

AGENDA ITEMS FOR 62nd MEETING OF TECHNICAL REVIEW COMMITTEE (TRC)

Dated: 25th May 2017, at 10:00 AM

Venue:- Narmada Conference Hall, Ground Floor, Jal Block, Ministry of Environment, Forest & Climate Change, Indira Paryavaran Bhawan, Zor Bagh Road, New Delhi-110003

In the Chair: Shri R.K.Garg

AGENDA

AGENDA 1: Clarifications/Amendment with Regard To Hazardous and other Wastes (Management, Handling & Trans-Boundary Movement) Rules, 2016

1.1 Review Of List Of Critical Care Medical Equipment submitted By Directorate General Of Health Services (DGHS), M/O Health And Family Welfare for notifying under the ambit Of Hazardous and other Wastes (Management, Handling And Trans-Boundary Movement) Rules, 2016 (F.No. 23-4/2009-HSMD)

SCHEDULE VI of HW Rules, 2016 which provide the list of 'Hazardous and Other wastes prohibited for import', "used critical care medical equipment for re-use" has been banned for import. Critical care medical equipment has been defined in the Rules as "lifesaving equipment and includes such equipment as specified by the Ministry of Health and Family Welfare from time to time.;

Directorate General of Health Services, Ministry of Health and Family Welfare had submitted Minutes of working group on draft Hazardous and other wastes (Management, Handling & Trans-boundary movement) Rules, 2015 along with a list of equipment for the critical/ intensive care unit as per the guidelines issued by Indian society of Critical Medicines supplied by All India Institute of Medical Sciences, New Delhi.

On the basis of recommendation of the meeting following has been forwarded for consideration with respect to provision on import of second hand medical equipment under the HW Rules, 2016:

- i. The Committee in DGHS also deliberated on blanket ban on second hand medical equipment and reached a consensus that the refurbished high value and high end medical equipment's import may be permitted subject to following conditions:*
 - a) Such equipment has not been phased out from the importing country and is not considered obsolete in that country;*
 - b) Such equipment does not contain any hazardous material/ substances listed under any international regulation/ law and or by government of India;*
 - c) The equipment must have a residual life of 5 to 7 years for which supplier or manufacturer must provide hardware and software support including warranty (under IPC MoHFW follow 2 year warranty and 5 year CMC);*
 - d) The Original Equipment Manufacturer (OEM) of such equipment will take back the equipment if required for purpose of disposal as per international norms.*

- ii The list of equipment for the critical/ intensive care unit as per the Guidelines issued by the Indian Society of Critical Care Medicine comprised of:

S.No.	Name of the Equipment
High End and High cost Equipment	
1.	Bedside Monitors (for ICU)
2.	Monitors for HDU(High Dependency Unit)
3.	Ventilators
4.	Non-invasive ventilators
5.	Fibroptic Bronchoscope
6.	Head End Panel
7.	Defibrillator
8.	ABG (arterial Blood Gas) Machine
9.	Crash/Resuscitation trolley
10.	Pulse Oxymeter (small units)
11.	Freeze(medical grade refrigerator)
12.	Haemodialysis Machine
13.	Continuous renal replacement therapy
14.	CO, SVR, ScvO2 monitor Continuous central venous oxygen saturation (ScvO2) systemic vascular resistance (SVR)
15.	Intermittent Leg compressing Machine
16.	Intubating Video Scope
17.	ICU dedicated ultrasound and echo machine
18.	Bedside X ray
Other Equipment	
19.	Rigid Cervical Spine collars
20.	Ambu Mask Different sizes
21.	I A(intra aortic) Balloon Pump
22.	Infusion Pumps
23.	Syringe Pumps
24.	ICU Beds (Shock Proof)
25.	Over Bed Tables
26.	Glucometer

TRC along with representatives from Ministry of Health and Family Welfare, Atomic Energy Regulatory Board deliberated in detail in the 55th Meeting of the Technical Review Committee held during 27th and 28th June 2016 for finalizing the list of critical care medical equipment to be banned under the notification.

Recommendations:

- (i) The committee noted that the criteria as proposed by DGHS for review of applications for import of second hand medical equipment are followed by the Ministry and accordingly is already under practice.
- (ii) The Committee along with the representatives of Ministry of Health and Family Welfare, Atomic Energy Regulatory Board deliberated and recommended to include the following critical care medical care instruments in the ban list and notify as AMENDMENT under the HW Rules, 2016:

S.No.	Name of the Equipment
High End and High cost Equipment	
1.	Bedside Monitors (for ICU)

2.	<i>Monitors for HDU(High Dependency Unit)</i>
3.	<i>Ventilators</i>
4.	<i>Non-invasive ventilators</i>
5.	<i>Fiberoptic Bronchoscope</i>
6.	<i>Head End Panel</i>
7.	<i>Defibrillator</i>
8.	<i>ABG (arterial Blood Gas) Machine</i>
9.	<i>Crash/Resuscitation trolley</i>
10.	<i>Pulse Oxymeter (small units)</i>
11.	<i>Freeze(medical grade refrigerator)</i>
12.	<i>Haemodialysis Machine</i>
13.	<i>Continuous renal replacement therapy</i>
14.	<i>CO, Systemic vascular resistance (SVR), Continuous central venous oxygen saturation monitor (ScvO2)</i>
15.	<i>Intermittent Leg compressing Machine</i>
16.	<i>Intubating Video Scope</i>
17.	<i>Echo machine</i>
18.	<i>Bedside X ray</i>
<i>Other Equipment</i>	
19.	<i>Intra aortic (IA) Balloon Pump</i>
20.	<i>Infusion Pumps</i>
21.	<i>Syringe Pumps</i>
22.	<i>ICU Beds (Shock Proof)</i>
23.	<i>Glucometer</i>

While reviewing the minutes of the Meeting, the competent authority decided that the list of critical care medical equipment as submitted require justification for prohibition which was sought from Ministry of Health and Family Welfare (MOHFW).

MOHFW has submitted the following revised/updated list of critical care medical equipment for "Critical/Intensive care unit as per guidelines issued by the Indian Society of Critical Care Medicines (provided by AIIMS) and revised/ updated following Meeting held at Dte. GHS on 30th December 2016:

<i>S.No.</i>	<i>Name of the Equipment</i>
<i>High End and High cost Equipment</i>	
1.	<i>Bedside Monitors (for ICU)</i>
2.	<i>Monitors for HDU(High Dependency Unit)</i>
3.	<i>Ventilators</i>
4.	<i>Non-invasive ventilators</i>
5.	<i>Fiberoptic Bronchoscope</i>
6.	<i>Head End Panel</i>
7.	<i>Defibrillator</i>
8.	<i>ABG (Arterial Blood Gas) Machine</i>
9.	<i>Crash/Resuscitation trolley</i>
10.	<i>Pulse Oxymeter (small units)</i>
11.	<i>Haemodialysis Machine</i>
12.	<i>Continuous renal replacement therapy (CRRT)</i>
13.	<i>CO, SVR, ScvO2 monitor</i>
14.	<i>Intermittent Leg compressing Machine</i>
15.	<i>Intubating Video Scope</i>
16.	<i>ICU dedicated ultrasound and echo machine</i>

17.	<i>Bedside X ray</i>
18.	<i>Temporary pacemaker pulse generator</i>
19.	<i>Intra-arterial and central venous pressure monitors</i>
20.	<i>ECMO (extra-corporeal membrane oxygenation machine)</i>
21.	<i>DVT prevention pump</i>
Other Equipment	
22.	<i>Rigid Cervical Spine collars</i>
23.	<i>Ambu Mask Different sizes</i>
24.	<i>IA (intra aortic) Balloon Pump</i>
25.	<i>Infusion Pumps</i>
26.	<i>Syringe Pumps</i>
27.	<i>ICU Beds (Shock Proof)(Fibre)</i>
28.	<i>Glucometer</i>
29.	<i>Air Mattress</i>
30.	<i>Laryngeal mask airway (LMA)</i>
31.	<i>Percutaneous dilation tracheostomy kit</i>

The Committee may deliberate with respect to the Hazardous and other waste (Management and Trans-boundary Movement) Rules, 2016.

1.2 Removal of De-inking Sludge from Hazardous Waste Category Representation of Gujarat Paper Mills Association (23-146/2016-HSMD):

De-Inking Sludge is considered as a Hazardous Waste category. In this regard the applicant has given a work for assessment of De-Inking Sludge for Categorization under Hazardous Waste Rules 2008. Gujarat Paper Mills Association (GPMA) had also attached the detailed Technical report submitted by ERM India Pvt. Ltd on “assessment of Deinking Sludge for categorization under HW Rules, 2008: Vapi, Gujarat”(Shah Paper Mills Limited).

GPMA had submitted that as per their report all parameters are within the limit but in the case of AOX the suggested limit of AOX has not been notified as a standard by the Government of India. As per the Article "Development of AOX Standards for Large Scale Pulp and Paper Industries", that was published by the Central Pollution Control Board, India in the year 2007, a mass based concentration limit of AOX was suggested to Ministry of Environment & Forest for consideration as 2.5 Kg. AOX per MT of dry sludge (i.e. 2,500 mg/kg.) as against their result of AOX which is 263 mg/kg as per the report of ERM on the Pg. No. 10.

The applicant had also enclosed the copy of report of Confederation of European Paper Industry (CEPI) wherein they are using De-Inking Sludge for various purposes mainly for land restoration and mine filling. As per their report, it is classified that "land restoration covers the use of dried sludge as a product applied on derelict land, damaged industrial sites topsoil, or during road constructions, topping of landfills, mine filling etc." as depicted on Pg. No. 37 of their report.

Ministry has been requested to consider de-inking sludge generating from the process of paper mill as Non-hazardous and to grant necessary permission for the utilization of said waste for land filling/ mine filling.

The matter was considered in the 58th Meeting of the Technical Review committee and was deferred as the applicant was not present for technical discussion.

The matter was re-deliberated in the 59th Meeting of the Technical review Committee held on 30th and 31st January 2017. Following was the recommendation of the Committee:

Though the applicant was invited for presentation and technical discussion, the applicant did not turn up. The same issue was also in the agenda of the earlier two TRC meetings and there also the applicant was invited yet no body turned up, in view of the fact that no additional information has been supplied; the Committee reiterates its earlier recommendation which is given below:

“The Committee noted that as per Schedule I item 32, pulp and paper industry, process sludge containing organic halides (AOX) is categorized as hazardous waste. The de-inking sludge generated in the paper and pulp industry based on waste paper, thus is a hazardous waste. The analysis report submitted by the GPMA also indicates that the sludge contains 263 mg/kg of AOX. Although there are no conc. limits indicated in Schedule II, it is known that organic halides have potential for eco-toxicity. It is therefore not considered to be prudent to take the sludge containing AOX out of the category of hazardous waste and allow it to be used for landfilling. However it can be utilized for making fibre boards etc. with the permission of CPCB under Rule 9 of HW Rules, 2016”.

In this regard, a delegation of Indian Agro & Recycled Paper Mills Association comprising members from different parts of the country has requested to meet the Committee and apprise the issues confronted by the paper mills in India on disposal of de-inking sludge.

The Committee may deliberate with regard to Hazardous and other wastes (Management and Trans-boundary Movement) Rules, 2016.

Agenda 1.3: Categorization of sulphuric acid as a by-product rather than as a hazardous waste- representation by M/s Nirma Limited

The matter with regard to Categorization of sulphuric acid as a by-product rather than as a hazardous waste, a representation by M/s Nirma Limited has been deliberated upon in the 58th Meeting of the Technical Review Committee.

The applicant had earlier submitted that they are having their Synthetic Detergent & Single Super Phosphate (SSP) manufacturing facility at Moraiya, Ta. Sanand, Dist. Ahmedabad, Gujarat. Sulphuric Acid (80%) is generated from the unit as well as other units of Nirma Ltd. along with its sister industries, is as such used as a raw material in manufacturing of SSP. While manufacturing the synthetic detergent sulphuric acid ranging 80-86% is generated and is as such reused as a raw material for manufacturing of SSP. Production of synthetic detergent is mainly done in two steps viz Acid slurry preparation and Synthetic detergent powder preparation.

- i. Production of acid slurry is done by sulfonation of linear alkyl benzene (LAB) with 22% Oleum and sulphuric acid and circulation of cooling water. When sulphonation is completed after five to six hours, the charge is allowed to settle and lower layer

which is composed of sulphuric acid is separated and further as such utilized in manufacturing of SSP.



- ii. Acid slurry is further neutralized with soda ash and sodium salt of LAB to obtain standard synthetic detergent powder.



Sulphuric acid generated from the process is considered as D2 category waste of Schedule II under the Hazardous Waste, Rules, 2008 and Rule 11 of the said Rule which is presently considered as Rule 9 as per the HW rules, 2016. Utilization of such waste can be possible after getting permission from CPCB.

However the definition of “Hazardous Waste” in the HW Rules, 2016 is provided as “Hazardous Waste means any waste which by reason of characteristics such as physical, chemical, biological, reactive, toxic, flammable, explosive or corrosive causes danger is likely to cause danger to health or environment, whether alone or in contact with other wastes or substances”. The definition provided is exclusively considering the waste material only. As per the definition of “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.

Which is further explained as:

- (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;

From the definitions provided in the Rule, the applicant has inferred that if any material has no further use to the generator for the purpose to the generator for the purpose of production, transformation or consumption, than only it can be considered as waste material.

Based on the aforesaid information, the Committee had recommended the following:

The Committee deliberated on the issue raised by M/s Nirma Ltd.. The Committee is well aware of the fact that during the sulphonation process Sulphuric Acid of concentration 60-80% is generated and goes by the name of Spent Sulphuric Acid. Normal Sulphuric Acid is produced in concentration of 98% and is used for various application including the sulphonation of LAB. Spent Acid on the other hand is used only for specific application like production of Single Super Phosphate and depends upon the demand nearby its location of generation. In some cases where there is no demand it is neutralized by Lime to produce Gypsum which again is considered as a waste which may however be used in cement plant if the logistics favours. Thus, the fact of utilization alone cannot qualify the item to be called byproduct. The

Committee suggested that the applicant may take permission under Rule 9 of the HW Rules, 2016.

Subsequent to Committee's recommendation, the applicant has submitted the following:

Spent acid (60%-80%) generated can be utilized in different processes. Some of the processes are:

- i. Manufacturing of single super phosphate;
- ii. Manufacturing of sulphate salts of inorganic chemicals such as $\text{FeSO}_4 \cdot 7\text{H}_2\text{O}$, $\text{CuSO}_4 \cdot 2\text{H}_2\text{O}$;
- iii. CPC Blue pigment purification and many more.

Further, units of the above listed products/processes and many other in which the spent sulphuric acid can be utilized, without any treatment, are located near to the units from which the spent acid is being generated. Result of which, the generated spent acid can be easily transport and utilized without providing any further treatment.

Ministry has been requested for re-consideration regarding categorization of spent sulphuric acid as a by-product rather than as a hazardous waste.

The Committee may deliberate may deliberate with regard to Hazardous and other wastes (Management and Trans-boundary Movement) Rules, 2016.

Agenda 1.4: Clarification regarding certain materials produced during refining of crude edible oil to be designated as by-products and not categorized as hazardous waste- representation from M/s Cargill India Pvt. Ltd.

Cargill, a global corporation, provides food, agriculture, financial and industrial products and services to the world. In India, Cargill's operations started in 1987 and it has businesses in refined oils, food ingredients, grain and oilseeds, sugar, cotton, animal nutrition and trade structured finance.

During refining of crude edible and manufacturing of Refined Edible Oil and Vanaspati Oil, various by-products namely Soap stock, Acid oil, skimming sludge, spent earth and Deo-Distillate (Deo Distillation Residue) are generated. Acid Oil, spent Earth and Deo-distillate, which are generated during crude oil refining, were classified as products by the Gujarat Pollution Control Board in their CCA/CTO. In addition the applicant has stated that they have started processing acid oil for distilled fatty acid which is generating soap stock and skimming sludge which is not classified under products/by products category.

The applicant has further submitted that soap stock, acid oil, skimming sludge, spent earth and deo-distillate produced during the refining process of crude edible oil are not to be categorized as hazardous waste and to be designated as products/by-products.

As per HW Rules, 2016, waste may be defined as

“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;

In line of the definition, the applicant has submitted that all these materials are directly used as raw material by the industries they supply to. The details of generation and end use of these materials are given in the following table:

S.no	Name of material	End use of material	Name of end users
1.	Soap Stock	Skimming sludge (Soap) & Acid oil (Paint)	Cargill India Pvt. Ltd. Kurkumbh
2.	Acid Oil	Paint	Kansai Nerolac Paints Ltd. through Cargillm India Pvt. Ltd. Kurkumbh
3.	Skimming Sludge	Soap/Cosmetics	Sai baba soap & trading
4.	Spent Earth	Oil Recovery	Shakti Agri Foods (India) Pvt. Ltd through Ahir Trading
5.	Deo Distillate	Soap	Wipro enterprise, Hindustan Lever, Lakme Lever

Thus as per the new HW rules, 2016, all these materials produced during our refining process of crude edible oil can clearly be designated as by product and not categorized as hazardous waste.

- All these materials mainly contain fatty matter and do not contain any hazardous constituents for which they may be considered as hazardous waste.
- All these materials have good demand and worth of Rs. 26/- to Rs. 30/- per kg in the market. All these items are also registered as one of our products with the excise department and are sold with tax invoice.

The Committee may deliberate with regard to Hazardous and other wastes (Management & Trans-boundary Movement) Rules,2016.

AGENDA 2: Clarifications with regard to E-waste (Management) Rules, 2016

Agenda 2.1: Clarification on Extended Producer Responsibility obligations under E-waste Rules, 2016- representation from Toshiba India Private Limited

Toshiba India Private Limited (TIPL) has submitted that it has discontinued all operations of its laptop business i.e. sales and after sales service of Toshiba laptops after 30th September 2016; and pursuant to discontinuation of sales and after sales service of laptops in India, TIPL no longer remains a producer as per the definition of producer under the e-waste Rules and therefore does not require to obtain an EPR Authorization for the laptops.

TIPL is currently placing a very limited quantity of EEE in Indian market in the form of TV spare parts to meet its after sales service obligations. Further, TIPL is placing negligible quantity of spare parts for home appliances in the Indian Market as there are very few service requests from its customers.

As TIPL is no longer selling or placing any EEE other than spares of TV and home appliances, we are of the view that TIPL has to apply for EPR Authorization with respect to spare parts only (for TV and Home Appliances). And, for such authorization, scope of TIPL's EPR plan should be limited to fixing of collection targets only for spare parts of TVs and home appliances, instead of the completely built units of TV and home appliances.

Ministry has been requested to provide clarifications to TIPL in order to enable them to apply for EPR Authorisation for spare parts of televisions and Home Appliances instead of completely built units of TVs and home appliances.

The matter has been deliberated upon in the 58th Meeting of the Technical Review Committee held on 29th and 30th November 2016. Following was the recommendation of the committee:

The Committee noted that the M/s TIPL has stopped selling Toshiba Brand laptop, TVs, Refrigerators and washing machines prior to 30th September, 2016. However, as far as laptops are concerned currently that are being sold and service in India by another group company Toshiba Singapore Pvt. Ltd. under the same brand i.e Toshiba Laptops. For home appliances such as TVs, Washing Machines and Refrigerator TIPL shall continue to honour the warranty commitment till March, 2019. Therefore, TIPL shall continue to exist in India as a legal entity to fulfill their warranty obligation.

The Committee observed that EPR existed given under the e-waste Rules, 2011. To what extent they have complied with those obligations is not known. The Committee therefore suggested that the TIPL may be invited to clarify this point. Further to what extent their group company namely Toshiba Singapore Pvt. Ltd. who will continue to sell Toshiba Brand laptops in India will take over the responsibility of collection of e-waste under EPR for laptops supplied by TIPL is also to be clarified.

The Committee may deliberate with regard to E-waste (Management) Rules, 2016