया

4. परिसंकटमय और अन्य अपशिष्टों के प्रबंधन के लिए अधिभोगी के दायित्व –

(1) परिसंकटमय और अन्य अपशिष्टों के प्रबंधन के लिए अधिभोगी निम्नलिखित कदमों का पालन करेंगे, अर्थात् :

(क) निवारण;
(ख) न्यूनीकरण;
(ग) पुन: प्रयोग;
(घ) पुन: चक्रीकरण;
(ड.) सह-प्रसंस्करण सहित पुन:प्राप्ति, उपयोग;
(च) सुरक्षित निपटान;

(2) अधिभोगी परिसंकटमय और अन्य अपशिष्टों के सुरक्षित और पर्यावरणीय अनुकूल प्रबंध के लिए उत्तरदायी होगा |

(3) किसी अधिभोगी के स्थापन में सृजित परिसंकटमय और अन्य अपशिष्ट को किसी अधिृकत वास्तविक प्रयोगकर्ता को भेजा या बेचा जाएगा या किसी अधिकृत निपटान सुविधा में इसका निपटान किया जाएगा।

(4) किसी अधिभोगी के स्थापन से परिसंकटमय और अन्य अपशिष्ट का इन नियमों के उपबंधों के अनुरूप प्राधिकृत वास्तविक प्रयोक्ता या प्राधिकृत निपटान सुविधा तक परिवहन किया जाएगा।

(5) ऐसा अधिभोगी जो अपने परिसंकटमय और अन्य अपशिष्टों का शोधन या निपटान, शोधन के प्रचालक द्वारा कराना चाहता है वहां भंडारण और निपटान सुविधा उस सुविधा के प्रचालक और ऐसी जानकारी जो सुरक्षित भंडारण और निपटान के लिए आवश्यक हो, दी जाएगी।

(6) अधिभोगी परिसंकटमय और अन्य अपशिष्टों के प्रबंधन के समय सभी पर्याप्त उपाय करेगा-

(क) संदूषकों को नियंत्रित करेगा और दुर्घटनाओं को रोकेगा तथा मानव और पर्यावरण पर उनके परिणामों को सीमित करेगा; और

(ख) स्थल पर कार्य कर रहे व्यक्तियों को समुचित प्रशिक्षण, उपकरण और उनकी सुरक्षा को सुनिश्चित करने के लिए आवश्यक जानकारी उपलब्ध कराएगा |

(5) परिसंकटमय और अन्य अपशिष्टों के पर्यावरणीय अनुकूल प्रबंध के लिए राज्य सरकार के दायित्व - (1) राज्य में उद्योग विभाग या राज्य सरकार द्वारा इस संबंध में प्राधिकृत कोई अन्य सरकारी अभिकरण, विद्यमान और भावी आद्योगिक पार्क, संपदा और औद्योगिक समूहों में परिसंकटमय या अन्य अपशिष्ट के पुन:चक्रीकरण, पूर्व-प्रसंस्करण और अन्य उपयोग के लिए औद्योगिक स्थान या शेड का निर्धारण या आवंटन सुनिश्चित करना;

(2) राज्य में श्रम विभाग या राज्य सरकार द्वारा इस संबंध में प्राधिकृत किसी सरकारी अभिकरण द्वारा निम्नलिखित कार्य किए जाएंगे, -

(क) पुन:चक्रीकरण, पूर्व-प्रसंस्करण और अन्य उपयोग संबंधी कार्यकलापों में लगे कार्मिकों की पहचान और पंजीकरण सुनिश्चित करना;

(ख) ऐसी सुविधाओं की स्थापना में सुगमता प्रदान करने के लिए ऐसे कार्मिकों के समूहों को बनाने में सहायता प्रदान करना;

(ग) पुन:चक्रीकरण, पुन:प्रसंस्करण और अन्य उपयोग में लगे कार्मिकों के लिए औद्योगिक कौशल विकास संबंधी कार्यकलाप करना;

(घ) वार्षिक निगरानी करना और पुन:चक्रीकरण, पुन:प्रसंस्करण और अन्य उपयोग में लगे कार्मिकों की सुरक्षा और स्वास्थ्य को सुनिश्चित करना।

(3) प्रत्येक राज्य सरकार द्वारा इन उपबंधों के प्रभावी कार्यान्वयन के लिए एकीकृत योजना बनाई जा सकती है और केन्द्रीय सरकार में पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय को वार्षिक रिपोर्ट प्रस्तुत की जा सकती है।

(6) परिसंकटमय और अन्य अपशिष्टों के प्रबंधन के लिए प्राधिकार का मंजूर किया जाना.-(1) परिसंकटमय और अन्य अपशिष्टों के प्रहस्तन, उत्पादन संग्रहण, भंडारण, पैकेजिंग, परिवहन, प्रयोग, शोधन, प्रसंस्करण, पुन:चक्रीकरण, पुन: प्राप्ति, पूर्व-प्रसंस्करण, सह-प्रसंस्करण, उपयोग, बिक्री, अंतरण या निपटान में लगी सुविधा के प्रत्येक अधिभोगी द्वारा प्ररुप 1 में राज्य प्रदूषण नियंत्रण बोर्ड को

आवेदन किया जाना और इन नियमों के प्रकाशन की तारीख से साठ दिनों की अवधि के अंदर राज्य प्रदूषण नियंत्रण बोर्ड से प्राधिकार प्राप्त करना अपेक्षित होगा। प्राधिकार के लिए ऐसे आवेदन के साथ निम्नलिखित दस्तावेजों में से प्रत्येक की एक प्रति होगी, अर्थात् :

(क) जल (प्रदूषण निवारण और नियंत्रण अधिनियम, 1974 (1974 का 25) और / वायु प्रदूषण निवारण और नियंत्रण अधिनियम, 1985 (1985 का 21) के अधीन राज्य प्रदूषण नियंत्रण बोर्ड से प्रचालन की सहमति।

(ख) जल (प्रदूषण निवारण और नियंत्रण अधिनियम, 1974 (1974 का 25) और / वायु (प्रदूषण निवारण और नियंत्रण अधिनियम, 1981 (1981 का 21) के अधीन राज्य प्रदूषण नियंत्रण बोर्ड द्वारा मंजूर स्थापना की सहमति।

(ग) प्राधिकार के नवीकरण के मामले में, परिसंकटमय और अन्य अपशिष्टों के लिए प्राधिकार में विनिर्दिष्ट बहि:स्राव, उत्सर्जन मानकों और शर्तों के संबंध में स्व-प्रमाणित अनुपालन रिपोर्ट।

परन्तु यह कि प्राधिकार के लिए नवीकरण का आवेदन ऐसे प्राधिकार की समाप्ति के तीन मास पूर्व किया जा सकेगा :

परंतु यह और कि-

(i) परन्तु यह और कि इन नियमों के प्रारंभ की तारीख से पूर्व परिसंकटमय अपशिष्ट (प्रबंध, प्रहस्तन और सीमापार संचलन) नियम, 2008 के उपबंधों के अधीन प्राधिकृत किसी व्यक्ति से ऐसे प्राधिकार की अवधि की समाप्ति तक प्राधिकार का आवेदन करने की अपेक्षा नहीं होगी।

(ii) अनुसूची IV में विनिर्दिष्ट परिसंकटमय अपशिष्ट के पुनर्चक्रण या पुनर्संस्करण में लगा कोई व्यक्ति जिसके पास परिसंकटमय अपशिष्ट (प्रबंधन, प्रहस्तन और सीमापार संचलन) नियम, 2008 के अधीन रजिस्ट्रीकरण है, को ऐसे रजिस्ट्रीकरण के अवसान की अवधि तक प्राधिकार के लिए आवेदन करना अपेक्षित नहीं है ।

(2) राज्य प्रदूषण नियंत्रण बोर्ड प्राधिकार के लिए सभी परिप्रेक्ष्य में पूर्ण आवेदन की प्राप्ति पर ऐसी जांच के पश्चात् जिसे वह आवश्यक समझे और समाधान होने पर कि आवेदक परिसंकटमय अपशिष्ट या उसके समान किसी वस्तु के लिए यथा स्थिति, संग्रहण, भंडारण, पैकिंग परिवहन, शोधन, प्रसंस्करण, उपयोग, विध्वंस, पुनर्चक्रण, पुन: प्राप्ति, पूर्व-प्रसंस्करण, सह-प्रसंस्करण, उपयोग, विक्रय का प्रस्ताव, हस्तांतरण या निपटान, के लिए समुचित सुविधाएं रखता है और तकनीकी क्षमताओं तथा उपस्कर जो केंद्रीय प्रदूषण बोर्ड द्वारा समय समय पर और स्थल निरीक्षण के माध्यम से विनिर्दिष्ट मानक प्रचालन प्रक्रिया और अन्य दिशा निर्देशों के अनुरुप हैं, एक सौ बीस दिन की अवधि में आवेदक को प्ररुप 2 में प्राधिकार जो पांच वर्ष की अवधि के लिए विधि मान्य होगा और उसमें अधिकथित ऐसी दशाओं के अध्यधीन होगा, देगा। अनुसूची IV में दिए गए अनुसार सामान्य रूप से पुनचक्रीकरणयोग्य परिसंकटमय अपशिष्ट के लिए, केन्द्रीय प्रदूषण नियंत्रण बोर्ड द्वारा पहले से ही तैयार किए गए मार्गदर्शक सिद्धांत अपनाए जाएंगे :

परंतु यह कि प्राधिकार के नवीकरण के दशा में राज्य प्रदूषण नियंत्रण बोर्ड ऐसे प्राधिकार प्रदान करने से पहले अपना समाधान करेगा कि यह पूर्व से प्रदान किए गए किसी प्राधिकार में विनिर्दिष्ट दशाओं के उल्लंघन में नहीं है और इसे निरीक्षण रिपोर्ट में अभिलिखित किया जाएगा।

(3) राज्य प्रदूषण नियंत्रण बोर्ड द्वारा उपनियम (2) के अधीन प्रदत्त प्राधिकार के साथ उस बोर्ड द्वारा हस्ताक्षरित क्षेत्र निरीक्षण रिपोर्ट की प्रति जिसके परिसंकटमय या उसके समान किसी वस्तु में और अन्य अपशिष्टों संग्रहण, भंडारण, पैकेजिंग, परिवहन, उपचार प्रसंस्करण, उपयोग, विध्वंस, पुनर्चक्रण, प्रति प्राप्ति, पूर्व-प्रसंस्करण, सह-प्रसंस्करण, उपयोग और विक्रय का प्रस्ताव, अंतरण या निपटान के लिए पर्याप्त सुविधाओं की सूचना होगी और केंद्रीय प्रदूषण नियंत्रण बोर्ड द्वारा समय समय पर विनिर्दिष्ट मानक प्रसंस्करण प्रचालन के मार्गदर्शक सिद्धांतों का अनुपालन करेगा ।

(4) राज्य प्रदूषण नियंत्रण बोर्ड आवेदक की उसमें कारणों को अभिलिखित करते हुए और सुनवाई का युक्तियुक्त अवसर देते हुए इन नियमों के अधीन किसी प्राधिकार को प्रदान करने से इंकार कर सकेगा ।

(5) इन नियमों के अधीन प्राधिकृत प्रत्येक अधिभोगी उसके द्वारा प्रबंधित प्ररुप 3 में परिसंकटमय और अन्य अपशिष्टों के अभिलेख रखेगा और तैयार करेगा तथा प्ररुप 4 में विनिर्दिष्ट ब्यौरों के सहित वार्षिक रुप से 30 जून या उससे पूर्व प्रत्येक वित्तीय वर्ष जो उस विवरणी से संबंधित है, को राज्य प्रदूषण नियंत्रण बोर्ड को प्रस्तुत करेगा ।

(6) राज्य प्रदूषण नियंत्रण बोर्ड परिसंकटमय और अन्य अपशिष्टों के प्रबंधन के लिए इन नियमों के अधीन अधिरोपित दशाओं की विशिष्टियां सहित एक रजिस्टर रखेगा और यह कार्यालय समय के दौरान किसी भी हितबद्ध या प्रभावित व्यक्ति के निरीक्षण के लिए खुला रहेगा।

(7) परिसंकटमय और अन्य अपशिष्टों के प्राधिकृत वास्तविक प्रयोक्ता खरीदे गए परिसंकटमय और अन्य अपशिष्टों के अभिलेखों के प्राधिकार के साथ राज्य प्रदूषण नियंत्रण बोर्ड द्वारा जारी की गई पासबुक में रखेगा।

(8) प्राधिकृत वास्तविक उपयोगकर्ता को परिसंकटमय और अन्य अपशिष्टों को केवल वास्तविक प्रयोगकर्ता की पासबुक में प्रविष्टि करने के बाद ही सौंपा जाएगा।

7. प्राधिकार को निलंबित या रद्द करने की शक्ति.- (1) राज्य प्रदूषण नियंत्रण बोर्ड, यदि उसके विचार में प्राधिकार का धारक प्राधिकार में दशाओं या अधिनियम के किसी उपबंध में या इन नियमों में से किसी को भी अनुपालन करने में असफल रहा है तो उसको सुनवाई का अवसर देगा और उसके कारणों को अभिलिखित करने के पश्चात् नियम 6 के अधीन ऐसी अवधि जो वह लोक हित में आवश्यक समझे जारी प्राधिकार को रद्द या निलंबित कर सकेगा ।

(2) प्राधिकार में निलंबित या रद्द होने पर राज्य प्रदूषण नियंत्रण बोर्ड व्यक्ति जिसका प्राधिकार निलंबित या रद्द किया गया है, को परिसंकटमय अपशिष्ट को सुरक्षित भंडारण और प्रबंध के लिए निर्देश दे सकेगा और ऐसा व्यक्ति ऐसा निर्देशों का अनुपालन करेगा ।

8. परिसंकटमय और अन्य अपशिष्टों का भंडारण.- (1) प्रसुविधाओं के अधिभोगी, नब्बे दिन से अनधिक अवधि के लिए परिसंकटमय और अन्य अपशिष्टों को भंडार कर सकेगा और ऐसे अपशिष्टों में विक्रय अंतरण, भंडार, पुनर्चक्रण, पुन:प्राप्ति, पूर्व-प्रसंस्करण, सह-प्रसंस्करण और उपयोग का अभिलेख रखेगा और इन अभिलेखों को निरीक्षण के लिए उपलब्ध रखेगा ।

परंतु यह कि राज्य प्रदूषण नियंत्रण बोर्ड निम्नलिखित मामलों के नब्बे दिन की अवधि को विस्तारित कर सकेगा, अर्थात् :-

(i) प्रतिवर्ष दस टन तक छोटे सृजनकर्ता उनकी वार्षिक क्षमता के एक सौ अस्सी दिनों तक;

(ii) वास्तविक प्रयोक्ता और निपटान सुविधा के प्रचालक उनकी वार्षिक क्षमता के एक सौ अस्सी दिन तक।

(iii) अधिभोगी जो संबद्ध राज्य में शोधन, भंडारण, निपटान प्रसुविधा नहीं रखते हैं;

(iv) अपशिष्ट जिन्हें इनके पुनचर्क्रण, पुन: प्राप्ति, पूर्व-प्रसंस्करण, सह-प्रसंस्करण या

उपयोग के लिए प्रक्रिया के विकास हेतु विशिष्ट रूप से भंडारित किए जाने की आवश्यकता हो;

(v) किसी अन्य मामले में, औचित्यपूर्ण आधार पर एक सौ अस्सी दिनों तक।

9. परिसंकटमय और अन्य अपशिष्टों का उपयोग.- (1) उत्पादक के परिसर सहित (यदि यह प्रक्रिया का भाग नहीं है) एक संसाधन के रूप में परिसंकटमय और अन्य अपशिष्टों उपयोग या सह-प्रसंस्करण या किसी अन्य प्रयोग के लिए पूर्व-प्रसंस्करण, केवल केन्द्रीय प्रदूषण नियंत्रण बोर्ड द्वारा दिए गए दिशानिर्देशों या मानक के आधार पर अपशिष्ट के संबंध में राज्य प्रदूषण नियंत्रण बोर्ड से प्राधिकार प्राप्त करने के पश्चात् ही किया जाएगा।

(2) जहां विशिष्ट उपयोग के लिए मानक प्रचालन पद्धतियां या मार्गदर्शक सिद्धांत उपलब्ध न हों, वहां केन्द्रीय प्रदूषण नियंत्रण बोर्ड से अनुमोदन की वांछा की जाएगी जो परीक्षणों के आधार पर अनुमोदन प्रदान करेगा और इसके बाद केन्द्रीय प्रदूषण नियंत्रण बोर्ड द्वारा मानक प्रचालन प्रक्रियाएं या दिशानिर्देश तैयार किए जाएंगे:

परंतु यह कि यदि परीक्षण विशिष्ट उपयोग के संबंध में विशेष अपशिष्ट के लिए किया गया है तथा पर्यावरण मानकों का अनुपालन उपदर्शित किया गया है तो राज्य प्रदूषण नियंत्रण बोर्ड द्वारा इसी अपशिष्ट तथा उपयोग के संबंध में केन्द्रीय प्रदूषण नियंत्रण बोर्ड द्वारा अलग से परीक्षण की अपेक्षा के बिना प्राधिकार मंजूर किया जा सकता है और ऐसे सफल परीक्षण के मामलों के केन्द्रीय प्रदूषण नियंत्रण बोर्ड सभी राज्य प्रदूषण नियंत्रण बोर्डों को सूचित करेगा।

(3) सीमेंट संयंत्रों में अपशिष्ट के सह-प्रसंस्करण के लिए परीक्षणों की आवश्यकता नहीं होगी जिसके लिए मार्गदर्शक सिद्धांत केन्द्रीय प्रदूषण नियंत्रण बोर्ड द्वारा पहले ही उपलब्ध करा दिए गए हैं; तथापि वास्तविक उपयोगकर्ता द्वारा अपशिष्ट के सह-प्रसंसकरण के संबंध में सीमेंट संयंत्र के लिए पर्यावरण (संरक्षण) अधिनियम, 1986 (1986 का 29) के अंतर्गत अधिसूचित मानकों का अनुपालन सुनिश्चित किया जाएगा:

परंतु यह कि मानकों के अधिसूचित होने तक परिसंकटमय और अन्य अपशिष्ट के अन्य उपयोग हेतु यथा प्रयोज्य प्रक्रिया अपनाई जाएगी, जैसाकि ऊपर उपदर्शित किया गया है।

10. **वास्तविक प्रयोक्ताओं के लिए मानक प्रचालन पद्धति या मार्गदर्शक सिद्धांत.-** पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय या केन्द्रीय प्रदूषण नियंत्रण बोर्ड द्वारा समय समय पर परिसंकटमय और अन्य अपशिष्टों के पर्यावरणीय अनुकूल प्रबंधन के लिए मानक प्रचालन पद्धतियां या मार्गदर्शक सिद्धांत जारी कर सकेगा।

अध्याय III
परिसंकटमय और अन्य अपशिष्ट का आयात और निर्यात

11. परिसंकटमय और अन्य अपशिष्टों का आयात और निर्यात (सीमापार संचलन).- पर्यावरण वन और जलवायु परिवर्तन मंत्रालय, इन नियमों के उपबंधों के अनुसार परिसंकटमय और अन्य अपशिष्टों के सीमापार संचलन के लिए नोडल मंत्रालय होगा ।

12. परिसंकटमय और अन्य अपशिष्टों के आयात और निर्यात के लिए कार्यनीति.- (1) परिसंकटमय और अन्य अपशिष्ट का किसी अन्य देश से भारत में निस्तारण करने के लिए कोई आयात अनुज्ञेय नहीं होगा ।

(2) परिसंकटमय और अन्य अपशिष्ट का आयात केवल पुनर्चक्रण, पुन:प्राप्ति, पुन:उपयोग और सह-प्रसंस्करण सहित, उपयोग के लिए ही अनुज्ञेय होगा ।

(3) अनुसूची III के भाग क में परिसंकटमय अपशिष्ट का आयात निर्यातक देश की पूर्व सूचित सहमति के साथ वास्तविक प्रयोक्ताओं के लिए अनुज्ञेय होगा और इसके लिए पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय की अनुमति अपेक्षित होगी।

(4) अनुसूची III के भाग ख में अन्य अपशिष्टों का आयात पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय की अनुमति से अनुज्ञेय होगा।

(5) अनुसूची III के भाग घ में अन्य अपशिष्टों का नियम 13 में दी गई प्रक्रिया के अनुसार और उपर्युक्त अनुसूची के नीचे की टिप्पणी के अनुसार अनुज्ञेय होगा।

(6) अनुसूची VI में विनिर्दिष्ट परिसंकटमय और अन्य अपशिष्टों का आयात अनुज्ञेय नहीं होगा।

(7) भारत से अनुसूची III और अनुसूची VI के भाग क और भाग ख में सूचीबद्ध परिसंकटमय और अन्य अपशिष्टों का आयात पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय की अनुमति से होगा। अनुसूची III और अनुसूची VI के भाग क में सूचीबद्ध परिसंकटमय और अन्य अपशिष्टों के आयात के लिए आवेदनों के मामले में, उन पर आयातक देश की पूर्व सूचित सहमति के आधार पर विचार किया जाएगा।

(8) परिसंकटमय और अन्य अपशिष्टों, जो अनुसूची III में विनिर्दिष्ट नहीं हैं, किंतु अनुसूची III के भाग ग में उल्लिखित परिसंकटमय लक्षण दर्शातें हैं, के आयात तथा निर्यात के लिए इन्हें यथा स्थिति, भारत से आयात या निर्यात, किए जाने से पूर्व पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय की पूर्व लिखित अनुमति अपेक्षित होगी।

13. परिसंकटमय और अन्य अपशिष्टों के निर्यात की प्रक्रिया - (1) अनुसूची ।।। के भाग क और भाग ख में निर्दिष्ट परिसंकटमय और अन्य अपशिष्टों के आयात या सीमापारीय संचलन हेतु वहन के इच्छुक वास्तविक प्रयोक्ता प्ररूप 5 के साथ इसमें सूचीबद्ध दस्तावेज सहित अनुसूची ।।। के भाग क के संबंध में निर्यातक देश के पूर्व सूचित सहमति सहित प्रस्तावित आयात के लिए पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय को आवेदन करेंगे और इसके साथ ही संबंधित राज्य प्रदूषण नियंत्रण बोर्ड के सूचनार्थ आवेदन की एक प्रति भेजेंगे और इस संबंध में संबंधित राज्य प्रदूषण बोर्ड से पावती आवेदन सहित पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय को प्रस्तुत की जाएगी।

(2) अनुसूची ।।। के भाग घ में सूचीबद्ध अन्य अपशिष्टों के आयात के लिए आयातक के लिए पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय की अनुमति अपेक्षित नहीं होगी। तथापि, आयातक द्वारा अनुसूची VIII में सूचीलबद्ध दस्तावेजों के अतिरिक्त यथास्थिति, निम्नलिखित दस्तावेजों, जैसा भी मामला हो, के साथ सीमा शुल्क प्राधिकरणों को प्ररूप 6 के अनुसार अपेक्षित सूचना प्रस्तुत की जाएगी। अनुसूची VIII (बेसेल सं. बी 1110) के क्रमांक 4 (ड.) से 4 (झ) में सूचीबद्ध प्रयुक्त वैद्युत तथा इलेक्ट्रॉनिकी संयोजनों के लिए इन नियमों के अंतर्गत प्रलेखन की कोई विशेष्ट अपेक्षा नहीं है :

(क) विदेश व्यापार महानिदेशालय से आयात अनुज्ञप्ति, यदि लागू हो;

(ख) जल (प्रदूषण का निवारण एवं नियंत्रण) अधिनियम, 1974 (1974 का 25) और वायु (प्रदूषण का निवारण एवं नियंत्रण) अधिनियम, 1981 (1981 का 21) और समय-समय पर यथा संशोधित इन नियमों के साथ-साथ ई-अपशिष्ट (प्रबंधन एवं प्रहस्तन) नियम, 2011, जो भी प्रयोज्य हो, के अंतर्गत प्राधिकार के अंतर्गत विधि मान्य सहमतियां;

(ग) ऐसा आयातक जो व्यापारी है, वास्तविक प्रयोक्ताओं की ओर से अपशिष्ट का आयात करता है, द्वारा प्ररूप 7 में एक बार का प्राधिकार प्राप्त करेगा और इस प्राधिकार की एक प्रति प्ररुप 6 के साथ संलग्न की जाएगी।

(3) अनुसूची 3 के भाग ख के लिए, समय-समय पर यथासंशोधित ई-अपशिष्ट (प्रबंधन एवं प्रहस्तन) नियम, 2011 की अनुसूची I के अंतर्गत यथा सूचीबद्ध किसी प्रयुक्त वैद्युत और इलेक्ट्रॉनिकी संयोजनों या अतिरिक्त पूर्जों या संघटक के भाग या उपभोज्य वस्तुओं के आयात के मामले में, आयातक को उक्त (प्रबंधन एवं प्रहस्तन) नियम, 2011 के अंतर्गत उत्पादक के रूप में विस्तारित उत्पादक दायित्व-प्राधिकार प्राप्त करने की आवश्यकता होगी।

(4) अनूसूची ।।। के भाग घ में सूचीबद्ध अपशिष्टों के प्रेषण की स्वीकृति से पूर्व, सीमा शुल्क प्राधिकरणों द्वारा अनुसूची VIII के कॉलम (3) में दिए गए अनुसार दस्तावेजों का सत्यापन किया जाएगा।

(5) अनुसूची ।।। के भाग क और भाग ख के संबंध में पूर्ण आवेदन की प्राप्ति पर, पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय द्वारा राज्य प्रदूषण नियंत्रण बोर्डों से प्राप्त टिप्पणियों और प्रेक्षणों, यदि कोई हों, पर विचार करते हुए आवेदन की जांच की आएगी और आयातक के पास निम्नलिखित के होने की शर्त के अध्यधीन साठ दिनों की अवधि के अंदर आयात के लिए अनुमति प्रदान की जा सकती है -

(i) पर्यावरणीय दृष्टि से अनुकूल सुविधाएं;

(ii) उत्पन्न अपशिष्टों के शोधन तथा निपटान के लिए पर्याप्त व्यवस्थाएं;

(iii) राज्य प्रदूषण नियंत्रण बोर्ड से विधि मान्य प्राधिकार और अनुमति;

(iv) अनुसूची ।।। के भाग क के अपशिष्टों के मामले में निर्यातक देश से पूर्व सूचित सहमति।

(6) पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय द्वारा संबंधित पत्तन तथा सीमा शुल्क प्राधिकरणों, केन्द्रीय प्रदूषण नियंत्रण बोर्ड और संबंधित राज्य प्रदूषण नियंत्रण बोर्ड को अनुमति की प्रति प्रेषित की जाएगी ताकि अनुसूची VIII में दिए गए उनके संबंधित कार्यों के बारे में अनुपालन सुनिश्चित किया जा सके।

(7) परिसंकटमय और अन्य अपशिष्टों का आयातक अपने द्वारा आयातित परिसंकटमय और अन्य अपशिष्ट के अभिलेखों का रख-रखाव प्ररूप 3 में करेगा और इस प्रकार रखे गए अभिलेखों को निरीक्षण हेतु उपलब्ध कराया जाएगा।

(8) परिसंकटमय और अन्य अपशिष्टों का आयातक वित्त वर्ष जिसका संबंध विवरणी से हो, के 30 जून को या उससे पहले राज्य प्रदूषण नियंत्रण बोर्ड को प्ररूप 4 में वार्षिक विवरणी दाखिल करेगा।

(9) परीक्षण या अनुसंधान और विकास उद्देश्यों के लिए आयात किए जा रहे परिसंकटमय और अन्य अपशिष्टों के 1000 ग्राम या 1000 मि.ली. तक के नमूनों को इन नियमों के अंतर्गत आयात हेतु अनुमति प्राप्त करने की आवश्यकता से छूट होगी।

(10) पत्तन और सीमा शुल्क प्राधिकरणों द्वारा सुनिश्चित किया जाएगा कि नौभार के साथ प्ररुप 6 में दिए गए अनुसार संचलन दस्तावेज हो और संदेह के मामले में निर्यातक देश द्वारा प्रत्यायोजित या मान्यता प्राप्त प्रयोगशाला से अपशिष्ट नौभार के विश्लेषण की परीक्षण रिपोर्ट का सीमा शुल्क द्वारा सत्यापन किया जाए।

14. भारत से परिसंकटमय और अन्य अपशिष्ट के निर्यात की प्रक्रिया.- (1) अनुसूची ।।। के भाग क, अनुसूची ।।। के भाग ख और अनुसूची VI में विनिर्दिष्ट अपशिष्ट का निर्यात करने का इच्छुक कोई अधिभोगी अनुसूची ।।। के भाग क और अनुसूची VI में विनिर्दिष्ट अपशिष्टों के संबंध में निर्यात करने वाले देश से लिखित में पूर्व सूचित सहमति के साथ परिसंकटमय और अन्य अपशिष्टों के प्रस्तावित सीमापरीय संचलन के लिए पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय को बीमा कवर के साथ प्ररुप 5 में आवेदन प्रस्तुत करेगा।

(2) उप-नियम (1) के अधीन किसी आवेदन की प्राप्ति पर, पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय पूर्ण आवेदन जमा करने की तारीख से साठ दिन की अवधि में प्रस्तावित निर्यात के लिए अनुमति दे सकता है और ऐसी दशाएं अधिरोपित कर सकेगा जो वह आवश्यक समझे ।

(3) पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय उप-नियम (2) के अधीन प्रदत्त अनुमति की प्रति राज्य के राज्य प्रदूषण नियत्रंण बोर्ड जहां अपशिष्ट उत्पन्न हुआ हो और उस राज्य के प्रदूषण नियंत्रण बोर्ड को जहां निर्यात का पत्तन अवस्थित है तथा संबंधित पत्तन और सीमा शुल्क प्राधिकरणों को, निर्यात अनुमति की दशाओं का अनुपालन सुनिश्चित करने के लिए अग्रेषित करेगा ।

(4) निर्यातक यह सुनिश्चित करेगा कि आयात करने वाले देश से पूर्व सूचित सहमति, जहां कहीं लागू हो, प्राप्त होने से पूर्व नौभार को नहीं भेजा जाएगा ।

(5) निर्यातक यह सुनिश्चित करेगा कि नौभार के साथ प्ररूप 6 में संचलन दस्तावेज होंगे ।

(6) परिसंकटमय और अन्य अपशिष्टों का निर्यातक प्ररूप 3 में उसके द्वारा निर्यात किए गए परिसंकटमय या अन्य अपशिष्ट का अभिलेख रखेगा और ऐसे रखे गए अभिलेखों को निरीक्षण के लिए उपलब्ध कराएगा ।

15. अवैध यातायात.- (1) भारत के बाहर और भीतर परिसंकटमय या अन्य अपशिष्टों का निर्यात और आयात अवैध समझा जाएगा यदि, -

(i) यह इन नियमों के अनुसार केंद्रीय सरकार की अनुज्ञा के बिना है, या

(ii) अनुज्ञा झुठे और मिथ्या विवरण देकर या कपट से प्राप्त की गई है;

(iii) यह संचलन दस्तावेज में उपबंधित शिपिंग ब्यौरों के अनुसार नहीं है; या

(iv) इसका परिणाम जानबूझकर परिसंकटमय अपशिष्टों और अन्य अपशिष्टों के बेसल अभिसमय और अंतरराष्ट्रीय या राष्ट्रीय विधि के सामान्य सिद्धांतों के अतिक्रमण में किए गए व्ययन (अर्थात् नष्ट करना) में निकलता है ।

(2) परिसंकटमय या अन्य अपशिष्ट के अवैध आयात की दशा में, आयातकर्ता अपशिष्ट के भारत में पहुंचने की तारीख से नब्बे दिनों की अवधि के भीतर अपनी लागत पर प्रश्नगत अपशिष्ट का पुन: निर्यात करेगा और इसका क्रियान्वयन संबंधित पत्तन और सीमा शुल्क प्राधिकरण द्वारा सुनिश्चित किया जाएगा। पत्तन और सीमा शुल्क प्राधिकरणों द्वारा ऐसे अपशिष्ट के निपटान की दशा में, वे यह कार्य उस राज्य के प्रदूषण नियंत्रण बोर्ड, जहां पत्तन विद्यमान है, की अनुमति से इन नियमों के अनुसार करेंगे।

(3) परिसंकटमय या अन्य अपशिष्ट के अवैध आयात की दशा में, जहां आयातक का पता लगाना संभव न हो, तो अपशिष्ट को सीमा शुल्क प्राधिकरण द्वारा किसी ऐसे प्रयोक्ता को बेचा जा सकता है जिसके पास संबंधित राज्य प्रदूषण नियंत्रण बोर्ड से इन नियमों के अंतर्गत प्राधिकार हो या प्राधिकृत शोधन, भंडारण और निपटान सुविधा को भेजा जा सकता है।

अध्याय - IV

परिसंकटमय तथा अन्य अपशिष्टों के शोधन, भंडारण और निपटान के लिए सुविधा

16. परिसंकटमय तथा अन्य अपशिष्टों के शोधन, भंडारण और निपटान के लिए सुविधा.- (1) राज्य सरकार, अधिभोगी, किसी सुविधा का प्रचालन या अधिभोगियों का संगम व्यष्टिक रूप से या संयुक्त रूप से या पृथक रूप से राज्य में परिसंकटमय और अन्य अपशिष्टों के शोधन, भंडारण और निपटान की सुविधा स्थापित करने के लिए स्थलों की पहचान करने के लिए जिम्मेदार होंगे।

(2) सामान्य सुविधा का प्रचालन या आबाध सुविधा का अधिभोगी, इस संबंध में केंद्रीय प्रदूषण नियंत्रण बोर्ड द्वारा समय-समय पर जारी किए गए तकनीकी मार्गदर्शक सिद्धांतों के अनुसार, उपचार, भंडारण और व्ययन सुविधा डिजाइन और स्थापित करेगा और इस संबंध में राज्य प्रदूषण नियंत्रण बोर्ड से डिजाइन और ले-आउट का अनुमोदन प्राप्त करेगा।

(3) राज्य प्रदूषण नियंत्रण बोर्ड नियमित रूप से साझा या आबाध शोधन, भंडारण और निपटान सुविधाओं के स्थापन तथा प्रचालन को मानीटर करेगा।

(4) साझा सुविधा का प्रचालक या आबाध सुविधा का अधिभोगी केंद्रीय प्रदूषण नियंत्रण बोर्ड द्वारा समय-समय पर जारी किए गए मार्ग-दर्शक सिद्धांतों या मानक प्रचालन प्रक्रियाओं के अनुसार सुविधा के सुरक्षित और पर्यावरणीय दृष्टि से अनुकूल प्रचालन तथा इसके समापन और समापन पश्चात की अवस्था के लिए जिम्मेदार होगा।

(5) साझा सुविधा प्रचालक या आबाध सुविधा के अधिभोगी द्वारा प्रहस्तित किए गए परिसंकटमय और अन्य अपशिष्टों का प्ररुप-3 में अभिलेख रखा जाएगा।

(6) साझा सुविधा का प्रचालक या आबाध सुविधा का अधिभोगी वित्त वर्ष जिसका संबंध विवरणी से हो, के 30 जून को या उससे पहले राज्य प्रदूषण नियंत्रण बोर्ड को प्ररूप 4 में वार्षिक विवरणी दाखिल करेगा।

अध्याय V

परिसंकटमय अपशिष्ट की पैकेजिंग, लेबलीकरण और परिवहन

17. **पैकेजिंग और लेबलीकरण.-** (1) परिसंकटमय या अन्य अपशिष्टों का प्रहस्तन करने वाले किसी अधिभोगी और शोधन, भंडारण तथा निपटान सुविधा के प्रचालक द्वारा यह सुनिश्चित किया जाएगा कि परिसंकटमय और अन्य अपशिष्टों की पैकेजिंग केन्द्रीय प्रदूषण नियंत्रण बोर्ड द्वारा समय-समय पर जारी मार्गदर्शक सिद्धांतों के अनुसार सुरक्षित प्रहस्तन, भंडारण और परिवहन के लिए उपयुक्त तरीके से की जाए। लेबलिंग का कार्य प्ररुप 8 के अनुसार किया जाएगा।

(2) लेबल ऐसी सामग्री का बना होगा जो धोने योग्य न हो, दृश्यमान हो और जलवायु कारकों को सहन करने में समर्थ हो।

18. परिसंकटमय और अन्य अन्य अपशिष्टों का परिवहन.- (1) परिसंकटमय और अन्य अपशिष्ट का परिवहन इन नियमों और मोटर यान अधिनियम, 1988 के अधीन केन्द्रीय सरकार द्वारा बनाए गए नियमों तथा इस संबंध में समय-समय पर केन्द्रीय प्रदूषण नियंत्रण बोर्ड द्वारा जारी मार्गदर्शक सिद्धांतों के अनुसार होगा।

(2) अधिभोगी परिवहनकर्ता को अपशिष्ट की परिसंकटमय प्रकृति के संबंध में प्ररूप 9 में सुसंगत सूचना और आपात स्थिति की दशा में किए जाने वाले उपायों को उपलब्ध कराएगा और परिसंकटमय और अन्य अपशिष्ट आधानों को प्ररूप 8 के अनुसार चिन्हित करेगा।

(3) परिसंकटमय और अन्य अपशिष्ट के अंतिम निपटान के लिए ऐसी सुविधा तक परिवहन, जो अपशिष्ट उत्पन्न होने वाले राज्य से अलग राज्य में मौजूद हो, तक परिवहन के मामले में प्रेषणकर्ता द्वारा दोनों राज्यों के राज्य प्रदूषण नियंत्रण बोर्ड से 'अनापत्ति प्रमाणपत्र' प्राप्त किया जाएगा।

(4) परिसंकटमय और अन्य अपशिष्ट के पुनर्चक्रण या सह-प्रसंस्करण सहित उपयोग के लिए परिवहन के मामले में, प्रेषक द्वारा परिवहनकर्ता को अपशिष्ट सौंपे जाने से पूर्व दोनों राज्य प्रदूषण नियंत्रण बोर्डों को सूचित किया जाएगा।

(5) परिसंकटमय और अन्य अपशिष्ट के पुनर्चक्रण, सह-प्रसंस्करण सहित उपयोग या निपटान के लिए मूल राज्य और गंतव्य से अलग राज्य के माध्यम से पारगमन के मामले में, प्रेषणकर्ता परिवहनकर्ता को अपशिष्ट सौंपे जाने से पूर्व पारगमन राज्यों के संबंधित राज्य प्रदूषण नियंत्रण बोर्ड को पूर्व सूचना देगा।

(6) परिसंकटमय और अन्य अपशिष्ट के परिवहन के मामले में, सुरक्षित परिवहन का दायित्व प्रेषणकर्ता या प्राप्तकर्ता, जो भी परिवहन की व्यवस्था करता हो और संबंधित राज्य प्रदूषण नियंत्रण बोर्ड से परिवहन के लिए आवश्यक प्राधिकार रखता हो, की होगी। यह दायित्व मालसूची में स्पष्ट रूप से बताया जाना चाहिए।

(7) परिवहन के लिए प्राधिकार की प्राप्ति प्रेषणकर्ता या प्राप्तकर्ता द्वारा की जाएगी जिसकी ओर से परिवहन की व्यवस्था की जा रही है।

19. केवल देश के भीतर ही प्रयोग किए जाने वाले परिसंकटमय और अन्य अपशिष्ट के लिए मालसूची प्रणाली (संचालन दस्तावेज).- (1) अपशिष्ट का प्रेषणकर्ता नीचे दिए गए रंजक कूट को मिलाकर प्ररुप 10 में मालसूची की सात प्रतियां तैयार करेगा और प्रेषणकर्ता द्वारा सभी सात प्रतियों पर हस्ताक्षर किए जाएंगे।

रंजक कूट सहित प्रति संख्या	प्रयोजन
(1)	(2)
प्रति 1 (श्वेत)	प्रेषणकर्ता द्वारा सभी सात प्रतियों को हस्ताक्षर करने के बाद राज्य प्रदूषण नियंत्रण बोर्ड को अग्रेषित की जाएगी।
प्रति 2 (पीला)	प्रेषणकर्ता द्वारा परिवहनकर्ता के उस पर हस्ताक्षर लेने के पश्चात् अपने पास रखी जाएगी और शेष 5 प्रतियों को परिवहनकर्ता द्वारा ले जाया जाएगा।
प्रति 3 (गुलाबी)	अपशिष्ट प्राप्त करने के पश्चात् प्राप्तकर्ता (वास्तविक प्रयोक्ता या शोधन, भंडारण और निपटान सुविधा प्रचालक) द्वारा अपने पास रखी जाएगी और शेष 4 प्रतियों पर प्राप्तकर्ता द्वारा विधिवत हस्ताक्षर किए जाएंगे।
प्रति 4 (संतरी)	अपशिष्ट को स्वीकार किए जाने के पश्चात् प्राप्तकर्ता द्वारा परिवहनकर्ता को सौंपी जाएगी।
प्रति 5 (हरा)	प्राप्तकर्ता द्वारा राज्य प्रदूषण नियंत्रण बोर्ड को भेजी जाएगी।
प्रति 6 (नीला)	प्राप्तकर्ता द्वारा प्रेषणकर्ता को भेजी जाएगी।
प्रति 7 (भूरा)	यदि प्रेषणकर्ता अन्य राज्य में है तो प्राप्तकर्ता द्वारा प्रेषणकर्ता के राज्य प्रदूषण नियंत्रण बोर्ड को भेजी जाएगी।

(2) प्रेषणकर्ता प्रति 1 (श्वेत) को राज्य प्रदूषण नियंत्रण बोर्ड को अग्रेषित करेगा और परिसंकटमय अपशिष्ट या अन्य अपशिष्ट के किसी वहन राज्य से परिवहन करने की दशा में प्रेषणकर्ता अपशिष्ट के संचलन के बारे में वहन राज्यों के राज्य प्रदूषण बोर्डों को सूचित करेगा।

(3) कोई परिवहनकर्ता परिवहन के लिए प्रेषणकर्ता से अपशिष्ट को तब तक स्वीकार नहीं करेगा जब तक उसके साथ प्रकट करने के लिए हस्ताक्षरित 3 से 7 प्रतियां संलग्न न हों ।

(4) परिवहनकर्ता प्रकट करने के लिए प्राप्तकर्ता द्वारा तारीख सहित सम्यकत: हस्ताक्षरित प्रति 3 से 7 को अपशिष्ट कन्साइनमेंट के साथ प्रस्तुत करेगा ।

(5) अपशिष्ट को स्वीकार करने के पश्चात् प्राप्तकर्ता द्वारा परिवहनकर्ता को प्रति 4 (संतरा) सौंपी जाएगी और प्रति 5 (हरा) अपने राज्य प्रदूषण नियंत्रण बोर्ड को और प्रति 6 (नीला) प्रेषणकर्ता को तथा प्रति 3 (गुलाबी) प्राप्तकर्ता के पास रहेगी।

(6) यदि प्रेषणकर्ता अन्य राज्य में हो तो प्रति 7 (भूरा) केवल राज्य प्रदूषण नियंत्रण बोर्ड को ही भेजी जाएगी।

अध्याय VI
विविध

20. अभिलेख और विवरणी.- (1) परिसंकटमय या अन्य अपशिष्टों का प्रहस्तन करने वाले अधिभोगी और निपटान सुविधा के प्रचालक द्वारा ऐसे प्रचालनों का प्ररुप 3 में अभिलेख रखा जाएगा।

(2) परिसंकटमय या अन्य अपशिष्टों का प्रहस्तन करने वाले अधिभोगी और निपटान सुविधा के प्रचालक द्वारा प्ररुप राज्य प्रदूषण नियंत्रण बोर्ड को प्ररूप 4 में वार्षिक विवरणी भेजी जाएगी।

(3) राज्य प्रदूषण नियंत्रण बोर्ड, परिसंकटमय और अन्य अपशिष्टों के निपटान हेतु सुविधाओं के अधिभोगियों और प्रचालकों से प्राप्त वार्षिक विवरणी के आधार पर उत्पन्न, पुनर्चक्रित प्रतिप्राप्त, सह-प्रसंस्करणकृत सहित उपयोग में लाए गए अपशिष्ट; पुन:आयातित तथा निपटान किए गए अपशिष्ट की वार्षिक सूची बनाएगा और प्रत्येक वर्ष 30 सितम्बर तक केन्द्रीय प्रदूषण नियंत्रण बोर्ड को प्रस्तुत करेगा। राज्य प्रदूषण नियंत्रण बोर्ड द्वारा परिसंकटमय अपशिष्ट उत्पन्नकर्ताओं, वास्तविक प्रयोक्ताओं तथा और साझा तथा अबाध निपटान सुविधाओं की सूची भी तैयार की जाएगी और प्रत्येक दो वर्ष में केन्द्रीय प्रदूषण नियंत्रण बोर्ड को सूचना प्रस्तुत की जाएगी।

(4) केन्द्रीय प्रदूषण नियंत्रण बोर्ड परिसंकटमय और अन्य अपशिष्टों के प्रबंधन संबंधन की समेकित समीक्षा रिपोर्ट तैयार करेगा और वर्ष में एक बार 30 दिसम्बर से पहले अपने सिफारिशों के साथ इसे पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय को भेजेगा।

21. प्राधिकारियों का दायित्व – अनुसूची VII के स्तंभ (2) में विनिर्दिष्ट प्राधिकारी इन नियमों के उपबंधों के अधीन रहते हुए उस अनुसूची के स्तंभ (3) में विनिर्दिष्ट कर्तव्यों को करेगा।

22. दुर्घटना की रिपोर्ट करना. - जब किसी परिसंकटमय या अपशिष्ट का प्रहस्तन करने वाले अधिभोगी और निपटान सुविधा के प्रचालक की सुविधा में परिवहन के दौरान कोई दुर्घटना होती है तो अधिभोगी या प्रचालक या परिवहनकर्ता द्वारा तत्काल राज्य प्रदूषण नियंत्रण बोर्ड को दुर्घटना के विषय में टेलीफोन, ई-मेल के माध्यम से सूचना दी जाएगी और इसके बाद प्ररुप 11 में एक रिपोर्ट भेजी जाएगी।

23 निपटान सुविधा के अधिभोगी, आयातकर्ता या निर्यातकर्ता और प्रचालक का दायित्व.-

(1) **निपटान सुविधा के अधिभोगी, आयातकर्ता या निर्यातकर्ता और प्रचालक** पर्यावरण या तृतीय पक्ष को परिसंकटमय अपशिष्ट और अन्य अपशिष्ट के अनुचित प्रहस्तन और प्रबंधन के कारण कारित सभी क्षतियों के लिए दायी होंगे।

(2) निपटान सुविधा का अधिभोगी और प्रचालक केन्द्रीय प्रदूषण नियंत्रण बोर्ड की पूर्वानुमति से राज्य प्रदूषण नियंत्रण बोर्ड को इन नियमों के उपबंधों के अधीन किसी उल्लंघन के लिए उद्ग्रहण के रूप में वित्तीय शास्तियों का संदाय करने के लिए दायी होंगे

24. अपील.- (1) राज्य प्रदूषण नियंत्रण बोर्ड के उसके प्राधिकार को रद्द करने, निरस्त करने या उसके नवीकरण से इनकार करने के लिए व्यथित कोई व्यक्ति उस तारीख से तीस दिन की अवधि के भीतर जिसको उसे आदेश संसूचित किया गया था प्ररूप 12 में अपीलीय प्राधिकारी अर्थात् राज्य के पर्यावरण सचिव को अपील कर सकेगा।

(2) अपील प्राधिकार तीस दिन की उक्त अवधि के समापन के पश्चात् अपील पर विचार कर सकेगा यदि उसका यह समाधान हो जाता है कि अपीलार्थी पर्याप्त कारण से समय के भीतर अपील फाइल करने से निवारित था।

(3) इस नियम के अधीन फाइल की गई प्रत्येक अपील का निपटारा इसके फाइल किए जाने की तारीख से साठ दिनों की अवधि के भीतर किया जाएगा।

अनुसूची I

[नियम 3(1)(17)(i) देखें]

परिसंकटमय अपशिष्ट उत्पन्न करने वाली प्रक्रियाओं की सूची

क्र.सं.	**प्रकिया**	**परिसंकटमय अपशिष्ट ***
(1)	**(2)**	**(3)**
1.	पेट्रोकेमिकल प्रक्रियाएं और पाइरोलिटिक संक्रियाएं	1.1 फरनेस या रिएक्टर अवशेष और कचरा 1.2 टैरी अवशेष और आसवन प्रक्रिया से स्टिल बौटम 1.3 ऑयली स्लज पायस 1.4 कार्बनिक अवशेष 1.5 ईंधनों को क्षार से धोने पर बचा अवशेष 1.6 स्पेन्ट केटालिस्ट और मॉलीक्यूलर सीव्स 1.7 अपशिष्ट जल के शोधन से ऑयल
2.	कच्चे तेल और प्राकृतिक गैस का उत्पादन	2.1 जल युक्त कीचड़ को छोड़कर ड्रिल कटिंग्स 2.2 तेल युक्त स्लज 2.3 तेल युक्त ड्रिलिंग मड
3.	पोत वाहनों सहित पेट्रोलियम तेल भंडारण की टंकियों की सफाई, उन्हें खाली करना और उनका रख-रखाव	3.1 तेल युक्त कार्गो अवशेष, वाशिंग वॉटर और स्लज 3.2 केमिकल युक्त कार्गो अवशेष और स्लज 3.3 स्लज और तेल से संदूषित फिल्टर्स 3.4 पोत वाहनों से तेल युक्त बैलास्ट वॉटर
4.	प्रयुक्त तेल का पेट्रोलियम परिष्करण या पुन: प्रसंस्करण या अपशिष्ट तेल का पुन: चक्रण	4.1 तैलीय स्लज या पायस 4.2 स्पैंट कैटालिस्ट 4.3 स्लॉप तेल 4.4 प्रक्रिया से उत्पन्न कार्बनिक अवशेष 4.5 तेल युक्त स्पेन्ट क्ले
5.	हाइड्रोलिक सिस्टम या अन्य अनुप्रयोगों में लुब्रीकेन्ट के रूप में मिनरल या सिन्थेटिक तेल का उपयोग करते हुए औद्योगिक प्रचालन	5.1 प्रयुक्त या स्पेन्ट ऑयल 5.2 तेल युक्त अपशिष्ट या अवशेष 5.3 अपशिष्ट कटिंग तेल
6.	जिंक का गौण उत्पादन और/या औद्योगिक उपयोग	6.1 जिंक सल्फेट और अन्य जिंक संघटकों के उत्पादन के बाद उत्पन्न स्लज और फिल्टर प्रैस केक 6.2 विक्षेपी रूप में जिंक फाईन्स या धूल कण या स्कीमिन्ग 6.3 जिंक भस्म या स्किमिन्ग के प्रसंस्करण से उत्पन्न अन्य अवशेष 6.4 फ्लू गैस धूल कण और अन्य विविक्त कण

7.	अल्युमिनियम को छोड़कर जिंक या लेड या कॉपर और अन्य नॉन-फेरस धातुओं का प्रारंभिक उत्पादन	7.1 रोस्टिंग से उत्पन्न फ्लू धूलकण 7.2 प्रोसेस अवशेष 7.3 आर्सेनिक युक्त स्लज 7.4 स्लज और अवशेष सहित नॉन फेरस धातु 7.5 मार्जक से स्लज
8.	कॉपर का गौण उत्पादन	8.1 स्पैन्ट इलेक्ट्रोलिटिक घोल 8.2 स्लज और फिल्टर केक्स 8.3 फ्ले गैस धूलकण और अन्य विविक्त कण
9.	लेड का गौण उत्पादन	9.1 लेड युक्त अवशेष 9.2 लेड एश या फ्लू गैस से विविक्त कण 9.3 प्रयुक्त बैट्रियों से एसिड
10.	कैडमियम और आर्सनिक और उनके संघटकों का उत्पादन और/या औद्योगिक उपयोग	10.1 कैडमियम और आर्सनिक युक्त अवशेष
11.	प्रारंभिक और गौण एल्युमिनियम का उत्पादन	11.1 ऑफ गैस अभिक्रिया से स्लज 11.2 पॉट लाईनिंग अपशिष्ट सहित कैथोड अवशिष्ट 11.3 अपशिष्ट युक्त तार 11.4 फ्लू गैस धूल कण और अन्य विविक्त कण 11.5 ड्रॉस और साल्ट स्लज शोधन से उत्पन्न अपशिष्ट 11.6 प्रयुक्त एनोड बट्स 11.7 एल्युमिना परिष्करणी से वेनेडियम स्लज
12.	धातु सतह शोधन जैसे कि इचिंग, स्टेनिंग, पॉलिश करना, गेल्वा नाईजिंग, सफाई करना, ग्रीस हटाना, प्लेटिंग आदि	12.1 अम्ल और क्षार अवशेष 12.2 स्पेंट अम्ल और क्षार 12.3 सल्फाइड, सायनाइड और विषैले धातुओं से युक्त स्पैन्ट बाथ या स्लज 12.4 कार्बनिक विलायकों से युक्त बाथ से उत्पन्न स्लज 12.5 फास्फेट स्लज 12.6 स्टेनिंग बाथ से स्लज 12.7 ताम्बा निक्षारण अवशेष 12.8 प्लेटिंग मैटल स्लज
13.	अन्य लौह एलोय सहित आयन और इस्पात का उत्पादन (इलेक्ट्रिकक फरनेस, स्टील रोलिंग और फिनिशिंग मिल्स, कोक ऑवन और उपोत्पाद संयंत्र)	13.1 स्पेंट पिकलिंग लिकर 13.2 अम्ल रिकवरी इकाई से स्लज 13.3 बेनजोल अम्ल स्लज 13.4 डिकेन्टर टंकी टार स्लज 13.5 टार भंडारण की टंकी का अवशेष 13.6 कोक ओवन उपोत्पाद संयंत्र से अवशेष
14.	हार्डनगिंग ऑफ स्टील	14.1 सायनाइड - नाइट्रेट या नाइट्राईट युक्त स्लज 14.2 स्पेन्ट हार्डनिंग साल्ट
15.	एस्बेस्टस या एस्बेस्टस युक्त पदार्थों का उत्पादन	15.1 एस्बेस्टस युक्त अवशेष 15.2 डिस्कार्डेड एस्बेस्टस 15.3 गैस निकासी शोधन से उत्पन्न धूल कण या विविक्त कण
16.	कास्टिक सोडा और क्लोरीन का उत्पादन	16.1 मर्करी सेल प्रक्रिया से उत्पन्न मर्करीधारक स्लज 16.2 अवशेष या स्लज और फिल्टर केक्स 16.3 ब्राईन स्लज
17.	खनिज अम्लों का उत्पादन	17.1 प्रक्रिया अम्लीय अवशेष, फिल्टर केक, धूल कण 17.2 स्पेंट कैटालिस्ट
18.	नाइट्रोजनस और काम्प्लैक्स उर्वरकों का उत्पादन	18.1 स्पेंट उत्प्रेरक 18.2 कार्बन अवशेष 18.3 आर्सेनिक युक्त स्लज या अवशेष 18.4 वॉटर कूलिंग टावर से क्रोमियम स्लज
19.	फीनोल का उत्पादन	19.1 फीनोल युक्त अवशेष या स्लज 19.2 स्पेंट उत्प्रेरक

20.	विलायकों का उत्पादन और/या औद्योगिक उपयोग	20.1 संदूषित एरोमेटिक, एलिफेटिक या नेफटेनिक विलायकों से युक्त विलायक जो पुन: उपयोग के लिए उपयुक्त हो या न हो 20.2 स्पेंट विलायक 20.3 आसवन अवशेष 20.4 प्रक्रिया स्लज
21.	पेंट, रंजक, लेकर्स, वार्निश, प्लास्टिकों और स्याही का उत्पादन और/या औद्योगिक उपयोग	21.1 प्रक्रिया अपशिष्ट, अवशेष और स्लज 21.2 स्पेंट विलायक
22.	प्लास्टिक का उत्पादन	22.1 स्पेंट उत्प्रेरक 22.2 प्रक्रिया अवशेष
23.	गोंद, कार्बनिक सीमेंट, आसंजक और रेजिन का उत्पादन और/या औद्योगिक उपयोग	23.1 अपशिष्ट या अवशेष (जो वनस्पति या जीव जन्तु सामग्री से न बना हो) 23.2 स्पेंट विलायक
24.	केनवस और कपड़े का उत्पादन	24.1 रासायनिक अवशेष
25.	काष्ठ परिरक्षियों का औद्योगिक उत्पादन और निरुपण	25.1 रासायनिक अवशेष 25.2 काष्ठ क्षार बाथ से अवशेष
26.	कृत्रिम रंजकों, मध्यवर्ती रंजकों और रंगों का उत्पादन या औद्योगिक उपयोग	26.1 प्रक्रिया अपशिष्ट स्लज/अम्ल, विषाक्त धातुओं, कार्बनिक यौगिकों से युक्त अवशेष 26.2 वायु फिलटरेशन तंत्र से धूल कण 26.3 स्पेंट अम्ल 26.4 स्पेंट विलायक 26.5 स्पेंट उत्प्रेरक
27.	कार्बनिक - सिलिकॉन यौगिक का उत्पादन	27.1 प्रक्रिया अवशेष
28.	औषधी/फार्मास्यूटिकल्स और स्वास्थ्य परिचर्या का उत्पादन/निरूपण	28.1 प्रक्रिया अवशेष और अपशिष्ट 28.2 स्पेंट उत्प्रेरक 28.3 स्पेंट कार्बन 28.4 ऑफ स्पेसीफिकेशन उत्पाद 28.5 वे उत्पाद जिनकी तिथि बीत चुकी है 28.6 स्पेन्ट विलायक
29.	स्टाक - पाईल्स सहित कीटनाशकों का उत्पादन और निरुपण	29.1 प्रक्रिया अपशिष्ट/अवशेष 29.2 अवशेष कीटनाशकों से युक्त स्लज 29.3 जिनकी तिथि बीत चुकी है और ऑफ-स्पेसीफिकेशन कीटनाशक 29.4 स्पेंट विलायक 29.5 स्पेंट उत्प्रेरक 29.6 स्पेंट अम्ल
30.	चर्मशोधन	30.1 अवशेष और स्लज युक्त क्रोमियम
31.	इलेक्ट्रोनिक उद्योग	31.1 प्रक्रिया अवशेष और अपशिष्ट 31.2 स्पेंट एचिंग रसायन और विलायक
32.	लुगदी और कागज उद्योग	32.1 स्पेंट रसायन 32.2 तेज अम्ल और क्षार के उपयोग से उत्पन्न संक्षारक अपशिष्ट 32.3 घुलनशील कार्बनिक हेलाईट्स (एओएक्स) युक्त प्रक्रिया स्लज
33.	परिसंकटमय अपशिष्टों/ रसायनों के प्रहस्तन के लिए प्रयुक्त बेरेलों/कन्टेनरों का विसंदूषण	33.1 परिसंकटमय रसायनों/अपशिष्टों से संदूषित खाली बैरल/कंटेनर/लाईनर 33.2 संदूषित कॉटन रैग या अन्य सफाई सामग्री
34.	परिसंकटमय अपशिष्टों/ रसायनों के प्रहस्तन के लिए प्रयुक्त बेरेलों/कन्टेनरों का विसंदूषण	34.1 विसंदूषण से उत्पन्न रसायन युक्त अवशेष 34.2 बैरेलों/कन्टेनरों की सफाई/निपटान से उत्पन्न अपशिष्ट जल के शोधन से स्लज
35.	इस अनुसूची में प्रक्रियाओं से निकास हुए वायु/गैसों, जल और अपशिष्ट जल का शुद्धिकरण और शोधन और साझा औद्योगिक बहि:स्राव शोधन संयंत्र (सीईटीपी)	35.1 निकास वायु या गैस सफाई अवशेष 35.2 विषाक्त धातु युक्त स्पेंट आयन एक्सचेंज रेसिन 35.3 अपशिष्ट जल के शोधन से उत्पन्न रासायनिक स्लज 35.4 ऑयल और ग्रीस स्किमिंग 35.5 कूलिंग जल से क्रोमियम स्लज

36.	कार्बनिक संघटकों/विलायकों के लिए शुद्धिकरण प्रक्रिया	36.1 किसी भी प्रक्रिया या आसवन के अवशेष 36.2 स्पेंट कार्बन या फिल्टर मीडियम
37.	परिसंकटमय अपशिष्ट पदार्थों की शोधन प्रक्रियाएं, उदाहरणार्थ पूर्व प्रसंस्करण, भष्मीकरण और सांद्रण	37.1 वेट स्क्रबर्स से स्लज 37.2 भष्मीकरण से उत्पन्न राख और गलू गैस क्लीनिंग अवशेष 37.3 सांद्रण या वाष्पीकरण अवशेष
38.	क्रोमिनियम, मैंगनीज, निकेल, कैडमियन इत्यादि जैसी भारी धातुओं से युक्त अयस्कों का रासायनिक का प्रसंस्करण	38.1 प्रकिया अवशेष 38.2 स्पेंट अम्ल

*** इस अनुसूची में अन्तर्विष्ट अपशिष्ट पदार्थों को शामिल करना, अनुसूची II के उपयोग को यह दर्शाने के लिए प्रवारित नहीं करता है कि अपशिष्ट पदार्थ परिसंकटमय नहीं है। विवाद के मामले में, यह मामला पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय द्वारा गठित की गई तकनीकी समीक्षा समिति को भेजा जाएगा।**

टिप्पण: उच्च मात्रा कम प्रभाव वाले अपशिष्ट पदार्थ जैसे फ्लाई ऐश, फॉसफोजिप्सम, रेड मड, जेरोसाइट, पायरोमेटलर्जिकल प्रचालनों से स्लैग्स, माईन टेलिंगस और अयस्क बेनिफिसियेशन रिजेक्ट्स को परिसंकटमय अपशिष्टों की श्रेणी से हटाया गया है। इन अपशिष्टों के प्रबंधन के संबंध में पृथक मार्गदर्शक सिद्धांत केन्द्रीय प्रदूषण नियंत्रण बोर्ड द्वारा जारी किए जाएंगे।

अनुसूची II

[नियम 3(1)(17)(ii) देखें]

सांद्रता सीमाओं सहित अपशिष्ट घटकों की सूची

वर्ग क : निक्षालन सांद्रता सीमाओं पर आधारित [विषाक्तता लक्षण निक्षालन प्रक्रिया (टीसीएलपी) या घुलनशील प्रारंभिक सीमा सांद्रता (एसटीएलसी)]

वर्ग	संघटक	सांद्रता मि.ग्रा/ली.में
(1)	(2)	(3)
क1	आर्सेनिक	5.0
क2	बेरियम	100.0
क3	कैडमियम	1.0
क4	क्रोमियम और/या क्रोमियम (III) यौगिक	5.0
क5	लेड	5.0
क6	मैगनीज	10.0
क7	पारा	0.2
क8	सेलेनियम	1.0
क9	चांदी	5.0
क10	अमोनिया	50*
क11	साइनाइड	20*
क12	नाइट्रेट (नाइट्रेट-नाइट्रोजन के रूप में)	1000.0
क13	सल्फाइड (एच$_2$एस के रूप में)	5.0
क14	1,1 - डायक्लोरोइथिलीन	0.7
क15	1,2 - डायक्लोरोइथेन	0.5
क16	1,4 - डायक्लोरोबेंजीन	7.5
क17	2,4,5 - ट्राइक्लोरोफिनॉल	400.0
क18	2,4,6 - ट्राइक्लोरोफिनॉल	2.0
क19	2,4 - डायनाइट्रोटॉलुइन	0.13
क20	बेंजीन	0.5

वर्ग	संघटक	सांद्रता मि.ग्रा/ली.में
(1)	(2)	(3)
क21	बेंजो (क) पायरिन	0.001
क22	ब्रोमोडाइक्लोरोमिथेन	6.0
क23	ब्रोमोफॉर्म	10.0
क24	कार्बनटेट्राक्लोराइड	0.5
क25	क्लोरोबेंजीन	100.0
क26	क्लोरोफॉर्म	6.0
क27	क्रिसोल (ऑर्थो + मीटा + पारा)	200.0
क28	डाईब्रोमोक्लोरोमिथेन	10.0
क29	हेक्साक्लोरोबेंजिन	0.13
क30	हेक्साक्लोरोब्यूटाडिन	0.5
क31	हेक्साक्लोराइथेन	3.0
क32	मिथाइलइथाइल किटोन	200.0
क33	नेपथलिन	5.0
क34	नाइट्रोबेंजिन	2.0
क35	पेंटाक्लोरोफेनोल	100.0
क36	पाइरीडिन	5.0
क37	टेट्राक्लोरोइथिलीन	0.7
क38	ट्राईक्लोरोइथिलीन	0.5
क39	विनाइलक्लोरोइड	0.2
क40	2,4,5 - टी.पी. (सिलवेक्स)	1.0
क41	2,4 - डाइक्लोरोफिनॉक्सीएसेटिक एसिड	10.0
क42	अलाक्लोर	2.0
क43	अल्फा एचसीएच	0.001
क44	एट्राजाइन	0.2
क45	बीटा एचसीएच	0.004
क46	ब्यूटाक्लोर	12.5
क47	क्लोरडेन	0.03
क48	क्लोरपाइरीफॉस	9.0
क49	डेल्टा एचसीएच	0.004
क50	एंडोसल्फान (अल्फा + बीटा + सल्फेट)	0.04
क51	एंड्रिन	0.02
क52	इथियॉन	0.3
क53	हेप्टाक्लोर (और इसके इपॉक साइड)	0.008
क54	आइसोप्रोटूरॉन	0.9
क55	लिंडेन	0.4
क56	मालाथियॉन	19
क57	मिथॉक्सीक्लोर	10
क58	मिथाईलपाराथिअन	0.7
क59	मोनोक्रोटोफॉस	0.1
क60	फोरेट	0.2

वर्ग	संघटक	सांद्रता मि.ग्रा/ली.में
(1)	(2)	(3)
क61	टॉक्साफिन	0.5
क62	एन्टीमोनी	15
क63	बेरिलियम	0.75
क64	क्रोमियम (vi)	5.0
क65	कोबाल्ट	80.0
क66	तांबा	25.0
क67	मोलिवडेनम	350
क68	निकेल	20.0
क69	थैलियम	7.0
क70	वानाडियम	24.0
क71	जिंक	250
क72	फ्लोराइड	180.0
क73	अल्ड्रिन	0.14
क74	डाईक्लोरीडाईफिनाइलट्राईक्लोरीइथेन (डीडीटी), डाईक्लोरीडाईफिनाइलडाईक्लोरीइथिलिन (डीडीई), डाईक्लोरीडाईफिनाइलडाईक्लोरीइथेन (डीडीडी)	0.1
क75	डाईएल्ड्रिन	0.8
क76	किपोन	2.1
क77	माइरेक्स	2.1
क78	पोलीक्लोरोनिटेड बाईफिनाइल	5.0
क79	डॉईऑक्सिन 2,3,7,8-टीसीडीडी	0.001

वर्ग ख : कुल प्रारंभिक सीमा सांद्रता (टीटीएलसी) पर आधारित

वर्ग	संघटक	सांद्रता मि.ग्रा./कि.ग्रा.
(1)	(2)	(3)
ख1	ऐस्बेस्टस	10000
ख2	टोटल पेट्रोलियम हाइड्रोकार्बन (टीपीएच) (सी5 - सी 36)	5000

टिप्पणी :

(1) वर्ग क के क1 से क61 में संघटकों की सूची के लिए परीक्षण पद्धति विषाक्तता लक्षण निक्षालन प्रक्रिया (टीसीएलपी) पर आधारित होगा और निक्षालन योग्य संघटकों के निष्कर्षण हेतु यूएसईपीए परीक्षण पद्धति 1311 का प्रयोग किया जाएगा।

(2) वर्ग क के क62 से क79 के घटकों की सूची के लिए परीक्षण पद्धति घुलनशील प्रारंभिक सीमा सांद्रता (एसटीएलसी) पर आधारित होगी और कैलिफोर्निया कोड विनियमन (सीसीआर) के शीर्षक 22 की धारा 66261 के परिशिष्ट ।। में दी गई अपशिष्ट निष्कर्षण परीक्षण (डब्ल्यूएटी) प्रक्रिया का प्रयोग किया जाएगा।

(3) अमोनिया (क10), साइनाइड (क11) और क्रोमियम VI क64 के मामले में, निष्कर्षण टीसीएलपी/एसटीएलसी पक्रियाओं में निर्दिष्ट निक्षालन माध्यम की बजाय डिस्टिल्ड पानी का प्रयोग करके किया जाएगा।

(4) इन निक्षालन पद्धतियों का उपर्युक्त विशिष्ट लीचिंग/एक्सट्रेक्शन प्रक्रिया सार केन्द्रीय प्रदूषण नियंत्रण बोर्ड द्वारा प्रकाशित परिसंकटमय अपशिष्ट के लक्षण वर्णन तथा विश्लेषण के मैनुअल में शामिल है और यदि यदि यह पद्धति उक्त मैनुअल में शामिल न हो तो मापन के लिए उपयुक्त संदर्भ पद्धति अपनाई जा सकती है।

(5) एस्बेस्टस के मामले में, निर्दिष्ट सांद्रता सीमाएं केवल तभी लागू होंगी यदि सामग्री भुरभुरी, पाउडरीकृत या महीन टुकड़े की अवस्था में हो।

(6) अपशिष्ट में विश्लेषित किए जाने वाले परिसंकटमय घटक उद्योग की प्रकृति और प्रक्रिया में प्रयुक्त सामग्रियों के प्रासंगिक होंगे।

(7) ऐसे अपशिष्ट जिसमें नीचे सूचीबद्ध घटकों में से कोई एक पाया जाए तो उन्हें परिसंकटमय समझा जाएगा परंतु यह कि वे इस अनुसूची के वर्ग ग में सूचीबद्ध विशेषताओं को प्रदर्शित करें :

1.	एसिड एमाइड

2.	एसिड हाइड्राइड
3.	एमाइन
4.	एंथ्रासिन
5.	श्रेणी क में सूचीबद्ध को छोड़कर अन्य ऐरोमेटिक कंपाउंड
6.	ब्रोमेट, (हाइपो-ब्रोमाइट)
7.	क्लोरेट (हाइपो-क्लोराइट्स)
8.	कार्बोनील
9.	फेरो- सिलिकेट और एलाय
10.	हैलोजेन - ऐसे यौगिक वाली सामग्री जो आर्द्र वायु या जल के साथ संपर्क में आने पर एसिडिक वाष्प उत्पन्न करते हैं अर्थात सिलिकॉन ट्रेट्राक्लोराइड, एल्युमिनियम क्लोराइड, टाइटेनियम टेट्राक्लोराइड
11.	हैलोजन - साइलेनेस
12.	हैलोजिनेटेड एलिफेटिक कंपाउंड
13.	हाइड्राजाइन
14.	हाइड्राइड
15.	अकार्बनिक एसिड
16.	अकार्बनिक पेरॉक्साइड
17.	अकार्बनिक टिन कंपाउंड
18.	लोडेट
19.	(आइसो ऑर थायो-) साइनेट
20.	मैंगनीज-सिलिकेट
21.	मर्कैप्टन
22.	मेटल कार्बोनिल
23.	मेटल हाइड्रोजन सल्फेट
24.	नाइट्राइड
25.	नाइट्राइल
26.	कार्बनिक ऐजो और एजोक्सी कंपाउंड
27.	कार्बनिक पेरोक्साइड
28.	कार्बनिक ऑक्सीजन कंपाउंड
29.	कार्बनिक सल्फर कंपाउंड
30.	कार्बनिक-टिन कंपाउंड
31.	कार्बनिक नाइट्रो-और नाइट्रोसो कंपाउंड
32.	हाइड्रोजन, कार्बन, सिलिकॉन, आयरन, एल्युमिनियम, टाइटेनियम, मैंगनीज, मैग्नीशियम, कैल्शियम के ऑक्साइडों और हाइड्रोक्साइडों को छोड़कर ऑक्साइड और हाइड्रोऑक्साइड
33.	फिनैनथ्रिनिन
34.	फिनॉलिक कंपाउंड
35.	एल्युमिनियम कैल्सियम और आयरन के फॉस्फेटों को छोड़कर फॉस्फेट कंपाउंड
36.	प्री-एसिड के साल्ट
37.	कुल सल्फर
38.	टंग्स्टन कंपाउंड
39.	टेल्युरियम और टेल्युरियम कंपाउंड
40.	सफेद और लाल फॉस्फेरस

41.	2-एसिटाइलएमिनोफ्लोरिन
42.	4-एमिनोडाइफिनाइल
43.	बेंजीडाइन और इसके साल्ट
44.	बिस (क्लोरोमिथाइल) इथर
45.	मिथाइल क्लोरोमिथाइल इथर
46.	1,2 - डाइब्रोमो-3-क्लोरोप्रोपेन
47.	3,3- डाइक्लोरोबेंजिडाइन और इसके साल्ट
48.	4-डाइमिथाइलएमिनोएजोबेंजिन
49.	4-नाइट्रोबाइफिनाइल
50.	बीटा-प्रोपायोलैक्टोन

वर्ग ग : परिसंकटमय विशेषताओं के आधार पर

ऊपर दिए गए सांद्रता सीमा के अलावा, पदार्थ या अपशिष्ट को परिसंकटमय अपशिष्ट के रूप में वगीकृत किया जाएगा यदि अपशिष्ट में निम्नलिखित में से कोड परिसंकटमय भी संघटक की उपस्थिति प्रदर्शित होती हो:

वर्ग ग1: ज्वलनशील- अपशिष्ट जिके नमूने में ज्वलनशील या आग पकड़ने वाला निम्नलिखित में से कोई भी गुण प्रदर्शित हो, नामत :-

(i) ज्वलनशील द्रव, या द्रवों का मिश्रण, या द्रव जिसके घोल में ठोस या आस्थगन (उदाहरणार्थ, पेंट, वार्निश, रोगन आदि, परंतु वैसे सत्व या अपशिष्ट शामिल न हों जिन्हें उनकी परिसंकटमय विशिष्ट के कारण अन्यथा वगीकृत किया गया हो), जिनसे 60^0 सेल्यिस के कम तापमान पर ज्वलनशील वाष्प उत्सर्जित होती हो। इस दीप्ति बिंदु का मापन एएसटीएमडी 93-79 के अनुरूप क्लोज्ड कप टेस्ट प्रणाली द्वारा या केन्द्रीय प्रदूषण नियंत्रण बोर्ड द्वारा प्रकाशित एक समतुल्य परीक्षण पद्धति द्वारा यथा निर्धारित तरीके से किया जाएगा;

(ii) जो द्रव न होते हुए भी मानक तापमान और दबाव पर घर्षण, नमी के अपशोषण या स्वत: प्रवर्तित रासायनिक परिवर्तनों और सुलगाने पर प्रबलता से निरंतर जलते हुए परिसंकट उत्पन्न करने में सक्षम हों ;

(iii) जो दहनीय संपीडित गैस हो;

(iv) जो ऑक्सीकारक हो और विशिष्टिकरण के उद्देश्य से वैसा पदार्थ जैसे क्लोरेट, परमैंगनेट, अकार्बनिक पेरोक्साइड, या नाइट्रेट हैं, जो कार्बनिक पदार्थ के दहन को तीव्र करने के लिए तत्परता से ऑक्सीजन नसर्जित करते हैं।

वर्ग ग2: संक्षारकता- अपशिष्ट जिसके प्रतिनिधिक नमूने में निम्नलिखित में से संक्षारकता की कोई भी विशिष्टि प्रदर्थित होती हो, नामत :-

(i) जो जल युक्त हो और जिसका पीएच 2 के समतुल्य या उससे न्यून या 12.5 के समतुल्य या अधिक हो;

(ii) जो द्रव हो और इस्पात (एसएई1020) का परीक्षयमान 55^0 सेल्सियस के तापमान पर 6.35 मिमी प्रतिवर्ष की दर से संक्षरण करें;

(iii) जो जलयुक्त न हो और, समभार जल के साथ मिश्रित किए जाने पर ऐसा कोल बनाता हो, जिसका पीएच2 से न्यून या 12.5 से अधिक या समतुल्य हो;

(iv) जो द्रव न हो और, समतुल्य भार जल के साथ मिश्रित किए जाने पर ऐसा द्रव उत्पन्न करता हो जो इस्पात (एसएई1020) को परीक्षयमान 55^0 सेल्सियस के तापमान पर 6.35 मिमी प्रतिवर्ष से अधिक की दर संक्षरित करता हो।

टिप्पणी :

संक्षारकता निर्धारित करने के उद्देश्य से, पीएच निर्धारण के लिए भारतीय मानक ब्यूरो 9040 ग पद्धति, संक्षारकता विशेषताओं को स्थापित करने के लिए स्टील (एसएई1020) की दिशा में संक्षारकता के लिए एनएसीई टीएम 01 69 : धातुओं के प्रयोगशाला संक्षारण परीक्षण और ईपीए 1110क पद्धति को अपनाया जाएगा।

वर्ग ग3: प्रतिक्रियात्वमकता विस्फोटक- ठोस अपशिष्ट प्रतिक्रियात्मक विशिष्ट युक्त माना जाएगा यदि अपशिष्ट का प्रतिनिधिक नमूना निम्नलिखित प्रदर्शित करें, नामत :-

(i) जो सामान्य या अस्थिर हो बिना डिटोनेटिंग के आसानी से उग्र परिवर्तन उत्पन्न करता हो;

(ii) जो जल के साथ तीव्र प्रतिक्रिया करे या जल के साथ प्रछन्न विस्फोटक मिश्रण बनाता हो;

(iii) जो जल के साथ मिश्रित किए जाने पर मानव स्वास्थ्य या पर्यावरण के लिए खतरनाक मात्रा में विषैली गैस, वाष्प या धूम्र उत्पन्न करें;

(iv) जो सायनाइड या सल्फाइड हो, जिसे 2 और 12.5 पीएच अवस्थिति में एक्सपोज किए जाने पर मानव स्वास्थ्य या पर्यावरण के लिए खतरनाक मात्रा में विषैली गैस, वाष्प या धूम्र उत्पन्न होता हो;

(v) जो डिटोनेशन या विस्फोटक प्रतिक्रिया करने में सक्षम हो, यदि इसे प्रबल अनभयस्त स्रोत के सामीण्य या परिरुद्ध तापित किया जाए;

(vi) जो डिटोनेशन या विस्फोटक अपघटन या मानक तापमान और दबाव पर प्रतिक्रिया करने में सक्षम हो;

(vii) जो प्रतिबंधित विस्फोटक हो।

वर्ग ग4: विषाक्त - अपशिष्ट विषाक्तता का लक्षण प्रदर्शित करता है, यदि

(i) अपशिष्ट के संघटकों की सांद्रता इस अनुसूची के वर्ग क और ख में सूचीबद्ध सीमा के समतुल्य या उसमें अनुज्ञेय निर्धारित सीमा से अधिक हो;

(ii) यह प्रति किलोग्राम 2500 मि.ग्रा. से कम तीक्ष्ण मौखिक एलडी50 रहा हो;

(iii) इसमें प्रति किलोग्राम 4300 मि.ग्रा. से कम तीक्ष्ण त्वचीय एलडी50 रहा हो;

(iv) गैस या वाष्प के रूप में प्रति मिलियन 10000 भाग से कम तीक्ष्ण अंत:श्वसन एलसी50 रहा हो;

(v) विलियन जल में प्रति लीटर 500 मि.ग्रा. के सांद्रण और बीआईएस परीक्षण पद्धति 6582-2001 में यथानिर्दिष्ट परीक्षण परिस्थितियों में जेब्राफिश (ब्रेकिडेनियो रेरियो) के लिए 96 घंटे के अंदर 50 प्रतिशत मृत्यु दर के साथ तीक्ष्ण जलीय विषाक्तता रखता हो;

(vi) अनुभव या मानक संदर्भ परीक्षण पद्धति के आधार पर जो मानव स्वास्थ्य या पर्यावरण को अपनी कैंसरकारी, म्यूटाजेनेसिटी, इंडोक्रइिन भंगुरता, अचिर विषाक्तता, चिर विषाक्तता, जैव संग्राही गुणों या पर्यावरण में उपस्थिति के कारण खतरा उत्पन्न करे।

वर्ग ग5 : पदार्थ या अपशिष्ट जो स्वत: ज्वलनशील हो - ऐसे पदार्थ या अपशिष्ट जिनके परिवहन में सामान्य स्थितियों के अंतर्गत स्वत: गर्म होने या वायु के संपर्क में आने पर गर्म होने और तत्पश्चात इसमें आग पकड़ लेने की प्रवृत्ति हो।

वर्ग ग6 : पदार्थ या अपशिष्ट जो जल से मिश्रित होने पर ज्वलनशील गैस उत्सर्जित करते हों - ऐसे पदार्थ या अपशिष्ट जो जल से संपर्क में आने पर स्वत: ज्वलनशील हों या खतरनाक मात्रा में ज्वलनशील गैस उत्पन्न करते हों।

वर्ग ग7 : ऑक्सीकारक - ऐसे पदार्थ या अपशिष्ट जो स्वयं अनिवार्य रूप से दहनशील न हों, किन्तु सामान्यतया ऑक्सीजन उत्पन्न करके अन्य सामग्री में आग लगने के कारक या सहायक हो सकते हैं।

वर्ग ग8 : कार्बनिक पेराऑक्साइड : ऐसे कार्बनिक पदार्थ या अपशिष्ट जिनमें वाइवेलेंट ओ-ओ संरचना हो, जिनमें एक्जोथर्मिक स्वत: त्वरित विघटन हो सकता हो।

वर्ग ग9 : विष (तीव्र) : ऐसे पदार्थ या अपशिष्ट जिन्हें यदि निगल या सूंघ लिया जाए या त्वचा से संपर्क में आ जाएं तो मृत्यु का कारण बन सकते हों, गंभीर क्षति पहुंचा सकते हों या स्वास्थ के लिए हानिकारक हो सकते हों।

वर्ग ग10 : संक्रामक पदार्थ - ऐसे पदार्थ या अपशिष्ट जिनमें व्यवहार्य सूक्ष्म जीव या उनके विष हों जो पशुओं या मनुष्यों में बीमारी फैलाते हों।

वर्ग ग11 : वायु या जल से संपर्क में आने पर विषाक्त गैसों का उत्सर्जन - ऐसे पदार्थ या अपशिष्ट जो वायु या जल से संपर्क में आने पर खतरनाक मात्रा में विषाक्त गैसें उत्सर्जित करें।

वर्ग ग12 : पारि-विषाक्त - ऐसे पदार्थ या अपशिष्ट, जो यदि उत्सर्जित हो जाएं तो पर्यावरण पर तात्कालिक या विलंबित रूप से पर्यावरण पर प्रतिकूल प्रभाव डाल सकते हों या विषैले प्रभाव छोड़ सकते हों।

वर्ग ग13 : जो किसी उपाय से निस्तारण के पश्चात अन्य सामग्री विसर्जित कर सकते हों अर्थात लीचेट जिसमें ऊपर सूचीबद्ध विशेषताओं में से कोई एक विशेषता हो सकती है।

अनुसूची III

(नियम 3 (1) (17)(iii), (3)(23),12,13 और 14 देखें)

(भाग क)

भाग क : पूर्व सूचित स्वीकृति सहित आयात और निर्यात के लिए अनुप्रयुक्त परिसंकटमय अपशिष्टों पदार्थों की सूची बेसल कन्वेंशन का उपाबंध VIII*)

बेसल सं.	परिसंकटमय अपशिष्ट का वर्णन
(1)	**(2)**
क 1	**धातु और धातु युक्त अपशिष्ट**
क 1010	धातु अपशिष्ट और वे अपशिष्ट जिसमें निम्नलिखित किसी भी धातु के एलाय हों किन्तु भाग ख और भाग घ में विशिष्ट रूप से सूचीबद्ध ऐसे अपशिष्टों को छोड़कर - एंटिमनी - कैडमियम - सीसा - टेल्यूरियम
क 1020	अपशिष्ट जिनमें संघटक या संदूषक हैं, स्थूल रुप में धातु अपशिष्टों को छोड़कर, कोई या निम्नलिखित : - एंटिमनी, एंटिमनी यौगिक - कैडमियम, कैडमियम यौगिक - सीसा, सीसा यौगिक - टेल्यूरियम, टेलयूरियम यौगिक
क 1040	अपशिष्ट जिनमें धातु कार्बोनाईल संघटक हो
क 1050	गैल्वेनिक गाद
क 1070	जस्ता प्रसंस्करण, धुल और आपंक से निच्छालित अवशेष अर्थात जेरोसाइट, हेमेटाईट आदि
क 1080	सांद्रणों में सीसा और कैडमियम वाली सूची ख में सम्मिलित न किए गए अपशिष्ट जिंक अवशेष के भाग ग में उपदर्शित परिसंकटमय लक्षण संप्रदर्शित करने के लिए पर्याप्त है।
क 1090	विद्युतरोधी तांबे की तारों के भष्मीकरण से प्राप्त भष्म
क 1100	तांबा प्रगालक की गैस शोधन प्रणाली से प्राप्त धूल और अवशेष
क 1120	तांबा विद्युत परिष्करण और विद्युत प्रापण की संक्रियाओं में से विद्युत अपघटनी शोधन प्रणाली के एनोड अवपंक को छोड़कर अपशिष्ट स्लज
क 1140	अपशिष्ट क्यूपुरिक क्लोराइड और कॉपर साइनाइड उत्प्रेरक जो तरल स्वरूप में न हों, अनुसूची VI में संबंधित इंदराज नोट करें
क 1150	मुद्रित परिपथों के भष्मीकरण से उत्पन्न मूल्यवान धातु भष्म जो भाग ख के अंतर्गत न हो
क 1160	अपशिष्ट लेड एसिड बैटरियां या संपूर्ण या कुचली हुईं
क 1170	बिन छटी पुरानी बैटरियों का सम्मिश्रण जो भाग ख बैटरियों में शामिल नहीं हैं। अपशिष्ट बैटरियां जो अनुसूची ।। में उल्लिखित भाग ख निहित संघटकों में विनिर्दिष्ट नहीं हैं, परिसंकटमय हैं।
क 2	**मुख्यत: अकार्बनिक संघटकों वाले अपशिष्ट जिसमें धातु और कार्बनिक पदार्थ अंतर्विष्ट हों**
क 2010	कैथोड किरण नालिकाएं और अन्य सक्रियकृत कांच से सक्रियकृत कांच के अपशिष्ट
क 2030	कैटालिस्ट अपशिष्ट किन्तु सूची ख में विनिर्दिष्ट ऐसे अपशिष्टों को छोड़कर
क 3	**मुख्यता कार्बनिक संघटकों वाले अपशिष्ट, जिसमें धातु और अकार्बनिक सामग्री हों**
क 3010	पेट्रोलियम कोक और बिटुमेन के उत्पादन या प्रसंस्करण से उत्पन्न अपशिष्ट
क 3020	अपशिष्ट खनिज तेल जो उनके मूल रुप में आशायित उपयोग के लिए अनुपयुक्त हों
क 3050	रेसिन लेटेक्स, प्लास्टिसाइजर, सरेश या आसजंकों के उत्पादन, संरुपण एवं उपयोग से उत्पन्न ऐसे अपशिष्ट, सूची ख में विर्निदिष्ट ऐसे अपशिष्टों को छोड़कर (ख 4020)

क 3120	श्रेडिंग से फ्लफ-लाइट फ्रैक्शन
क 3130	अपशिष्ट कार्बनिक फास्फोरस यौगिक
क 4	**ऐसे अपशिष्ट जिनमें या तो अकार्बनिक या कार्बनिक संघटक हों।**
क 4010	भेषज उत्पादों के उत्पादन और निर्मित तथा उपयोग से उत्पन्न अपशिष्ट किन्तु उन अपशिष्टों को छोड़कर जो सूची ख में विनिर्दिष्ट हैं।
क 4040	काष्ठ संरेक्षी रसायन के विनिर्माण संरुपण और उपयोग से उत्पन्न अपशिष्ट (इसमें काष्ठ संरक्षण रसायनों से उपचारित काष्ट शामिल नहीं है)
क 4070	स्याही, रंजक, वणक, आसव, प्रलाक्षा वार्निश के उत्पादन, संरुपण और उपयोग से उत्पन्न अपशिष्ट सूची ख में विनिर्दिष्ट को छोड़कर (4010)
क 4100	औद्योगिक बहिगैस के शोधन के लिए औद्योगिक प्रदूषण नियंत्रण उपकरणों से प्राप्त अपशिष्ट ऐसे अपशिष्टों को छोड़कर जो सूची ख में विनिर्दिष्ट हैं
क 4120	अपशिष्ट जिसमें पेरोऑक्साइड हो सकता है, मिश्रित हो सकता है या संदूषित हो सकता है
क 4130	ऐसे अपशिष्ट पैकेज और आद्यान, जिनमें अनुसूची 3 के भाग ग की खतरनाक विशेषताओं को परिलक्षित करने के लिए पर्याप्त सांद्रण में अनुसूची ।। के घटक शामिल हों
क 4140	अनुसूची ।। में उल्लिखित और अनुसूची ।।। के भाग ग की खतरनाक विशेषताओं का प्रदर्शित करने वाले घटक के तदनुरूपी विशिष्टी या पुराने रसायनों (विनिर्माता द्वारा संस्तुत अवधि के अंदर प्रयोग न किया गया) से युक्त या मिश्रित अपशिष्ट
क 4160	मुक्तशेष सक्रियत कार्बन जो सूची ख में शामिल नहीं है (ख 2060)

*यह सूची परिसंकटमय अपशिष्ट के सीमा पार संचलन पर बेसल कन्वेंशन के उपाबंध VIII पर आधारित है तथा इसमें कन्वेंशन के अनुच्छेद 1, पैरा 1 (क) के अधीन परिसंकटमय के रुप में माने गए अपशिष्ट समाविष्ट हैं। इस सूची में अपशिष्टों का समावेशन परिसंकटमय के शब्द को अलग नहीं करता है।

बेसल कन्वेंशन के उपाबंध VIII में (इस अनुसूची के भाग ग) में दिए गए परिसंकटमय लक्षणों के उपयोग से प्रदर्शित होता है कि अपशिष्ट परिसंकटमय नहीं है। **भाग-क में परिसंकटमय अपशिष्ट प्रतिबंधित हैं तथा पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय की अनुमति तथा विदेश व्यापार महानिदेशालय के लाइसेंस, यदि लागू हो, के बिना उनका आयात किए जाने की अनुज्ञा नहीं दी जा सकती।**

भाग ख

आयात और निर्यात के लिए लागू होने वाले अन्य अपशिष्टों की सूची, जिनके लिए पूर्व सूचित सहमति अपेक्षित नहीं है। (बेसल कन्वेशन का उपाबंध IX*)

बेसल सं.	**अपशिष्टों का वर्णन**
ख 1	**धातु और धातुयुक्त अपशिष्ट**
ख1010	धात्विक, गैर-परिक्षेपण रुप में धातु और धातु एलॉय अपशिष्ट :
	-थोरियम स्क्रैप
	-रेयर अर्थ स्क्रैप
ख 1020	निम्नलिखित (शीट, प्लेट, बीम, छड़ इत्यादि) के रूप में निर्मित एलॉय सहित स्वच्छ, असंदूषित धातु स्क्रैप :
	- एंटिमनी स्क्रैप
	-बेरिलियम स्क्रैप
	- कैडमियम स्क्रैप
	- सीसा स्क्रैप (सीसा अम्ल बैटरियों को छोड़कर)
	-सिलिनियम स्क्रैप
	- टेल्युरियम स्क्रैप
ख 1030	अपशिष्ट निहित अपवर्तक धातुएं

ख 1031	धात्विक परिक्षेपण रुप (धातु चूर्ण) में मोल्बिडेनम, अंगस्टन, टिटेनियम, टेंटालूम, नियोबियम एवं रहेनियम धातु और मिश्र धातु अपशिष्ट, सूची क के अंतर्गत प्रविष्टि क 1050 में विनिर्दिष्ट ऐसे अपशिष्टों को छोड़कर, गाल्वनिक स्क्रैप
ख 1040	विद्युतशक्ति उत्पादन के समंजक स्क्रैप जो स्नेहक तेल, पीसीबी या पीसीटी द्वारा परिसंकटमय तय करने की सीमा तक प्रदूषित न हो।
ख 1050	भाग ग विशेषताओं को प्रदर्शित करने के लिए पर्याप्त सांद्रता में अनुसूची II में वर्णित कैडमियम, एंटिमनी, शीशा और टेल्यूरियम निहित मिश्रित अलौह धातु हैवी फ्रैक्शन स्क्रैप
ख 1060	पाउडर सहित धात्विक एलिमेंटल रुप में अपशिष्ट सिलिनियम और टेल्यूरियम
ख 1070	ताम्र और ताम्र मिश्र धातुओं का अपशिष्ट विक्षेपित रुप में जब तक कि उनमें अनुसूची II में उल्लिखित कोई संघटक जो भाग ग की विशेषताओं का प्रदर्शन करने की सीमाओं तक विनिर्दिष्ट सांद्रण सीमाओं तक अंतर्विष्ट न हो।
ख 1080	जिंक भस्म और अपशिष्ट जिसमें मिश्र अपशिष्ट विक्षेपित रुप में हो जब तक कि उनमें अनुसूची II में उल्लिखित कोई संघटक जो भाग ग की विशेषताओं का प्रदर्शन करने की सीमाओं तक विनिर्दिष्ट सांद्रण सीमाओं तक अंतर्विष्ट न हो।
ख 1090	मानक बैटरी विनिर्देश के अनुरुप अपशिष्ट बैटरियां, सीसा, कैडमियम या पारे से बनी बैटरियों को छोड़कर।
ख 1100	धातुओं को गलाने, प्रगलन और परिष्करण से उत्पन्न अपशिष्ट युक्त धातु :
	- आर्सेनिक, शीशा या कैडमियम निहित स्लैग जो प्रसंस्करण या परिष्करण के लिए ताम्र प्रसंस्करण से प्राप्त होता हो।
	- पुन: परिष्करण हेतु बहुमूल्य धातुओं के प्रसंस्करण से प्राप्त स्लैग ताम्र ग्लन से उत्पन्न क्रुसिबल सहित रिफ्रैक्ट्री संस्तर के अपशिष्ट
	0.5% से कम टिन सहित टैंटेलम युक्त टिन स्लैग
ख 1110	अनुसूची III के भाग ग में सूचीबद्ध एसेम्बलीज को छोड़कर प्रयुक्त विद्युत और इलैक्ट्रॉनिक एसेम्बलीज
	- वैद्युत और इलैक्ट्रोनिक एसेम्बलीज जिनमें केवल धातुएं या मिश्र धातुएं हों -इलैक्ट्रिकल और इलैक्ट्रोनिक पुर्जों के ऐसे स्क्रैप अपशिष्ट (छपाईयुक्त सर्किट बोर्ड सहित) जिनमें अनुसूची III के भाग क में शामिल एक्यूमुलेटर्स तथा अन्य बैटरियां, मरकरी स्विच, कैथोड रे ट्यूबों के कांच व अन्य क्रियाशील कांच पीसीबी कैपीसिटर्स इत्यादि न हो या कैडमियम, मरकरी, सीसा पॉलीक्लोरीनेटिड बाई फिनाइल जैसे अवयवों से संदूषित न हो या उन चीजों से जिनमें इन्हें निकाला गया हो और उनमें अनुसूची III के भाग ग में निहित विशेषता, उसमें विनिर्दिष्ट सांद्रण की सीमा तक न हों।
ख 1120	प्रयुक्त कैटलिस्ट सिवाए ऐसे तरल पदार्थों के जिसका उपयोग कैटालिस्ट के रुप में किया गया हो, जिनमें निम्न में से कोई भी शामिल हो : ट्रांजीशन धातुएं, भाग क और अनुसूची VI में शामिल अपशिष्ट कैटालिस्ट को छोड़कर (प्रयुक्त कैटालिस्ट, कैटालिस्ट के रुप में उपयोग किए गए तरल पदार्थ या अन्य कैटालिस्ट) : स्कैन्डियम टाइटेनियम वेनेडियम क्रोमियम मैंगनीज लौह कोबाल्ट निकेल कॉपर जिंक यट्रियम जिरकोनियम नियोबियम मॉलिब्डेनम हैफनियम टैंटालम टंगस्टन रेनियम लैन्थेनाइड (दुर्लभ-भू धातुएं) : लैन्थेनम सीरियम प्रासियोडायमियम नियोडाईमियम समेरियम यूरोपियम गेडोलिनियम टरबियम डिसप्रोसियम होलमियम इर्बियम थुलियम येटरवियम लुटेटियम

ख 1130	कैटालिस्टयुक्त क्लीन्ड स्पैंट बहुमूल्य धातु
ख 1140	ठोस रुप में बहुमूल्य धातु, जिसके अंतर्विष्ट अपशिष्ट जिसके अंतर्विष्ट अनुरेख अकार्बनिक साइनाइड हो
ख 1150	समुचित पैकेजिंग तथा लेबलिंग के साथ प्रक्षिण्ण स्वरूप में मूल्यवान धातु, और मिश्र धातु अपशिष्ट (सोना, चांदी, प्लेटिनम वर्ग के किन्तु पारा को छोड़कर)
ख 1160	मुद्रित सर्कट बोर्ड के भस्मीकरण बहुमूल्य धातु भस्म, (सूची क क 1150 से संबंधित प्रविष्टि नोट करें)
ख 1170	फोटोग्राफिक फिल्म के भस्मीकरण से बहुमूल्य धातु भस्म
ख 1180	चांदी हैलाइड और धात्विक चांदी वाली अपशिष्ट फोटोग्राफिक फिल्म
ख 1190	चांदी हैलाइड और धात्विक चांदी वाला अपशिष्ट फोटोग्राफिक कागज
ख 1200	आयरन और स्टील के विनिर्माण से उत्पन्न ग्रेनुलेटिड स्लैग
ख 1210	आयरन और स्टील के उत्पादन से उत्पन्न स्लैग जिसमें टिटेनियम डाइ-ऑक्साइड और वेनेडियम के स्रोत के रुप में स्लैग शामिल हैं
ख 1220	जिंक उत्पादन के स्लैग, कैमिकली स्टैब्लाइज्ड, जिसमें आयरन अंश अधिक है (20% से अधिक) और जिसे औद्योगिक विनिर्देशों के अनुसार मुख्यत: निर्माण के लिए प्रसंस्कृत किया गया है
ख 1230	आयरन और स्टील के विनिर्माण से उत्पन्न मिल स्केलिंग**
ख 1240	कापर-ऑक्साइड मिल स्केल
ख 2	**मुख्यत: अकार्बनिक संघटक वाले अपशिष्ट धातु जिनमें धातु और कार्बनिक तत्व हो सकते हैं।**
ख 2010	गैर-विक्षेपित रुप में खनन संक्रियाओं से अपशिष्ट :
	- प्राकृतिक ग्रेफाइट अपशिष्ट
	- स्लेट अपशिष्ट
	- अभ्रक अपशिष्ट
	- ल्यूसाइट, नेफलाइन और नेफलाइन साइनाइट अपशिष्ट
	- फेल्डसपार अपशिष्ट
	- फ्लोरस्फार अपशिष्ट
	- फाउंड्री संक्रियाओं में प्रयुक्त सिलिका को छोड़कर ठोस रुप में सिलिका अपशिष्ट
ख 2020	गैर-विक्षेपित रुप में कांच अपशिष्ट : - कांच क्युलेट और अन्य अपशिष्ट कैथोड रे ट्यूबों अन्य और एक्टिवेटिड कांच से एक्टिवेटिड क्यूलेट के अलावा कांच स्क्रैप
ख 2030	गैर-विक्षेपित रुप में सेरामिक अपशिष्ट :
	सेरामिक अपशिष्ट और स्क्रैप (धातु सेरामिक लवण) - सेरामिक आधारित रेशें
ख 2040	मुख्यतया अकार्बनिक घटक वाले अन्य अपशिष्ट :
	- फ्लू गैस डीसलफरीजेशन से उत्पन्न आंशिक परिष्कृत कैल्शियम सल्फेट (एफजीडी) - भवन गिराने से उत्पन्न अपशिष्ट जिप्सम वालबोर्ड या प्लास्टर बोर्ड -मुख्य रूप से निर्माण और अपघर्षी अनुप्रयोगों के लिए औद्योगिक विशिष्टियों के अनुसार प्रसंस्कृत और उच्च लौह तत्व (20% से अधिक) वाले रासायनिक रूप से स्थिर, ताम्र उत्पादन से स्लैग - ठोस रुप में सल्फर - कैल्शियम सायनामाइड के उत्पादन से लाइमस्टोन (पीएच < 9) - सोडियम, पोटेशियम, कैल्शियम क्लोराइड - कारबोरन्डम (सिलिकॉन कारबाइड) - खंडित कंक्रीट

	- लिथियम टेन्टालम और कांच स्क्रैप वाला निहित लिथियम-नियोबियम
ख 2060	अनुसूची ।। के किसी घटक के भाग ग के लक्षणों के प्रदर्शन की सीमा तक युक्त स्पैन्ट एक्टिवेटेड कार्बन, उदाहरणार्थ पेयजल की अभिक्रिया और खाद्य उद्योग की प्रक्रियाओं और विटामिन उत्पादन के कारण होने वाले स्पैन्ट एक्टिवेटिड कार्बन (भाग क (क 4160) पर सम्बद्ध प्रविष्टि नोट करें)
ख 2070	कैल्शियम फ्लोराइड स्लज
ख 2080	अनुसूची VI में शामिल नहीं रसायन उद्योग प्रक्रियाओं से उत्पन्न होने वाले अपशिष्ट जिप्सम (क 2040 में संबंधित प्रविष्ट नोट करें)।
ख 2090	पेट्रोलियम कोक या बिटुमन से बने स्टील या एल्युमीनियम उत्पादन से उत्पन्न अपशिष्ट एनोड बट्स, जो कि सामान्य औद्योगिक विनिर्देशों के अनुसार साफ किए गए हैं (क्लोर एल्कली इलैक्ट्रोलाइसिस में एनोड बट्स और मैटालर्जीकल उद्योग को छोड़कर)
ख 2100	एल्युमिनियम के अपशिष्ट हाइड्रेट्स तथा अपशिष्ट अल्युमिना तथा गैस सफाई, फ्लोक्युलेशन या फिल्टर प्रक्रियाओं के लिए प्रयुक्त ऐसी सामग्रियों को छोड़कर
ख 2130	सड़क निर्माण और रख-रखाव से बिटुमिनस सामग्री (एस्फाल्ट अपशिष्ट) जिसमें टार शामिल न हो (अनुसूची VI, क 3200 में संबंधित प्रविष्टि नोट करें)
ख 3	**मुख्यतया कार्बनिक संघटक वाले अपशिष्ट, जिनमें धातु और अकार्बनिक पदार्थ हो सकते हैं**
ख 3027	लेबल सामग्री उत्पादन में प्रयुक्त कच्ची सामग्रियों से युक्त स्व-आसंजक लेबल लैमिनेट अपशिष्ट
ख 3030	टेक्सटाइल अपशिष्ट निम्नलिखित सामग्रियां बशर्ते कि वे अन्य अपशिष्टों से मिश्रित न हों और निम्नलिखित विशिष्टियों से तैयार किए गए हों : - रेशम अपशिष्ट (रिलिंग, धागा अपशिष्ट और गार्नेटेड स्टॉक के लिए अनुपयुक्त कॉकून सहित) • कार्डेड या कॉम्ब्ड नहीं • अन्य - धागा अपशिष्ट सहित किन्तु गार्नेटेड स्टॉक को छोड़कर ऊन या पशु के महीन या खुरदरे बाल का अपशिष्ट • ऊन या पशु के पतले बाल के नवॉयल • ऊन या पशु के पतले बाल के अन्य अपशिष्ट • पशु के खुरदरे बाल के अपशिष्ट - सूती अपशिष्ट (धागा अपशिष्ट और गार्नेटेड स्टॉक सहित) • धागा अपशिष्ट (सूत अपशिष्ट सहित) • गार्नेटेड स्टॉक • अन्य - पटसन की रस्सी और अपशिष्ट - रस्सी और शुद्ध पटुआ के अपशिष्ट (धागा अपशिष्ट और गार्नेटेड स्टॉक सहित) (कनाविस स्टीवा एल.) - रस्सी और जूट और अन्य टेक्सटाइल बास्ट फाइबर (पटसन, शुद्ध पटुआ और रामी को छोड़कर) के अपशिष्ट (धागा अपशिष्ट और गार्नेटेड स्टॉक सहित) - रस्सी और सिसाल तथा जेनस वनकुमारी के अन्य टेक्सटाइल रेशों के अपशिष्ट (धागा अपशिष्ट तथा गार्नेटेड स्टॉक सहित) - रस्सी, नवॉयल तथा नारियल के अपशिष्ट (धागा अपशिष्ट तथा गार्नेटेड स्टॉक सहित) - रस्सी, नवॉयल तथा अबाका के अपशिष्ट (धागा अपशिष्ट तथा गार्नेटेड स्टॉक सहित) (मनीला पटुआ या मुसा टेक्सटाइल वर्ग) - रस्सी, नवॉयल तथा नारियल और अन्य वनस्पति टेक्सटाइल रेशों, जिन्हें अन्यत्र कहीं अधिसूचित या सम्मिलित नहीं किया गया है, के अपशिष्ट (धागा अपशिष्ट तथा गार्नेटेड स्टॉक सहित) - मानव निर्मित रेशों के अपशिष्ट (नवॉयल, धागा अपशिष्ट और गार्नेटेड स्टॉक सहित) • सिंथेटिक रेशों के • कृत्रिम रेशों के - फटे पुराने वस्त्र और अन्य फटे पुराने टेक्सटाइल पदार्थ - प्रयुक्त रैग, स्क्रैप सुतली, कॉर्डेज, रस्सी तथा केबल और सुतली, कॉर्डेज, रस्सी की फटी पुरानी सामग्रियां या टेक्सटाइल सामग्रियों के केबल

	• छंटनी किए हुए • अन्य
ख3035	अपशिष्ट टेक्सटाइल फ्लोर कवरिंग, कार्पेट
ख3040	रबर अपशिष्ट निम्नलिखित सामग्रियां, बशर्ते कि उन्हें अन्य अपशिष्टों के साथ मिश्रित न किया जाए : □ हार्ड रबर (जैसे इबोनाइट) का अपशिष्ट तथा स्क्रैप □ अन्य रबर अपशिष्ट (अन्यत्र निर्दिष्ट ऐसे अपशिष्टों को छोड़कर)
ख3050	अशोधित कॉर्क तथा काष्ठ अपशिष्ट : - काष्ठ अपशिष्ट तथा स्क्रैप, चाहे उन्हें लट्ठों, ब्रिकेटों, पेलेटों या समान स्वरूप में संकुचित किया गया हो या नहीं - कॉर्क अपशिष्ट : कुचले गए, दानेदार या ग्राउंड कॉर्क
ख3060	कृषि-खाद्य उद्योगों से उत्पन्न होने वाले अपशिष्ट, बशर्ते कि वे संक्रामक न हों : - वाइन ली - शुष्क तथा स्टेराइल किए गए सब्जी के अपशिष्ट, अवशिष्ट और उपोत्पाद, चाहे पशुओं के खिलाने में प्रयुक्त पेलेट के रूप में हों या न हों, जिन्हें अन्यत्र अधिसूचित या सम्मिलित नहीं किया गया हो - डेगरा : वसायुक्त पदार्थों या पशु या वनस्पति वैक्स के शोधन के परिणामस्वरूप प्राप्त अवशिष्ट - हड्डियों तथा सिंग के अपशिष्ट, निष्काम, वसामुक्त, समान्य रूप से तैयार (किन्तु आकार में काटे गए नहीं), एसिड से शोधित या जिलेटिन मुक्त - मत्स्य अपशिष्ट - कोकोआ के छिलके, भूसी, चमड़े और अन्य कोकोआ अपशिष्ट - उपोत्पादों को छोड़कर कृषि-खाद्य उद्योग से उत्पन्न अन्य अपशिष्ट जो मानव या पशु उपभोग के लिए राष्ट्रीय तथा अंतरराष्ट्रीय अपेक्षाओं और मानकों का अनुपालन करते हों।
ख3070	निम्नलिखित अपशिष्ट : - मानव केश का अपशिष्ट - अपशिष्ट पुआल - पशु चारे के रूप में प्रयोग किए जाने के लिए पेंसिलिन के उत्पादन से प्राप्त डीएक्टिवेटेड फंगस माइसेलियम
ख3080	रबर के छटनी अपशिष्ट और स्क्रैप
ख3090	चमड़े के गादों को छोड़कर चमड़े के छंटनी तथा अन्य अपशिष्ट या चमड़े की सामग्रियों के उत्पादन के लिए अनुपयुक्त चमड़े के घटक जिनमें हेक्सावैलेंट क्रोमियम मिश्रण और बायोसाइड सम्मिलित न हो (अनुसूची VI, क3100 में संबंधित प्रविष्टि देखें)
ख3100	चमड़े की धूल, राख, गाद या मैदा जिनमें हेक्सावैलेंट क्रोमियम मिश्रण और बायोसाइड सम्मिलित न हो (अनुसूची VI, क3090 में संबंधित प्रविष्टि देखें)
ख3110	फेलमोंगरी अपशिष्ट जिसमें जिनमें हेक्सावैलेंट क्रोमियम मिश्रण या बायोसाइड या संक्रामक पदार्थ सम्मिलित न हो (अनुसूची VI, क3110 में संबंधित प्रविष्टि देखें)
ख3120	खाद्य रंजकों से मिश्रित अपशिष्ट
ख 3130	अपशिष्ट पॉलीमर ईथर और अपशिष्ट गैर-परिसंकटमय मोनोमर ईथर पेराक्साइड फोरमिंग में अक्षम
ख 3140	न्यूमैटिक और अन्य टायर अपशिष्ट, संसाधन पुन:प्राप्ति, पुन:चक्रण, पुन:सुधार किन्तु प्रत्यक्ष पुन:उपयोग न किए जाने वालों को छोड़कर
ख 4	**ऐसे अपशिष्ट, जिनमें अकार्बनिक और कार्बनिक घटक हो सकते हैं :**
ख 4010	मुख्यतया जल आधारित या लेटैक्स पेंट, स्याही और हार्डेड वार्निश वाले अपशिष्ट, जिनमें कार्बनिक, साल्वेट, भारी धातु या बायोसाइट उस सीमा तक नहीं है कि उन्हें परिसंकटमय कहा जा सके (भाग क 4070 में संबंधित प्रविष्टि देखें)
ख 4020	रेसिन, लेटैक्स, प्लास्टिसाइजर ग्लूस या एडहैसिव के उत्पादन, निर्माण और उपयोग से उत्पन्न अपशिष्ट जो भाग क में सूचीबद्ध नहीं हैं, साल्वेंटमुक्त हैं और उस सीमा तक अन्य संदूषक जो भाग ग की विशेषताओं को नहीं दर्शाते हैं (भाग क, क3050 में संबंधित प्रविष्टि देखें)
ख 4030	बैटरी सहित प्रयुक्त एकल प्रयोग कैमरा, जो भाग क में शामिल नहीं है।
ख 4030	बैटरी सहित प्रयुक्त एकल प्रयोग कैमरा, जो भाग क में शामिल नहीं है।

* यह सूची परिसंकटमय अपशिष्टों के सीमापार संचलन संबंधी बेसल कन्वेंशन के उपाबंध-IX पर आधारित है और इसमें वे अपशिष्ट सम्मिलित हैं, जो बेसल कन्वेंशन के अनुच्छेद-। में परिसंकटमय के रुप में वर्णित नहीं किए गए हैं। **भाग ख में अपशिष्ट प्रतिबंधित हैं और** इनका निर्यात पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय और विदेश व्यापार लाइसेंस महानिदेशालय, यदि लागू हो, की अनुमति के बिना करने की अनुमति नहीं दी जा सकती है।

नोट :

(1) कॉपर धातुमल, जिसमें तांबा 65% से अधिक और सीसा और कैडमियम क्रमश:1.25% और 0.1% तक या इससे कम, स्पैंट क्लींड मेटल कैटालिस्ट तांबा हो; और तांबा रिवर्ट्स, केक और विशिष्ट, जिसमें सीसा और कैडमियम क्रमश: 1.25% और 0.1% या इससे कम हो, को पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय में राज्य प्रदूषण नियंत्रण बोर्ड द्वारा प्राधिकृत इकाईयों (वास्तविक प्रयोक्ताओं) को विदेश व्यापार महानिदेशालय के लाइसेंस के बिना और पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय की स्वीकृति से अनुमति है। तांबा रिवर्टस, केक और अपशिष्ट जिनमें सीसा और कैडमियम क्रमश: 1.25% और 0.1% से अधिक है, या उस प्रतिबंधित संवर्ग में है जिसके लिए पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय (वास्तविक प्रयोक्ता) से अनुमति प्राप्त इकाईयों द्वारा प्रसंस्करण या पुन:उपयोग के लिए विदेश व्यापार महानिदेशालय के लाइसेंस के विरूद्ध आयात की अनुमति है।

(2) जिंक राख या वियोजन में स्कीमिंग, जिसमें जिंक 65% से अधिक और सीसा और कैडमियम क्रमश 1.25% और 0.1% या इससे कम है और स्पैट क्लीन्ड मेटल कैटालिस्ट, जिसमें जिंक है, विदेश व्यापार महानिदेशालय की अनुज्ञप्ति के बिना पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय (वास्तविक उपभोक्ता) के साथ रजिस्ट्रीकृत यूनिटों को रजिस्ट्रीकरण पत्र में उपदर्शित वार्षिक मात्रा सीमा तक आयात की अनुमति है। जिंक राख और स्कीमिंग, जिसमें जिंक 65% से कम है और सीसा और कैडमियम क्रमश 1.25% और 0.1% या इससे अधिक है और हार्ड जिंक स्पैल्टर और ताम्र धातुमल, जिसमें सीसा 1.25% से अधिक है, उस निर्बन्धित प्रवर्ग के अधीन है जिसके लिए पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय (वास्तविक उपभोक्ता) से रजिस्ट्रीकृत इकाईयों द्वारा प्रसंस्करण या पुन:उपयोग के प्रयोजन के लिए विदेश व्यापार महानिदेशालय अनुज्ञप्ति पर आयात की अनुमति दी गई है।

भाग ग
परिसंकटमय विशेषताओं की सूची

कोड **विशेषता**

एच 1 **विस्फोटक**

कोई विस्फोटक पदार्थ या अपशिष्ट ठोस या तरल पदार्थ या अपशिष्ट (या पदार्थों या अपशिष्टों का मिश्रण) है, जो स्वयं में रासायनिक प्रतिक्रिया द्वारा ऐसे तापमान और दाब और ऐसी गति पर गैस उत्पादन में समर्थ है, जो आस-पास की वस्तुओं को हानि पहुंचाता है ।

एच 3 **ज्वलनशील द्रव**

"ज्वलनीय" शब्द का वही अर्थ है जो ज्वलनशील का है। ज्वलनशील द्रव्य ऐसे द्रव्य सा द्रव्यों का मिश्रण है या विलयन या निलंबन से ठोसयुक्त द्रव्य है "(उदाहरणार्थ पेंट, वार्निश, रोगन इत्यादि, किन्तु इनमें ऐसे पदार्थ या अपशिष्ट सम्मिलित नहीं है, जिन्हें उनके खतरनाक विशेषताओं के कारण अन्य रुप में वर्गीकृत किया गया है) जो क्लोज्ड-कप टेस्ट में 60.5 डिग्री सेल्सियस से अनाधिक के तापमान पर या ओपन-कप टेस्ट में 60.5 डिग्री सेल्सियस से अनाधिक के तापमान पर ज्वलनीय वाष्प छोड़ते हैं। (चूंकि ओपन-कप टेस्ट और क्लोज्ड-कप टेस्ट के परिणाम सर्वथा तुलनीय नहीं हैं और समान जांच के पृथक परिणाम भी परिवर्तनशील हैं, अत: ऐसे अंतरों को अनुज्ञात करने के लिए उपरोक्त अंकों से विनियमनों में फेरबदल करना इस परिभाषा के अभिप्राय के अनुरूप होगा)।

एच 4.1 **ज्वलनीय ठोस**

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विस्फोटक के रुप में वर्गीकृत से भिन्न ठोस अपशिष्ट ठोस जो परिवहन के दौरान झेली गई परिस्थितियों के अधीन आसानी से आग पकड़ लेते हैं या घर्षण, स्वप्रतिक्रिया से आग लगा सकते हैं।

एच 4.2 **ऐसे पदार्थ या अपशिष्ट, जो स्वत: ज्वलनशील है**

ऐसे पदार्थ या अपशिष्ट, जिनके परिवहन में सामान्य परिस्थितियों के अधीन स्वत: गर्म होने की संभावना होती है या जो वायु के संपर्क में आने पर गर्म हो जाते हैं और फिर आग पकड़ सकते हैं।

एच 4.3 **जल से संपर्क होने पर ज्वलनीय गैसें उत्सर्जित करने वाले पदार्थ या अपशिष्ट**

ऐसे पदार्थ या अपशिष्ट, जो जल से परस्पर क्रिया द्वारा स्वत: ज्वलनीय बनने के या खतरनाक मात्रा में ज्वलनीय गैसे छोड़ सकते हैं।

एच 5.1 **ऑक्सीकरण**

ऐसे पदार्थ या अपशिष्ट, जो स्वयं आवश्यक रुप से दहनशील नहीं हैं, किन्तु साधारणतया ऑक्सीजन छोड़कर अन्य सामग्री में आग लगा सकते हें, आग लगाने में सहायक हो सकते हैं।

एच 5.2 **कार्बनिक पैरोक्साइड्स**

ऐसे कार्बनिक पदार्थ या अपशिष्ट, जिनमें वाइवेलंट ओ-ओ संरचना है व ऊष्मीय अस्थिर पदार्थ है, जिनमें स्वत: त्वरित ऊष्माक्षेपक विघटन हो सकता है।

एच 6.1 **विष (तीव्र)**

ऐसे पदार्थ या अपशिष्ट, जो यदि निगल या सूंघ लिए जाएं या त्वचा से संपर्क द्वारा या तो मृत्यु का कारण बनने, गंभीर क्षति पहुंचाने या स्वास्थ्य के लिए हानिकारक हो सकते हैं।

एच 6.2 **संक्रामक पदार्थ**

ऐसे पदार्थ या अपशिष्ट, जो ऐसे जीवनक्षम सूक्ष्म जीवों या उनके ऐसे जीव विष से मुक्त हैं, जो पशुओं या मनुष्यों में बीमारी फैलाते हैं या ऐसा संदेह है।

एच 8 **संक्षारक**

ऐसे पदार्थ या अपशिष्ट, जो रासायनिक क्रिया द्वारा जीवित ऊतकों के संपर्क में आने पर गंभीर क्षति पहुंचाएंगे, या परिवहन के साधनों को काफी क्षति पहुंचाएंगे या नष्ट भी कर देंगे, ये अन्य परिसंकट उत्पन्न कर सकते हैं।

एच 10 **वायु या जल के संपर्क में विषैली गैसों का उत्सर्जन**

ऐसे पदार्थ या अपशिष्ट, जो वायु या जल से परस्पर क्रिया द्वारा खतरनाक परिमाणों में विषैली गैसें छोड़ सकते हैं।

एच 11 **विषैली (विलंबित या चिरकालिक)**

ऐसे पदार्थ या अपशिष्ट, जो यदि सूंघ लिए जाएं या जिनका अंतग्रर्हण कर लिया जाए या यदि त्वचा में प्रवेश कर लें तो विलंबित या चिरकालिक प्रभाव दिखा सकते हैं, जिनमें कासिनेंजेनसिटी शामिल हैं।

एच 12 **पारि-विषाक्त**

ऐसे पदार्थ या अपशिष्ट, जो यदि उत्सर्जित हो जाएं तो पर्यावरण पर बायोएकुमुलेशन के द्वारा तुरंत या विलंबित प्रतिकूल प्रभाव और/या बायोटिक प्रणाली पर विषैला प्रभाव छोड़ते हैं या छोड़ सकते हैं।

एच 13 जो किसी उपाय से निस्तारण के पश्चात अन्य सामग्री छोड़ने में समर्थ हैं, उदाहरणार्थ लीचेट, जिसमें ऊपर सूचीबद्ध कोई एक लक्षण भी है।

भाग घ

आयात और निर्यात के लिए लागू होने वाले अन्य अपशिष्टों की सूची, जिनके लिए पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय की अनुमति पूर्व सूचित सहमति अपेक्षित नहीं है। (बेसल कन्वेशन का उपाबंध IX*)

बेसल सं.	**अपशिष्टों का वर्णन**
ख 1	**धातु और धातुयुक्त अपशिष्ट**
ख1010	धात्विक, गैर-परिक्षेपण रुप में धातु और धातु एलॉय अपशिष्ट :
	- बहुमूल्य धातु (सोना, चांदी, प्लेटिनम किंतु पारा नहीं)**
	- लोहा और स्टील स्क्रैप**
	- निकल स्क्रैप**
	- एल्यूमिनियम स्क्रैप**
	- जिंक स्क्रैप**
	- टिन स्क्रैप**
	- टंगस्टन स्क्रैप**
	- मॉलिब्डेनम स्क्रैप**
	- टैंटालम स्क्रैप**
	- कोबाल्ट स्क्रैप**
	- विस्मथ स्क्रैप**
	- टाईटैनियम स्क्रैप**
	- जरकोनियम स्क्रैप**
	- मैगनीज स्क्रैप**
	- जरमेनियम स्क्रैप**
	- वेनेडियम स्क्रैप**
	- हैफनियम स्क्रैप**
	- इंडियम स्क्रैप**
	- नियोबियम स्क्रैप**
	- रेनियम स्क्रैप**
	- गैलियम स्क्रैप**
	- मैग्नीशियम स्क्रैप**
	- तांबा स्क्रैप**
	- क्रोमियम स्क्रैप**
ख 1050	मिश्र अलौह धातु हैवी फ्रैक्शन स्क्रैप जिसमें भाग ख 1050 में निर्दिष्ट धातुओं से अलग धातु मिश्रित हों और भाग ग की विशेषताओं का प्रदर्शन करने के लिए पर्याप्त सांद्रण में अनुसूची II में संघटक शामिल न हों।
ख 1100	धातुओं को गलाने, प्रगलन और परिष्करण से उत्पन्न अपशिष्ट युक्त धातु
	- हार्ड जिंक स्पेलटर**
	- जिंक युक्त ड्रोस ** : ~ गैल्वेनाइजिंग स्लैब जिंक टॉपड्रोस (>90% जिंक) ~ गैल्वेनाइजिंग स्लैब जिंक बॉटम ड्रोस (>92% जिंक) ~ जिंक डाई कास्टिग ड्रोस (>85% जिंक) ~ हाट डिप गैल्वेनाइजर्स स्लैब जिंक ड्रोस (बैच) (>92% जिंक)

	~ जिंक स्किमिंग्स
	- एल्युमिनियम स्कीमिंग (या स्कीम) लवण स्लैग को छोड़कर
ख 1110	वैद्युत और इलैक्ट्रोनिक एसैम्बलीज (प्रिंटिड सर्किट बोर्ड, इलेक्ट्रॉनिक संघटक और तार सहित), जो प्रत्यक्ष पुन: प्रयोग के प्रयोजन हेतु और पुनचर्क्रण या अंतिम निपटान के लिए न हों
	- प्रयुक्त वैद्युत और इलैक्ट्रोनिक एसैम्बलीज जिनका आयात मरम्मत के लिए और मरम्मत के बाद आयात के एक वर्ष के अंदर वापस निर्यात के लिए किया गया हो * * *
	- प्रयुक्त वैद्युत और इलैक्ट्रोनिक एसैम्बलीज जिनका आयात किराए के लिए और आयात के एक वर्ष के अंदर वापस निर्यात के लिए किया गया हो * * *
	- प्रयुक्त वैद्युत और इलैक्ट्रोनिक एसैम्बलीज जिनका निर्यात मरम्मत के लिए और मरम्मत के बाद पुन: आयात के लिए किया गया हो
	- प्रयुक्त वैद्युत और इलैक्ट्रोनिक एसैम्बलीज जिनका आयात परीक्षण, अनुसंधान एवं विकास, परियोजना कार्य उद्देश्यों और आयात की तारीख से तीन वर्षों की अवधि के अंदर वापस पुन: निर्यात करने के लिए किया गया हो * * *
	- वारंटी पुन:स्थापनों के लिए आयातित कलपुर्जे परंतु यह कि सामान संख्या में खराब या अकार्यशील पुर्जे आयात के एक वर्ष की अवधि के अंदर वापस निर्यात किए जा रहे हों * * *
	- रक्षा मंत्रालय, अंतरिक्ष विभाग और परमाणु ऊर्जा विभाग द्वारा आयात की गई प्रयुक्त वैद्युत और इलैक्ट्रोनिक एसैम्बलीज * * *
	- प्रयुक्त वैद्युत और इलैक्ट्रोनिक एसैम्बलीज (भारी संख्या में नहीं; संख्या तीन या इससे कम) जिनका आयात व्यक्तियों के लिए अपने निजी प्रयोगों के लिए किया गया हो
	- प्रयुक्त लैपटॉप, पर्सनल कंप्यूटर, मोबाईल, टैबलेट प्रत्येक में से एक जिसका एक आयात संघटनों द्वारा एक वर्ष के अंदर किया जाता हो
	- एकल व्यक्तियों के स्वामित्व और आवास के स्थानांतरण पर आयातित प्रयुक्त वैद्युत और इलैक्ट्रोनिक एसैम्बलीज
	- प्रयुक्त मल्टी फंक्शन प्रिंट और कॉपी करने की मशीनें (एमएफडी) * * * *
	- प्रयुक्त वैद्युत और इलैक्ट्रोनिक एसैम्बलीज जिनका आयात एअरलाइनों द्वारा एअर क्राफ्टों के अनुरक्षण के लिए किया गया हो और उन्हें जहाज पर या सीमा शुल्क बंधित क्षेत्रों के एअर साइड पर स्थित संबंधी एअर लाइन भंडारणों में रखा गया हो
ख 3	**मुख्यत: कार्बनिक संघटक वाले अपशिष्ट, जिनमें धातु और अकार्बनिक पदार्थ हो सकते हैं**
ख 3020	पेपर, पेपर बोर्ड और पेपर उत्पाद अपशिष्ट * * निम्नलिखित सामग्री, बशर्ते उन्हें खतरनाक अपशिष्टों में नहीं मिलाया गया है : निम्नलिखित के पेपर अपशिष्ट और पेपर या पेपर बोर्ड स्क्रैप: - अविरंजित पेपर या पेपर बोर्ड या लहरदार पेपर या पेपर बोर्ड - अन्य पेपर या पेपर बोर्ड मुख्यतया रंजित रसायन लुगदी से बने, व्यापक रुप से रंगा न गया हो - मुख्यतया यांत्रिक लुगदी (उदाहरणार्थ समाचार पत्र, पत्रिका और ऐसे ही मुद्रित सामग्री) से बना पेपर या पेपर बोर्ड - अन्य, किंतु उन तक सीमित नहीं 1) लेमिनेटिड पेपर बोर्ड, 2) अवर्गीकृत स्क्रैप
ख 3140	- एअर क्राफ्टों के अनुरक्षण के लिए एअरलाइनों द्वारा रिट्रिडिंग के लिए आयात किए गए और रिट्रिडिंग के बाद पुन: निर्यात किए जाने के लिए मूल उपकरण विनिर्माताओं को निर्यात किए गए एअरक्राफ्ट टायर और उन्हें जहाज पर या सीमा शुल्क बंधित क्षेत्रों के एअर साइड पर स्थित संबंधी एअर लाइन भंडारणों में रखा गया हो

टिप्पणी :

* यह सूची परिसंकटमय अपशिष्टों के सीमापार संचलन संबंधी बेसल कन्वेंशन के उपाबंध-IX पर आधारित है और इसमें वे अपशिष्ट सम्मिलित हैं, जो बेसल कन्वेंशन के अनुच्छेद-। में परिसंकटमय के रुप में वर्णित नहीं किए गए हैं।

* * देश में आयात की अनुमति वास्तविक प्रयोक्ता या एक बारगी (आधार पर राज्य प्रदूषण नियंत्रण बोर्ड द्वारा प्राधिकृत वास्तविक प्रयोक्ता की ओर से व्यापारी को सीमा शुल्क प्राधिकरण द्वारा इन नियमों की अनुसूची VIII में निर्दिष्ट दस्तावेजों के सत्यापन के अध्यधीन है।

* * * देश में आयात की अनुमति केवल मूल उपकरण निर्माताओं से वास्तविक प्रयोक्ताओं को और सीमा शुल्क प्राधिकरण द्वारा इन नियमों की अनुसूची VIII में निर्दिष्ट दस्तावेजों के सत्यापन के अध्यधीन है।

* * * * देश में आयात की अनुमति वास्तविक प्रयोक्ता या इन नियमों की अनुसूची VIII के अंतर्गत यथा निर्दिष्ट सीमाशुल्क प्राधिकरण द्वारा अपेक्षित और सत्यापित दस्तावेजों के अनुरूप वास्तविक प्रयोक्ता की ओर से व्यापारी को है। एक बार एमएफडी के स्वदेशी रूप से विनिर्मित हो जाने पर मल्टीफक्शन प्रिंट और कॉपी करने की मशीन के लिए मुक्त व्यापार की नीति की समीक्षा की जाएगी।

अनुसूची III के भाग ग में बिना "तारे" वाले सूचीबद्ध अन्य सभी अपशिष्टों के लिए सीमा शुल्क प्राधिकरण की शर्तों, यदि कोई हों, के अनुपालन के अध्यधीन पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय से किसी भी दस्तावेज के बिना अनुमति है।

अनुसूची IV

[नियम 6 (1) (ii) और 6(2) देखें)]

सामान्य रूप से पुन:चक्रण योग्य परिसंकटमय अपशिष्टों की सूची

क्र. सं.	**अपशिष्ट**
(1)	**(2)**
1	पीतल ड्रास
2	कॉपर ड्रास
3	कॉपर ऑक्साइड मिल स्केल
4	कॉपर प्रत्यावृत, केक और अवशिष्ट
5	विपेक्षित रुप में अपशिष्ट कॉपर और कॉपर मिश्र
6	और प्रसंस्करण या शोधन के लिए कॉपर प्रसंस्करण से धातुमल
7	आईएसआरआई कोड पदार्थ अर्थात "ड्रयूड" सहित विद्युतरोधी कॉपर तार स्क्रैब या पीवीसी सीटिंग के साथ कॉपर
8	जेली फिल्ड कॉपर तारें
9	कॉपर वाली स्पैंट क्लीयरड मैटल कैटलिस्ट
10	निकिल, कैडमियम, जिंक, कॉपर और आर्सेनिक वनेडियम और कोबाल्ट वाले स्पैंट कैटलिस्ट
11	जिंक ड्रास-हॉट डिप गैल्वनाइजर स्लैब
12	जिंक ड्रास-बाटम ड्रास
13	गैल्वानाईजिंग और डाई-कास्टिंग प्रचालनों से होने वाली जिंक राख/स्क्रीमिंग
14	स्मैलटिंग और धातुओं के शोधन से उत्पन्न जिंक राख/स्क्रीमिंग/अन्य जिंक वाले अपशिष्ट
15	बिखरने वाले जिंक अलाय अपशिष्टों सहित जिंक राख और अपशिष्ट
16	जिंक वाले स्पैंट क्लीयर्ड मैटल कैटालिस्ट
17	बैटरी (प्रबंधन और प्रहस्तन) नियम, 2001 के अधीन न आने वाली ग्रिड प्लेट सहित प्रयुक्त लैड एसिड बैटरी प्लेट्स और अन्य लैड स्क्रैप/राख/अपशिष्ट। (*बैटरी स्क्रैप अर्थात आईएसआरआई कोड में सम्मिलित लैड, बैटरी प्लेट्स, कोड वर्ड "रेल्स" बैटरी लग्स आईएसआरआई में सम्मिलित कोडवर्ड "रेक्स"; आईएसआरआई कोड में शामिल स्क्रैप ड्रेन/शुष्क, लैड बैटरीज) कोड वर्ड "रेन्स"
18	वैद्युत और इलेक्ट्रॉनिक पुर्जों के अपशिष्ट घटक, जिसमें अनुसूची III भाग क में सूचीबद्ध एक्युमुलेटर्स और अन्य बैटरियों के संघटक, मरकरी स्विच, कैथोड-रे ट्यूबस से क्रियाशील ग्लास क्यूलेट्स और अन्य क्रियाशील ग्लास और पीसीबी - केपीसिटेर्स और अन्य अनुसूची II के संघटकों के साथ अन्य संदूषित घटक (यथा कैडमियम, मरकरी, लेड, पोलीक्लोरिनेटिड, बाइफिनाइल) उस सीमा तक शामिल है कि ये इस अनुसूची III के भाग ग में निर्देशित परिसंकट लक्षण प्रदर्शित करते हैं।

19	पेंट और इंक स्लज/अवशिष्ट
20	प्रयुक्त तेल और अपशिष्ट तेल

अनुसूची V

[नियम 3 (36) और 3(39) देखें]

भाग क

पुन:चक्रण के लिए उपयुक्त प्रयुक्त तेल के विनिर्देश

क्र.सं.	पैरामीटर	अधिकतम अनुज्ञेय सीमाएं
(1)	(2)	(3)
1	पोलीक्लोरीनेटिड वाईफिनाइल (पीसीबी)	<2 पीपीएम*
2	सीसा	100 पीपीएम
3	आर्सेनिक	5 पीपीएम
4	कैडमियम + क्रोमियम + निकल	500 पीपीएम
5	पोलीऐरोमेटिक हाइड्रोकार्बन्स (पीएएच)	6%

भाग ख

अपशिष्ट तेल से व्युत्पन्न ईंधन के विनिर्देश

क्र.सं.	पैरामीटर	अधिकतम अनुज्ञेय सीमाएं
(1)	(2)	(3)
1	सेडिमेंट	0.25%
2	सीसा	100 पीपीएम
3	आर्सेनिक	5 पीपीएम
4	कैडमियम + क्रोमियम + निकल	500 पीपीएम
5	पोलीऐरोमेटिक हाइड्रोकार्बन्स (पीएएच)	6%
6	कुल हेलोजन	4000 पीपीएम
7	पोलीकोलरीनेटि बाई-फिलाइल (पीसीबी)	<2 पीपीएम*
8	सल्फर	4.5%
9	जल तत्व	1%

* इलेक्ट्रॉन कैपचर डिटेक्टर (ईसीडी) का प्रयोग करते हुए गैस लिक्विड क्रोमेटोग्राफी (जीएलसी) द्वारा संसूचन सीमा 2 पीपीएम है।

अनुसूची VI

[नियम 12 (6) , 12(7) और 14(1) देखें]

आयात के लिए प्रतिषिद्ध परिसंकटमय और अन्य अपशिष्ट

बेसल सं.*	परिसंकटमय और अन्य अपशिष्टों का वर्णन
(1)	(2)
क 1010	धातु अपशिष्ट निम्नलिखित में से किसी भी समिश्रण का अपशिष्ट किंतु अनुसूची III के भाग ख और भाग ग में विशिष्ट रूप से सूचीबद्ध ऐसे अपशिष्टों को छोड़कर
	- आर्सेनिक

	- बेरेलियम
	- मरकरी
	- सेलेनियम
	- थेलियम
क 1020	अपशिष्ट जिनमें संघटक या संदूषक हैं, स्थूल रुप में धातु अपशिष्टों को छोड़कर, निम्नलिखित में से कोई : - बेरेलियम; बेरेलियम यौगिक - सेलेनियम; सेलेनियम यौगिक
क 1030	वे अपशिष्ट, जिनमें निम्निलिखित से कोई संघटक् संदूषक सम्मिलित हो : - आर्सेनिक; आर्सेनिक यौगिक - पारा; पारा यौगिक - थेलियम; थेलियम यौगिक
क 1040	संघटक के रूप में हेक्सावेलेन्ट क्रोमियम यौगिक वाला अपशिष्ट
क 1140	तरल स्वरूप में अपशिष्ट की क्यूरपिक क्लोराइड और कॉपर सायनाइड केटालिस्ट (अनुसूची III के भाग क में संबंधित प्रविष्टि देखें)
क 1060	धातुओं के अम्लोपचार से उत्पन्न अपशिष्ट लीकर
क 1110	कॉपर विद्युत परिष्करण और विद्युत प्राषण सनक्रियाओं से उत्पन्न स्पेंट विद्युत अपघटनी विलयन
क 1130	स्पेंट उत्कीर्णन विलयन जिसमें घुलित कॉपर हो
क 1180	अपशिष्ट वैद्युत एवं इलैक्ट्रानिक एसैम्बलीज या स्कैप (विद्युत उत्पादन से उत्पन्न स्क्रैप एसैम्बलीज शामिल नहीं हैं) जिनमें एक्यूमुलेटर जैसे घटक और अनुसूची III भाग क में सम्मिलित अन्य बैटरियां, मर्करी स्वीच, कैथोड - किरन ट्यूब से उद्वलित ग्लास और कुछ सीमा तक अन्य उद्वलित ग्लास और पीसीबी - कैपेसिटर या अनुसूची II के घटकों (अर्थात कैडमियम, मर्करी, सीसा, पॉलीक्लोरिनेटिड बाईफिनाइल) से संदूषित घटक जो अनुसूची III के भाग ग में इंगित जोखिम पूर्ण लक्षण प्रदर्शित करते हैं (भाग खख 1110 में संबंधित प्रविष्टि देखें)
क 1190	वेस्ट मैटल केबल्स, प्लास्टिक कोटिड या इन्सुलेटिड या कोलतार के साथ संदूषित, पीसीबी, सीसा कैडमियम अन्य ओरगेनोहेलोजन संघटक या अन्य घटक जैसा कि अनुसूची II में उल्लिखित है, जिस सीमा तक वे अनुसूची III के भाग ग में इंगित परिसंकटमय विशेषताएं प्रदर्शित करें।
क 2	**मुख्यत: अकार्बनिक संघटकों वाले अपशिष्ट जिसमें धातु और कार्बनिक पदार्थ अंतर्विष्ट हों**
क 2020	अकार्बनिक फ्लोरीन संघटक के अपशिष्ट, जो द्रव या स्लज के रुप में है, किन्तु जिसमें भाग ख में निर्दिष्ट ऐसे अपशिष्ट शामिल नहीं हैं
क 2040	रासायनिक औद्योगिक प्रक्रिया से उद्भूत अपशिष्ट जिप्सम यदि वह अनुसूची II में उल्लिखित संघटक जो अनुसूची III के भाग ग में इंगित परिसंकटमय विशेषताएं इंगित करते हों (भाग खख 2080 में संबंधित प्रविष्टि देखें)
क 2050	अपशिष्ट एस्बेस्टस (धूल और रेशा)
क2060	कोयला चालित विद्युत संयंत्र फ्लाई-ऐश जिसमें भाग ग की विशेषताओं को पर्याप्त रूप से प्रदर्शित करने की सीमा तक सांद्रण में अनुसूची II के संघटक शामिल हों
क 3	**मुख्यत: कार्बनिक संघटक वाले अपशिष्ट जिनमें धातु और अकार्बनिक सामग्री हों**
क 3030	ऐसे अपशिष्ट, जिनमें सीसा अपरकोटररोधी यौगिक स्लज या अंतर्विष्ट है या उनमें है या उनसे संदूषित है।
क 3040	अपशिष्ट तापीय (उष्मा स्थानांतरण) तरल
क 3060	अपशिष्ट नाइट्रोसेलुलोस
क 3070	द्रव या स्लज के रूप में क्लोरोफिनोल सहित अपशिष्ट फिनोल , फिनोल यौगिक
क 3080	अपशिष्ट ईथर जिसके अंतर्गत वह नहीं है जो सूची ख में विनिर्दिष्ट नहीं है
क 3090	अपशिष्ट चर्म धूल, भस्म, स्लज या विचूर्ण जब उसमें हेक्सावेलेंट क्रोमियम यौगिक या बायोसाइड हो (भाग खख 3100 में संबंधित प्रविष्टि देखें)

क 3100	चर्म शोधन और अन्य चर्म अपशिष्ट या चर्मयौगिक अपशिष्ट जो कि चर्म वस्तुओं के निर्माण में उपयुक्त न हो। हेक्सावेलेंट क्रोमियम यौगिक और बायोसाइड हो (भाग खख 3090 में संबंधित प्रविष्टि देखें)।
क 3110	फेलमोंजरी अपशिष्ट, जिसमें हेक्सावेलेंट क्रोमियम यौगिक या बायोसाइड या संक्रामक पदार्थ भी है (भाग खख 3110 में संबंधित प्रविष्टि देखें)।
क3140	अपशिष्ट अहैलोजनीकृत कार्बनिक विलायक किंतु उन अपशिष्टों को छोड़कर जो भाग ख में विनिर्दिष्ट हैं
क 3150	अपशिष्ट हैलोजनीकृत कार्बनिक बिलयन
क3160	अपशिष्ट हैलोजनीकृत या अहैलोजनीकृत निर्जला आसवन अवशेष जो कार्बनिक विलायक पुन: प्राप्ति की संक्रिया से उत्पन्न हो
क3170	ऐलीफैटिक हैलोजनीकृत हाइड्रोकार्बन के उत्पादन से उत्पन्न अपशिष्ट (जैसे क्लोरोमेथेन, हाइक्लोरोईथेन, विनाइल क्लोराइड, विनिलीडीन क्लोराइड, एलिल क्लोराइड और एपिक्लोरहाइड्रिन)
क 3180	अपशिष्ट पदार्थ और वस्तुएं, जिनमें संदूषण के साथ पॉलीक्लोरीनेटिड बाईफिलाईल (पीसीबी), पॉली क्लोरेनेटिड टरफिनाइल (पीसीटी), पॉलीक्लोरिनेटिड नैफ्थलीन (पीसीएन) या पॉली ब्रोमिनेटिड बाइफिनाइल (पीबीबी) या इन यौगिकों का कोई अन्य पॉलीब्रॉमिनेटिड एनेलॉग शामिल है।
क 3190	अपशिष्ट टैरी अवशिष्ट (एस्फाल्ट सीमेंट के सिवाय), जो कि शोधन, आसवन या किसी कार्बनिक सामग्री के पाइरोलिटिक शोधन से उद्भूत होते हैं।
क3200	सड़क निर्माण और अनुरक्षण कार्यों से उत्पन्न बिटुमिनस सामग्री (एस्फाल्ट अपशिष्ट) (भाग ख, ख 2130 में संबंधित प्रविष्टि देखें)।
क 4	**ऐसे अपशिष्ट जिनमें या तो अकार्बनिक या कार्बनिक संघटक हों।**
क 4020	नैदानिक और संबंधित अपशिष्ट ; मेडिकल, नर्सिंग, डेंटल, वेटेनरी या वैसे ही कार्यों से उत्पन्न अपशिष्ट तथा अस्पताल या रोगियों के अन्वेषण या निदान के दौरान या अनुसंधान परियोजनाओं के दौरान उत्पन्न अपशिष्ट।
क 4030	बायोसाइड और फाइटो-फार्मास्युटिकल्स के उत्पादन, निर्माण और प्रयोग से प्राप्त अपशिष्ट, जिनमें कीटनाशी, शाकनाशी अपशिष्ट भी हैं जो विनिर्देश से पृथक कालातीत (विनिर्माता द्वारा संस्तुति अवधि के अंदर अप्रयुक्त) हैं या उसके अभिप्रेत मूल उपयोग के लिए अनुपयुक्त हैं।
क 4050	वे अपशिष्ट, जो निम्नलिखित में से किसी से मिलकर बने हैं, सम्मिलित हैं या उनमें से किसी से संदूषित हैं : - मूल्यवान धातु को छोड़कर अकार्बनिक साइनायड, अकार्बनिक सायनाइड के ठोस रुप में मिलकर बने हों - कार्बनिक साइनाइड
क 4060	अपशिष्ट तेल/जल, हाइड्रोकार्बन/जल मिश्रण, इमल्सन
क4080	विस्फोटक प्रकृति के अपशिष्ट (किंतु भाग ख में विनिर्दिष्ट ऐसे अपशिष्टों को छोड़कर)
क4090	इस अनुसूची के ख 2120 में विनिर्दिष्ट से अलग अम्लीय या बेसिक विलयन
क 4110	वे अपशिष्ट, जो निम्नलिखित में से किसी से मिलकर बने हैं, सम्मिलित हैं या उनमें से किसी से संदूषित हैं : - कोई सजातीय पॉलीक्लोरीकृत डाइबेंजोफ्यूरान - कोई सजातीय पॉलीक्लोरीकृत डाइबेंजो-पी-डाइऑक्सीन
क4150	अनुसंधान और विकास या अध्यापन कार्यकलापों से उत्पन्न अपशिष्ट रसायन पदार्थ जिनकी पहचान नहीं की गई है और/या नए हो और उनके मानव स्वास्थ्य और/या पर्यावरण पर पड़ने वाले प्रभाव ज्ञात न हो
ख 1	**धातु और धातु मिश्रित अपशिष्ट**
ख 1110	पुन: प्रयोग हेतु प्रयुक्त गहन देखरेख वाले चिकित्सा उपकरण
ख1115	प्लास्टिक से इंसुलेटिड या कोटिड अपशिष्ट सामग्री, जो इस अनुसूची के क1190 में शामिल नहीं हैं, किसी अवस्था में संसाधन पुन:प्राप्ति, पुनर्चक्रण, पुन:रूद्धार, प्रत्यक्ष पुन:उपयोग या वैकल्पिक प्रयोगों या किसी अन्य निपटान संबंधी संक्रियाओं के लिए अभिप्रेत, अनियंत्रित तापीय प्रक्रियाओं जैसे खुले में जलाना को छोड़कर
ख1250	कार्यकाल पूरा कर चुके वाहनों के अपशिष्ट जिनमें तरल या अन्य परिसंकटमय संघटक शामिल न हों
ख 2	**मुख्यत: अकार्बनिक संघटक वाले अपशिष्ट जिनमें धातु और कार्बनिक तत्व शामिल हो सकते हैं**
ख2050	कोयला चालित विद्युत संयंत्र के फ्लाई-ऐश, इस अनुसूची के ख2060 में संबंधित प्रविष्टि देखें

ख2110	बॉक्साइट अवशिष्ट (लाल मिट्टी) (11.5 से कम तक पीएच हल्का किया गया)
ख2120	2 से अधिक और 11.5 से कम पीएच के साथ अपशिष्ट एसिड अथवा बेसिक घोल, जो क्षयकारी या अन्यथा परिसंकटमय नहीं है (इस अनुसूची के ख 4090 में प्रविष्टि देखें)
ख 3	**मुख्यत: कार्बनिक संघटक वाले अपशिष्ट, जिनमें धातु और अकार्बनिक पदार्थ शामिल हो सकते हैं**
ख3010	ठोस प्लास्टिक अपशिष्ट एक विशिष्टि तक तैयार निम्नलिखित प्लास्टिक या मिश्रित प्लास्टिक अपशिष्ट : - नॉन-हैलोजिनेटिड पॉलिमर और कोपॉलिमर के प्लास्टिक स्क्रैप जिनमें निम्नलिखित सम्मिलित हो किंतु निम्नलिखित तक सीमित न हों : इथिलीन, स्टाइरीन, पॉलिप्रपिलीन, पॉलिइथीलीन, टेरिफ थैलेट, एक्रिलोनाइट्राइल, ब्यूटाडाइन, पोलिएसिटल, पोलिएमाइड, पोलिब्यूटिलीन, टेरिफ थैलेट, पोली कार्बोनेट, पोलिइथर, पोलिफनिलिन, सल्फाइड, एक्रिलिक पोलिमर, अल्केन सी10 - सी13 (प्लास्टिसाइसजर), पोलियूरिथेन (सीएफसी रहित), पोलिसिलोक्सेन, पोलिमिथाइल मिथाक्राइलेट, पोलि विनाइल अल्कोहल, पोलिविनाइल ब्यूटाइराल, पोलिविनाइल एसिटेट - निम्नलिखित सहित शोधित अपशिष्ट रेसिन या संघनन उत्पाद : यूरिया फार्मल्डिहाइड रेसिन, फेनोल फर्मल्डिहाइड रेसिन, मेलामाइन फर्मल्डिहाइड रेसिन, इपोक्सि रेसिन, अल्काइड रेसिन, पोलिएमाइड - निम्नलिखित फ्लोरिनेटेड पोलिमर अपशिष्ट (उपभोग पश्चात अपशिष्ट को छोड़कर) : परफ्लोरोइथिलिन/प्रोपिलिन, परफ्लोरो अल्कोक्सी अल्केन, टेट्राफ्लोरोइथिलीन/परफ्लोरो विनाइल ईथर (पीएफए), टेट्राफ्लोरोइथिलीन/परफ्लोरो मिथाइल विनाइल ईथर (एमएफए), मेटाफ्लोरो अल्कोक्सी अल्केन, पोलिविनाइलफ्लोराइड, पोलिविनाइलडेनिफ्लोराइड
ख3026	तरल पदार्थों के लिए सुसंहत पैकेजिंग के पूर्व-शोधन से उत्पन्न निम्नलिखित अपशिष्ट, जिनमें अनुसूची II में उल्लिखित संघटक भाग ग की विशेषताओं का प्रदर्शन करने के लिए पर्याप्त सांद्रण में शामिल न हों : - गैर-पृथक्करण योग्य प्लास्टिक फ्रैक्शन - गैर-पृथक्करण योग्य प्लास्टिक-एलुमिनियम फ्रैक्शन
ख3065	पशु या वनस्पति मूलक अपशिष्ट खाद्य वसा और तेल - (यथा फ्राइंग तेल)
ख3140	अपशिष्ट न्यूमेटिक टायर प्रत्यक्ष पुन: उपयोग के लिए
भ46	घरेलू संग्रहित अपशिष्ट/नगरीय अपशिष्ट
भ47	घरेलू अपशिष्ट के भष्मीकरण से उत्पन्न अवशेष

अनुसूची-VII

[नियम 13(6) और 21 देखें]

प्राधिकरणों और तदनुरूपी कर्त्तव्यों की सूची

क्र.सं.	**प्राधिकरण**	**तत्संबंधी कर्तव्य**
(1)	**(2)**	**(3)**
1	पर्यावरण (संरक्षण) अधिनियम, 1986 के अंतर्गत पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय	i. परिसंकट अपशिष्टों की पहचान करना ii. परिसंकटमय अपशिष्टों के निर्यातकर्ताओं को अनुमति iii परिसंकटमय अपशिष्टों के आयाकर्ताओं को अनुमति

		iv. भारत से परिसंकटमय अपशिष्टों के अभिवहन के लिए अनुमति v. परिसंकटमय और अन्य अपशिष्ट के पर्यावरण अनुकूल प्रबंधन को बढ़ावा देना vi. परिसंकटमय और अन्य अपशिष्ट प्रबंधन से संबंधित कार्यकलाप संबंधी प्रशिक्षण और जागरुकता कार्यक्रम प्रायोजित करना।
2	जल (प्रदूषण निवारण एवं नियंत्रण) अधिनियम, 1974 के अंतर्गत गठित केन्द्रीय प्रदूषण नियंत्रण बोर्ड	i. राज्य प्रदूषण नियंत्रण बोर्डों के कार्यकलापों का समन्वय। ii. परिसंकटमय और अन्य अपशिष्टों के प्रबंध को संचालित करने वाले प्राधिकारियों के लिए प्रशिक्षण पाठ्यक्रम का आयोजन। iii. अपशिष्ट और लीचेट की अभिक्रिया और व्ययन के लिए मानकों और विनिर्देशों की सिफारिश करना। परिसंकटमय अपशिष्टों के वर्गीकरण के लिए प्रक्रियाओं की सिफारिश करना। iv. परिसंकटमय अपशिष्ट के प्रहस्तन की सुविधाओं का यथा आवश्यकता निरीक्षण करना v. इन नियमों में शामिल करने के लिए अपशिष्ट की पहचान करने के लिए क्षेत्र विशिष्ट प्रलेखन vi. परिसंकटमय और अन्य अपशिष्टों के निवारण या न्यूनीकरण और प्रहस्तन के लिए दिशानिर्देश तैयार करना और अद्यतन करना vii. परिसंकटमय और अन्य अपशिष्टों के पुनर्चक्रण, उपयोग पूर्व-प्रसंस्करण सह-प्रसंस्करण के लिए मार्गनिर्देशों/मानक प्रचालन पद्धतियों को तैयार और अद्यतन करना viii. परिसंकटमय अपशिष्ट के प्रबंधन संबंधी वार्षिक समीक्षा रिपोर्ट तैयार करना ix. पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय द्वारा समय-समय पर सौंपा गया कोई अन्य कार्य
3	राज्य सरकार/संघ राज्य क्षेत्र सरकार/प्रशासन	i. साझा परिसंकटमय और अन्य अपशिष्ट शोधन भंडारण और निपटान सुविधा (टीएसडीएफ) के लिए स्थल की पहचान करना ii. पर्यावरण प्रभाव आकलन रिपोर्टों का मूल्यांकन और स्थल के अनुमोदन के निर्णय की सूचना देना या स्थल अधिग्रहण करना या प्रसुविधा के प्रचालक या दखलदार या दखलदारों के संघ को स्थल के अधिग्रहण की सूचना देना iii. स्थलों की अधिसूचना iv. राज्य या संघ राज्य क्षेत्रों में सभी संभाव या विद्यमान निपटान स्थलों की सूची को समय-समय पर प्रकाशित करना
4	जल (प्रदूषण निवारण एवं नियंत्रण) अधिनियम, 1974 के अंतर्गत गठित राज्य प्रदूषण नियंत्रण बोर्ड या प्रदूषण नियंत्रण समितियां	i. परिसंकटमय और अन्य अपशिष्टों का सूचीकरण ii. प्राधिकार का दिया जाना और नवीकरण iii. पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय द्वारा जारी निर्यात और आयात सहित प्राधिकार के विभिन्न उपबंधों और शर्तों के अनुपालन को मॉनीटर करना iv. आयातकर्ताओं द्वारा आयात के लिए दिए गए आवेदनों की जांच करना और उन आवेदनों को पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय को अग्रेषित करना v. परिसंकटमय और अन्य अपशिष्टों की उत्पत्ति को रोकने या कम करने या न्यून करने के कार्यक्रमों का क्रियान्वयन vi. इन नियमों के उल्लंघन के विरुद्ध कार्रवाई करना vii. पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय द्वारा समय-समय पर इन

		नियमों के अंतर्गत सौंपा गया कोई अन्य कार्य
5	विदेश व्यापार (विकास और विनियमन) अधिनियम, 1992 के अंतर्गत गठित विदेश व्यापार महानिदेशालय	i. परिसंकटमय और अन्य अपशिष्टों के आयात के लिए अनुज्ञप्ति का अनुदान ii. आयात या निर्यात के लिए प्रतिषिद्ध परिसंकटमय और अन्य अपशिष्टों के लिए अनुज्ञप्ति से इंकार करना।
6	भारतीय पत्तन अधिनियम, 1908 (1908 का 15) के अधीन पत्तन प्राधिकरण और सीमा-शुल्क अधिनियम, 1962 (1962 का 52) के अंतर्गत सीमा शुल्क प्राधिकरण	i. दस्तावेजों का सत्यापन करना ii. किसी अवैध व्यापार के बारे में पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय को सूचित करना iii. आयात और निर्यात के लिए अनुमति दिए गए अपशिष्टों का यथा आवश्यकता विश्लेषण करना iv. इन नियमों के उपबंधों और परिसंकटमय और अन्य अपशिष्टों के विश्लेषण के संबंध में पदाधिकारियों को प्रशिक्षित करना v. भारतीय पत्तन अधिनियम, 1908 या सीमा-शुल्क अधिनियम, 1962 के अंतर्गत उल्लंघनों के लिए निर्यातकर्ता या आयातकर्ता के विरुद्ध कार्रवाई करना।

अनुसूची VIII

[नियम 13 (2) और 13(4) देखे)]

अनुसूची III के भाग में विनिर्दिष्ट और अन्य अपशिष्टों के आयात के लिए सीमा-शुल्क प्राधिकरण द्वारा सत्यापन के लिए दस्तावेजों की सूची

क्र.सं.	बेसल सं.	अन्य अपशिष्ट का विवरण	दस्तावेजों की सूची
(1)	(2)	(3)	(4)
1	ख1010	धात्विक, गैर-परिक्षेपण रुप में धातु और धातु एलॉय अपशिष्ट : - बहुमूल्य धातु (सोना, चांदी, प्लेटिनम किंतु पारा नहीं) - लोहा और स्टील स्क्रैप - निकल स्क्रैप - एल्यूमिनियम स्क्रैप - जिंक स्क्रैप - टिन स्क्रैप - टंगस्टन स्क्रैप - मॉलिब्डेनम स्क्रैप - टैंटालम स्क्रैप - कोबाल्ट स्क्रैप - विस्मथ स्क्रैप - टाईटैनियम स्क्रैप - जरकोनियम स्क्रैप - मैगनीज स्क्रैप - जरमेनियम स्क्रैप - वेनेडियम स्क्रैप - हैफनियम स्क्रैप - इंडियम स्क्रैप	(क) विधिवत भरा हुआ प्ररूप 6 - संचलन दस्तावेज; (ख) जहां कहीं लागू हो, विदेश व्यापार महानिदेशालय से आयात अनुज्ञप्ति; (ग) निर्यात करने वाले देश की निरीक्षण अभिकरण या विदेश व्यापार महानिदेशालय द्वारा अनुमोदित निरीक्षण एवं प्रमाणन अभिकरण द्वारा जारी पूर्व-शिपमेंट निरीक्षण प्रमाण पत्र; (घ) वास्तविक प्रयोक्ताओं के लिए वायु तथा जल अधिनियमों के अंतर्गत कार्य करने के लिए विधि मान्य सहमति पत्र और इन नियमों के अंतर्गत प्राधिकार । व्यापारियों के लिए केवल संबंधित राज्य प्रदूषण नियंत्रण बोर्ड से एक बार का वैध प्राधिकार अपेक्षित है ; (ड) आयात किए जा रहे अपशिष्ट की रासायनिक विश्लेषण संबंधी रिपोर्ट; (च) पिछले वित्त वर्ष में आयात के लिए संबंधित राज्य प्रदूषण नियंत्रण बोर्ड को फाइल की गई वार्षिक विवरण की पावती प्रति ।

		- नियोबियम स्क्रैप - रेनियम स्क्रैप - गैलियम स्क्रैप - मैग्नीशियम स्क्रैप - तांबा स्क्रैप - क्रोमियम स्क्रैप	
2	ख1050	मिश्र अलौह धातु, हैवी फ्रैक्शन स्क्रैप जिसमें भाग ख 1050 में निर्दिष्ट धातुओं से अलग धातु मिश्रित हों और भाग ग की विशेषताओं का प्रदर्शन करने के लिए पर्याप्त सांद्रण में अनुसूची II में उल्लिखित संघटक शामिल न हों।	(क) विधिवत भरा हुआ प्ररूप 6 - संचलन दस्तावेज; (ख) जहां कहीं लागू हो, विदेश व्यापार महानिदेशालय से आयात अनुज्ञप्ति; (ग) निर्यात करने वाले देश की निरीक्षण अभिकरण या विदेश व्यापार महानिदेशालय द्वारा अनुमोदित निरीक्षण एवं प्रमाणन अभिकरण द्वारा जारी पूर्व-शिपमेंट निरीक्षण प्रमाण पत्र; (घ) वास्तविक प्रयोक्ताओं के लिए वायु तथा जल अधिनियमों के अंतर्गत कार्य करने के लिए विधि मान्य सहमति पत्र और इन नियमों के अंतर्गत प्राधिकार । व्यापारियों के लिए केवल संबंधित राज्य प्रदूषण नियंत्रण बोर्ड से एक बार का विधि मान्य प्राधिकार अपेक्षित है ; (ङ) आयात किए जा रहे अपशिष्ट की रासायनिक विश्लेषण संबंधी रिपोर्ट; (च) पिछले वित्त वर्ष में आयात के लिए संबंधित राज्य प्रदूषण नियंत्रण बोर्ड को फाइल की गई वार्षिक विवरण की पावती प्रति ।
3	ख1100	धातुओं को गलाने, प्रगलन और परिष्करण से उत्पन्न अपशिष्ट युक्त धातु - हार्ड जिंक स्पेलटर - जिंक युक्त ड्रोस : ~ गैल्वेनाइजिंग स्लैब जिंक टॉप ड्रोस (>90% जिंक) ~ गैल्वेनाइजिंग स्लैब जिंक बॉटम ड्रोस (>92% जिंक) ~ जिंक डाई कास्टिग ड्रोस (>85% जिंक) ~ हाट डिप गैल्वेनाइजर्स स्लैब जिंक ड्रोस (बैच) (>92% जिंक) ~ जिंक स्किमिंग्स - एल्युमिनियम स्कीमिंग (या स्कीम) लवण स्लैग को छोड़कर	(क) विधिवत भरा हुआ प्ररूप 6 - संचलन दस्तावेज; (ख) जहां कहीं लागू हो, विदेश व्यापार महानिदेशालय से आयात अनुज्ञप्ति; (ग) निर्यात करने वाले देश की निरीक्षण अभिकरण या विदेश व्यापार महानिदेशालय द्वारा अनुमोदित निरीक्षण एवं प्रमाणन अभिकरण द्वारा जारी पूर्व-शिपमेंट निरीक्षण प्रमाण पत्र; (घ) वास्तविक प्रयोक्ताओं के लिए वायु तथा जल अधिनियमों के अंतर्गत कार्य करने के लिए विधि मान्य सहमति पत्र और इन नियमों के अंतर्गत प्राधिकार । व्यापारियों के लिए केवल संबंधित राज्य प्रदूषण नियंत्रण बोर्ड से एक बार का वैध प्राधिकार अपेक्षित है ; (ङ) आयात किए जा रहे अपशिष्ट की रासायनिक विश्लेषण संबंधी रिपोर्ट; (च) पिछले वित्त वर्ष में आयात के लिए संबंधित राज्य प्रदूषण नियंत्रण बोर्ड को फाइल की गई वार्षिक विवरणी की पावती प्रति ।
4	ख1110	वैद्युत और इलैक्ट्रोनिक एसैम्बलीज (प्रिंटिड सर्किट बोर्ड, इलेक्ट्रॉनिक संघटक और तार सहित), जो प्रत्यक्ष पुन: प्रयोग के प्रयोजन हेतु और पुनचर्क्रण या अंतिम निपटान के लिए न हों	
(क)		प्रयुक्त वैद्युत और इलैक्ट्रोनिक एसैम्बलीज जिनका आयात मरम्मत के लिए और मरम्मत के बाद आयात के एक वर्ष के अंदर वापस निर्यात के लिए किया गया हो	(क) विधिवत भरा हुआ प्ररूप 6 - संचलन दस्तावेज; (ख) पुन: निर्यात के लिए वचन पत्र; (ग) पूववर्ती आयात का विवरण, यदि उनके पुन: निर्यात के संबंध में कोई पुष्टि हो; (घ) पिछले वित्त वर्ष में आयात के लिए संबंधित राज्य प्रदूषण नियंत्रण बोर्ड को फाइल की गई वार्षिक विवरण की पावती प्रति; (ङ) पुन: निर्यात किए जा रहे मरम्मत किए गए और मरम्मत न किए जा सकने योग्य वैद्युत तथा इलेक्ट्रांनिक एसैम्बलीज और

			कलपुर्जों या अंग या घटक या उपभोज्य वस्तुओं का ग्रहण करने के लिए निर्यात करने वाली कंपनी से प्रमाण पत्र ।
(ख)		प्रयुक्त वैद्युत और इलैक्ट्रोनिक एसैम्बलीज जिनका आयात किराए के लिए और आयात के एक वर्ष के अंदर वापस निर्यात के लिए किया गया हो	(क) विधिवत भरा हुआ प्ररूप 6 - संचलन दस्तावेज; (ख) पुन: निर्यात के लिए वचन पत्र; (ग) पूववर्ती आयात का विवरण, यदि उनके पुन: निर्यात के संबंध में कोई पुष्टि हो; (घ) पिछले वित्त वर्ष में आयात के लिए संबंधित राज्य प्रदूषण नियंत्रण बोर्ड को फाइल की गई वार्षिक विवरण की पावती प्रति ।
(ग)		प्रयुक्त वैद्युत और इलैक्ट्रोनिक एसैम्बलीज जिनका निर्यात मरम्मत के लिए और मरम्मत के बाद पुन: आयात के लिए किया गया हो	(क) विधिवत भरा हुआ प्ररूप 6 - संचलन दस्तावेज; (ख) त्रुटिपूर्ण वैद्युत और इलेक्ट्रॉनिक एसैम्बलीज के निर्यात का प्रमाण अर्थात् सीमा शुल्क प्राधिकरण द्वारा अधिप्रमाणित शिपिंग या वायु मार्ग संबंधी दस्तावेज ।
(घ)		प्रयुक्त वैद्युत और इलैक्ट्रोनिक एसैम्बलीज जिनका आयात परीक्षण, अनुसंधान एवं विकास, परियोजना कार्य उद्देश्यों और आयात की तारीख से तीन वर्षों की अवधि के अंदर वापस पुन: निर्यात करने के लिए किया गया हो	(क) विधिवत भरा हुआ प्ररूप 6 - संचलन दस्तावेज; (ख) पुन: निर्यात के लिए वचन पत्र; (ग) पूववर्ती आयात का विवरण, यदि उनके पुन: निर्यात के संबंध में कोई पुष्टि हो; (घ) निर्यात करने वाले देश की अधिकृत अभिकरण से चार्टर्ड इंजीनियर प्रमाण पत्र या प्रमाण पत्र जिसमें कार्यशीलता, विनिर्माण की तारीख, अवशिष्ट काल और क्रम संख्या लिखी गई हो; (ङ) पिछले वित्त वर्ष में आयात के लिए संबंधित राज्य प्रदूषण नियंत्रण बोर्ड को फाइल की गई वार्षिक विवरण की पावती प्रति; (च) तीन वर्ष के अंत में पुन: निर्यात किए जा रहे पुराने कार्यशील या अकार्यशील वैद्युत तथा इलेक्ट्रांनिक एसैम्बलीज और/या कलपुर्जों या अंग या घटक या उपभोज्य वस्तुओं का ग्रहण करने के लिए निर्यात करने वाली कंपनी से प्रमाण पत्र ।
(ङ)		वारंटी पुन:स्थापनों के लिए आयातित कलपुर्जे परंतु यह कि सामान संख्या में खराब या अकार्यशील पुर्जे आयात के एक वर्ष की अवधि के अंदर वापस निर्यात किए जा रहे हों	(क) विधिवत भरा हुआ प्ररूप 6 - संचलन दस्तावेज; (ख) यदि खराब संघटक के स्थान पर प्रतिस्थापन के रूप में नवीकृत संघटकों आयात किया जा रहा हो तो समतुल्य संख्या के खराब संघटकों के आयात हेतु वचन पत्र; (ग) पूववर्ती आयात का विवरण, यदि उनके पुन: निर्यात के संबंध में कोई पुष्टि हो; (घ) पुन: निर्यात किए जा रहे खराब या अकार्यशील और कलपुर्जों या अंग या घटक या उपभोज्य वस्तुओं का ग्रहण करने के लिए निर्यात करने वाली कंपनी से प्रमाण पत्र; (ङ) वारंटी अवधि के दौरान वैद्युत तथा इलैक्ट्रांनिक की मरम्मत के लिए पुराने या नवीकृत कलपुर्जों के प्रयोग के संबंध में घोषित नीति संबंधी दस्तावेज ।
(च)		रक्षा मंत्रालय, अंतरिक्ष विभाग और परमाणु ऊर्जा विभाग द्वारा आयात की गई प्रयुक्त वैद्युत और इलैक्ट्रोनिक एसैम्बलीज	---
(छ)		प्रयुक्त वैद्युत और इलैक्ट्रोनिक एसैम्बलीज (भारी संख्या में नहीं; संख्या तीन या इससे कम) जिनका आयात व्यक्तियों के लिए अपने निजी प्रयोगों के लिए किया गया हो	---
(ज)		प्रयुक्त लैपटॉप, पर्सनल कंप्यूटर, मोबाईल, टैबलेट प्रत्येक में से तीन जिसका आयात संघटनों द्वारा एक वर्ष के अंदर किया जाता हो	---
(झ)		एकल व्यक्तियों के स्वामित्व और आवास के स्थानांतरण पर आयातित प्रयुक्त वैद्युत और इलैक्ट्रोनिक एसैम्बलीज	सीमा शुल्क प्राधिकरण के विद्यमान मार्ग निर्देशों के अनुसार

(ञ)		प्रयुक्त वैद्युत और इलैक्ट्रोनिक एसैम्बलीज जिनका आयात एअरलाइनों द्वारा एअर क्राफ्टों के अनुरक्षण के लिए किया गया हो और उन्हें जहाज पर या सीमा शुल्क बंधित क्षेत्रों के एअर साइड पर स्थित संबंधी एअर लाइन भंडारणों में रखा गया हो	---
(ट)		प्रयुक्त मल्टी फंक्शन प्रिंट और कॉपी करने की मशीनें (एमएफडी)*	(क) लदान और पैकेजिंग के बिल सहित मूल देश का प्रमाण पत्र ; (ख) कम से कम पांच वर्षों के अवशेष कार्यकाल और क्रम संख्या वाली वस्तुओं की कार्यशीलता के लिए निरीक्षण अभिकरण द्वारा जारी और निर्यात करने वाले देश या विदेश व्यापार महानिदेशालय द्वारा अनुमोदित निरीक्षण एवं प्रमाणन अभिकरण से प्रमाणित प्रमाण पत्र; (ग) उत्पादक के रूप में समय समय पर यथा संशोधित ई-अपशिष्ट (प्रबंधन एवं प्रहस्तन) नियम, 2011 के अंतर्गत विस्तारित उत्पादक दायित्व - प्राधिकार; (घ) एमएफडी ए3 और इससे बढ़े आकार की प्रिंटिंग के लिए होगा; (ङ) पिछले वित्त वर्ष में आयात के लिए संबंधित राज्य प्रदूषण नियंत्रण बोर्ड को फाइल की गई वार्षिक विवरण की पावती प्रति।
5	ख3020	पेपर, पेपर बोर्ड और पेपर उत्पाद अपशिष्ट निम्नलिखित सामग्री, बशर्ते उन्हें खतरनाक अपशिष्टों में नहीं मिलाया गया है : निम्नलिखित के पेपर अपशिष्ट और पेपर या पेपर बोर्ड स्क्रैप: - अविरंजित पेपर या पेपर बोर्ड या लहरदार पेपर या पेपर बोर्ड - अन्य पेपर या पेपर बोर्ड मुख्यत: रंजित रसायन लुगदी से बने, व्यापक रुप से रंगा न गया हो - मुख्यत: यांत्रिक लुगदी (उदाहरणार्थ समाचार पत्र, पत्रिका और ऐसे ही मुद्रित सामग्री) से बना पेपर या पेपर बोर्ड - अन्य, किंतु उन तक सीमित नहीं 1) लेमिनेटिड पेपर बोर्ड, 2) अवर्गीकृत स्क्रैप	(क) विधिवत भरा हुआ प्ररूप 6 - संचलन दस्तावेज; (ख) विदेश व्यापार महानिदेशालय से आयात अनुज्ञप्ति, जहां कहीं प्रयोज्य हो; (ग) निर्यात करने वाले देश की निरीक्षण अभिकरण या विदेश व्यापार महानिदेशालय द्वारा अनुमोदित निरीक्षण एवं प्रमाणन अभिकरण द्वारा जारी पूर्व-शिपमेंट निरीक्षण प्रमाण पत्र; घ) वास्तविक प्रयोक्ताओं के लिए इन नियमों के अंतर्गत कार्य करने के लिए विधि मान्य सहमति पत्र। व्यापारियों के लिए केवल संबंधित राज्य प्रदूषण नियंत्रण बोर्ड से एक बार का वैध प्राधिकार अपेक्षित है; (ङ) आयात किए जा रहे अपशिष्ट की रासायनिक विश्लेषण संबंधी रिपोर्ट; (च) पिछले वित्त वर्ष में आयात के लिए संबंधित राज्य प्रदूषण नियंत्रण बोर्ड को फाइल की गई वार्षिक विवरणी की पावती प्रति ।
6	ख3140	एअर क्राफ्टों के अनुरक्षण के लिए एअरलाइनों द्वारा रिट्रिडिंग के लिए आयात किए गए और रिट्रिडिंग के बाद पुन: निर्यात किए जाने के लिए मूल उपकरण विनिर्माताओं को निर्यात किए गए एअरक्राफ्ट टायर और उन्हें जहाज पर या सीमा शुल्क बंधित क्षेत्रों के एअर साइड पर स्थित संबंधी एअर लाइन भंडारणों में रखा गया हो	सीमा शुल्क प्राधिकरण के विद्यमान मार्ग निर्देशों के अनुसार

*** टिप्पणी** एमएफडी के स्वदेशी रूप से निर्माण हो जाने पर मल्टी फंक्शन प्रिंट और कॉपी करने की मशीन के लिए मुक्त व्यापार की नीति की समीक्षा की जाएगी।

प्ररुप 1

[नियम 6(1) देखें]

परिसंकटमय और अन्य अपशिष्ट के संग्रहण/परिवहन/ग्रहण/भंडारण/पुनर्चक्रण/पुन: प्रसंस्करण/शोधन/ निस्तारण/आयात/ निर्यात के लिए प्राधिकार प्रदान/नवीकरण के लिए अपेक्षित आवेदन

भाग क : सामान्य (सभी के द्वारा भरा जाए)

1. (क) इकाई का नाम और पता और प्रसुविधा का अवस्थान :

(ख) प्रसुविधा के अधिभोगी या निस्तारण सुविधा के प्रचालक का नाम और पदनाम, टेलीफोन, फैक्स और ई-मेल सहित

(ग) जिसके लिए प्राधिकार अपेक्षित हो (कृपया समुचित क्रियाकलाप(पों) को इंगित करें)

(i)	उत्पादन	☐
(ii)	संग्रहण	☐
(iii)	भंडारण	☐
(iv)	परिवहन	☐
(v)	ग्रहण	☐
(vi)	पुन: प्रयोग	☐
(vii)	पुनर्चक्रण	☐
(viii)	पुन: प्राप्ति	☐
(ix)	पूर्व प्रसंस्करण	☐
(x)	सहप्रसंस्करण	☐
(xi)	उपयोग	☐
(xii)	शोधन	☐
(xiii)	निस्तारण	☐
(xiv)	भस्मीकरण	☐

(घ) प्राधिकार के नवीनीकरण के मामले में पूर्व प्राधिकार संख्या और तारीख और पूर्व की पर्यावरणीय स्वीकृत की शर्तों, जहां कहीं लागू हो, के संबंध में अनुपालन रिपोर्टों सहित पिछले तीन वर्षों की वार्षिक विवरणियों की प्रतियां उपलब्ध कराएं :

2. (क) प्रतिवर्ष प्रहस्तन किए जाने वो अपशिष्ट की प्रकृति और मात्रा (मीट्रिक टन या किलो लीटर में)

(ख) किसी भी समय भंडारित अपशिष्ट की प्रकृति और मात्रा (मीट्रिक टन या किलो लीटर में)

3. (क) उत्पादन की कमीशिनिंग और उत्पादन का वर्ष :

(ख) उद्योग में कार्य होते हैं :

(i)	01 शिफ्ट	☐
(ii)	02 शिफ्ट	☐
(iii)	चौबीसों घंटे	☐

4. आपात-कालीन प्रतिक्रिया योजना (ईआरपी) की प्रति उपलब्ध कराएं जिसमें केन्द्रीय प्रदूषण नियंत्रण बोर्ड के मार्गदर्शक सिद्धांतों में यथा विनिर्दिष्ट आपात स्थितियों (अर्थात्) छलकना या रिसाव होना या आग लगना) स्थितियों से निपटने के लिए प्रक्रियाओं का निराकरण किया गया हो। ऐसे ईआरपी में निम्नलिखित, किंतु इन तक सीमित नहीं, शामिल नहीं होंगे :

- घटनाओं को सीमित और नियंत्रित करना ताकि प्रभावों को न्यूनतम किया जा सके और लोगों, पर्यावरण और संपत्ति के समक्ष उत्पनन होने वाले खतरे को सीमित किया जा सके;
- लोगों पर पर्यावरण के संरक्षण के लिए आवश्यक उपायों का क्रियान्वयन करना;
- उपलब्ध सुरक्षा उपकरणों और संसाधनों के विवरण सहित घटनाओं की स्थितियों और उनके परिणामों को नियंत्रित करने के लिए की जाने वाली अपेक्षित कार्रवाहियों का विवरण;
- स्टाफ द्वारा किए जाने वाले अपेक्षित कर्त्तव्यों में उनके प्रशिक्षण की व्यवस्था;

• संबंधित प्राधिकारियों और आपात सेवाओं को सूचित किए जाने की व्यवस्था; और

• आफ साइट उपशमन में सहायता प्रदान करने की व्यवस्था।

5. परिसंकटमय और अन्य अपशिष्टों के प्रहस्तन के दौरान उनके बिखरने, रिसाव या आग लगने की स्थिति में बैंक गारंटी प्रस्तुत करने की गुजाइश सहित सभी प्रावधानों का अनुपालन करने के संबंध में वचनबंध या घोषणा उपलब्ध कराएं।

भाग ख : परिसंकटमय अपशिष्ट के उत्पन्नकर्ताओं के द्वारा भरा जाए

1. (क) विनिर्मित उत्पाद और सहउत्पाद (नाम और प्रतिवर्ष उत्पादवार मात्रा) :

(ख) इनपुट और आउटपुट दर्शाते हुए प्रक्रिया फ्लोशीट सहित प्रक्रिया का विवरण (कच्ची सामग्रियां, रसायन, उत्पाद, सहउत्पाद, अपशिष्ट, उत्सर्जन, मलजल इत्यादि)। कृपया अलग से शीट संलग्न करें :

(ग) प्रतिवर्ष उत्पन्न अपशिष्ट की विशेषताएं (अपशिष्टवार) और मात्रा

(घ) उपर्युक्त (ग) के प्रबंधन की पद्धति :

I. संयंत्र के अंदर प्रतिभूत भंडारण की क्षमता और पद्धति;

II. संयंत्र के अंदर उपयोग (विवरण उपलब्ध कराएं);

III. यदि संयंत्र के अंदर उपयोग में न लाया जाता हो तो कृपया विवरण दें कि इस अपशिष्ट का क्या किया जाता है;

IV. वास्तविक प्रयोक्ताओं/ टीएसडीएफ को परिवहन की व्यवस्था ।

(ड़) उपर्युक्त बिंदु (ग) के सभी अपशिष्टों के सुरक्षित प्रहस्तन के लिए उपलब्ध कराए गए पर्यावरण सुरक्षा उपायों और पर्यावरण सुविधाओं का विवरण:

2. परिसंकटमय रसायन का विनिर्माण, भंडारण और आयात नियम 1989 के अधीन यथापरिभाषित परिसंकटमय रसायनों के भंडारण से इन नियमों के अनुसार उत्पन्न परिसंकटमय और अन्य अपशिष्ट

भाग ग : शोधन, भंडारण और निस्तारण सुविधा के प्रचालकों द्वारा भरा जाए

1. निम्नलिखित सहित सुविधा का विवरण उपलब्ध कराएं :

(i) स्थान की अवस्थिति, ले-आउट सहित नक्शा उपलब्ध कराएं;

(ii) अपशिष्ट का सुरक्षित भंडारण और भंडारण क्षमता;

(iii) शोधन प्रक्रियाएं और उनकी क्षमताएं;

(iv) प्रतिभूत खत्ता स्थल;

(v) भस्मीकरण, यदि कोई हो;

(vi) लीचेट संग्रहण और शोधन प्रणाली;

(vii) अग्नि शमन प्रणालियां;

(viii) निगरानी सहित पर्यावरण प्रबंधन योजना; और

(ix) उत्पन्नकर्ताओं से अपशिष्ट का परिवहन करने की व्यवस्था ।

2. शोधन, भंडारण और निस्तारण सुविधा स्थल पर किए जाने वाले किसी अन्य कार्यकलाप का विवरण उपलब्ध कराएं।

3. पर्यावरण पूर्वानुमति की प्रति संलग्न करें।

भाग घ : परिसंकटमय या अन्य अपशिष्टों के पुन:चक्रणकर्ताओं या पूर्व-प्रसंस्करणकर्ताओं या सह प्रसंस्करणकर्ताओं या प्रयोक्ताओं द्वारा भरा जाए

1. स्वदेशी या आयात अथवा दोनों स्रोतों से प्रतिवर्ष प्राप्त विभिन्न अपशिष्टों की प्रकृति और मात्रा :

2. जिला उद्योग केन्द्र या किसी अन्य प्राधिकृत सरकारी अभिकरण द्वारा जारी पंजीकरण के अनुसार संस्थापित क्षमता :

3. भंडारण क्षमता सहित अपशिष्टों के प्रतिभूत भंडारण का विवरण उपलब्ध कराएं :

4. इनपुट और आउटपुट दर्शाते हुए प्रक्रिया फ्लोशीट सहित प्रक्रिया का विवरण (इनपुट अपशिष्ट रसायन, उत्पाद, सहउत्पाद, उत्पन्न अपशिष्ट, उत्सर्जन, मलजल इत्यादि)। कृपया अलग से शीट संलग्न करें :

5. उत्पादों या सहउत्पादों के अंतिम प्रयोक्ताओं का विवरण उपलब्ध कराएं:

6. अपशिष्ट की निस्तारण की पद्धति सहित बहिस्राव शोधन संयंत्र, स्क्रबर इत्यादि जैसी प्रदूषण नियंत्रण प्रणालियों का विवरण उपलब्ध कराएं :

7. वृतिक स्वास्थ्य और सुरक्षा उपायों का विवरण उपलब्ध कराएं :

8. क्या सुविधा की संस्थापना केन्द्रीय प्रदूषण नियंत्रण बोर्ड के मार्गदर्शक सिद्धांतों के अनुरूप की गई है? यदि हां तो इन मार्गदर्शक सिद्धांतों के अनुपालन संबंधी रिपोर्ट उपलब्ध कराएं :

9. प्रसुविधा तक अपशिष्ट के परिवहन की व्यवस्था:

आवेदक के हस्ताक्षर

तारीख .... पदनाम

स्थान ....

प्ररूप 2

[नियम 6(2) देखें]

राज्य प्रदूषण नियंत्रण बोर्ड द्वारा अधिभोगियों, पुन:त्र्रकणकर्ताओं, पुन: प्रसंस्करणकर्ताओं, पुन:प्रयोक्ताओं, प्रयोक्ताओं और निस्तारण सुविधाओं के प्रचालकों के प्राधिकार की मंजूरी या नवीनीकरण का प्ररुप

1. प्राधिकार की संख्या और जारी करने की तारीख :
2. आवेदन का संदर्भ (संख्या और तारीख)
3. ....के...........को ....में स्थित परिसर में परिसंकटमय या अन्य अपशिष्ट के उत्पादन, संग्रहण, ग्रहण भंडारण, परिवहन, पुन: प्रयोग, पुन:त्र्रकण, पुन: प्राप्ति, पूर्व प्रसंस्करण, सह प्रसंस्करण, उपयोग, शोधन निस्तारण या किसी अन्य प्रयोग के लिए संलग्न हस्ताक्षरित निरीक्षण रिपोर्ट के आधार एतदद्वारा प्राधिकार की मंजूरी दी जाती है।

प्राधिकार का विवरण

क्र.सं.	इन नियमों की अनुसूचियों I, II और III के अनुसार परिसंकटमय अपशिष्ट की श्रेणी	निस्तारण या पुन:त्र्रकण या उपयोग या सह प्रसंस्करण इत्यादि की प्राधिकृत पद्धति	मात्रा टन/वर्ष

(1) प्राधिकार .... की अवधि के लिए विधि मान्य होगा।

(2) प्राधिकार निम्नलिखित सामान्य और विशिष्ट शर्तों के अध्यधीन होगा। (कृपया सामान्य शर्तों के अतिरिक्त लगाई जाने वाली किन्ही आवश्यक विशिष्ट शर्तों, यदि कोई हों, को स्पष्ट करें:

प्राधिकार की सामान्य शर्तें :

1. प्राधिकृत व्यक्ति पर्यावरण (संरक्षण) अधिनियम, 1986 और उसके अंतर्गत बनाए गए नियमों के उपबंधों का अनुपालन करेगा।

2. प्राधिकार या उसका नवीनीकरण राज्य प्रदूषण नियंत्रण बोर्ड द्वारा प्राधिकृत अधिकारी के अनुरोध पर निरीक्षण के लिए प्रस्तुत किया जाएगा।

3. प्राधिकृत व्यक्ति उसे प्राधिकार के माध्यम से अनुज्ञेय को छोड़कर परिसंकटमय और अन्य अपशिष्टों को किराए पर नहीं देगा, उधार नहीं देगा, विक्रय नहीं करेगा, अंतरण नहीं करेगा या अन्यथा परिवहन नहीं करेगा।

4. प्राधिकृत व्यक्ति द्वारा आवेदन में यथा उल्लिखित कार्मिकों, उपकरणों या कार्यदशाओं में अप्राधिकृत परिवर्तन उसके प्राधिकार के भंग का कारक होगा।

5. प्राधिकृत व्यक्ति बिखराव, रिसाव, आग इत्यादि जैसे सभी प्रकार के स्थल विशिष्ट संभावित दृश्यों और उनके संभावित प्रभावों पर विचार करते हुए आपात कार्यवाही प्रक्रिया (ईआरपी) क्रियान्वित करेगा जिसके लिए यह प्राधिकार प्रदान किया जा रहा है और साथ ही नियमित समय अंतराल पर इस संबंध में मॉक ड्रिल करेगा।

6. प्राधिकृत व्यक्ति 'परिसंकटमय अपशिष्ट के हथालन तथा निस्तारण के कारण होने वाली पर्यावरणीय क्षति के लिए कार्यान्वयन दायित्व और दंड' के संबंध में केन्द्रीय प्रदूषण नियंत्रण बोर्ड के मार्गदर्शक सिद्धांतों में रेखांकित किए गए उपबंधों का अनुपालन करेगा।

7. प्राधिकृत व्यक्ति का यह कर्तव्य होगा कि वह प्रसुविधा बंद करने हेतु राज्य प्रदूषण नियंत्रण बोर्ड की पूर्वानुमति प्राप्त करे।

8. आयातित परिसंकटमय और अन्य अपशिष्ट का अभिवहन और किसी आकस्मिक दुर्घटना तथा उसकी निकासी संक्रिया के लिए पूर्ण रूप से बीमा किया जाएगा।

9. आयातित परिसंकटमय और अन्य अपशिष्ट की खपत के अभिलेख का रखरखाव किया जाएगा ।

10. आयातित परिसंकटमय या अन्य अपशिष्टों के पुन:चक्रण या पुन: प्रयोग या पुन: प्राप्ति या पुन: प्रसंस्करण या पुन: उपयोग के दौरान उत्पन्न होने वाले परिसंकटमय और अन्य अपशिष्ट का शोधन और निस्तारण प्राधिकार की विशिष्ट शर्तों के अनुरूप किया जाएगा ।

11. आयातकर्ता या निर्यातकर्ता आयात या निर्यात और क्षति, यदि कोई हो, के न्यूनीकरण, का खर्च वहन करेगा।

12. प्राधिकार के नवीनीकरण के लिए कोई आवेदन इन नियमों के अंतर्गत अधिकथित के अनुसार किया जाएगा।

13. पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय या केन्द्रीय प्रदूषण नियंत्रण बोर्ड द्वारा समय-समय पर जारी मार्गदर्शक सिद्धांतों के अनुसार अनुपालन के लिए कोई अन्य शर्तें।

14. वार्षिक विवरणी वर्ष के 31 मार्च की अवधि को सुनिश्चित करते हुए 30 जून तक दर्ज की जाएगी।

ख. विशिष्ट शर्तें:

तारीख :

जारी करने वाले प्राधिकारी के हस्ताक्षर
पदनाम और मुद्रा

प्ररुप 3

[नियम 6 (5), 13(7),14(6),16(5) और 20(1) देखें]

परिसंकटमय और अन्य अपशिष्टों के अभिलेख के रखरखाव हेतु प्रारुप

1. प्रसुविधा का नाम और पता :

2. प्राधिकार जारी किए जाने की तारीख और उसकी संदर्भ संख्या :

3. प्रहस्तन किए गए (उत्पन्न या प्राप्त) परिसंकटमय और अन्य अपशिष्टों का वर्णन :

तारीख	**इन नियमों की अनुसूचियों I, II और III के अनुसार श्रेणी सहित अपशिष्ट का प्रकार**	**कुल मात्रा (मीट्रिक टन)**	**भंडारण की प्रगति**	**गंतव्य स्थान या जहां से प्राप्त हुआ है**

** उपर्युक्त तालिका को स्वदेशी और आयातित अपशिष्ट के लिए अलग-अलग भरें।*

4. भेजे गए उत्पादों सहित परिसंकटमय और अन्य अपशिष्टों के प्रबंधन और पुनर्चक्रणकर्ता या पूर्व प्रसंस्करणकर्ता और प्रयोक्ता के मामले में किसे भेजा गया, का तारीखवार विवरण :

5. पर्यावरणीय निगरानी की तारीख (प्राधिकार या केन्द्रीय प्रदूषण नियंत्रण बोर्ड के मार्गनिर्देशों के अनुसार)

अधिभोगी के हस्ताक्षर

तारीख ....
स्थान ....

प्ररूप 4

[नियम 6 (5), 13(8), 16(6) और 20 (2)]

वार्षिक विवरणियां फाइल करने के लिए प्रारूप

[अप्रैल से मार्च की पूर्ववर्ती अवधि के लिए प्रत्येक वर्ष के 30 जून तक राज्य प्रदूषण नियंत्रण बोर्ड को प्रस्तुत किया जाए]

1. प्रसुविधा का नाम और पता :

2. प्राधिकार संख्या और जारी करने की तारीख :

3. प्राधिकृत व्यक्ति का नाम, टेलीफोन, फैक्स नम्बर और ई-मेल सहित पूरा पता :

4. वर्ष के दौरान उत्पादन (उत्पादवार) जहां कहीं प्रयोज्य हो

भाग क. परिसंकटमय अपशिष्ट के उत्पन्नकर्ता के द्वारा भरा जाए

1. उत्पन्न अपशिष्ट की श्रेणीवार कुल मात्रा

2. प्रेषित की गई मात्रा

(i) निपटान सुविधा को

(ii) पुन:चक्रणकर्ता या सह-प्रसंस्करणकर्ता या पूर्व प्रसंस्करणकर्ता को

(iii) अन्य

3. आंतरिक रूप से उपयोग में लाई गई मात्रा, यदि कोई हो

4. वर्ष के अंत में भंडारित मात्रा-

भाग ख. शोधन, भंडारण और निपटान सुविधा के प्रचालकों द्वारा भरा जाए

1. प्राप्त की गई कुल मात्रा-

2. वर्ष के प्रारंभ में भंडार में मात्रा-

3. शोधित मात्रा-
4. खत्ता स्थलों में निस्तारित और शोधन के पश्चात मात्रा-

5. भस्मीकरण की गई मात्रा (यदि लागू हो)-

6. ऊपर विनिर्दिष्ट से अलग प्रसंस्करण की गई मात्रा-

7. वर्ष के अंत में भंडारित मात्रा-

भाग ग. पुन:चक्रणकर्ताओं या सह-प्रसंस्करणकर्ताओं या अन्य प्रयोक्ताओं द्वारा भरा जाए

1. वर्ष के दौरान प्राप्त अपशिष्ट की मात्रा-

(i) घरेलू स्रोत

(ii) आयातित (यदि लागू हो)

2. वर्ष के प्रारंभ में भंडार में मात्रा-

3. पुनर्चक्रित की गई या सह-प्रसंस्करण की गई या प्रयुक्त मात्रा-
4. प्रेषण किए गए उत्पादों की मात्रा (जहां कहीं लागू हो)-

5. उत्पन्न अपशिष्ट की मात्रा-

6. निस्तारित अपशिष्ट की मात्रा-

7. पुन: निर्यात की गई मात्रा (जहां कहीं लागू हो)-

8. वर्ष के अंत में भंडारित मात्रा-

तारीख .....
स्थान .....

अधिभोगी या निपटान सुविधा
के प्रचालक के हस्ताक्षर :

प्ररुप 5

[नियम 13(1) और 14(1) देखें]

पुनर्प्रयोग या पुनर्चक्रण या पुन: प्राप्ति या सह-प्रसंस्करण या उपयोग के लिए परिसंकटमय और अन्य अपशिष्ट के आयात या निर्यात के लिए आवेदन

आवेदक द्वारा भरा जाए

क्र.सं.	**विवरण**	**आयातक या निर्यातक द्वारा दिया जाने वाला विवरण**
(1)	**(2)**	**(3)**
1.	भारत में आयातकर्ता या निर्यातकर्ता (नाम और पता)	
	संपर्क व्यक्ति	
	टेलीफोन,फैक्स और ई-मेल	
	सुविधा का स्थान/पता	
	आयात या निर्यात का कारण	
2.	भारत के बाहर आयातकर्ता या निर्यातकर्ता (नाम और पता)	
3.	आयात या निर्यात किए जाने वाले अपशिष्ट का विवरण	
	(क) मात्रा (ख) बेसल सं. (ग) एकल/बहु संचलन (घ) अपशिष्ट का रासायनिक संघटन (विवरण संलग्न करें, जहां लागू हो) (ड.) भौतिक विशेषताएं (च) विशेष प्रहस्तन अपेक्षाएं, यदि लागू हों	
4.	अनुसूची ।।।क के परिसंकटमय अपशिष्ट के लिए क्या पूर्व सूचित सहमति प्राप्त की गई है	
5.	**आयातकर्ता के लिए** (क) पर्यावरणीय सुरक्षोपायों सहित प्रक्रिया का विवरण (अलग से शीट	

	संलग्न करें) (ख) पुनर्चक्रण या सह-प्रसंस्करण या पुन: प्राप्ति या उपयोग की क्षमता **राज्य प्रदूषण नियंत्रण बोर्ड से विधि मान्य प्राधिकार और प्रचालन की वैध सहमति में से प्रत्येक की प्रति संलग्न करें।**	
6.	पिछले तीन वर्षों में पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय की अनुमति के प्रति आयात का विवरण	
7.	प्रवेश का बंदरगाह	

8. वचन बंध

मैं सत्यानिष्ठा से घोषणा करता हूं कि :

(i) दी गई जानकारी मेरे सर्वोत्तम ज्ञान के अनुसार पूर्ण और सही है और विधिक रूप से प्रवर्तनीय लिखित बाध्यताओं के संबंध में करार कर लिया गया है कि और यह कि कोई लागू बीमा अथवा अन्य वित्तीय प्रतिभूतियां सीमापार संचलन को शामिल करते हुए लागू हैं या लागू रहेंगी।

(ii) अनुज्ञात अपशिष्ट का अभिवहन और किसी आकस्मिक दुर्घटना तथा उसकी निकासी संक्रिया के लिए पूर्ण रूप से बीमा किया जाएगा।

(iii) आयातित अपशिष्ट की खपत और अंतिम दशा का अभिलेखन किया जाएगा और प्रत्येक तिमाही में राज्य प्रदूषण नियंत्रण बोर्ड को उसकी रिपोर्ट भेजी जाएगी।

(iv) ऐसे परिसंकटमय अपशिष्ट, जो कच्ची सामग्री के रूप में आयातित परिसंकटमय अपशिष्ट के उपयोग से हमारे परिसर में उत्पन्न होता है, का शोधन और निपटान प्राधिकार की शर्तों के अनुसार किया जाएगा।

(v) मैं निर्यात और नुकसान, यदि कोई हो के न्यूनीकरण का खर्च वहन करने की सहमति देता हूं।

(vi) मुझे इस बात की जानकारी है कि मिथ्या प्रमाण पत्र/वचनबंध देने/इन नियमों और विधिपूर्ण आदेशों का अनुपालन न करने के लिए विशेष शास्तियों की व्यवस्था है, जिसके अंतर्गत जुर्माने और कारावास की संभावना भी है।

(vii) यदि आयातकर्ता को स्वीकार्य न हो तो निर्यात किए गए अपशिष्ट वापस ले लिए जाएंगे।

आवेदक के हस्ताक्षर
पदनाम

तारीख .....

स्थान.....

प्ररुप 6

[नियम 13(2), 13(10) और 14(5)देखें]

सीमापार संचालन - संचलन दस्तावेज

क्र.सं.	**विवरण**		**निर्यातक/आयातक द्वारा दिए जाने वाला विवरण**
1	निर्यातकर्ता (नाम और पता) संपर्क व्यक्ति टेलीफोन,फैक्स और ई-मेल	:	
2.	अपशिष्ट उत्पन्नकर्ता (नाम और पता): संपर्क व्यक्ति टेलीफोन,फैक्स और ई-मेल	:	
	उत्पत्ति स्थल	:	

3.	आयातकर्ता या वास्तविक प्रयोक्ता (नाम और पता) संपर्क व्यक्ति टेलीफोन,फैक्स और ई-मेल	: : :	
4.	व्यापारी (नाम और पता) संपर्क व्यक्ति टेलीफोन,फैक्स और ई-मेल		
	वास्तविक प्रयोक्ता का विवरण (नाम, पता, टेलीफोन और ई-मेल)		
5.	आवेदक की संदर्भ संख्या (यदि कोई हो)	:	
6.	लदान पत्र (प्रतिलिपि संलग्न करें)	:	
7.	आयात/निर्यात का देश		
8.	अपशिष्ट का सामान्य विवरण		
	(क) मात्रा (ख) भौतिक विशेषताएं (ग) अपशिष्ट का रासायनिक संघटन, जहां लागू हो विवरण संलग्न करें (घ) बेसल सं. (ड.) यूएन पोत परिवहन सं. (च) यूएन वर्ग (छ) यूएन सं. (ज) एच संख्या (झ) वाई संख्या (ञ) आईटीसी (एचएस) (ट) सीमाशुल्क कोड (एच.एस.) (ठ) अन्य (विशेष ब्यौरा दें)		
9.	पैकेजों का प्रकार		
	संख्या		
10.	दुर्घटनाओं की स्थिति में आपात प्रावधान सहित विशेष प्रहस्तन अपेक्षाएं		
11.	एकल/बहु पारेषण के अध्यधीन संचलन		
	बहु संचलन की स्थिति में - (क) प्रत्येक पारेषण की संभावित तारीख या पारेषणों की बारंबारता (ख) अनुमानित कुल मात्रा और प्रत्येक पारेषण की मात्रा		
12.	अपशिष्ट का परिवाहक (नाम और पता)[1] संपर्क व्यक्ति टेलीफोन, फैक्स और ई-मेल		
	पंजीकरण संख्या		
	परिवहन का साधन (सड़क, रेल, अंतर्देशीय जल मार्ग, समुद्र, वायु)[2]		
	अंतरण की तारीख		
	वाहक के प्रतिनिधि के हस्ताक्षर		
13.	**परिसंकटमय और अन्य अपशिष्ट के लिए निर्यातक की घोषणा :**		

	मैं प्रमाणित करता हूं कि ऊपर क्र.सं.1 से 12 तक दी गई जानकारी मेरे सर्वोत्तम ज्ञान के अनुसार पूर्ण और सही है। मैं यह भी प्रमाणित करता हूं कि विधिक रूप से प्रवर्तनीय लिखित बाध्यताओं की बाबत यह करार कर लिया गया है कि कोई लागू बीमा या अन्य वित्तीय प्रतिभूतियां सीमापार पारगमन को शामिल करते हुए लागू रहेंगी। तारीख :..... हस्ताक्षर :..... नाम :.....		
आयातकर्ता (वास्तविक प्रयोक्ता या व्यापारी) द्वारा भरा जाए			
14.	आयातकर्ता/वास्तविक प्रयोक्ता/व्यापारी[2/3] द्वारा प्राप्त माल		
	प्राप्त मात्रा .....कि.ग्रा./ली. तारीख : नाम : हस्ताक्षर:		
15.	पुन: प्राप्ति की पद्धतियां		
	आर कोड* प्रयुक्त प्राद्योगिकी (विवरण संलग्न करें, यदि आवश्यक हो)		
16.	मैं यह प्रमाणित करता हूं कि इन नियमों के तहत शामिल घोषित माल के अलावा उपर्युक्त प्रेषित माल में अन्य कुछ भी आयातित और पुन: चक्रित नहीं किया जाएगा। हस्ताक्षर : तारीख :		
17.	संचलन सहमति के लिए विशिष्ट शर्तें, यदि लागू हों		(विवरण संलग्न करें)
नोट :-(1) सूची संलग्न करें, यदि एक से अधिक हो; (2) उपयुक्त विकल्प चुने; (3) आपात स्थिति में तत्काल सक्षम प्राधिकारी से संपर्क करें; (4) यदि वाहक एक से अधिक हो, तो क्र.सं.12 में विदित सूचना दें।			

संचलन प्रलेख में प्रयुक्त लघु रूपों की सूची

पुन: प्राप्ति संक्रियाएं (*)

आर1 ईंधन (प्रत्यक्ष भस्मीकरण से भिन्न) या ऊर्जा उत्पादन के अन्य साधनों के रूप में प्रयोग।

आर2 विलायक का उद्धरण/पुनरूत्पादन।

आर3 ऐसे कार्बनिक पदार्थों का पुनर्चक्रण/उद्धरण, जो विलायक के रूप में प्रयुक्त नहीं हुए हैं।

आर4 धातुओं और धातु सम्मिश्रणों का पुनर्चक्रण/उद्धरण।

आर5 अन्य अकार्बनिक पदार्थों का पुनर्चक्रण/उद्धरण ।

आर6 अम्ल और क्षारों का पुनरूत्पादन ।

आर7 प्रदूषण उपशमन के लिए प्रयुक्त संघटकों की पुन: प्राप्ति ।

आर8 उत्प्रेरकों से संघटकों की पुन: प्राप्ति ।

आर9 प्रयुक्त तेल का पुन:परिशोधन या पहले प्रयुक्त तेल के अन्य पुनरूपयोग।

आर10 भूमि उपचार जिसके परिणामस्वरूप कृषि या परिस्थितिकीय सुधार का फायदा।

आर11 सं. आर 1 से आर 10 तक की किसी भी संक्रिया से प्राप्त अवशिष्ट सामग्रियों का प्रयोग।

तारीख: हस्ताक्षर:
स्थान : पदनाम :

प्ररूप 7

[नियम 13(2)(ग) देखें]

अनुसूची III के भाग घ के अपशिष्ट के लिए व्यापारियों के एकबारगी प्राधिकार के लिए आवेदन पत्र का प्ररूप

(व्यापारी द्वारा राज्य प्रदूषण नियंत्रण बोर्ड को प्रस्तुत किया जाए)

1.	व्यापारी का नाम और पता, टेलीफोन, फैक्स संख्या और ई-मेल सहित	:	
2.	टिन/वैट संख्या/आयात/निर्यात कोड	:	
3.	आयात किए जाने वाले अन्य अपशिष्ट का विवरण और मात्रा	:	
4.	भंडारण, यदि कोई हो, का विवरण	:	
5.	प्राधिकृत वास्तविक उपयोगकर्ता(ओं) का/के नाम और पता/पते	:	

प्राधिकृत व्यक्ति के हस्ताक्षर

तारीख :
स्थान :

प्ररूप 8

[नियम 17(1) और 18(2) देखें]

परिसंकटमय और अन्य अपशिष्ट के कंटेनरों की लेबलिंग

सावधानी से प्रहस्तन करें

इन नियमों की अनुसूचियों II और III के भाग ग के अनुसार अपशिष्ट की श्रेणी और विशेषताएं.....	असंगत अपशिष्ट और पदार्थ .....
कुल मात्रा	भंडारण की तारीख
अपशिष्ट की भौतिक अवस्था (ठोस/अर्द्ध ठोस/द्रव) :	
प्रेषणकर्ता का नाम और पता	प्राप्तकर्ता का नाम और पता
फोन	फोन .....
ई-मेल	ई-मेल .....
टेलीफोन और फैक्स संख्या	टेलीफोन और फैक्स संख्या .....
संपर्क व्यक्ति	संपर्क व्यक्ति .....
आपात स्थिति में कृपया संपर्क करें	

टिप्पणी :

1. लेबल की पृष्ठभूमि का रंग - *फ्लोरेसेंट येलो*
2. शब्द 'परिसंकटमय अपशिष्ट' और 'सावधानी से प्रहस्तन करें' हिन्दी, अंग्रेजी और क्षेत्रीय भाषा में स्पष्ट रूप से और लाल रंग में लिखे जाएं।
3. शब्द 'अन्य अपशिष्ट' हिन्दी, अंग्रेजी और क्षेत्रीय भाषा में संतरे रंग में स्पष्ट रूप से लिखे जाएं।

4. लेबल न मिटने वाली और मौसम सह सामग्री का होना चाहिए।

प्ररुप 9

[नियम 18(2) देखें]

परिवहन आपात स्थिति (ट्रेम) कार्ड

[अपशिष्ट के प्रेषणकर्ता द्वारा दिए गए परिसंकटमय और अन्य अपशिष्टों के परिवहन के दौरान परिवाहक द्वारा साथ रखा जाए]

1. परिसंकटमय और अन्य अपशिष्टों की विशेषताएं :

क्र. सं.	**अपशिष्ट का प्रकार**	**भौतिक गुण**	**रासायनिक संघटक**	**प्रभाव संबंधी परिसंकट**	**प्राथमिक उपचार आवश्यकताएं**

2. आग की स्थिति में अपनाई जाने वाली प्रक्रिया :

3. बिखरने/दुर्घटना/विस्फोट की स्थिति में अपनाई जाने प्रक्रिया :

4. विशेषज्ञ सेवाओं के लिए कृपया संपर्क करें :
   (i) नाम और पता :
   (ii) टेलीफोन नं. :

(प्रेषणकर्ता का नाम, संपर्क के लिए नम्बर और हस्ताक्षर)

तारीख ....
स्थान ....

प्ररूप 10

[नियम 19(1) देखें]

परिसंकटमय और अन्य अपशिष्ट संबंधी मालसूची

1.	प्रेषणकर्ता का नाम और डाक का पता : (फोन नं. और ई-मेल सहित)	
2.	प्रेषणकर्ता का प्राधिकार संख्या :	
3.	सूची दस्तावेज संख्या :	
4.	परिवाहक का नाम और पता : (फोन नं. और ई-मेल सहित)	
5.	वाहन का प्रकार :	(ट्रक/टैंकर/विशेष वाहन)
6.	परिवाहक की पंजीकरण संख्या	
7.	वाहन की पंजीकरण संख्या	
8.	प्राप्तकर्ता का नाम और डाक का पता (फोन नं. और ई-मेल सहित)	
9.	प्राप्तकर्ता का प्राधिकार संख्या	
10	अपशिष्ट का विवरण	
11.	कुल मात्रा	.............घन मी. या मीट्रिक टन

	कंटेनरों की संख्या	संख्या.....
12.	वास्तविक स्वरूप	(ठोस/अर्ध ठोस/गाद/तैलीय/टैरी/स्लरी/द्रव)
13.	प्रहस्तन संबंधी विशेष अनुदेश और अतिरिक्त सूचना	
14.	प्रेषणकर्ता का प्रमाण-पत्र	मैं यह घोषणा करता हूं कि पारेषण की अंतर्वस्तुएं समुचित पोत परिवहन के नाम से ऊपर पूर्णतया और सही रुप में वर्णित की गई है और उन्हें प्रवर्गीकृत पैक चिन्हांकित और लेबलित किया गया है और वह लागू राष्ट्रीय सरकारी विनियमों के अनुसार सड़क द्वारा परिवहन के लिए सभी प्रकार से उपयुक्त दशा में हैं।
	नाम और मुहर : हस्ताक्षर:	माह दिन वर्ष
15.	अपशिष्ट की प्राप्ति के लिए परिवाहक की अभिस्वीकृति	
	टंकित नाम और स्टैम्प : हस्ताक्षर	माह दिन वर्ष
16.	परिसंकटमय और अन्य अपशिष्ट की प्राप्ति की बाबत प्राप्तकर्ता का प्रमाण-पत्र	
	टंकित नाम और स्टैम्प : हस्ताक्षर	माह दिन वर्ष

प्रारूप 11

[नियम 22 देखें]

दुर्घटना की रिपोर्ट करने के लिए प्रपत्र

[प्रसुविधा या प्रेषणकर्ता या प्राप्तकर्ता या परिवहनकर्ता द्वारा राज्य प्रदूषण नियंत्रण बोर्ड को प्रस्तुत किया जाए]

1. दुर्घटना की तारीख और समय :
2. दुर्घटना के कारकों का क्रम :
3. दुर्घटना में शामिल परिसंकटमय और अन्य अपशिष्टों का विवरण :
4. स्वास्थ्य या पर्यावरण पर दुर्घटना के प्रभावों के मूल्यांकन की तारीख :
5. किए गए आपातकालीन उपाए :
6. दुर्घटना के प्रभावों को समाप्त करने के लिए उठाए गए कदम :
7. ऐसी दुर्घटनाओं की पुनरावृत्ति रोकने के लिए उठाए गए कदम :

तारीख : **हस्ताक्षर :**

स्थान : **पदनाम :**

प्ररूप 12

[नियम 24(1) देखें]

राज्य प्रदूषण नियंत्रण बोर्ड द्वारा जारी आदेश के विरुद्ध अपील दायर करने का आवेदन

1. अपील करने वाले व्यक्ति का नाम और पता :
2. आदेश की संख्या, तारीख और उस प्राधिकरण का पता जिसके विरुद्ध अपील की जा रही है : (आदेश की प्रमाणित प्रति संलग्न करें)

3. अपील करने का आधार :

4. मांगी गई राहत :

5. पैरा 2 में संदर्भित आदेश, जिसके विरुद्ध अपील दायर की जा रही है, के अतिरिक्त अनुलग्नकों की सूची :

हस्ताक्षर.....

तारीख :

नाम और पता .....

----------X----------X----------

[23-16/2009-एचएसएमडी]

विश्वनाथ सिन्हा, संयुक्त सचिव

MINISTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE

NOTIFICATION

New Delhi, the 4th April, 2016

G.S.R. 395(E).—Whereas the draft rules, namely the Hazardous And Other Wastes (Management and Transboundary Movement) Rules, 2015, were published by the Government of India in the Ministry of Environment, Forest and Climate Change *vide* number G.S.R. 582(E), dated the 24th July, 2015 in the Gazette of India, Extraordinary Part II, section 3, sub-section (ii) inviting objections and suggestions from all persons likely to be affected thereby, before the expiry of the 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 the copies of the said Gazette containing the said notification were made available to the public on the 24th day of July, 2015;

AND WHEREAS the objections and suggestions 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 sections 6, 8 and 25 of the Environment (Protection) Act, 1986 (29 of 1986), and in supersession of the Hazardous Wastes (Management, Handling and Transboundary Movement) Rules, 2008, except as respects things done or omitted to be done before such supersession, the Central Government hereby makes the following rules, namely:-

CHAPTER I

PRELIMINARY

1. Short title and commencement. - (1) These rules may be called the Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016.

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

2. Application. - These rules shall apply to the management of hazardous and other wastes as specified in the Schedules to these rules but shall not apply to -

(a) waste-water and exhaust gases as covered under the provisions of the Water (Prevention and Control of Pollution) Act, 1974 (6 of 1974) and the Air (Prevention and Control of Pollution) Act, 1981 (14 of 1981) and the rules made thereunder and as amended from time to time;

(b) wastes arising out of the operation from ships beyond five kilometres of the relevant baseline as covered under the provisions of the Merchant Shipping Act, 1958 (44 of 1958) and the rules made thereunder and as amended from time to time;

(c) radio-active wastes as covered under the provisions of the Atomic Energy Act, 1962 (33 of 1962) and the rules made thereunder and as amended from time to time;

(d) bio-medical wastes covered under the Bio-Medical Wastes (Management and Handling) Rules, 1998 made under the Act and as amended from time to time; and

(e) wastes covered under the Municipal Solid Wastes (Management and Handling) Rules, 2000 made under the Act and as amended from time to time.

3. Definitions. - (1) In these rules, unless the context otherwise requires,-

1. "Act" means the Environment (Protection) Act, 1986 (29 of 1986);

2. "actual user" means an occupier who procures and processes hazardous and other waste for reuse, recycling, recovery, pre-processing, utilisation including co-processing;

3. "authorisation" means permission for generation, handling, collection, reception, treatment, transport, storage, reuse, recycling, recovery, pre-processing, utilisation including co-processing and disposal of hazardous wastes granted under sub-rule (2) of rule 6;

4. "Basel Convention" means the United Nations Environment Programme Convention on the Control of Transboundary Movement of Hazardous Wastes and their Disposal;

5. "captive treatment, storage and disposal facility" means a facility developed within the premises of an occupier for treatment, storage and disposal of wastes generated during manufacture, processing, treatment, package, storage, transportation, use, collection, destruction, conversion, offering for sale, transfer or the like of hazardous and other wastes;

6. "Central Pollution Control Board" means the Central Pollution Control Board constituted under sub-section (1) of section 3 of the Water (Prevention and Control of Pollution) Act, 1974 (6 of 1974);

7. "common treatment, storage and disposal facility" means a common facility identified and established individually or jointly or severally by the State Government, occupier, operator of a facility or any association of occupiers that shall be used as common facility by multiple occupiers or actual users for treatment, storage and disposal of the hazardous and other wastes;

8. "co-processing" means the use of waste materials in manufacturing processes for the purpose of energy or resource recovery or both and resultant reduction in the use of conventional fuels or raw materials or both through substitution;

9. "critical care medical equipment" means life saving equipment and includes such equipment as specified by the Ministry of Health and Family Welfare from time to time;

10. "disposal" means any operation which does not lead to reuse, recycling, recovery, utilisation including co-processing and includes physico-chemical treatment, biological treatment, incineration and disposal in secured landfill;

11. "export", with its grammatical variations and cognate expressions, means taking out of India to a place outside India;

12. "exporter" means any person or occupier under the jurisdiction of the exporting country who exports hazardous or other wastes, including the country which exports hazardous or other waste;

13. "environmentally sound management of hazardous and other wastes" means taking all steps required to ensure that the hazardous and other wastes are managed in a manner which shall protect health and the environment against the adverse effects which may result from such waste;

14. "environmentally sound technologies" means any technology approved by the Central Government from time to time;

15. "facility" means any establishment wherein the processes incidental to the generation, handling, collection, reception, treatment, storage, reuse, recycling, recovery, pre-processing, co-processing, utilisation and disposal of hazardous and, or, other wastes are carried out;

16. "Form" means a form appended to these rules;

17. "hazardous waste" means any waste which by reason of characteristics such as physical, chemical, biological, reactive, toxic, flammable, explosive or corrosive, causes danger or is likely to cause danger to health or environment, whether alone or in contact with other wastes or substances, and shall include -
    (i) waste specified under column (3) of Schedule I;
    (ii) waste having equal to or more than the concentration limits specified for the constituents in class A and class B of Schedule II or any of the characteristics as specified in class C of Schedule II; and
    (iii) wastes specified in Part A of Schedule III in respect of import or export of such wastes or the wastes not specified in Part A but exhibit hazardous characteristics specified in Part C of Schedule III;

18. "import", with its grammatical variations and cognate expressions, means bringing into India from a place outside India;

19. "importer" mean any person or occupier who imports hazardous or other waste;

20. "manifest" means transporting document prepared and signed by the sender authorised in accordance with the provisions of these rules;

21. "occupier" in relation to any factory or premises, means a person who has, control over the affairs of the factory or the premises and includes in relation to any hazardous and other wastes, the person in possession of the hazardous or other waste;

22. "operator of disposal facility" means a person who owns or operates a facility for collection, reception, treatment, storage and disposal of hazardous and other wastes;

23. "other wastes" means wastes specified in Part B and Part D of Schedule III for import or export and includes all such waste generated indigenously within the country;

24. "pre-processing" means the treatment of waste to make it suitable for co-processing or recycling or for any further processing;

25. "recycling" means reclamation and processing of hazardous or other wastes in an environmentally sound manner for the originally intended purpose or for other purposes;

26. "reuse" means use of hazardous or other waste for the purpose of its original use or other use;

27. "recovery" means any operation or activity wherein specific materials are recovered;

28. "Schedule" means a Schedule appended to these rules;

29. "State Government" in relation to a Union territory means, the Administrator thereof appointed under article 239 of the Constitution;

30. "State Pollution Control Board" means the State Pollution Control Board constituted under section 4 of the Water (Prevention and Control of Pollution) Act, 1974 (6 of 1974) and includes, in relation to a Union territory, the Pollution Control Committee;

31. "storage" mean storing any hazardous or other waste for a temporary period, at the end of which such waste is processed or disposed of;

32. "transboundary movement" means any movement of hazardous or other wastes from an area under the jurisdiction of one country to or through an area under the jurisdiction of another country or to or through an area not under the jurisdiction of any country, provided that at least two countries are involved in the movement;

33. "transport" means off-site movement of hazardous or other wastes by air, rail, road or water;

34. "transporter" means a person engaged in the off-site transportation of hazardous or other waste by air, rail, road or water;

35. "treatment" means a method, technique or process, designed to modify the physical, chemical or biological characteristics or composition of any hazardous or other waste so as to reduce its potential to cause harm;

36. "used oil" means any oil-

(i) derived from crude oil or mixtures containing synthetic oil including spent oil, used engine oil, gear oil, hydraulic oil, turbine oil, compressor oil, industrial gear oil, heat transfer oil, transformer oil and their tank bottom sludges; and
(ii) suitable for reprocessing, if it meets the specification laid down in Part A of Schedule V but does not include waste oil;

37. "utilisation" means use of hazardous or other waste as a resource;

38. "waste" means materials that are not products or by-products, for which the generator has no further use for the purposes of production, transformation or consumption.

Explanation.- for the purposes of this clause,
(i) waste includes the materials that may be generated during, the extraction of raw materials, the processing of raw materials into intermediates and final products, the consumption of final products, and through other human activities and excludes residuals recycled or reused at the place of generation; and
(ii) by-product means a material that is not intended to be produced but gets produced in the production process of intended product and is used as such;

39. "waste oil" means any oil which includes spills of crude oil, emulsions, tank bottom sludge and slop oil generated from petroleum refineries, installations or ships and can be used as fuel in furnaces for energy recovery, if it meets the specifications laid down in Part-B of Schedule V either as such or after reprocessing.

(2) Words and expressions used in these rules and not defined but defined in the Act shall have the meanings respectively assigned to them in the Act.

CHAPTER II

PROCEDURE FOR MANAGEMENT OF HAZARDOUS AND OTHER WASTES

4. Responsibilities of the occupier for management of hazardous and other wastes.-

(1) For the management of hazardous and other wastes, an occupier shall follow the following steps, namely:-
(a) prevention;
(b) minimization;
(c) reuse,
(d) recycling;
(e) recovery, utilisation including co-processing;
(f) safe disposal.

(2) The occupier shall be responsible for safe and environmentally sound management of hazardous and other wastes.

(3) The hazardous and other wastes generated in the establishment of an occupier shall be sent or sold to an authorised actual user or shall be disposed of in an authorised disposal facility.

(4) The hazardous and other wastes shall be transported from an occupier's establishment to an authorised actual user or to an authorised disposal facility in accordance with the provisions of these rules.

(5) The occupier who intends to get its hazardous and other wastes treated and disposed of by the operator of a treatment, storage and disposal facility shall give to the operator of that facility, such specific information as may be needed for safe storage and disposal.

(6) The occupier shall take all the steps while managing hazardous and other wastes to-
(a) contain contaminants and prevent accidents and limit their consequences on human beings and the environment; and

(b) provide persons working in the site with appropriate training, equipment and the information necessary to ensure their safety.

5. Responsibilities of State Government for environmentally sound management of hazardous and other wastes. – (1) Department of Industry in the State or any other government agency authorised in this regard by the State Government, to ensure earmarking or allocation of industrial space or shed for recycling, pre-processing and other utilisation of hazardous or other waste in the existing and upcoming industrial park, estate and industrial clusters;

(2) Department of Labour in the State or any other government agency authorised in this regard by the State Government shall,-

(a) ensure recognition and registration of workers involved in recycling, pre-processing and other utilisation activities;
(b) assist formation of groups of such workers to facilitate setting up such facilities;
(c) undertake industrial skill development activities for the workers involved in recycling, pre-processing and other utilisation;
(d) undertake annual monitoring and to ensure safety and health of workers involved in recycling, pre-processing and other utilisation.

(3) Every State Government may prepare integrated plan for effective implementation of these provisions and to submit annual report to the Ministry of Environment, Forest and Climate Change, in the Central Government.

6. Grant of authorisation for managing hazardous and other wastes.- (1) Every occupier of the facility who is engaged in handling, generation, collection, storage, packaging, transportation, use, treatment, processing, recycling, recovery, pre-processing, co-processing, utilisation, offering for sale, transfer or disposal of the hazardous and other wastes shall be required to make an application in **Form 1** to the State Pollution Control Board and obtain an authorisation from the State Pollution Control Board within a period of sixty days from the date of publication of these rules. Such application for authorisation shall be accompanied with a copy each of the following documents, namely:-

(a) consent to establish granted by the State Pollution Control Board under the Water (Prevention and Control of Pollution) Act, 1974 (25 of 1974) and the Air (Prevention and Control of Pollution) Act, 1981 (21 of 1981);
(b) Consent to operate granted by the State Pollution Control Board under the Water (Prevention and Control of Pollution) Act, 1974 (25 of 1974) and/or Air (Prevention and Control of Pollution) Act, 1981, (21 of 1981);
(c) in case of renewal of authorisation, a self-certified compliance report in respect of effluent, emission standards and the conditions specified in the authorisation for hazardous and other wastes:

Provided that an application for renewal of authorisation may be made three months before the expiry of such authorisation:

Provided further that-

(i) any person authorised under the provisions of the Hazardous Waste (Management, Handling and Transboundary Movement) Rules, 2008, prior to the date of commencement of these rules, shall not be required to make an application for authorisation till the period of expiry of such authorisation;
(ii) any person engaged in recycling or reprocessing of the hazardous waste specified in Schedule IV and having registration under the provisions of the Hazardous Waste (Management, Handling and Transboundary Movement) Rules, 2008, shall not be required to make an application for authorisation till the period of expiry of such registration.

(2) On receipt of an application complete in all respects for the authorisation, the State Pollution Control Board may, after such inquiry as it considers necessary, and on being satisfied that the applicant possesses appropriate facilities for collection, storage, packaging, transportation, treatment, processing, use, destruction, recycling, recovery, pre-processing, co-processing, utilisation, offering for sale, transfer or disposal of the hazardous and other waste, as the case may be, and after ensuring technical capabilities and equipment complying with the standard operating procedure or other guidelines specified by the Central Pollution Control Board from time to time and through site inspection, grant within a period of one hundred and twenty days, an authorisation in **Form 2** to the applicant, which shall be valid for a period of five years subject to such conditions as may be laid down therein. For commonly recyclable hazardous waste as given in Schedule IV, the guidelines already prepared by the Central Pollution Control Board shall be followed:

Provided that in the case of an application for renewal of authorisation, the State Pollution Control Board may, before granting such authorisation, satisfy itself that there has been no violation of the conditions specified in the authorisation earlier granted by it and same shall be recorded in the inspection report.

(3) The authorisation granted by the State Pollution Control Board under sub-rule (2) shall be accompanied by a copy of the field inspection report signed by that Board indicating the adequacy of facilities for collection, storage, packaging, transportation, treatment, processing, use, destruction, recycling, recovery, pre-processing, co-processing, utilisation, offering for sale, transfer or disposal of the hazardous and other wastes and compliance to the guidelines or standard operating procedures specified by the Central Pollution Control Board from time to time.

(4) The State Pollution Control Board may, for the reasons to be recorded in writing and after giving reasonable opportunity of being heard to the applicant, refuse to grant any authorisation under these rules.

(5) Every occupier authorised under these rules, shall maintain a record of hazardous and other wastes managed by him in **Form 3** and prepare and submit to the State Pollution Control Board, an annual return containing the details specified in **Form 4** on or before the 30th day of June following the financial year to which that return relates.

(6) The State Pollution Control Board shall maintain a register containing particulars of the conditions imposed under these rules for management of hazardous and other wastes and it shall be open for inspection during office hours to any interested or affected person.

(7) The authorised actual user of hazardous and other wastes shall maintain records of hazardous and other wastes purchased in a passbook issued by the State Pollution Control Board along with the authorisation.

(8) Handing over of the hazardous and other wastes to the authorised actual user shall be only after making the entry into the passbook of the actual user.

7. Power to suspend or cancel an authorisation.- (1) The State Pollution Control Board, may, if in its opinion the holder of the authorisation has failed to comply with any of the conditions of the authorisation or with any provisions of the Act or these rules and after giving him a reasonable opportunity of being heard and after recording reasons thereof in writing cancel or suspend the authorisation issued under rule 6 for such period as it considers necessary in the public interest.

(2) Upon suspension or cancellation of the authorisation, the State Pollution Control Board may give directions to the person whose authorisation has been suspended or cancelled for the safe storage and management of the hazardous and other wastes, and such occupier shall comply with such directions.

8. Storage of hazardous and other wastes.- (1) The occupiers of facilities may store the hazardous and other wastes for a period not exceeding ninety days and shall maintain a record of sale, transfer, storage, recycling, recovery, pre-processing, co-processing and utilisation of such wastes and make these records available for inspection:

Provided that the State Pollution Control Board may extend the said period of ninety days in following cases, namely:-

(i) small generators (up to ten tonnes per annum) up to one hundred and eighty days of their annual capacity;
(ii) actual users and disposal facility operators up to one hundred and eighty days of their annual capacity,
(iii) occupiers who do not have access to any treatment, storage, disposal facility in the concerned State; or
(iv) the waste which needs to be specifically stored for development of a process for its recycling, recovery, pre-processing, co-processing or utilisation;
(v) in any other case, on justifiable grounds up to one hundred and eighty days.

9. Utilisation of hazardous and other wastes.- (1) The utilisation of hazardous and other wastes as a resource or after pre-processing either for co-processing or for any other use, including within the premises of the generator (if it is not part of process), shall be carried out only after obtaining authorisation from the State Pollution Control Board in respect of waste on the basis of standard operating procedures or guidelines provided by the Central Pollution Control Board.

(2) Where standard operating procedures or guidelines are not available for specific utilisation, the approval has to be sought from Central Pollution Control Board which shall be granting approval on the basis of trial runs and thereafter, standard operating procedures or guidelines shall be prepared by Central Pollution Control Board:

Provided, if trial run has been conducted for particular waste with respect to particular utilisation and compliance to the environmental standards has been demonstrated, authorisation may be granted by the State Pollution Control Board with respect to the same waste and utilisation, without need of separate trial run by Central Pollution Control Board and such cases of successful trial run, Central Pollution Control Board shall intimate all the State Pollution Control Board regarding the same.

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(3) No trial runs shall be required for co-processing of waste in cement plants for which guidelines by the Central Pollution Control Board are already available; however, the actual users shall ensure compliance to the standards notified under the Environment (Protection) Act,1986 (29 of 1986), for cement plant with respect to co-processing of waste:

Provided that till the time the standards are notified, the procedure as applicable to other kind of utilisation of hazardous and other waste, as enumerated above shall be followed.

10. Standard Operating Procedure or guidelines for actual users.- The Ministry of Environment, Forest and Climate Change or the Central Pollution Control Board may issue guidelines or standard operating procedures for environmentally sound management of hazardous and other wastes from time to time.

CHAPTER III

IMPORT AND EXPORT OF HAZARDOUS AND OTHER WASTES

11. Import and export (transboundary movement) of hazardous and other wastes.- The Ministry of Environment, Forest and Climate Change shall be the nodal Ministry to deal with the transboundary movement of the hazardous and other wastes in accordance with the provisions of these rules.

12. Strategy for Import and export of hazardous and other wastes.- (1) No import of the hazardous and other wastes from any country to India for disposal shall be permitted.

(2) The import of hazardous and other wastes from any country shall be permitted only for recycling, recovery, reuse and utilisation including co-processing.

(3) The import of hazardous waste in Part A of Schedule III may be allowed to actual users with the prior informed consent of the exporting country and shall require the permission of the Ministry of Environment, Forest and Climate Change.

(4) The import of other wastes in Part B of Schedule III may be allowed to actual users with the permission of the Ministry of Environment, Forest and Climate Change.

(5) The import of other wastes in Part D of Schedule III will be allowed as per procedure given in rule 13 and as per the note below the said Schedule.

(6) No import of the hazardous and other wastes specified in Schedule VI shall be permitted.

(7) The export of hazardous and other wastes from India listed in Part A and Part B of Schedule III and Schedule VI shall be with the permission of Ministry of Environment, Forest and Climate Change. In case of applications for export of hazardous and other waste listed in Part A of Schedule III and Schedule VI, they shall be considered on the basis of prior informed consent of the importing country.

(8) The import and export of hazardous and other wastes not specified in Schedule III, but exhibiting the hazardous characteristics outlined in Part C of Schedule III shall require prior written permission of the Ministry of Environment, Forest and Climate Change before it is imported to or exported from India, as the case may be.

13. Procedure for import of hazardous and other wastes.- (1) Actual users intending to import or transit for transboundary movement of hazardous and other wastes specified in Part A and Part B of Schedule III shall apply in **Form 5** along with the documents listed therein, to the Ministry of Environment, Forest and Climate Change for the proposed import together with the prior informed consent of the exporting country in respect of Part A of Schedule III waste, and shall send a copy of the application, simultaneously, to the concerned State Pollution Control Board for information and the acknowledgement in this respect from the concerned State Pollution Control Board shall be submitted to the Ministry of Environment, Forest and Climate Change along with the application.

(2) For the import of other wastes listed in Part D of Schedule III, the importer shall not require the permission of the Ministry of Environment, Forest and Climate Change. However, the importer shall furnish the required information as per **Form 6** to the Customs authorities, accompanied with the following documents in addition to those listed in Schedule VIII, wherever applicable. For used electrical and electronic assemblies listed at serial numbers 4 (e) to 4(i) of Schedule VIII (Basel No. B1110), there is no specific requirement of documentation under these rules:

(a) the import license from Directorate General of Foreign Trade, if applicable;

(b) the valid consents under the Water (Prevention and Control of Pollution) Act, 1974 (25 of 1974) and the Air (Prevention and Control of Pollution) Act, 1981 (21 of 1981) and the authorisation under these rules as well as the authorisation under the E-Waste (Management and Handling) Rules, 2011, as amended from time to time, whichever applicable;

(c) importer who is a trader, importing waste on behalf of actual users, shall obtain one time authorisation in **Form 7** and copy of this authorisation shall be appended to **Form 6**.

(3) For Part B of Schedule III, in case of import of any used electrical and electronic assemblies or spares or part or component or consumables as listed under Schedule I of the E-Waste (Management and Handling) Rules, 2011, as amended from time to time, the importer need to obtain extended producer responsibility-authorisation as producer under the said E-Waste (Management and Handling) Rules, 2011.

(4) Prior to clearing of consignment of wastes listed in Part D of Schedule III, the Custom authorities shall verify the documents as given in column (3) of Schedule VIII.

(5) On receipt of the complete application with respect to Part A and Part B of Schedule III, the Ministry of Environment, Forest and Climate Change shall examine the application considering the comments and observations, if any, received from the State Pollution Control Boards, and may grant the permission for import within a period of sixty days subject to the condition that the importer has -

(i) the environmentally sound facilities;
(ii) adequate arrangements for treatment and disposal of wastes generated;
(iii) a valid authorisation and consents from the State Pollution Control Board;
(iv) prior informed consent from the exporting country in case of Part A of Schedule III wastes.

(6) The Ministry of Environment, Forest and Climate Change shall forward a copy of the permission to the concerned Port and Customs authorities, Central Pollution Control Board and the concerned State Pollution Control Board for ensuring compliance with respect to their respective functions given in Schedule VII.

(7) The importer of the hazardous and other wastes shall maintain records of the hazardous and other waste imported by him in **Form 3** and the record so maintained shall be made available for inspection.

(8) The importer of the hazardous and other wastes shall file an annual return in **Form 4** to the State Pollution Control Board on or before the 30th day of June following the financial year to which that return relates.

(9) Samples of hazardous and other wastes being imported for testing or research and development purposes up to 1000 gm or 1000 ml shall be exempted from need of taking permission for import under these rules.

(10) The Port and Customs authorities shall ensure that shipment is accompanied with the movement document as given in **Form 6** and the test report of analysis of the waste, consignment, wherever applicable, from a laboratory accredited or recognised by the exporting country. In case of any doubt, the customs may verify the analysis.

14. Procedure for Export of hazardous and other wastes from India.- (1) Any occupier intending to export waste specified in Part A of Schedule III, Part B of Schedule III and Schedule VI, shall make an application in **Form 5** along with insurance cover to the Ministry of Environment, Forest and Climate Change for the proposed transboundary movement of the hazardous and other wastes together with the prior informed consent in writing from the importing country in respect of wastes specified in Part A of Schedule III and Schedule VI.

(2) On receipt of an application under sub-rule (1), the Ministry of Environment, Forest and Climate Change may give permission for the proposed export within a period of sixty days from the date of submission of complete application and may impose such conditions as it may consider necessary.

(3) The Ministry of Environment, Forest and Climate Change shall forward a copy of the permission granted under sub-rule (2) to the State Pollution Control Board of the State where the waste is generated and the Pollution Control Board of the State where the port of export is located and the concerned Port and Customs authorities for ensuring compliance of the conditions of the export permission.

(4) The exporter shall ensure that no consignment is shipped before the prior informed consent is received from the importing country, wherever applicable.

(5) The exporter shall also ensure that the shipment is accompanied with movement document in **Form 6.**

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(6) The exporter of the hazardous and other wastes shall maintain the records of the hazardous or other waste exported by him in **Form 3** and the record so maintained shall be available for inspection.

15. Illegal traffic.- (1) The export and import of hazardous or other wastes from and into India, respectively shall be deemed illegal, if,-

(i) it is without permission of the Central Government in accordance with these rules; or
(ii) the permission has been obtained through falsification, mis-representation or fraud; or
(iii) it does not conform to the shipping details provided in the movement documents; or
(iv) it results in deliberate disposal (i.e., dumping) of hazardous or other waste in contravention of the Basel Convention and of general principles of international or domestic law.

(2) In case of illegal import of the hazardous or other waste, the importer shall re-export the waste in question at his cost within a period of ninety days from the date of its arrival into India and its implementation will be ensured by the concerned Port and the Custom authority. In case of disposal of such waste by the Port and Custom authorities, they shall do so in accordance with these rules with the permission of the Pollution Control Board of the State where the Port exists.

(3) In case of illegal import of hazardous or other waste, where the importer is not traceable then the waste either can be sold by the Customs authority to any user having authorisation under these rules from the concerned State Pollution Control Board or can be sent to authorised treatment, storage and disposal facility.

CHAPTER - IV
TREATMENT, STORAGE AND DISPOSAL FACILITY FOR HAZARDOUS AND OTHER WASTES

16. Treatment, storage and disposal facility for hazardous and other wastes.- (1) The State Government, occupier, operator of a facility or any association of occupiers shall individually or jointly or severally be responsible for identification of sites for establishing the facility for treatment, storage and disposal of the hazardous and other waste in the State.

(2) The operator of common facility or occupier of a captive facility, shall design and set up the treatment, storage and disposal facility as per technical guidelines issued by the Central Pollution Control Board in this regard from time to time and shall obtain approval from the State Pollution Control Board for design and layout in this regard.

(3) The State Pollution Control Board shall monitor the setting up and operation of the common or captive treatment, storage and disposal facility, regularly.

(4) The operator of common facility or occupier of a captive facility shall be responsible for safe and environmentally sound operation of the facility and its closure and post closure phase, as per guidelines or standard operating procedures issued by the Central Pollution Control Board from time to time.

(5) The operator of common facility or occupier of a captive facility shall maintain records of hazardous and other wastes handled by him in **Form 3.**

(6) The operator of common facility or occupier of a captive facility shall file an annual return in **Form 4** to the State Pollution Control Board on or before the 30th day of June following the financial year to which that return relates.

CHAPTER - V
PACKAGING, LABELLING, AND TRANSPORT OF HAZARDOUS AND OTHER WASTES.

17. Packaging and Labelling.- (1) Any occupier handling hazardous or other wastes and operator of the treatment, storage and disposal facility shall ensure that the hazardous and other wastes are packaged in a manner suitable for safe handling, storage and transport as per the guidelines issued by the Central Pollution Control Board from time to time. The labelling shall be done as per **Form 8.**

(2) The label shall be of non-washable material, weather proof and easily visible.

18. Transportation of hazardous and other wastes.- (1) The transport of the hazardous and other waste shall be in accordance with the provisions of these rules and the rules made by the Central Government under the Motor Vehicles Act, 1988 and the guidelines issued by the Central Pollution Control Board from time to time in this regard.

(2) The occupier shall provide the transporter with the relevant information in **Form 9,** regarding the hazardous nature of the wastes and measures to be taken in case of an emergency and shall label the hazardous and other wastes containers as per **Form 8**.

(3) In case of transportation of hazardous and other waste for final disposal to a facility existing in a State other than the State where the waste is generated, the sender shall obtain 'No Objection Certificate' from the State Pollution Control Board of both the States.

(4) In case of transportation of hazardous and other waste for recycling or utilisation including co-processing, the sender shall intimate both the State Pollution Control Boards before handing over the waste to the transporter.

(5) In case of transit of hazardous and other waste for recycling, utilisation including co-processing or disposal through a State other than the States of origin and destination, the sender shall give prior intimation to the concerned State Pollution Control Board of the States of transit before handing over the wastes to the transporter.

(6) In case of transportation of hazardous and other waste, the responsibility of safe transport shall be either of the sender or the receiver whosoever arranges the transport and has the necessary authorisation for transport from the concerned State Pollution Control Board. This responsibility should be clearly indicated in the manifest.

(7) The authorisation for transport shall be obtained either by the sender or the receiver on whose behalf the transport is being arranged.

19. Manifest system (Movement Document) for hazardous and other waste to be used within the country only.- (1) The sender of the waste shall prepare seven copies of the manifest in **Form 10** comprising of colour code indicated below and all seven copies shall be signed by the sender:

Copy number with colour code	**Purpose**
(1)	**(2)**
Copy 1 (White)	To be forwarded by the sender to the State Pollution Control Board after signing all the seven copies.
Copy 2 (Yellow)	To be retained by the sender after taking signature on it from the transporter and the rest of the five signed copies to be carried by the transporter.
Copy 3 (Pink)	To be retained by the receiver (actual user or treatment storage and disposal facility operator) after receiving the waste and the remaining four copies are to be duly signed by the receiver.
Copy 4 (Orange)	To be handed over to the transporter by the receiver after accepting waste.
Copy 5 (Green)	To be sent by the receiver to the State Pollution Control Board.
Copy 6 (Blue)	To be sent by the receiver to the sender.
Copy 7 (Grey)	To be sent by the receiver to the State Pollution Control Board of the sender in case the sender is in another State.

(2) The sender shall forward copy 1 (white) to the State Pollution Control Board, and in case the hazardous or other wastes is likely to be transported through any transit State, the sender shall intimate State Pollution Control Boards of transit States about the movement of the waste.

(3) No transporter shall accept waste from the sender for transport unless it is accompanied by signed copies 3 to 7 of the manifest.

(4) The transporter shall submit copies 3 to 7 of the manifest duly signed with date to the receiver along with the waste consignment.

(5) The receiver after acceptance of the waste shall hand over copy 4 (orange) to the transporter and send copy 5 (green) to his State Pollution Control Board and send copy 6 (blue) to the sender and the copy 3 (pink) shall be retained by the reciever.

(6) The copy 7 (grey) shall only be sent to the State Pollution Control Board of the sender, if the sender is in another State.

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CHAPTER VI
MISCELLANEOUS

20. Records and returns.- (1) The occupier handling hazardous or other wastes and operator of disposal facility shall maintain records of such operations in **Form 3.**

(2) The occupier handling hazardous and other wastes and operator of disposal facility shall send annual returns to the State Pollution Control Board in **Form 4.**

(3) The State Pollution Control Board based on the annual returns received from the occupiers and the operators of the facilities for disposal of hazardous and other wastes shall prepare an annual inventory of the waste generated; waste recycled, recovered, utilised including co-processed; waste re-exported and waste disposed and submit to the Central Pollution Control Board by the 30th day of September every year. The State Pollution Control Board shall also prepare the inventory of hazardous waste generators, actual users, and common and captive disposal facilities and shall submit the information to Central Pollution Control Board every two years.

(4) The Central Pollution Control Board shall prepare the consolidated review report on management of hazardous and other wastes and forward it to the Ministry of Environment, Forest and Climate Change, along with its recommendations before the 30th day of December once in every year.

21. Responsibility of authorities. - The authority specified in column (2) of Schedule VII shall perform the duties as specified in column (3) of the said Schedule subject to the provisions of these rules.

22. Accident reporting. - Where an accident occurs at the facility of the occupier handling hazardous or other wastes and operator of the disposal facility or during transportation, the occupier or the operator or the transporter shall immediately intimate the State Pollution Control Board through telephone, e-mail about the accident and subsequently send a report in **Form 11.**

23. Liability of occupier, importer or exporter and operator of a disposal facility.-
(1) The occupier, importer or exporter and operator of the disposal facility shall be liable for all damages caused to the environment or third party due to improper handling and management of the hazardous and other waste.
(2) The occupier and the operator of the disposal facility shall be liable to pay financial penalties as levied for any violation of the provisions under these rules by the State Pollution Control Board with the prior approval of the Central Pollution Control Board.

24. Appeal.- (1) Any person aggrieved by an order of suspension or cancellation or refusal of authorisation or its renewal passed by the State Pollution Control Board may, within a period of thirty days from the date on which the order is communicated to him, prefer an appeal in **Form 12** to the Appellate Authority, namely, the Environment Secretary of the State.

(2) The Appellate Authority may entertain the appeal after 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.
(3) Every appeal filed under this rule shall be disposed of within a period of sixty days from the date of its filing.

SCHEDULE I
[See rule 3 (1) (17) (i)]
List of processes generating hazardous wastes

S.No.	Processes	Hazardous Waste*
(1)	(2)	(3)
1.	Petrochemical processes and pyrolytic operations	1.1 Furnace or reactor residue and debris 1.2 Tarry residues and still bottoms from distillation 1.3 Oily sludge emulsion 1.4 Organic residues 1.5 Residues from alkali wash of fuels 1.6 Spent catalyst and molecular sieves 1.7 Oil from wastewater treatment
2.	Crude oil and natural gas production	2.1 Drill cuttings excluding those from water based mud 2.2 Sludge containing oil 2.3 Drilling mud containing oil
3.	Cleaning, emptying and maintenance of petroleum oil storage tanks including ships	3.1 cargo residue, washing water and sludge containing oil 3.2 cargo residue and sludge containing chemicals 3.3 Sludge and filters contaminated with oil 3.4 Ballast water containing oil from ships

4.	Petroleum refining or re-processing of used oil or recycling of waste oil	4.1 Oil sludge or emulsion 4.2 Spent catalyst 4.3 Slop oil 4.4 Organic residue from processes 4.5 Spent clay containing oil
5.	Industrial operations using mineral or synthetic oil as lubricant in hydraulic systems or other applications	5.1 Used or spent oil 5.2 Wastes or residues containing oil 5.3 Waste cutting oils
6.	Secondary production and / or industrial use of zinc	6.1 Sludge and filter press cake arising out of production of Zinc Sulphate and other Zinc Compounds. 6.2 Zinc fines or dust or ash or skimmings in dispersible form 6.3 Other residues from processing of zinc ash or skimmings 6.4 Flue gas dust and other particulates
7.	Primary production of zinc or lead or copper and other non-ferrous metals except aluminium	7.1 Flue gas dust from roasting 7.2 Process residues 7.3 Arsenic-bearing sludge 7.4 Non-ferrous metal bearing sludge and residue. 7.5 Sludge from scrubbers
8.	Secondary production of copper	8.1 Spent electrolytic solutions 8.2 Sludge and filter cakes 8.3 Flue gas dust and other particulates
9.	Secondary production of lead	9.1 Lead bearing residues 9.2 Lead ash or particulate from flue gas 9.3 Acid from used batteries
10.	Production and/or industrial use of cadmium and arsenic and their compounds	10.1 Residues containing cadmium and arsenic
11.	Production of primary and secondary aluminum	11.1 Sludges from off-gas treatment 11.2 Cathode residues including pot lining wastes 11.3 Tar containing wastes 11.4 Flue gas dust and other particulates 11.5 Drosses and waste from treatment of salt sludge 11.6 Used anode butts 11.7 Vanadium sludge from alumina refineries
12.	Metal surface treatment, such as etching, staining, polishing, galvanizing, cleaning, degreasing, plating, etc.	12.1 Acidic and alkaline residues 12.2 Spent acid and alkali 12.3 Spent bath and sludge containing sulphide, cyanide and toxic metals 12.4 Sludge from bath containing organic solvents 12.5 Phosphate sludge 12.6 Sludge from staining bath 12.7 Copper etching residues 12.8 Plating metal sludge
13.	Production of iron and steel including other ferrous alloys (electric furnace; steel rolling and finishing mills; Coke oven and by products plant)	13.1 Spent pickling liquor 13.2 Sludge from acid recovery unit 13.3 Benzol acid sludge 13.4 Decanter tank tar sludge 13.5 Tar storage tank residue 13.6 Residues from coke oven by product plant.
14.	Hardening of steel	14.1 Cyanide-, nitrate-, or nitrite -containing sludge 14.2 Spent hardening salt
15.	Production of asbestos or asbestos-containing materials	15.1 Asbestos-containing residues 15.2 Discarded asbestos 15.3 Dust or particulates from exhaust gas treatment.
16.	Production of caustic soda and chlorine	16.1 Mercury bearing sludge generated from mercury cell process 16.2 Residue or sludges and filter cakes 16.3 Brine sludge
17.	Production of mineral acids	17.1 Process acidic residue, filter cake, dust 17.2 Spent catalyst
18.	Production of nitrogenous and complex fertilizers	18.1 Spent catalyst 18.2 Carbon residue

		18.3 Sludge or residue containing arsenic 18.4 Chromium sludge from water cooling tower
19.	Production of phenol	19.1 Residue or sludge containing phenol 19.2 Spent catalyst
20.	Production and/or industrial use of solvents	20.1 Contaminated aromatic, aliphatic or napthenic solvents may or may not be fit for reuse. 20.2 Spent solvents 20.3 Distillation residues 20.4 Process Sludge
21.	Production and/or industrial use of paints, pigments, lacquers, varnishes and inks	21.1 Process wastes, residues and sludges 21.2 Spent solvent
22.	Production of plastics	22.1 Spent catalysts 22.2 Process residues
23.	Production and /or industrial use of glues, organic cements, adhesive and resins	23.1 Wastes or residues (not made with vegetable or animal materials) 23.2 Spent solvents
24.	Production of canvas and textiles	24.1 Chemical residues
25.	Industrial production and formulation of wood preservatives	25.1 Chemical residues 25.2 Residues from wood alkali bath
26.	Production or industrial use of synthetic dyes, dye-intermediates and pigments	26.1 Process waste sludge/residues containing acid, toxic metals, organic compounds 26.2 Dust from air filtration system 26.3 Spent acid 26.4 Spent solvent 26.5 Spent catalyst
27.	Production of organic-silicone compound	27.1 Process residues
28.	Production/formulation of drugs/pharmaceutical and health care product	28.1 Process Residue and wastes 28.2 Spent catalyst 28.3 Spent carbon 28.4 Off specification products 28.5 Date-expired products 28.6 Spent solvents
29.	Production, and formulation of pesticides including stock-piles	29.1 Process wastes or residues 29.2 Sludge containing residual pesticides 29.3 Date-expired and off-specification pesticides 29.4 Spent solvents 29.5 Spent catalysts 29.6 Spent acids
30.	Leather tanneries	30.1 Chromium bearing residue and sludge
31.	Electronic Industry	31.1 Process residue and wastes 31.2 Spent etching chemicals and solvents
32.	Pulp and Paper Industry	32.1 Spent chemicals 32.2 Corrosive wastes arising from use of strong acid and bases 32.3 Process sludge containing adsorbable organic halides(AO_X)
33.	Handling of hazardous chemicals and wastes	33.1 Empty barrels/containers/liners contaminated with hazardous chemicals /wastes 33.2 Contaminated cotton rags or other cleaning materials
34.	De-contamination of barrels / containers used for handling of hazardous wastes/chemicals	34.1 Chemical-containing residue arising from decontamination. 34.2 Sludge from treatment of waste water arising out of cleaning / disposal of barrels / containers
35.	Purification and treatment of exhaust air/gases, water and waste water from the processes in this schedule and common industrial effluent treatment plants (CETP's)	35.1 Exhaust Air or Gas cleaning residue 35.2 Spent ion exchange resin containing toxic metals 35.3 Chemical sludge from waste water treatment 35.4 Oil and grease skimming 35.5 Chromium sludge from cooling water
36.	Purification process for organic compounds/solvents	36.1 Any process or distillation residue 36.2 Spent carbon or filter medium

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37.	Hazardous waste treatment processes, e.g. pre-processing, incineration and concentration	37.1 37.2 37.3	Sludge from wet scrubbers Ash from incinerator and flue gas cleaning residue Concentration or evaporation residues
38.	Chemical processing of Ores containing heavy metals such as Chromium, Manganese, Nickel, Cadmium etc.	38.1 38.2	Process residues Spent acid

*** The inclusion of wastes contained in this Schedule does not preclude the use of Schedule II to demonstrate that the waste is not hazardous. In case of dispute, the matter would be referred to the Technical Review Committee constituted by Ministry of Environment, Forest and Climate Change.**

Note: *The high volume low effect wastes such as fly ash, Phosphogypsum, red mud, jarosite, Slags from pyrometallurgical operations, mine tailings and ore beneficiation rejects are excluded from the category of hazardous wastes. Separate guidelines on the management of these wastes shall be issued by Central Pollution Control Board.*

SCHEDULE II

[See rule 3 (1) (17) (ii)]

List of waste constituents with concentration limits

Class A: Based on leachable concentration limits [Toxicity Characteristic Leaching Procedure (TCLP) or Soluble Threshold Limit Concentration (STLC)]

Class	Constituents	Concentration in mg/l
(1)	**(2)**	**(3)**
A1	Arsenic	5.0
A2	Barium	100.0
A3	Cadmium	1.0
A4	Chromium and/or Chromium (III) compounds	5.0
A5	Lead	5.0
A6	Manganese	10.0
A7	Mercury	0.2
A8	Selenium	1.0
A9	Silver	5.0
A10	Ammonia	50*
A11	Cyanide	20*
A12	Nitrate (as nitrate-nitrogen)	1000.0
A13	Sulphide (as H_2S)	5.0
A14	1,1-Dichloroethylene	0.7
A15	1,2-Dichloroethane	0.5
A16	1,4-Dichlorobenzene	7.5
A17	2,4,5-Trichlorophenol	400.0
A18	2,4,6-Trichlorophenol	2.0
A19	2,4-Dinitrotoluene	0.13
A20	Benzene	0.5
A21	Benzo (a) Pyrene	0.001
A22	Bromodicholromethane	6.0
A23	Bromoform	10.0
A24	Carbon tetrachloride	0.5
A25	Chlorobenzene	100.0
A26	Chloroform	6.0
A27	Cresol (ortho+ meta+ para)	200.0
A28	Dibromochloromethane	10.0
A29	Hexachlorobenzene	0.13
A30	Hexachlorobutadiene	0.5
A31	Hexachloroethane	3.0
A32	Methyl ethyl ketone	200.0

A33	Naphthalene	5.0
A34	Nitrobenzene	2.0
A35	Pentachlorophenol	100.0
A36	Pyridine	5.0
A37	Tetrachloroethylene	0.7
A38	Trichloroethylene	0.5
A39	Vinyl chloride	0.2
A40	2,4,5-TP (Silvex)	1.0
A41	2,4-Dichlorophenoxyacetic acid	10.0
A42	Alachlor	2.0
A43	Alpha HCH	0.001
A44	Atrazine	0.2
A45	Beta HCH	0.004
A46	Butachlor	12.5
A47	Chlordane	0.03
A48	Chlorpyriphos	9.0
A49	Delta HCH	0.004
A50	Endosulfan (alpha+ beta+ sulphate)	0.04
A51	Endrin	0.02
A52	Ethion	0.3
A53	Heptachlor (& its Epoxide)	0.008
A54	Isoproturon	0.9
A55	Lindane	0.4
A56	Malathion	19
A57	Methoxychlor	10
A58	Methyl parathion	0.7
A59	Monocrotophos	0.1
A60	Phorate	0.2
A61	Toxaphene	0.5
A62	Antimony	15
A63	Beryllium	0.75
A64	Chromium (VI)	5.0
A65	Cobalt	80.0
A66	Copper	25.0
A67	Molybdenum	350
A68	Nickel	20.0
A69	Thallium	7.0
A70	Vanadium	24.0
A71	Zinc	250
A72	Fluoride	180.0
A73	Aldrin	0.14
A74	Dichlorodiphenyltrichloroethane (DDT), Dichlorodiphenyldichloroethylene (DDE), Dichlorodiphenyldichloroethane (DDD)	0.1
A75	Dieldrin	0.8
A76	Kepone	2.1
A77	Mirex	2.1
A78	Polychlorinated biphenyls	5.0
A79	Dioxin (2,3,7,8-TCDD)	0.001

Class B: Based on Total Threshold Limit Concentration (TTLC)

Class	**Constituent**	**Concentration in mg/kg**
(1)	**(2)**	**(3)**
B1	Asbestos	10000
B2	Total Petroleum Hydrocarbons (TPH) (C5 - C36)	5,000

Note:

(1) The testing method for list of constituents at A1 to A61 in Class-A, shall be based on Toxicity Characteristic Leaching Procedure (TCLP) and for extraction of leachable constituents, USEPA Test Method 1311 shall be used.

(2) The testing method for list of constituents at A62 to A79 in Class- A, shall be based on Soluble Threshold Limit Concentration (STLC) and Waste Extraction Test (WET) Procedure given in Appendix II of section 66261 of Title 22 of California Code regulation (CCR) shall be used.

(3) In case of ammonia (A10), cyanide (A11) and chromium VI (A64), extractions shall be conducted using distilled water in place of the leaching media specified in the TCLP/STLC procedures.

(4) A summary of above specified leaching/extraction procedures is included in manual for characterization and analysis of hazardous waste published by Central Pollution Control Board and in case the method is not covered in the said manual, suitable reference method may be adopted for the measurement.

(5) In case of asbestos, the specified concentration limits apply only if the substances are in a friable, powdered or finely divided state.

(6) The hazardous constituents to be analyzed in the waste shall be relevant to the nature of the industry and the materials used in the process.

Wastes which contain any of the constituents listed below shall be considered as hazardous, provided they exhibit the characteristics listed in Class-C of this Schedule :

1.	Acid Amides
2.	Acid anhydrides
3.	Amines
4.	Anthracene
5.	Aromatic compounds other than those listed in Class A
6.	Bromates, (hypo-bromites)
7.	Chlorates (hypo-chlorites)
8.	Carbonyls
9.	Ferro-silicate and alloys
10.	Halogen- containing compounds which produce acidic vapours on contact with humid air or water e.g. silicon tetrachloride, aluminum chloride, titanium tetrachloride
11.	Halogen- silanes
12.	Halogenated Aliphatic Compounds
13.	Hydrazine (s)
14.	Hydrides
15.	Inorganic Acids
16.	Inorganic Peroxides
17.	Inorganic Tin Compounds
18.	Iodates
19.	(Iso- and thio-) Cyanates
20.	Manganese-silicate
21.	Mercaptans
22.	Metal Carbonyls
23.	Metal hydrogen sulphates
24.	Nitrides
25.	Nitriles
26.	Organic azo and azooxy Compounds
27.	Organic Peroxides
28.	Organic Oxygen Compounds
29.	Organic Sulphur Compounds
30.	Organo- Tin Compounds
31.	Organo nitro- and nitroso compounds

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32.	Oxides and hydroxides except those of hydrogen, carbon, silicon, iron, aluminum, titanium, manganese, magnesium, calcium
33.	Phenanthrene
34.	Phenolic Compounds
35.	Phosphate compounds except phosphates of aluminum, calcium and iron
36.	Salts of pre-acids
37.	Total Sulphur
38.	Tungsten Compounds
39.	Tellurium and tellurium compounds
40.	White and Red Phosphorus
41.	2-Acetylaminofluorene
42.	4-Aminodiphenyl
43.	Benzidine and its salts
44.	Bis (Chloromethyl) ether
45.	Methyl chloromethyl ether
46.	1,2-Dibromo-3-chloropropane
47.	3,3'-Dichlorobenzidine and its salts
48.	4-Dimethylaminoazobenzene
49.	4-Nitrobiphenyl
50.	Beta-Propiolactone

CLASS C : Based on hazardous Characteristics

Apart from the concentration limit given above, the substances or wastes shall be classified as hazardous waste if it exhibits any of the following characteristics due to the presence of any hazardous constituents:

Class C1: Flammable- A waste exhibits the characteristic of flammability or ignitability if a representative sample of the waste has any of the following properties, namely:-

(i) flammable liquids, or mixture of liquids, or liquids containing solids in solution or suspension (for example, paints, varnishes, lacquers, etc; but not including substances or wastes otherwise classified on account of their dangerous characteristics), which give off a flammable vapour at temperature less than 60°C. This flash point shall be measured as per ASTM D 93-79 closed-cup test method or as determined by an equivalent test method published by Central Pollution Control Board;

(ii) it is not a liquid and is capable, under standard temperature and pressure, of causing fire through friction, absorption of moisture or spontaneous chemical changes and, when ignited, burns vigorously and persistently creating a hazard;

(iii) it is an ignitable compressed gas;

(iv) It is an oxidizer and for the purposes of characterisation is a substance such as a chlorate, permanganate, inorganic peroxide, or a nitrate, that yields oxygen readily to stimulate the combustion of organic matter.

Class C2: Corrosive- A waste exhibits the characteristic of corrosivity if a representative sample of the waste has either of the following properties, namely:-

(i) it is aqueous and has a pH less than or equal to 2 or greater than or equal to 12.5;

(ii) it is a liquid and corrodes steel (SAE 1020) at a rate greater than 6.35 mm per year at a test temperature of 55 °C;

(iii) it is not aqueous and, when mixed with an equivalent weight of water, produces a solution having a pH less than or equal to 2 or greater than or equal to 12.5;

(iv) it is not a liquid and, when mixed with an equivalent weight of water, produces a liquid that corrodes steel (SAE1020) at a rate greater than 6.35 mm per year at a test temperature of 55 °C.

Note:

For the purpose of determining the corrosivity, the Bureau of Indian Standard 9040 C method for pH determination, NACE TM 01 69 : Laboratory Corrosion Testing of Metals and EPA 1110A method for corrosivity towards steel (SAE1020) to establish the corrosivity characteristics shall be adopted.

Class C3: Reactive or explosive- A waste exhibits the characteristic of reactivity if a representative sample of the waste it has any of the following properties, namely:-

(i) it is normally unstable and readily undergoes violent change without detonating;

(ii) it reacts violently with water or forms potentially explosive mixtures with water;

(iii) when mixed with water, it generates toxic gases, vapours or fumes in a quantity sufficient to present a danger to human health or the environment;

(iv) it is a cyanide or sulphide bearing waste which, when exposed to pH conditions between 2 and 12.5, can generate toxic gases, vapours or fumes in a quantity sufficient to present a danger to human health or the environmental;

(v) it is capable of detonation or explosive reaction if it is subjected to a strong initiating source or if heated under confinement;

(vi) it is readily capable of detonation or explosive decomposition or reaction at standard temperature and pressure;

(vii) it is a forbidden explosive.

Class C4: Toxic- A waste exhibits the characteristic of toxicity, if, :-

(i) the concentration of the waste constituents listed in Class A and B (of this schedule) are equal to or more than the permissible limits prescribed therein;

(ii) it has an acute oral LD50 less than 2,500 milligrams per kilogram;

(iii) it has an acute dermal LD50 less than 4,300 milligrams per kilogram;

(iv) it has an acute inhalation LC50 less than 10,000 parts per million as a gas or vapour;

(v) it has acute aquatic toxicity with 50% mortality within 96 hours for zebra fish (*Brachidanio rerio*) at a concentration of 500 milligrams per litre in dilution water and test conditions as specified in BIS test method 6582 – 2001.

(vi) it has been shown through experience or by any standard reference test- method to pose a hazard to human health or environment because of its carcinogenicity, mutagenecity, endocrine disruptivity, acute toxicity, chronic toxicity, bio-accumulative properties or persistence in the environment.

Class C5: Substances or Wastes liable to spontaneous combustion - Substances or Wastes which are liable to spontaneous heating under normal conditions encountered in transport, or to heating up on contact with air, and being then liable to catch fire.

Class C6: Substances or Wastes which, in contact with water emit flammable gases- Substances or Wastes which, by interaction with water, are liable to become spontaneously flammable or to give off flammable gases in dangerous quantities.

Class C7: Oxidizing - Substances or Wastes which, while in themselves not necessarily combustible, may, generally by yielding oxygen cause, or contribute to, the combustion of other materials.

Class C8: Organic Peroxides - Organic substances or Wastes which contain the bivalent O–O structure, which may undergo exothermic self-accelerating decomposition.

Class C9: Poisons (acute) - Substances or Wastes liable either to cause death or serious injury or to harm human health if swallowed or inhaled or by skin contact.

Class C10: Infectious ~~substances~~ - Substances or Wastes containing viable micro-organisms or their toxins which are known or suspected to cause disease in animals or humans.

Class C11: Liberation of toxic gases in contact with air or water - Substances or Wastes which, by interaction with air or water, are liable to give off toxic gases in dangerous quantities.

Class C12: Eco-toxic- Substances or Wastes which if released, present or may present immediate or delayed adverse impacts to the environment by means of bioaccumulation or toxic effects upon biotic systems or both.

Class C13: Capable, by any means, after disposal, of yielding another material, e.g., leachate, which possesses any of the characteristics listed above.

SCHEDULE III

[See rules 3 (1) (17) (iii), 3 (23), 12, 13 and 14]

Part A

List of hazardous wastes applicable for import and export with Prior Informed Consent [Annexure VIII of the Basel Convention*]

Basel No.	Description of Hazardous Wastes
(1)	**(2)**
A1	**Metal and Metal bearing wastes**
A1010	Metal wastes and waste consisting of alloys of any of the following but excluding such wastes specifically listed in Part B and Part D
	- Antimony
	- Cadmium
	- Lead
	- Tellurium
A1020	Waste having as constituents or contaminants, excluding metal wastes in massive form, any or the following:
	- Antimony, antimony compounds
	- Cadmium, cadmium compounds
	- Lead, lead compounds
	- Tellurium, tellurium compounds
A1040	Waste having metal carbonyls as constituents
A1050	Galvanic sludges
A1070	Leaching residues from zinc processing, dust and sludges such as jarosite, hematite, etc.
A1080	Waste zinc residues not included in Part B, containing lead and cadmium in concentrations sufficient to exhibit hazard characteristics indicated in Part C
A1090	Ashes from the incineration of insulated copper wire
A1100	Dusts and residues from gas cleaning systems of copper smelters
A1120	Waste sludges, excluding anode slimes, from electrolyte purification systems in copper electrorefining and electrowinning operations
A1140	Waste cupric chloride and copper cyanide catalysts not in liquid form note the related entry in Schedule VI
A1150	Precious metal ash from incineration of printed circuit boards not included in Part B
A1160	Waste lead acid batteries, whole or crushed
A1170	Unsorted waste batteries excluding mixtures of only Part B batteries. Waste batteries not specified in Part B containing constituents mentioned in Schedule II to an extent to render them hazardous
A2	**Wastes containing principally inorganic constituents, which may contain metals and organic materials**
A2010	Glass waste from cathode-ray tubes and other activated glasses
A2030	Waste catalysts but excluding such wastes specified in Part B
A3	**Wastes containing principally organic constituents, which may contain metals and inorganic materials**
A3010	Waste from the production or processing of petroleum coke and bitumen
A3020	Waste mineral oils unfit for their originally intended use
A3050	Wastes from production, formulation and use of resins, latex, plasticizers, glues or adhesives excluding such wastes specified in Part B (B4020)
A3120	Fluff-light fraction from shredding
A3130	Waste organic phosphorus compounds
A4	**Wastes which may contain either inorganic or organic constituents**
A4010	Wastes from the production, preparation and use of pharmaceutical products but excluding such waste specified in Part B
A4040	Wastes from the manufacture, formulation and use of wood-preserving chemicals (does not include wood treated with wood preserving chemicals)
A4070	Waste from the production, formulation and use of inks, dyes, pigments, paints, lacquers, varnish excluding those specified in Part B (B4010)
A4100	Wastes from industrial pollution control devices for cleaning of industrial off-gases but excluding such wastes specified in Part B
A4120	Wastes that contain, consist of or are contaminated with peroxides.
A4130	Wastes packages and containers containing Schedule II constituents in concentration sufficient to exhibit Part C of Schedule III hazard characteristics.

A4140	Waste consisting of or containing off specification or outdated chemicals (unused within the period recommended by the manufacturer) corresponding to constituents mentioned in Schedule II and exhibiting Part C of Schedule III hazard characteristics.
A4160	Spent activated carbon not included in Part B, B2060

*This List is based on Annexure VIII of the Basel Convention on Transboundary Movement of Hazardous Wastes and comprises of wastes characterized as hazardous under Article I, paragraph 1(a) of the Convention. Inclusion of wastes on this list does not preclude the use of hazard.
Characteristics given in Annexure VIII of the Basel Convention (Part C of this Schedule) to demonstrate that the wastes are not hazardous. **Hazardous wastes in Part-A are restricted and cannot be allowed to be imported without permission from the Ministry of Environment, Forest and Climate Change and the Directorate General of Foreign Trade license, if applicable.**

Part B

List of other wastes applicable for import and export and not requiring Prior Informed Consent [Annex IX of the Basel Convention*]

Basel No.	**Description of wastes**
(1)	**(2)**
B1	**Metal and metal-bearing wastes**
B1010	Metal and metal-alloy wastes in metallic, non-dispersible form:
	- Thorium scrap
	- Rare earths scrap
B1020	Clean, uncontaminated metal scrap, including alloys, in bulk finished form (sheet, plates, beams, rods, etc.), of:
	- Antimony scrap
	- Beryllium scrap
	- Cadmium scrap
	- -
	- Lead scrap (excluding lead acid batteries)
	- Selenium scrap
	- Tellurium scrap
B1030	Refractory metals containing residues
B1031	Molybdenum, tungsten, titanium, tantalum, niobium and rhenium metal and metal alloy wastes in metallic dispersible form (metal powder), excluding such wastes as specified in Part A under entry A1050, Galvanic sludges
B1040	Scrap assemblies from electrical power generation not contaminated with lubricating oil, PCB or PCT to an extent to render them hazardous
B1050	Mixed non-ferrous metal, heavy fraction scrap, containing cadmium, antimony, lead & tellurium mentioned in Schedule II in concentrations sufficient to exhibit Part C characteristics
B1060	Waste selenium and tellurium in metallic elemental form including powder
B1070	Waste of copper and copper alloys in dispersible form, unless they contain any of the constituents mentioned in Schedule II to an extent that they exhibit Part C characteristics
B1080	Zinc ash and residues including zinc alloys residues in dispersible form unless they contain any of the constituents mentioned in Schedule II in concentration such as to exhibit Part C characteristics
B1090	Waste batteries conforming to a standard battery specification, excluding those made with lead, cadmium or mercury
B1100	Metal bearing wastes arising from melting, smelting and refining of metals:
	- Slags from copper processing for further processing or refining containing arsenic, lead or cadmium
	- Slags from precious metals processing for further refining
	- Wastes of refractory linings, including crucibles, originating from copper smelting
	- Tantalum-bearing tin slags with less than 0.5% tin
B1110	Used Electrical and electronic assemblies other than those listed in Part D of Schedule III
	Electronic assemblies consisting only of metals or alloys Waste electrical and electronic assemblies or scrap (including printed circuit boards) not containing components such as accumulators and other batteries included in Part A of Schedule III, mercury-switches, glass from cathode-ray tubes and other activated glass and PCB-capacitors, or not

	contaminated with Schedule II constituents such as cadmium, mercury, lead, polychlorinated biphenyl) or from which these have been removed, to an extent that they do not possess any of the characteristics contained in Part C of Schedule III (note the related entry in Schedule VI, A1180)
B1120	Spent catalysts excluding liquids used as catalysts, containing any of: Transition metals, excluding waste catalysts (spent catalysts, liquid used catalysts or other catalysts) in Part A and Schedule VI: - Scandium - Titanium - Vanadium - Chromium - Manganese - Iron - Cobalt - Nickel - Copper - Zinc - Yttrium - Zirconium - Niobium - Molybdenum - Hafnium - Tantalum - Tungsten - Rhenium Lanthanides (rare earth metals): - Lanthanum - Cerium
	- Praseodymium - Neodymium - Samarium - Europium - Gadolinium - Terbium - Dysprosium - Holmium - Erbium - Thulium - Ytterbium - Lutetium
B1130	Cleaned spent precious metal bearing catalysts
B1140	Precious metal bearing residues in solid form which contain traces of inorganic cyanides
B1150	Precious metals and alloy wastes (gold , silver, the platinum group but not mercury) in a dispersible form, non-liquid form with appropriate packaging and labelling
B1160	Precious metal ash from the incineration of printed circuit boards (note the related entry in Part A A1150)
B1170	Precious metal ash from the incineration of photographic film
B1180	Waste photographic film containing silver halides and metallic silver
B1190	Waste photographic paper containing silver halides and metallic silver
B1200	Granulated slag arising from the manufacture of iron and steel
B1210	Slag arising from the manufacture of iron and steel including slags as a source of Titanium dioxide and Vanadium
B1220	Slag from zinc production, chemically stabilised, having a high iron content (above 20%) and processed according to industrial specifications mainly for construction
B1230	Mill scale arising from the manufacture of iron and steel
B1240	Copper Oxide mill-scale
B2	**Wastes containing principally inorganic constituents, which may contain metals and organic materials**
B2010	Wastes from mining operations in non-dispersible form:
	- Natural graphite waste
	- Slate wastes
	- Mica wastes
	- Leucite, nepheline and nepheline syenite waste
	- Feldspar waste
	- Fluorspar waste
	- Silica wastes in solid form excluding those used in foundry operations
B2020	Glass wastes in non-dispersible form: - Cullet and other waste and scrap of glass except for glass from cathode-ray tubes and other activated glasses
B2030	Ceramic wastes in non-dispersible form: - Cermet wastes and scrap (metal ceramic composites) - Ceramic based fibres
B2040	Other wastes containing principally inorganic constituents: - Partially refined calcium sulphate produced from flue gas desulphurization (FGD) - Waste gypsum wallboard or plasterboard arising from the demolition of buildings - Slag from copper production, chemically stabilized, having a high iron content (above

	20%) and processed according to industrial specifications mainly for construction and abrasive applications - Sulphur in solid form - Limestone from production of calcium cyanamide (pH<9) - Sodium, potassium, calcium chlorides - Carborundum (silicon carbide) - Broken concrete - Lithium-tantalum and lithium-niobium containing glass scraps
B2060	Spent activated carbon not containing any of Schedule II constituents to the extent they exhibit Part C characteristics, for example, carbon resulting from the treatment of potable water and processes of the food industry and vitamin production (note the related entry in Part A A4160)
B2070	Calcium fluoride sludge
B2080	Waste gypsum arising from chemical industry processes not included in Schedule VI (note the related entry in A2040)
B2090	Waste anode butts from steel or aluminium production made of petroleum coke or bitumen and cleaned to normal industry specifications (excluding anode butts from chlor alkali electrolyses and from metallurgical industry)
B2100	Waste hydrates of aluminium and waste alumina and residues from alumina production, excluding such materials used for gas cleaning, flocculation or filtration processes
B2130	Bituminous material (asphalt waste) from road construction and maintenance, not containing tar (note the related entry in Schedule VI, A3200)
B3	**Wastes containing principally organic constituents, which may contain metals and inorganic materials**
B3027	Self-adhesive label laminate waste containing raw materials used in label material production
B3030	Textile wastes The following materials, provided they are not mixed with other wastes and are prepared to a specification: - Silk waste (including cocoons unsuitable for reeling, yarn waste and garnetted stock) • not carded or combed • other - Waste of wool or of fine or coarse animal hair, including yarn waste but excluding garnetted stock • noils of wool or of fine animal hair • other waste of wool or of fine animal hair • waste of coarse animal hair - Cotton waste (including yarn waste and garnetted stock) • yarn waste (including thread waste) • garnetted stock • other - Flax tow and waste - Tow and waste (including yarn waste and garnetted stock) of true hemp (Cannabis sativa L.) - Tow and waste (including yarn waste and garnetted stock) of jute and other textile bast fibres (excluding flax, true hemp and ramie) - Tow and waste (including yarn waste and garnetted stock) of sisal and other textile fibres of the genus Agave - Tow, noils and waste (including yarn waste and garneted stock) of coconut - Tow, noils and waste (including yarn waste and garneted stock) of abaca (Manila hemp or Musa textilis Nee) - Tow, noils and waste (including yarn waste and garneted stock) of ramie and other vegetable textile fibres, not elsewhere specified or included - Waste (including noils, yarn waste and garnetted stock) of man-made fibres • of synthetic fibres • of artificial fibres - Worn clothing and other worn textile articles - Used rags, scrap twine, cordage, rope and cables and worn out articles of twine, cordage, rope or cables of textile materials • sorted • other
B3035	Waste textile floor coverings, carpets
B3040	Rubber Wastes

	The following materials, provided they are not mixed with other wastes: - Waste and scrap of hard rubber (e.g., ebonite) - Other rubber wastes (excluding such wastes specified elsewhere)
B3050	Untreated cork and wood waste: - Wood waste and scrap, whether or not agglomerated in logs, briquettes, pellets or similar forms - Cork waste: crushed, granulated or ground cork
B3060	Wastes arising from agro-food industries provided it is not infectious: - Wine lees - Dried and sterilized vegetable waste, residues and by-products, whether or not in the form of pellets, of a kind used in animal feeding, not elsewhere specified or included - Degras: residues resulting from the treatment of fatty substances or animal or vegetable waxes - Waste of bones and horn-cores, unworked, defatted, simply prepared (but not cut to shape), treated with acid or degelatinised - Fish waste - Cocoa shells, husks, skins and other cocoa waste - Other wastes from the agro-food industry excluding by-products which meet national and international requirements and standards for human or animal consumption
B3070	The following wastes: - Waste of human hair - Waste straw - Deactivated fungus mycelium from penicillin production to be used as animal feed
B3080	Waste parings and scrap of rubber
B3090	Paring and other wastes of leather or of composition leather not suitable for the manufacture of leather articles, excluding leather sludges, not containing hexavalent chromium compounds and biocides (note the related entry in Schedule VI, A3100)
B3100	Leather dust, ash, sludges or flours not containing hexavalent chromium compounds or biocides (note the related entry in Schedule VI, A3090)
B3110	Fellmongery wastes not containing hexavalent chromium compounds or biocides or infectious substances (note the related entry in Schedule VI, A3110)
B3120	Wastes consisting of food dyes
B3130	Waste polymer ethers and waste non-hazardous monomer ethers incapable of forming peroxides
B3140	Waste pneumatic and other tyres, excluding those which do not lead to resource recovery, recycling, reclamation but not for direct reuse
B4	**Wastes which may contain either inorganic or organic constituents**
B4010	Wastes consisting mainly of water-based or latex paints, inks and hardened varnishes not containing organic solvents, heavy metals or biocides to an extent to render them hazardous (note the related entry in Part A, A4070)
B4020	Wastes from production, formulation and use of resins, latex, plasticizers, glues or adhesives, not listed in Part A, free of solvents and other contaminants to an extent that they do not exhibit Part C characteristics (note the related entry in Part A, A3050)
B4030	Used single-use cameras, with batteries not included in Part A

* This list is based on Annexure IX of the Basel Convention on Transboundary Movement of Hazardous Wastes and comprises of wastes not characterized as hazardous under Article-I of the Basel Convention. **The wastes in Part- B are restricted and cannot be allowed to be imported without permission from the Ministry of Environment, Forest and Climate Change and the Directorate General of Foreign Trade license, if applicable.**

Note:

(1) Copper dross containing copper greater than 65% and lead and Cadmium equal to or less than 1.25% and 0.1% respectively; spent cleaned metal catalyst containing copper; and copper reverts, cake and residues containing lead and cadmium equal to or less than 1.25% and 0.1% respectively are allowed for import without Director General of Foreign Trade license to units (actual users) authorised by State Pollution Control Board and with the Ministry of Environment, Forest and Climate Change's permission. Copper reverts, cake and residues containing lead and cadmium greater than 1.25% and 0.1% respectively are under restricted category for which import is permitted only against Director General of Foreign Trade license for the purpose of processing or reuse by units permitted with the Ministry of Environment, Forest and Climate Change (actual users).

(2) Zinc ash or skimmings in dispersible form containing zinc more than 65% and lead and cadmium equal to or less than 1.25% and 0.1% respectively and spent cleaned metal catalyst containing zinc are allowed for import without Director General of Foreign Trade license to units authorised by State Pollution control Board, Ministry of Environment, Forest and Climate Change's permission (actual users) upto an annual quantity limit indicated in registration letter. Zinc ash and skimmings containing less than 65% zinc and lead and cadmium equal to or more than 1.25% and 0.1% respectively and hard zinc spelter and brass dross containing lead greater than 1.25% are under restricted category for which import is permitted against Director General of Foreign Trade license and only for purpose of processing or reuse by units registered with the Ministry of Environment Forest and Climate Change (actual users).

Part C
List of Hazardous Characteristics

Code	Characteristic
H 1	**Explosive** An explosive substance or waste is a solid or liquid substance or waste (or mixture of substances or wastes) which is in itself capable by chemical reaction of producing gas at such a temperature and pressure and at such a speed as to cause damage to the surrounding.
H 3	**Flammable liquids** The word "flammable" has the same meaning as "inflammable". Flammable liquids are liquids, or mixtures of liquids, or liquids containing solids in solution or suspension (for example, paints, varnishes, lacquers, etc. but not including substances or wastes otherwise classified on account of their dangerous characteristics) which give off a flammable vapour at temperatures of not more than 60.5ºC, closed-cup test, or not more than 65.6ºC, open-cup test. (Since the results of open-cups tests and of closed-cup tests are not strictly comparable and even individual results by the same test are often variable, regulations varying from the above figures to make allowance for such differences would be within the spirit of this definition).
H 4.1	**Flammable solids** Solids, or waste solids, other than those classed as explosives, which under conditions encountered in transport are readily combustible, or may cause or contribute to fire through friction.
H 4.2	**Substances or wastes liable to spontaneous combustion** Substances or wastes which are liable to spontaneous heating under normal conditions encountered in transport, or to heating up on contact with air, and being then liable to catch fire.
H 4.3	**Substances or wastes which, in contact with water emit flammable gases** Substances or wastes which, by interaction with water, are liable to become spontaneously flammable or to give off flammable gases in dangerous quantities.
H 5.1	**Oxidizing** Substances or wastes which, while in themselves not necessarily combustible, may, generally by yielding oxygen cause, or contribute to, the combustion or other materials.
H 5.2	**Organic Peroxides** Organic substances or wastes which contain the bivalent-o-o-structure are thermally unstable substances which may undergo exothermic self-accelerating decomposition.
H 6.1	**Poisons (acute)** Substances or wastes liable either to cause death or serious injury or to harm human health if swallowed or inhaled or by skin contact.
H 6.2	**Infectious substances** Substances or wastes containing viable micro-organisms or their toxins which are known or suspected to cause disease in animals or humans.
H 8	**Corrosives** Substances or wastes which, by chemical action, will cause severe damage when in contact with living tissue, or, in the case of leakage, will materially damage, or even destroy, other goods or the means of transport; they may also cause other hazards.
H 10	**Liberation of toxic gases in contact with air or water** Substances or wastes which, by interaction with air or water, are liable to give off toxic gases in dangerous quantities.
H 11	**Toxic (delayed or chronic)** Substances or wastes which, if they are inhaled or ingested or if they penetrate the skin, may involve delayed or chronic effects, including carcinogenicity).
H 12	**Eco-toxic** Substances or wastes which if released, present or may present immediate or delayed adverse impacts to the environment by means of bioaccumulation or toxic effects upon biotic systems or both.

H 13 **Capable,** by any means, after disposal, of yielding another material, e.g., leachate, which possesses any of the characteristics listed above.

Part D

List of other wastes applicable for import and export without permission from Ministry of Environment, Forest and Climate Change [Annex IX of the Basel Convention*]

Basel No.	Description of wastes
(1)	(2)
B1	**Metal and metal-bearing wastes**
B1010	Metal and metal-alloy wastes in metallic, non-dispersible form :
	- Precious metals (gold, silver, platinum but not mercury) * *
	- Iron and steel scrap * *
	- Nickel scrap * *
	- Aluminium scrap* *
	- Zinc scrap * *
	- Tin scrap * *
	- Tungsten scrap * *
	- Molybdenum scrap * *
	- Tantalum scrap * *
	- Cobalt scrap * *
	- Bismuth scrap * *
	- Titanium scrap * *
	- Zirconium scrap * *
	- Manganese scrap * *
	- Germanium scrap * *
	- Vanadium scrap * *
	- Hafnium scrap * *
	- Indium scrap * *
	- Niobium scrap * *
	- Rhenium scrap * *
	- Gallium scrap * *
	- Magnesium scrap * *
	- Copper scrap * *
	- Chromium scrap * *
B1050	Mixed non-ferrous metal, heavy fraction scrap, containing metals other than specified in Part B1050 and not containing constituents mentioned in Schedule II in concentrations sufficient to exhibit Part C characteristics* *
B1100	Metal bearing wastes arising from melting, smelting and refining of metals:
	- Hard Zinc spelter * *
	- Zinc-containing drosses * *: ~ Galvanizing slab zinc top dross (>90% Zn) ~ Galvanizing slab zinc bottom dross (>92% Zn) ~ Zinc die casting dross (>85% Zn) ~ Hot dip galvanizers slab zinc dross (batch) (>92% Zn) ~ Zinc skimmings
	– Aluminium skimmings (or skims) excluding salt slag
B1110	Electrical and electronic assemblies (including printed circuit boards, electronic components and wires) destined for direct reuse and not for recycling or final disposal
	- Used electrical and electronic assemblies imported for repair and to be re-exported back after repair within one year of import * * *
	- Used electrical and electronic assemblies imported for rental purpose and re-exported back within one year of import * * *
	- Used electrical and electronic assemblies exported for repair and to be re-import after repair
	- Used electrical and electronic assemblies imported for testing, research and development, project work purposes and to be re-exported back within a period of three years from the date of import * * *

	- Spares imported for warranty replacements provided equal number of defective or non-functional parts are exported back within one year of the import * * *
	- Used electrical and electronic assemblies imported by Ministry of Defence, Department of Space and Department of Atomic Energy * * *
	- Used electrical and electronic assemblies (not in bulk; quantity less than or equal to three) imported by the individuals for their personal uses
	- Used Laptop, Personal Computers, Mobile, Tablet up to 01 number each imported by organisations in a year
	- Used electrical and electronic assemblies owned by individuals and imported on transfer of residence
	- Used multifunction print and copying machines (MFDs)* * * *
	- Used electrical and electronic assemblies imported by airlines for aircraft maintenance and remaining either on board or under the custodianship of the respective airlines warehouses located on the airside of the custom bonded areas.
B3	**Wastes containing principally organic constituents, which may contain metals and inorganic materials**
B3020	Paper, paperboard and paper product wastes * * The following materials, provided they are not mixed with hazardous wastes: Waste and scrap of paper or paperboard of: - unbleached paper or paperboard or of corrugated paper or paperboard - other paper or paperboard, made mainly of bleached chemical pulp, not coloured in the mass - paper or paperboard made mainly of mechanical pulp (for example newspapers, journals and similar printed matter) - other, including but not limited to (1) laminated paperboard (2) unsorted scrap
B3140	Aircraft Tyres exported to Original Equipment Manufacturers for re-treading and re-imported after re-treading by airlines for aircraft maintenance and remaining either on board or under the custodianship of the respective airlines warehouses located on the airside of the custom bonded areas

Note:

* This list is based on Annexure IX of the Basel Convention on Transboundary Movement of Hazardous Wastes and comprises of wastes not characterized as hazardous under Article-I of the Basel Convention.

* * Import permitted in the country to the actual user or to the trader on behalf of the actual users authorised by SPCB on one time basis and subject to verification of documents specified in Schedule VIII of these rules by the Custom Authority.

* * * Import permitted in the country only to the actual users from Original Equipment Manufacturers (OEM) and subject to verification of documents specified in Schedule VIII of these rules by the Custom Authority.

* * * * Import permitted in the country to the actual users or trader on behalf of the actual user in accordance with the documents required and verified by the Custom Authority as specified under Schedule VIII of these rules. The policy for free trade for multifunction print and copying machine to be reviewed once the MFDs are domestically manufactured.

All other wastes listed in Part D of Schedule III having no "Stars" are permitted without any documents from MoEF&CC subject to compliance of the conditions of the Customs Authority, if any.

SCHEDULE IV

[*See rules 6 (1) (ii) and 6 (2)*]

List of commonly recyclable hazardous wastes

S.No.	Wastes
(1)	(2)
1.	Brass Dross
2.	Copper Dross
3.	Copper Oxide mill scale
4.	Copper reverts, cake and residue
5.	Waste Copper and copper alloys in dispersible from
6.	Slags from copper processing for further processing or refining
7.	Insulated Copper Wire Scrap or copper with PVC sheathing including ISRI-code material namely "Druid"
8.	Jelly filled Copper cables
9.	Spent cleared metal catalyst containing copper
10.	Spent catalyst containing nickel, cadmium, Zinc, copper, arsenic, vanadium and cobalt
11.	Zinc Dross-Hot dip Galvanizers SLAB
12.	Zinc Dross-Bottom Dross
13.	Zinc ash/Skimmings arising from galvanizing and die casting operations
14.	Zinc ash/Skimming/other zinc bearing wastes arising from smelting and refining
15.	Zinc ash and residues including zinc alloy residues in dispersible from
16.	Spent cleared metal catalyst containing zinc
17.	Used Lead acid battery including grid plates and other lead scrap/ashes/residues not covered under Batteries (Management and Handling) Rules, 2001. [Battery scrap, namely: Lead battery plates covered by ISRI, Code word "Rails" Battery lugs covered by ISRI, Code word "Rakes". Scrap drained/dry while intact, lead batteries covered by ISRI, Code word "rains".
18.	Components of waste electrical and electronic assembles comprising accumulators and other batteries included in Part A of Schedule III, mercury-switches, activated glass cullets from cathode-ray tubes and other activated glass and PCB-capacitors, or any other component contaminated with Schedule II constituents (e.g. cadmium, mercury, lead, polychlorinated biphenyl) to an extent that they exhibit hazard characteristics indicated in part C of Schedule III.
19.	Paint and ink Sludge/residues
20.	Used oil and waste oil

SCHEDULE V

[See rules 3 (36) and 3 (39)]

PART A

Specifications of Used Oil Suitable for recycling

S.No.	Parameter	Maximum permissible Limits
(1)	(2)	(3)
1.	Polychlorinated biphenyls (PCBs)	< 2ppm *
2.	Lead	100 ppm
3.	Arsenic	5 ppm
4.	Cadmium+Chromium+Nickel	500 ppm
5.	Polyaromatic hydrocarbons (PAH)	6%

Part B

Specification of fuel derived from waste oil

S.No.	Parameter	Maximum permissible limits
(1)	(2)	(3)
1.	Sediment	0.25%
2.	Lead	100 ppm
3.	Arsenic	5 ppm
4.	Cadmium+Chromium+Nickel	500 ppm

5.	Polyaromatic hydrocarbons (PAH)	6%
6.	Total halogents	4000 ppm
7.	Polychlorinated biphenyls (PCBs)	<2 ppm *
8.	Sulfur	4.5%
9.	Water Content	1%

*The detection limit is 2 ppm by gas Liquid Chromatography (GLC) using Electron Capture detector (ECD)

SCHEDULE VI

[See rules 12 (6), 12 (7) and 14(1)]

Hazardous and Other wastes prohibited for import

Basel No.	Description of hazardous and other wastes
(1)	**(2)**
A1	**Metal and Metal bearing wastes**
A1010	Metal wastes and waste consisting of alloys of any of the following but excluding such wastes specifically listed in Part B and Part D of Schedule III
	- Arsenic
	- Beryllium
	- Mercury
	- Selenium
	- Thallium
A1020	Wastes having as constituents or contaminants, excluding metal wastes in massive form, any of the following:
	- Beryllium; beryllium compounds
	- Selenium; selenium compounds
A1030	Wastes having as constituents or contaminants any of the following:
	- Arsenic; arsenic compounds
	- Mercury; mercury compounds
	- Thallium; thallium compounds
A1040	Waste having hexavalent chromium compounds as constituents
A1140	Waste cupric chloride and copper cyanide catalysts in liquid form (note the related entry in Part A of Schedule III)
A1060	Wastes liquors from the pickling of metals
A1110	Spent electrolytic solutions from copper electrorefining and electrowinning operations
A1130	Spent etching solutions containing dissolved copper
A1180	Waste electrical and electronic assembles or scrap (does not include scrap assemblies from electric power generation) containing components such as accumulators and other batteries included in Part A of Schedule III, mercury-switches, glass from cathode-ray tubes and other activated glass and PCB-capacitors, or contaminated with Schedule II constituents (e.g. cadmium, mercury, lead, polychlorinated biphenyl) to an extent that they exhibit hazard characteristics indicated in Part C of Schedule III (note the related entry in Part B B1110)
A1190	Waste metal cables coated or insulated with plastics containing or contaminated with coal tar, PCB, lead, cadmium, other organohalogen compounds or other constituents as mentioned in Schedule II to the extent that they exhibit hazard characteristics indicated in Part C of Schedule III
A2	**Wastes containing principally inorganic constituents, which may contain metals and organic materials**
A2020	Waste inorganic fluorine compounds in the form of liquids or sludges but excluding such wastes specified in Part B
A2040	Waste gypsum arising from chemical industry processes, if it contains any of the constituents mentioned in Schedule 2 to the extent that they exhibit hazard characteristics indicated in Part C of Schedule III (note the related entry in Part B B2080)
A2050	Waste asbestos (dusts and fibres)
A2060	Coal-fired power plant fly-ash containing Schedule II constituents in concentrations sufficient to exhibit Part C characteristics

A3	**Wastes containing principally organic constituents, which may contain metals and inorganic materials**
A3030	Wastes that contain, consist of or are contaminated with leaded anti-knock compounds sludges.
A3040	Waste thermal (heat transfer) fluids
A3060	Waste nitrocellulose
A3070	Waste phenols, phenol compounds including chlorophenol in the form of liquids or sludges
A3080	Waste ethers not including those specified in Part B
A3090	Waste leather dust, ash, sludges and flours when containing hexavalent chromium compounds or biocides (note the related entry in Part B B3100)
A3100	Waste paring and other waste of leather or of composition leather not suitable for the manufacture of leather articles, containing hexavalent chromium compound and biocides (note the related entry in Part B B3090)
A3110	Fellmongery wastes containing hexavalent chromium compounds or biocides or infectious substances (note the related entry in Part B B3110)
A3140	Waste non-halogenated organic solvents but excluding such wastes specified in Part B
A3150	Waste halogenated organic solvents
A3160	Waste halogenated or unhalogenated non-aqueous distillation residues arising from organic solvent recovery operations
A3170	Waste arising from the production of aliphatic halogenated hydrocarbons (such as chloromethane, dichloro-ethane, vinyl chloride, vinylidene chloride, allyl chloride and epichlorhydrin)
A3180	Wastes, substances and articles containing, consisting of or contaminated with polychlorinated biphenyl (PCB), polychlorinated terphenyl (PCT), polychlorinated naphthalene (PCN) or polybrominated biphenyl (PBB) or any other polybrominated analogues of these compounds
A3190	Waste tarry residues (excluding asphalt cements) arising from refining, distillation and any pyrolytic treatment of organic materials
A3200	Bituminous material (asphalt waste) from road construction and maintenance, containing tar (note the related entry in Part B, B2130)
A4	**Wastes which may contain either inorganic or organic constituents**
A4020	Clinical and related wastes; that is wastes arising from medical, nursing, dental, veterinary, or similar practices, and wastes generated in hospitals or other facilities during the investigation or treatment of patients, or research projects.
A4030	Waste from the production, formulation and use of biocide and phyto-pharmaceuticals, including waste pesticides and herbicides which are off-specification, out-dated (unused within the period recommended by the manufacturer), or unfit for their originally intended use,
A4050	Wastes that contain, consist of, or are contaminated with any of the following: - Inorganic cyanides, excepting precious-metal-bearing residues in solid form containing traces of inorganic cyanides. - Organic cyanides
A4060	Waste oils/water, hydrocarbons/water mixtures, emulsions
A4080	Wastes of an explosive nature (but excluding such wastes specified in Part B)
A4090	Waste acidic or basic solutions, other than those specified at B2120 of this Schedule
A4110	Wastes that contain, consist of or are contaminated with any of the following: - Any congenor of polychlorinated dibenzo-furan. - Any congenor of polychlorinated dibenzo-P-dioxin.
A4150	Waste chemical substances arising from research and development or teaching activities which are not identified and /or are new and whose effects on human health and /or the environment are not known
B1	**Metal and Metal bearing wastes**
B 1110	Used critical care medical equipment for re-use
B1115	Waste metal cables coated or insulated with plastics, not included in A1190 of this schedule, excluding those destined for operations which do not lead to resource recovery, recycling, reclamation, direct re-use or alternative uses or any other disposal operations involving, at any stage, uncontrolled thermal processes, such as open-burning.
B1250	Waste end-of-life motor vehicles, containing neither liquids nor other hazardous components
B2	**Wastes containing principally inorganic constituents, which may contain metals and organic materials**
B2050	Coal-fired power plant fly-ash, note the related entry at A2060 of this Schedule
B2110	Bauxite residue (red mud) (pH moderated to less than 11.5)
B2120	Waste acidic or basic solutions with a pH greater than 2 and less than 11.5, which are not corrosive or otherwise hazardous (note the related entry at A4090 of this schedule)
B3	**Wastes containing principally organic constituents, which may contain metals and inorganic**

	materials
B3010	Solid plastic waste The following plastic or mixed plastic waste, prepared to a specification: - Scrap plastic of non-halogenated polymers and co-polymers, including but not limited to the following: Ethylene, Styrene, Polypropylene, polyethylene terephthalate, Acrylonitrile, Butadiene, Polyacetals, Polyamides, polybutylene tere-phthalate, Polycarbonates, Polyethers, polyphenylene sulphides, acrylic polymers, alkanes C10-C13 (plasticiser), polyurethane (not containing CFC's), Polysiloxanes, polymethyl methacrylate, polyvinyl alcohol, polyvinyl butyral, Polyvinyl acetate - Cured waste resins or condensation products including the following: urea formaldehyde resins, phenol formaldehyde resins, melamine formaldehyde resins, epoxy resins, alkyd resins, polyamides - The following fluorinated polymer wastes (excluding post-consumer wastes): perfluoroethylene/ propylene, perfluoro alkoxy alkane, tetrafluoroethylene/per fluoro vinyl ether (PFA), tetrafluoroethylene/per fluoro methylvinyl ether (MFA), polyvinylfluoride , polyvinylidenefluoride
B3026	The following waste from the pre-treatment of composite packaging for liquids, not containing constituents mentioned in Schedule II in concentrations sufficient to exhibit Part C characteristics: - Non-separable plastic fraction - Non-separable plastic-aluminium fraction -
B3065	Waste edible fats and oils of animal or vegetable origin (e.g. frying oil)
B3140	Waste pneumatic tyres for direct reuse
Y 46	Wastes collected from household/municipal waste
Y 47	Residues arising from the incineration of household wastes

SCHEDULE VII

[*See rules 13 (6) and 21*]

List of authorities and corresponding duties

S. No.	**Authority**	**Corresponding Duties**
(1)	**(2)**	**(3)**
1.	Ministry of Environment, Forests and Climate Change under the Environment (Protection)Act, 1986	(i) Identification of hazardous and other wastes (ii) Permission to exporters of hazardous and other wastes (iii) Permission to importer of hazardous and other wastes (iv) Permission for transit of hazardous and other wastes through India. (v) Promote environmentally sound management of hazardous and other waste. (vi) Sponsoring of training and awareness programme on Hazardous and Other Waste Management related activities.
2.	Central Pollution Control Board constituted under the Water (Prevention and Control of Pollution) Act, 1974	(i) Co-ordination of activities of State Pollution Control Boards (ii) Conduct training courses for authorities dealing with management of hazardous and other wastes (iii) Recommend standards and specifications for treatment and disposal of wastes and leachates, recommend procedures for characterisation of hazardous wastes.

		(iv) Inspection of facilities handling hazardous waste as and when necessary. (v) Sector specific documentation to identify waste for inclusion in these rules. (vi) Prepare and update guidelines to prevent or minimise the generation and handling of hazardous and other wastes. (vii) Prepare and update guidelines/ Standard Operating Procedures (SoPs) for recycling, utilization, pre-processing, co-processing of hazardous and other wastes. (viii) To prepare annual review report on management of hazardous waste. (ix) Any other function assigned by the Ministry of Environment, Forest and Climate Change, from time to time.
3.	State Government/Union Territory Government/Administration	(i) Identification of site (s) for common Hazardous and Other Waste Treatment Storage and Disposal Facility (TSDF) (ii) Asses Environment Impact Assessment (EIA) reports and convey the decision of approval of site or otherwise Acquire the site or inform operator of facility or occupier or association of occupiers to acquire the site (iii) Notification of sites. (iv) Publish periodically an inventory of all potential or existing disposal sites in the State or Union Territory
4.	State Pollution Control Boards or Pollution Control Committees constituted under the Water (Prevention and Control of Pollution) Act, 1974	(i) Inventorisation of hazardous and other wastes (ii) Grant and renewal of authorisation (iii) Monitoring of compliance of various provisions and conditions of permission including conditions of permission for issued by Ministry of Environment, Forest and Climate Change for exports and imports (iv) Examining the applications for imports submitted by the importers and forwarding the same to Ministry of Environment, Forest and Climate Change (v) Implementation of programmes to prevent or reduce or minimise the generation of hazardous and other wastes. (vi) Action against violations of these rules. (vii) Any other function under these Rules assigned by Ministry of Environment, Forest and Climate Change from time to time.
5.	Directorate General of Foreign Trade constituted under the Foreign Trade (Development and Regulation) Act, 1992	(i) Grant of licence for import of hazardous and other wastes (ii) Refusal of licence for hazardous and other wastes prohibited for imports and export
6.	Port authority under Indian Ports Act, 1908 (15 of 1908) and Customs Authority under the Customs Act, 1962 (52 of 1962)	(i) Verify the documents (ii) Inform the Ministry of Environment, Forests and Climate Change of any illegal traffic (iii) Analyse wastes permitted for imports and exports, wherever required. (iv) Train officials on the provisions of these rules and in the analysis of hazardous and other wastes (v) Take action against exporter or importer for violations under the Indian Ports Act, 1908 or Customs Act, 1962

SCHEDULE VIII

[*See rules 13(2) and 13 (4)*]

List of documents for verification by Customs for import of other wastes specified in Part D of Schedule III

S. No.	Basel No.	Description of other wastes	List of Documents
(1)	(2)	(3)	(4)
1	B1010	Metal and metal-alloy wastes in metallic, non-dispersible form: - Precious metals (gold, silver, platinum) - Iron and steel scrap - Nickel scrap - Aluminium scrap - Zinc scrap - Tin scrap - Tungsten scrap - Molybdenum scrap - Tantalum scrap - Cobalt scrap - Bismuth scrap - Titanium scrap - Zirconium scrap - Manganese scrap - Germanium scrap - Vanadium scrap - Hafnium scrap - Indium scrap - Niobium scrap - Rhenium scrap - Gallium scrap - Magnesium scrap - Copper scrap - Chromium scrap	(a) Duly filled up Form 6 - Movement document; (b) The import license from Directorate General of Foreign Trade, wherever applicable; (c) Pre-shipment inspection certificate issued by the inspection agency of the exporting country or the inspection and certification agency approved by Directorate General of Foreign Trade; (d) The valid consents to operate under the Air and Water Acts and the authorisation under these rules, for actual users. For traders, only valid one time authorisation from concerned SPCB is required; (e) The chemical analysis report of the waste being imported; (f) an acknowledged copy of the annual return filed with concerned State Pollution Control Board for import in the last financial year.
2	B1050	Mixed non-ferrous metal, heavy fraction scrap, containing metals other than specified in Part B1050 and not containing constituents mentioned in Schedule II in concentrations sufficient to exhibit Part C characteristics* *	(a) Duly filled up Form 6 - Movement document; (b) The import license from Directorate General of Foreign Trade, wherever applicable; (c) Pre-shipment inspection certificate issued by the inspection agency of the exporting country or the inspection and certification agency approved by Directorate General of Foreign Trade; (d) The valid consents to operate under the Air and Water Acts and the authorisation under these rules, for actual users. For traders, only valid authorisation from concerned SPCB is required; (e) The chemical analysis report of the waste being imported; (f) An acknowledged copy of the annual return filed with concerned SPCB for import in the last financial year.
3	B1100	Metal bearing wastes arising from melting, smelting and refining of metals: - Hard Zinc spelter - Zinc-containing drosses: ~ Galvanizing slab zinc top dross (>90% Zn) ~ Galvanizing slab zinc bottom dross (>92% Zn) ~Zinc die casting dross (>85% Zn) ~ Hot dip galvanizers slab zinc dross (batch) (>92% Zn)	(a) Duly filled up Form 6 - Movement document; (b) The import license from Directorate General of Foreign Trade, wherever applicable; (c) Pre-shipment inspection certificate issued by the inspection agency of the exporting country or the inspection and certification agency approved by Directorate General of Foreign Trade; (d) The valid consents to operate under the Air and Water Acts and the authorisation under these rules, for actual users. For traders, only valid authorisation from concerned SPCB is

		~ Zinc skimmings – Aluminium skimmings (or skims) excluding salt slag	required; (e) The chemical analysis report of the waste being imported; (f) An acknowledged copy of the annual return filed with concerned SPCB for import in the last financial year.
4	B1110	Electrical and electronic assemblies (including printed circuit boards, electronic components and wires) destined for direct reuse and not for recycling or final disposal	
(a)		Used electrical and electronic assemblies imported for repair and to be re-exported after repair within one year of import	(a) Duly filled up Form 6 - Movement document; (b) Undertaking for re-export; (c) Details of previous import, if there has been any and confirmation regarding their re-export; (d) An acknowledged copy of the annual return filed with concerned SPCB for import in the last financial year (e) Certificate from exporting company for accepting the repaired and unrepairable electrical and electronic assemblies and the spares or part or component or consumables being re-exported.
(b)		Used electrical and electronic assemblies imported for rental purpose and re-exported back within one year of import	(a) Duly filled up Form 6 - Movement document; (b) Undertaking for re-export; (c) Details of previous import, if there has been any and confirmation regarding their re-export; (d) An acknowledged copy of the annual return filed with concerned SPCB for import in the last financial year
(c)		Used electrical and electronic assemblies exported for repair and to be re-imported after repair	(a) Duly filled up Form 6 - Movement document; (b) Proof of export of the defective electrical and electronic assemblies i.e. shipping or airway document authenticated by Customs
(d)		Used electrical and electronic assemblies imported for testing, research and development, project work purposes and to be re-exported back within a period of three years from the date of import	(a) Duly filled up Form 6 - Movement document; (b) Undertaking for re-export; (c) Details of previous import, if there has been any and confirmation regarding their re-export; (d) Chartered Engineer Certificate or certificate from accredited agency of exporting country indicating the functionality, manufacturing date, residual life and serial number; (e) an acknowledged copy of the annual return filed with concerned SPCB for import in the last financial year; (f) Certificate from exporting company for accepting the second hand functional or non-functional electrical and electronic assemblies and/or the spares or part or component or consumables being re-exported at the end of three years.
(e)		Spares imported for warranty replacements provided equal number of defective / non-functional parts are exported back within one year of the import.	(a) Duly filled up Form 6 - Movement document; (b) if refurbished components being imported as replacement to defective component then undertaking for export of equivalent numbers of defective components; (c) Details of previous import, if there has been any and confirmation regarding their re-export; (d) Certificate from exporting company for accepting the re-export of defective or non-functional spares or part or component or consumables being re-exported; (e) Documents on the declared policy regarding the use of second hand or refurbished spare

			parts for repair of electrical and electronic assemblies during warranty period.
(f)		Used electrical and electronic assemblies imported by Ministry of Defence, Department of Space and Department of Atomic Energy.	---
(g)		Used electrical and electronic assemblies (not in bulk; quantity less than or equal to three) imported by the individuals for their personal uses.	---
(h)		Used Laptop, Personal Computers, Mobile, Tablet up to 03 number each imported by organisations in a year.	---
(i)		Used electrical and electronic assemblies owned by individuals and imported on transfer of residence.	As per existing guidelines of Custom Authority
(j)		Used electrical and electronic assemblies, spares, imported by airlines for aircraft maintenance and remaining either on board or under the custodianship of the respective airlines warehouses located on the airside of the custom bonded areas.	----
(j)		Used multifunction print and copying machines (MFDs)*	(a) The country of Origin Certificate along with bill of lading and packaging; (b) The certificate issued by the inspection agency as certified by the exporting country or the inspection and certification agency approved by Directorate General Foreign Trade (DGFT) for functionality, having residual life of not less than five years and serial number; (c) Extended Producer Responsibility-Authorisation under e-waste (Management and Handling) Rules, 2011 as amended from time to time as Producer; (d) The MFDs shall be for printing A 3 size and above; (e) An acknowledged copy of the annual return filed with concerned SPCB for import in the last financial year.
5	B3020	Paper, paperboard and paper product wastes The following materials, provided they are not mixed with hazardous wastes: Waste and scrap of paper or paperboard of: - unbleached paper or paperboard or of corrugated paper or paperboard - other paper or paperboard, made mainly of bleached chemical pulp, not coloured in the mass - paper or paperboard made mainly of mechanical pulp (for example newspapers, journals and similar printed matter) - other, including but not limited to (1) laminated paperboard (2) unsorted scrap	(a) Duly filled up Form 6 – Movement document; (b) The import license from Directorate General of Foreign Trade, wherever applicable; (c) Pre-shipment inspection certificate issued by the inspection agency of the exporting country or the inspection and certification agency approved by Directorate General of Foreign Trade; (d) The valid consents to operate under the Air and Water Acts and the authorisation under these rules, for actual users. For traders, only valid authorisation from concerned SPCB is required; (e) The chemical analysis report of the waste being imported; (f) an acknowledged copy of the annual return filed with concerned State Pollution Control Board for import in the last financial year.

6.	B3140	Aircraft Tyres exported to Original Equipment Manufacturers for re-treading and re-imported after re-treading by airlines for aircraft maintenance and remaining either on board or under the custodianship of the respective airlines warehouses located on the airside of the custom bonded areas	As per existing guidelines of Custom Authority

Note: * The policy for free trade for multifunction print and copying machine to be reviewed once the MFDs are domestically manufactured.

FORM 1

[See rule 6 (1)]

Application required for grant/renewal of authorisation for generation or collection or storage or transport or reception or recycling or reuse or recovery or pre-processing or co-processing or utilisation or treatment or disposal of hazardous and other waste

Part A: General (to be filled by all)

1. (a) Name and address of the unit and location of facility :
(b) Name of the occupier of the facility or operator of disposal facility with designation, Tel, Fax and e-mail:
(c) Authorisation required for (Please tick mark appropriate activity or activities:

(i) Generation ☐
(ii) Collection ☐
(iii) Storage ☐
(iv) Transportation ☐
(v) Reception ☐
(vi) Reuse ☐
(vii) Recycling ☐
(viii) Recovery ☐
(ix) Pre-processing ☐
(x) Co-processing ☐
(xi) Utilisation ☐
(xii) Treatment ☐
(xiii) Disposal ☐
(xiv) Incineration ☐

(d) In case of renewal of authorisation previous authorisation numbers and dates and provide copies of annual returns of last three years including the compliance reports with respect to the conditions of Prior Environmental Clearance, wherever applicable:

2. (a) Nature and quantity of waste handled per annum (in metric tonne or kilo litre)
(b) Nature and quantity of waste stored at any time (in metric tonne or kilo litre)

3. (a) Year of commissioning and commencement of production:
(b) Whether the industry works:

(i) 01 Shift ☐
(ii) 02 Shifts ☐
(iii) Round the clock ☐

4. Provide copy of the Emergency Response Plan (ERP) which should address procedures for dealing with emergency situations (viz. Spillage or release or fire) as specified in the guidelines of Central Pollution Control Board. Such ERP shall comprise the following, but not limited to:

- Containing and controlling incidents so as to minimise the effects and to limit danger to the persons, environment and property;
- Implementing the measures necessary to protect persons and the environment;
- Description of the actions which should be taken to control the conditions at events and to limit their consequences, including a description of the safety equipment and resources available;
- Arrangements for training staff in the duties which they are expected to perform;
- Arrangements for informing concerned authorities and emergency services; and
- Arrangements for providing assistance with off-site mitigatory action.

5. Provide undertaking or declaration to comply with all provisions including the scope of submitting bank guarantee in the event of spillage, leakage or fire while handling the hazardous and other waste.

Part B: To be filled by hazardous waste generators

1. (a) Products and by-products manufactured (names and product wise quantity per annum):

(b) Process description including process flow sheet indicating inputs and outputs (raw materials, chemicals, products, by-products, wastes, emissions, waste water etc.) Please attach separate sheets:

(c) Characteristics (waste-wise) and Quantity of waste generation per annum:

(d) Mode of management of (c) above:

i. Capacity and mode of secured storage within the plant;
ii. Utilisation within the plant (provide details);
iii. If not utilised within the plant, please provide details of what is done with this waste;
iv. Arrangement for transportation to actual users/ TSDF;

(e) Details of the environmental safeguards and environmental facilities provided for safe handling of all the wastes at point (c) above;

2. Hazardous and other wastes generated as per these rules from storage of hazardous chemicals as defined under the Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989

Part C: To be filled by Treatment, storage and disposal facility operators

1. Provide details of the facility including:

(i) Location of site with layout map;
(ii) Safe storage of the waste and storage capacity;
(iii) The treatment processes and their capacities;
(iv) Secured landfills;
(v) Incineration, if any;
(vi) Leachate collection and treatment system;
(vii) Fire fighting systems;
(viii) Environmental management plan including monitoring; and
(ix) Arrangement for transportation of waste from generators.

2. Provide details of any other activities undertaken at the Treatment, storage and disposal facility site.

3. Attach a copy of prior Environmental Clearance.

Part D: To be filled by recyclers or pre-processors or co-processors or users of hazardous or other wastes

1. Nature and quantity of different wastes received per annum from domestic sources or imported or both:

2. Installed capacity as per registration issued by the District Industries Centre or any other authorised Government agency. Provide copy:

3. Provide details of secured storage of wastes including the storage capacity:

4. Process description including process flow sheet indicating equipment details, inputs and outputs (input wastes, chemicals, products, by-products, waste generated, emissions, waste water, etc.). Attach separate sheets:

5. Provide details of end users of products or by-products:

6. Provide details of pollution control systems such as Effluent Treatment Plant, scrubbers, etc. including mode of disposal of waste:

7. Provide details of occupational health and safety measures:

8. Has the facility been set up as per Central Pollution Control Board guidelines? If yes, provide a report on the compliance with the guidelines:

9. Arrangements for transportation of waste to the facility:

Signature of the Applicant
Designation

Date………………..

Place……………….

FORM 2

[See rule 6(2)]

FORM FOR GRANT OR RENEWAL OF AUTHORISATION BY STATE POLLUTION CONTROL BOARD TO THE OCCUPIERS, RECYCLERS, REPROCESSORS, REUSERS, USER AND OPERATORS OF DISPOSAL FACILITIES

1. Number of authorisation and date of issue :
2. Reference of application (No. and date) :
3. ………………of ……………………….is hereby granted an authorisation based on the enclosed signed inspection report for generation, collection, reception, storage, transport, reuse, recycling, recovery, pre-processing, co-processing, utilisation, treatment, disposal or any other use of hazardous or other wastes or both on the premises situated at…………………………....

Details of Authorisation

Sl. No.	Category of Hazardous Waste as per the Schedules I, II and III of these rules	Authorised mode of disposal or recycling or utilisation or co-processing, etc.	Quantity (ton/annum)

(1) The authorisation shall be valid for a period of …………………………………

(2) The authorisation is subject to the following general and specific conditions (Please specify any conditions that need to be imposed over and above general conditions, if any):

A. General conditions of authorisation:

1. The authorised person shall comply with the provisions of the Environment (Protection) Act, 1986, and the rules made there under.

2. The authorisation or its renewal shall be produced for inspection at the request of an officer authorised by the State Pollution Control Board.

3. The person authorised shall not rent, lend, sell, transfer or otherwise transport the hazardous and other wastes except what is permitted through this authorisation.

4. 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.

5. The person authorised shall implement Emergency Response Procedure (ERP) for which this authorisation is being granted considering all site specific possible scenarios such as spillages, leakages, fire etc. and their possible impacts and also carry out mock drill in this regard at regular interval of time;

6. The person authorised shall comply with the provisions outlined in the Central Pollution Control Board guidelines on "Implementing Liabilities for Environmental Damages due to Handling and Disposal of Hazardous Waste and Penalty"

7. It is the duty of the authorised person to take prior permission of the State Pollution Control Board to close down the facility.

8. The imported hazardous and other wastes shall be fully insured for transit as well as for any accidental occurrence and its clean-up operation.

9. The record of consumption and fate of the imported hazardous and other wastes shall be maintained.

10. The hazardous and other waste which gets generated during recycling or reuse or recovery or pre-processing or utilisation of imported hazardous or other wastes shall be treated and disposed of as per specific conditions of authorisation.

11. The importer or exporter shall bear the cost of import or export and mitigation of damages if any.

12. An application for the renewal of an authorisation shall be made as laid down under these Rules.

13. Any other conditions for compliance as per the Guidelines issued by the Ministry of Environment, Forest and Climate Change or Central Pollution Control Board from time to time.

14. Annual return shall be filed by June 30th for the period ensuring 31st March of the year.

B. Specific conditions:

Date:

Signature of Issuing Authority
Designation and Seal

FORM 3

[See rules 6(5), 13(7), 14(6), 16(5) and 20 (1)]

FORMAT FOR MAINTAINING RECORDS OF HAZARDOUS AND OTHER WASTES

1. Name and address of the facility :
2. Date of issuance of authorisation and its reference number :
3. Description of hazardous and other wastes handled (Generated or Received)

Date	**Type of waste with category as per Schedules I, II and III of these rules**	**Total quantity (Metric Tonnes)**	**Method of Storage**	**Destined to or received from**

** Fill up above table separately for indigenous and imported waste.*

4. Date wise description of management of hazardous and other wastes including products sent and to whom in case of recyclers or pre-processor or utiliser:
5. Date of environmental monitoring (as per authorisation or guidelines of Central Pollution Control Board):

Signature of occupier

Date………………..

Place……………….

FORM 4

[See rules 6(5), 13(8), 16(6) and 20 (2)]

FORM FOR FILING ANNUAL RETURNS

[To be submitted to State Pollution Control Board by 30th day of June of every year for the preceding period April to March]

1. Name and address of facility:

2. Authorisation No. and Date of issue:

3. Name of the authorised person and full address with telephone, fax number and e-mail:

4. Production during the year (product wise), wherever applicable

Part A. To be filled by hazardous waste generators

1. Total quantity of waste generated category wise

2. Quantity dispatched
   (i) to disposal facility
   (ii) to recycler or co-processors or pre-processor
   (iii) others

3. Quantity utilised in-house, if any -

4. Quantity in storage at the end of the year –

Part B. To be filled by Treatment, storage and disposal facility operators

1. Total quantity received -

2. Quantity in stock at the beginning of the year -

3. Quantity treated –

4. Quantity disposed in landfills as such and after treatment –

5. Quantity incinerated (if applicable) -

6. Quantity processed other than specified above -

7. Quantity in storage at the end of the year -

Part C. To be filled by recyclers or co-processors or other users

1. Quantity of waste received during the year –
   (i) domestic sources
   (ii) imported (if applicable)

2. Quantity in stock at the beginning of the year -

3. Quantity recycled or co-processed or used –

4. Quantity of products dispatched (wherever applicable) –

5. Quantity of waste generated -

6. Quantity of waste disposed -

7. Quantity re-exported (wherever applicable)-

8. Quantity in storage at the end of the year -

Signature of the Occupier or
Operator of the disposal facility

Date……..

Place…….

FORM 5

[See rules 13 (1) and 14 (1)]

APPLICATION FOR IMPORT OR EXPORT OF HAZARDOUS AND OTHER WASTE FOR REUSE OR RECYCLING OR RECOVERY OR CO-PROCESSING OR UTILISATION

TO BE FILLED IN BY APPLICANT

S. No.	Description	Details to be furnished by the importer or exporter
(1)	(2)	(3)
1.	Importer or Exporter (name and address) in India	
	Contact person	
	Tel, fax and e-mail	
	Facility location/address	
	Reason for import or export	
2.	Importer or exporter (name and address) outside of India	
3.	Details of waste to be imported or exported	
	(a) Quantity (b) Basel No. (c) Single/multiple movement (d) Chemical composition of waste (attach details), where applicable (e) Physical characteristics (f) Special handling requirements, if applicable	
4.	For Schedule III A hazardous waste whether Prior Informed Consent has been obtained	
5.	**For importer** (a) Process details along with environmental safeguard measures (attach separate sheet) (b) Capacity of recycling or co-processing or recovery or utilization **Enclose a copy each of valid authorisation and valid consent to operate from SPCB**	
6.	Details of import against the Ministry of Environment, Forest and Climate Change permission in the previous three years	
7.	Port of entry	

9. Undertaking :

I hereby solemnly undertake that:

(i) The information is complete and correct to the best of my knowledge and legally-enforceable written contractual obligations have been entered into and that my applicable insurance or other financial guarantees are or shall be in force covering the transboundary movement.

(ii) The waste permitted shall be fully insured for transit as well as for any accidental occurrence and its clean-up operation.

(iii) The record of consumption and fate of the imported waste shall be recorded and report sent to the SPCB every quarter.

(iv) The hazardous or other waste which gets generated in our premises by the use of imported hazardous or other wastes in the form of raw material shall be treated and disposed of as per conditions of authorisation.

(v) I agree to bear the cost of export and mitigation of damages if any.

(vi) I am aware that there are significant penalties for submitting a false certificate/ undertaking/ disobedience of the rules and lawful orders including the possibility of fine and imprisonment.

(vii) The exported wastes shall be taken back, if it is not acceptable to the importer.

Signature of the Applicant
Designation

Date………………..
Place……………….

FORM – 6

[See rules 13(2), 13 (10) and 14 (5)]

TRANSBOUNDARY MOVEMENT- MOVEMENT DOCUMENT

S.No	Description		Details to be furnished by the exporter or importer
(1)	(2)		(3)
1	Exporter (Name and Address) Contact Person Tele, Fax and email	: : :	
2.	Generator(s) of the waste (Name and Address)[1] Contact Person Tele, Fax and email	: : :	
	Site of generation	:	
3.	Importer or Actual user (Name and Address) Contact person Tele, Fax and email	: : :	
4.	Trader (Name and Address) Contact person Tele, Fax and email	: : :	
	Details of actual user (Name, Address, Telephone and email)	:	
5.	Corresponding to applicant Ref. No., If any	:	
6.	Bill of lading (attach copy)	:	
7.	Country of import/export	:	
8.	General description of waste	:	
	(a) Quantity (b) Physical characteristics (c) Chemical composition of waste (attach details), where applicable (d) Basel No. (e) UN Shipping name (f) UN Class (g) UN No (h) H Number (i) Y Number (j) ITC (HS)		

	(k) Customs Code (H.S.) (l) Other (specify)		
9.	Type of packages	:	
	Number	:	
10.	Special handling requirements including emergency provision in case of accidents	:	
11.	Movement subject to single/multiple consignment		
	In case of multiple movement- (a) Expected dates of each shipment or expected frequency of the shipments (b) Estimated total quantity and quantities for each individual shipment	: :	
12.	Transporter of waste (Name and Address)[1] Contact Person Tele, Fax and email	:	
	Registration number	:	
	Means of transport (road, rail, inland waterway, sea, air)[2]	:	
	Date of Transfer	:	
	Signature of Carrier's representative	:	
13.	**Exporter's declaration for hazardous and other waste:**		
	I certify that the information in Sl. Nos. 1 to 12 above are complete and correct to my best knowledge. I also certify that legally-enforceable written contractual obligations have been entered into and are in force covering the transboundary movement regulations/rules. Date:..... Signature:..... Name:.....		
TO BE COMPLETED BY IMPORTER (ACTUAL USER OR TRADER)			
14.	Shipment received by importer/ actual user/trader[2] [3]		
	Quantity received.....Kg/litres Date: Name: Signature:		
15.	Methods of recovery		
	R code*		
	Technology employed (Attached details if necessary)		
16.	I certify that nothing other than declared goods covered as per these rules is intended to be imported in the above referred consignment and will be recycled /utilized. Signature: Date:		
17.	SPECIFIC CONDITIONS ON CONSENTING TO THE MOVEMENT if applicable.		(attach details)
Notes:-(1) Attach list, if more than one; (2) Select appropriate option; (3) Immediately contact competent authority in case of any emergency; (4) If more than one transporter carriers, attach information as required in SL. No. 12.			

List of abbreviations used in the Movement Document

Recovery Operations (*)

R1 Use as a fuel (other than in direct incineration) or other means to generate energy.
R2 Solvent reclamation/regeneration.
R3 Recycling/reclamation of organic substances which are not used as solvents.

R4 Recycling/reclamation of metals and metal compounds.
R5 Recycling/reclamation of other inorganic materials.
R6 Regeneration of acids or bases.
R7 Recovery of components used for pollution abatement.
R8 Recovery of components from catalysts.
R9 Used oil re-refining or other reuses of previously used oil.
R10 Land treatment resulting in benefit to agriculture or ecological improvement
R11 Uses of residual materials obtained from any of the operations numbered R 1 to R 10

Date: **Signature:**

Place: **Designation:**

FORM 7

[See rule 13 (2) (c)]

APPLICATION FORM FOR ONE TIME AUTHORISATION OF TRADERS FOR PART- D OF SCHEDULE III, WASTE

[To be submitted by trader to the State Pollution Control Board]

1.	Name and address of trader with Telephone, Fax Number and e-mail	:	
2.	TIN/VAT Number/Import/ Export Code	:	
3.	Description and quantity of other waste to be imported	:	
4.	Details of storage, if any	:	
5.	Names and address of authorised actual user (s)	:	

Signature of the authorised person

Date:
Place:

FORM 8

[See rules 17 (1) and 18 (2)]

LABELLING OF CONTAINERS OF HAZARDOUS AND OTHER WASTE

Handle with care

Waste category and characteristics as per Part C of Schedules II and III of these rules ………………….	Incompatible wastes and substances ………………….
Total quantity …………………….	Date of storage
Physical State of the waste (Solid/Semi-solid/liquid):	
Sender's name and address	Receiver's name and address
Phone……………	Phone……………
E-mail…………….	E-mail…………….
Tel. and Fax No…………….	Tel. and Fax No…………….
Contact person……………………	Contact person……………………
In case of emergency please Contact …………………………	

Note:

1. *Background colour of labeI - fluorescent yellow.*
2. *The word, 'HAZARDOUS WASTES' and 'HANDLE WITH CARE' to be prominent and written in red, in Hindi, English and in vernacular language.*
3. *The word 'OTHER WASTES' to be written prominently in orange, in Hindi, English and in vernacular language.*

4. Label should be of non-washable material and weather proof.

FORM 9

[See rule 18 (2)]

TRANSPORT EMERGENCY (TREM) CARD

[To be carried by the transporter during transportation of hazardous and other wastes, provided by the sender of waste]

1. Characteristics of hazardous and other wastes:

S. No.	Type of waste	Physical properties/	Chemical constituents	Exposure hazards	First Aid requirements

2. Procedure to be followed in case of fire :
3. Procedure to be followed in case of spillage/accident/explosion :
4. For expert services, please contact :
   (i) Name and Address
   (ii) Telephone No. :

(Name, contact number and signature of sender)

Date……..
Place…….

FORM 10

[See rule 19 (1)]

MANIFEST FOR HAZARDOUS AND OTHER WASTE

1.	Sender's name and mailing address (including Phone No. and e-mail) :	
2.	Sender's authorisation No. :	
3.	Manifest Document No. :	
4.	Transporter's name and address: (including Phone No. and e-mail)	
5.	Type of vehicle :	(Truck/Tanker/Special Vehicle)
6.	Transporter's registration No. :	
7.	Vehicle registration No. :	
8.	Receiver's name and mailing address (including Phone No. and e-mail) :	
9.	Receiver's authorisation No. :	
10.	Waste description :	
11.	Total quantity : No. of Containers :	……..m^3 or MT ……..Nos.
12.	Physical form :	(Solid/Semi-Solid/Sludge/Oily/Tarry/Slurry/Liquid)
13.	Special handling instructions and additional information :	
14.	Sender's Certificate	I hereby declare that the contents of the consignment are fully and accurately described above by proper shipping name and are categorised, packed, marked, and labelled, and are in all respects in proper conditions for transport by road according to applicable national government regulations.
	Name and stamp: Signature: Month Day Year	
15.	Transporter acknowledgement of receipt of Wastes	
	Name and stamp: Signature: Month Day Year	
16.	Receiver's certification for receipt of hazardous and other waste	
	Name and stamp: Signature: Month Day Year	

FORM 11

[See rule 22]

FORMAT FOR REPORTING ACCIDENT

[To be submitted by the facility or sender or receiver or transporter to the State Pollution Control Board]

1. The date and time of the accident :
2. Sequence of events leading to accident :
3. Details of hazardous and other wastes involved in accident :
4. The date for assessing the effects of the accident on health or the environment :
5. The emergency measures taken :
6. The steps taken to alleviate the effects of accidents :
7. The steps take to prevent the recurrence of such an accident :

Date: **Signature:**

Place: **Designation:**

FORM 12

[See rule 24 (1)]

APPLICATION FOR FILING APPEAL
AGAINST THE ORDER PASSED BY STATE POLLUTION CONTROL BOARD

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

Signature………………….

Name and address…………

Date:

---x--x---

[23-16/2009- HSMD]

BISHWANATH SINHA, Jt. Secy.

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Item No. 02 Court No. 1

BEFORE THE NATIONAL GREEN TRIBUNAL
PRINCIPAL BENCH, NEW DELHI

Original Application No. 497/2024

News item titled "Impact of Pharmaceutical toxicity on the environment and its regulatory aspects" appearing in Current Science dated 25.02.2024

Date of hearing: 06.05.2024

CORAM: HON'BLE MR. JUSTICE PRAKASH SHRIVASTAVA, CHAIRPERSON
HON'BLE DR. A. SENTHIL VEL, EXPERT MEMBER

Respondent: Mr. Mohit Singhal, Adv. for CPCB (Through VC)

ORDER

1. This original application is registered on the basis of an article titled "Impact of Pharmaceutical toxicity on the environment and its regulatory aspects" published in the 'Current Science' dated 25.02.2024.

2. The news item discloses that pharmaceutical-induced environmental contamination needs urgent attention because around 43% of global rivers are facing risks from Active Pharmaceutical Ingredients (APIs). The continuous emissions are posing potential hazards to the environment and human health. It also states that discussions on chemical waste reduction face limitations due to incomplete knowledge about their toxicity to humans. It discloses that pharmacies sometimes cannot filter all the chemicals used in pharmaceutical production (e.g. solvents, active pharmaceutical ingredients (APIs), excipients, additives, by-products, intermediates, etc.). These chemicals cause ecosystem imbalances that give rise to chemical pollution in the environment. The article discloses the causes of pharmaceutical pollution as under:

"(1) ***Drug ingestion and excretion****: When organisms consume pharmaceuticals, their bodies metabolize and excrete inactive metabolites as waste products, eventually finding their way into the environment through urine and faecal matter.*

(2) ***Healthcare institutions disposal****: Hospitals and healthcare facilities contribute significantly to pharmaceutical pollution due to inadequate disposal practices or contraventions in rules and regulations of standards.*

(3) ***Drug manufacturing units****: Some drug manufacturers dispose of excess drugs and other used chemicals/by-products in landfills or flush them, leading to pollution through wastewater run-off.*

(4) ***Domestication of animals****: Drugs fed to domestic animals are not always entirely metabolized, resulting in the excretion of excess pharmaceuticals. This leads to the settling of metabolites in the top layers of the soil (Figure 1).*

(5) ***Agricultural usage****: Insecticides and pesticides sprayed on agricultural products can contaminate the surrounding ecosystem.*

(6) ***Domestic drug use and disposal****: Improper disposal of pharmaceutical and personal care products by consumers results in the pollution of streams, groundwater, lakes and rivers. Pharmaceutical waste, chemical waste, personal care products and their waste results in pollution in household as well as in environment."*

3. It also discloses the types of pharmaceutical pollutants as under:

"(1) ***Hazardous chemicals****: These are chemical compounds or chemicals that cause serious harm. For example, gases such as hydrogen chloride, benzene and toluene, or compounds and metals such as asbestos, cadmium, mercury and chromium.*

(2) ***Non-hazardous pollutants****: These are substances found in the workplace that do not cause any harmful effects to the employees on exposure. These pollutants may not be immediately toxic in low concentrations, their cumulative effects can still have significant impacts on human health, ecosystems and the environment as a whole.*

(3) ***Chemotherapy waste****: Chemotherapy waste include chemicals from pharmaceutical medications and personal care products. It includes empty medicine bottles and other medications.*

(4) ***Inert waste****: This refers to waste that is not chemical or biological and does not react either with any other compounds leading to accumulation in environment. These compounds are not biodegradable. Examples are sand and gravel, which are particularly relevant to landfills because inert waste generally requires lower disposal cost than biodegradable or*

compostable waste. It includes glass insulation, metal, wood, etc.

(5) ***Radioactive hazardous pollutants****: Radioactive (or nuclear) wastes are the products of nuclear power plants, power plants, hospitals and research facilities. Nuclear waste is also generated when nuclear reactors and other nuclear facilities are dismantled and destroyed. There are grouped into two broad categories: high-level radioactive waste and low-level radioactive waste. Examples include I-125, F-18 and I-131.*

(6) ***Biohazardous pollutants****: Biohazardous wastes (such as blood, body fluids and human cells), also known as biological waste, are potentially infectious and considered to threaten public health and the environment.*

4. It also gives the heads and sub-heads showing how pharmaceuticals enter into the environment by revealing as under:

*"**Patient usage**: The utilization of medications by patients, whether prescribed or over-the-counter, represents a significant contributor to chemical pollution. Essentially, a portion of the medications consumed by patients is naturally excreted, potentially entering the water systems after undergoing treatment in wastewater treatment plants. Additionally, pharmaceuticals can find their way into the environment through various means, such as inappropriate disposal of medications and discharge from manufacturing wastewater units. The release of drug compounds into the environment stems from multiple sources, including direct disposal from pharmaceutical manufacturing facilities, patient usage, animal excretion, aquafarming practices and the improper disposal of unused or expired medications (Figure 3).*

Medical institutions*: Medical institutions must return unused medications to the manufacturers or pharmaceutical waste recycling facilities. However, they are simply recycled or flushed. Thus, the lack of proper management leads to pharmaceutical waste in healthcare facilities.*

Water treatment facilities*: Inefficient removal of pharmaceutical residues occurs in water treatment plants, primarily attributed to inadequate design. Similar to the measures taken in water treatment plants, major efforts are taken to prevent the migration of these wastes into groundwater sources. Emphasis is laid on waste removal, employing various methods to impede waste entry into groundwater and other water bodies. Consequently, this waste is directed to landfills.*

Pharmaceutical waste processing facilities*: These specialized facilities manage substantial quantities of pharmaceutical chemical waste, producing residual waste even after undergoing processing. Waste from hospitals and various outlets is transported to these plants, undergoing efficient processing.*

Human and animal usage*: Both humans and animals utilize medications for immediate disease prevention post-consumption. However, excretion of these drugs from the body occurs through processes such as urination, defecation and sweating. Over time, these pharmaceutical remnants are expelled from the body, subsequently entering into the environment.*

Unused drugs*: Unused medications are usually discarded or flushed down the toilet. These medications eventually permeate the environment and water bodies, integrating into the ecosystem.*

Essential products*: Medications serve purposes beyond disease treatment. Some formulations are used in cosmetics, beauty products and aromatherapy sprays. When applied to the skin, not all the components are fully absorbed into the body; some are eliminated during bathing. Consequently, remnants are left in the environment, contributing to the accumulation of pharmaceutical waste.*

Residences and agricultural lands*: Crops cultivated in residential areas or on farms often undergo applications of pesticides, insecticides and fungicides. These substances safeguard crops from bacterial infections, insect infestations, viral threats and fungal diseases. Additionally, the spray is formulated to enhance crop growth and overall productivity. However, the usage of sprays lead to mixture of chemicals into groundwater, contributing to the generation of pharmaceutical waste."*

5. The pharmaceutical pollution and its effect are disclosed in the article as follows:

"(1) ***Impact on fish and aquatic life****: Numerous studies have demonstrated that oestrogen and similar chemicals feminise male fish, altering the male–female ratio. These substances, commonly found in birth-control pills and postmenopausal hormonal treatments, have led to the presence of hermaphrodite fish species with both male and female characteristics in the Potomac River, USA. Elevated estrogenic levels in river water contribute to the prevalence of female fish near pollution sources, and popular antidepressants have been detected in the brain tissue of fish downstream of wastewater treatment plants (Table 1).*

(2) ***Influence on wastewater treatment systems****: Antibiotics, frequently employed in disease treatment, possess properties that can impact sewage systems and the microbiological alterations of water. The presence of antibiotics in sewage treatment inhibits the activity of sewage bacteria and disrupts the decomposition of organic matter. Additionally, antibiotics can hinder nitrifying bacteria in the process of treating wastewater.*

(3) ***Effects on drinking water****: Chemicals in pharmaceuticals may mix with water or be flushed in the toilets after exiting the body. Mostly, municipal wastewater treatment plants do not fully eliminate these chemicals and impurities from drinking*

water, necessitating a combination of treatment methods. Although the levels of these chemicals in rivers and streams are relatively low compared to standard doses, there is a growing concern that prolonged exposure could result in health problems. The potential synergistic effects of these compounds, particularly endocrine disruptors, pose risks to biological processes such as growth, development, reproduction and hormonal control. Studies have raised alarms about the presence of these chemicals in surface water and groundwater since the 1990s.

(4) ***Prolonged environmental impact****: Certain chemical compounds persist in the environment and water bodies for an extended duration. When concentrations reach a specific threshold, typically 1 part per million, these chemicals begin to impact the environment. Some drugs, like antiepileptic medications, have prolonged effects, while others are pseudo-persistent, breaking down only after an extended period. This persistence continuously impacts the environment, with some substances having about 30% fat solubility, enabling bioaccumulation and potential entry into the food chain. Studies in Europe and the US have identified hundreds of these compounds in groundwater, sewage, treated wastewater and tap water, underscoring the widespread presence of these contaminants in various water sources.*

(5) ***Antibiotics****: Long associated with irresponsible use in human medicine and agriculture, antibiotics have also been linked to contamination from drug production. Studies conducted in India and China on antibiotic pollution during 2016 and 2017 support this conclusion (Table 1).*

(6) ***Consequences on wildlife****: The clean-up of sewage, whether by humans or chemicals, may affect wildlife as animals consume water containing these substances or swim in it. Research on the effects of chemicals on wildlife, while limited and uncertain, suggests potential significant impacts. Preliminary findings indicate that antidepressants may adversely affect their health, while reproductive suppressants may reduce fish populations in ponds."*

6. It discloses the status of chemical pollution in India in following terms:

"India is recognized as the third largest pharmaceutical producer on a global scale, with a substantial presence comprising about 3000 pharmaceutical plants and an extensive range of around 10,500 products. The pharmaceutical manufacturing sector in India is acknowledged for its significant environmental impact, standing out as one of the most influential industries in the country. Hyderabad, commonly known as the 'API capital of India', is the hub of the country's major pharmaceutical industry. Studies have shown that local residents consider the groundwater in industrial areas to be highly polluted with multidrug resistant bacteria. It is estimated that about 60,000 infants die every year in India due to high doses of

antibiotics. Antimicrobial resistance is caused by contamination of water containing antibiotics."

7. The article suggests possible ways for reduction of pharmaceutical waste as follows:

"• Exploring antibiotic use is a crucial research focus for prominent entities dedicated to safeguarding public and environmental health, such as the World Health Organization (WHO) and the European Commission.

- *The environmental contamination from pharmaceuticals presents an intricate and contentious challenge marked by unclear research, conflicting conclusions, diverse stakeholder interests and a high degree of complexity.*
- *Allocate resources to public education initiatives concerning the appropriate disposal of medications, integrating them into drug recovery programmes.*
- *Implement more stringent regulations to curb drug usage in numerous healthcare settings, including hospitals, nursing homes and other medical facilities.*
- *Urgently conduct further research to assess the potential impacts of these chemicals on human health.*
- *Implement measures to restrict bulk purchases of medicines, ensuring that only the necessary quantity is available and potentially mitigating excessive purchases.*
- *Emphasize proper disposal methods for water, advocating against indiscriminate disposal and instead promoting safe options such as burning or burying."*

8. The news item raises substantial issue relating to compliance of the environmental norms, especially by the pharmaceutical companies.

9. Power of the Tribunal to take up the matter *suo-motu* has been recognized by the Hon'ble Supreme Court in the matter of *"Municipal Corporation of Greater Mumbai vs. Ankita Sinha & Ors." reported in 2021 SCC Online SC 897*.

10. Since, it is a PAN India issue, therefore, we deem it proper to implead the following as respondents in the matter:

(1). Chief Secretary, State of Haryana.

(2). Chief Secretary, State of Rajasthan.

(3). Chief Secretary, State of Punjab.

(4). Chief Secretary, State of Himachal Pradesh.

(5). Chief Secretary, State of Uttar Pradesh.

(6). Chief Secretary, State of Chhattisgarh.

(7). Chief Secretary, State of Bihar.

(8). Chief Secretary, State of Uttarakhand.

(9). Chief Secretary, State of Jharkhand.

(10). Chief Secretary, State of Meghalaya.

(11). Chief Secretary, State of West Bengal.

(12). Chief Secretary, State of Maharashtra.

(13). Chief Secretary, State of Andhra Pradesh.

(14). Chief Secretary, State of Kerala.

(15). Chief Secretary, State of Tamil Nadu.

(16). Chief Secretary, State of Telangana.

(17). Chief Secretary, State of Karnataka.

(18). Chief Secretary, State of Madhya Pradesh.

(19). Chief Secretary, State of Odisha.

(20). Chief Secretary, State of Gujarat.

(21). Chief Secretary, State of Goa.

(22). Chief Secretary, State of Arunachal Pradesh.

(23). Chief Secretary, State of Sikkim.

(24). Chief Secretary, State of Nagaland.

(25). Chief Secretary, State of Manipur.

(26). Chief Secretary, State of Mizoram.

(27). Chief Secretary, State of Assam.

(28). Chief Secretary, State of Tripura.

(29). Chief Secretary, Union Territory of Delhi.

(30). Chief Secretary, Union Territory of Chandigarh.

(31). Chief Secretary, Union Territory of Andaman & Nicobar.

(32). Chief Secretary, Union Territory of Dadra and Nagar Haveli & Daman and Diu.

(33). Chief Secretary, Union Territory of Lakshadweep.

(34). Chief Secretary, Union Territory of Puducherry.

(35). Chief Secretary, Union Territory of Ladakh.

(36). Chief Secretary, Union Territory of Jammu & Kashmir.

(37). Member Secretary, Haryana State Pollution Control Board.

(38). Member Secretary, Rajasthan State Pollution Control Board.

(39). Member Secretary, Punjab State Pollution Control Board.

(40). Member Secretary, Himachal Pradesh State Pollution Control Board.

(41). Member Secretary, Uttar Pradesh State Pollution Control Board.

(42). Member Secretary, Chhattisgarh Environment Conservation Board.

(43). Member Secretary, Bihar State Pollution Control Board.

(44). Member Secretary, Uttarakhand State Pollution Control Board.

(45). Member Secretary, Jharkhand State Pollution Control Board.

(46). Member Secretary, Meghalaya State Pollution Control Board.

(47). Member Secretary, West Bengal State Pollution Control Board.

(48). Member Secretary, Maharashtra State Pollution Control Board.

(49). Member Secretary, Andhra Pradesh State Pollution Control Board.

(50). Member Secretary, Kerala State Pollution Control Board.

(51). Member Secretary, Tamil Nadu State Pollution Control Board.

(52). Member Secretary, Telangana State Pollution Control Board.

(53). Chief Secretary, Karnataka State Pollution Control Board.

(54). Member Secretary, Madhya Pradesh State Pollution Control Board.

(55). Member Secretary, Odisha State Pollution Control Board.

(56). Member Secretary, Gujarat State Pollution Control Board.

(57). Member Secretary, Goa State Pollution Control Board.

(58). Member Secretary, Arunachal Pradesh State Pollution Control Board.

(59). Member Secretary, Sikkim State Pollution Control Board.

(60). Member Secretary, Nagaland State Pollution Control Board.

(61). Member Secretary, Manipur State Pollution Control Board.

(62). Member Secretary, Mizoram State Pollution Control Board.

(63). Member Secretary, Assam State Pollution Control Board.

(64). Member Secretary, Tripura State Pollution Control Board.

(65). Member Secretary, Delhi Pollution Control Committee.

(66). Member Secretary, Chandigarh Pollution Control Committee.

(67). Member Secretary, Andaman & Nicobar Pollution Control Committee.

(68). Member Secretary, Pollution Control Committee, Dadra and Nagar Haveli & Daman and Diu.

(69). Member Secretary, Lakshadweep Pollution Control Committee.

(70). Member Secretary, Puducherry Pollution Control Committee.

(71). Member Secretary, Ladakh Pollution Control Committee.

(72). Member Secretary, Jammu & Kashmir Pollution Control Committee.

(73). Central Pollution Control Board through its Member Secretary.

(74). Ministry of Environment Forest and Climate Change through its Secretary.

(75). Ministry of Agriculture through the Secretary.

(76). Ministry of Dairying and Veterinary Science through the Secretary.

11. Let notice be issued to the above respondents, except the CPCB who is already represented through the Counsel, for filing their response at least one week before the next date of hearing disclosing the compliance of the norms by pharmaceutical company, the regulatory guidelines in force, number of pharmaceutical companies in each of the State and number of such companies complying with norms and number of companies against whom action is taken for violation of the norms as also the proposed action for prevention of environment from pharmaceutical toxicity.

12. Learned Counsel for CPCB seeks four weeks' time to file the reply.

13. List on 20.08.2024.

Prakash Shrivastava, CP

Dr. A. Senthil Vel, EM

May 06, 2024
Original Application No. 497/2024
DV