1. **Biocidal Products - G/TBT/N/EU/932 dated 27-Oct-2022**

|  |  |
| --- | --- |
| **Notifying Member** | European Union |
| **Type of Notification** | Regular |
| **Economic relevance** | High |
| **Technical Relevance** | Technical-New |
| **Last Date to offer comments** | 26-December-2022 |
| **Relevant Organization** | Chemexcil |
| **Folder Link** | [Link](https://seetharamanassociates-my.sharepoint.com/:f:/g/personal/satish_sarvada_co_in/EkkYc9eIl3FGtQG1f5H5fUoBTEDW6gDocQ1Hqi-9kFzFCg?e=rwbpzh) |

**Proposal in brief**

1. EU Commission proposed draft commission implementing of certain active substances for use in biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council.
2. This draft Commission Implementing Decision does not approve certain active substances in biocidal products pursuant to Regulation (EU) No 528/2012 of the European Parliament and of the Council.
3. Following active substance/product-type combinations were included in the review programme of existing active substances listed in Annex II to Regulation (EU) No 1062/2014. All the participants have withdrawn or are considered to have withdrawn their support, and no notification has been submitted for those to the European Chemicals Agency. Therefore, these active substance/product-type combinations were disapproved for use in biocidal products.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Entry in Annex II to Reg. (EU) No 1062/2014** | **Substance name** | **Rapporteur Member State** | **EC number** | **CAS number** | **Product- type(s)** |
| 1022 | Dialuminium chloride pentahydroxide | NL | 234-933-1 | 12042-91-0 | 2 |
| 691 | Sodium N- (hydroxymethyl) glycinate | AT | 274-357-8 | 70161-44-3 | 6 |
| 459 | Reaction mass of titanium dioxide and silver chloride | SE | Not available | Not available | 1, 2, 6, 7,  9, 10, 11 |
| 531 | (benzyloxy)methanol | AT | 238-588-8 | 14548-60-8 | 13 |
| 1016 | Silver chloride | SE | 232-033-3 | 7783-90-6 | 1 |
| 444 | 7a-ethyldihydro-1H,3H,5H- oxazolo[3,4-c]oxazole (EDHO) | PL | 231-810-4 | 7747-35-5 | 6, 13 |
| 797 | cis-1-(3-chloroallyl)-3,5,7-triaza-1- azoniaadamantane chloride (cis CTAC) | PL | 426-020-3 | 51229-78-8 | 6, 13 |
| 368 | Methenamine 3- chloroallylochloride (CTAC) | PL | 223-805-0 | 4080-31-3 | 6, 12, 13 |

**Analysis**

* EU notified that the agency published an open invitation to take over the role of participant for those active substance/product-type combinations for which the role of participant had not previously been taken over. For those combinations no notification has been submitted to the European Chemicals Agency within the time limit provided for by Article 14(2) of Delegated Regulation (EU) No 1062/2014. Therefore, those active substance/product-type combinations, in accordance with Article 20, first paragraph, point (b), of Delegated Regulation (EU) No 1062/2014, should not be approved for use in biocidal products.
* The said notification shall come into force on the 20th day following that of its publication in the official journal of the European Union. The same is proposed to be adopted in January 2023.

1. **Biocidal Products - G/TBT/N/EU/933 dated 27-Oct-2022**

|  |  |
| --- | --- |
| **Notifying Member** | European Union |
| **Type of Notification** | Regular |
| **Economic relevance** | High |
| **Technical Relevance** | Technical-New |
| **Last Date to offer comments** | 26-December-2022 |
| **Relevant Organization** | Chemexcil |
| **Folder Link** | [Link](https://seetharamanassociates-my.sharepoint.com/:f:/g/personal/satish_sarvada_co_in/EkkYc9eIl3FGtQG1f5H5fUoBTEDW6gDocQ1Hqi-9kFzFCg?e=rwbpzh) |

**Proposal in brief**

1. EU Commission proposed draft commission implementing decision not approving d-Allethrin as an existing active substance for use in biocidal products of product-type 18 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council.
2. According to the opinion of the Agency, biocidal products of product-type 18 containing d-Allethrin cannot be expected to meet the criteria laid down in Article 19(1), points (b)(iii), and (iv), of Regulation (EU) No 528/2012.
3. In its opinion, the Agency noted that the proposed reference specifications, established on the basis of data provided by one of the applicants, are not in line with the composition of the material that was used for testing to generate the toxicological data provided by the applicants. As a result, on the basis of the data provided in the applications, it could not be established whether the representative biocidal products could fulfil the criteria referred to in Article 19(1), point (b) of Regulation (EU) No 528/2012.

**Analysis**

* In the assessment report submitted by Germany to the European Chemicals Agency on 11 January 2017, it is in the opinion of the Agency that D-Allethrin possessed unacceptable risk to the general public and for environment.
* The said notification shall come into force on the 20th day following that of its publication in the official journal of the European Union. The same is proposed to be adopted in January 2023.

1. **Misc. Products (labelling)- G/TBT/N/ZAF/249 Dated 26-Oct-2022**

|  |  |
| --- | --- |
| **Notifying Member** | South Africa |
| **Type of Notification** | Regular notification |
| **Economic relevance** | Indeterminable |
| **Technical Relevance** | Technical-New |
| **Last Date to offer comments** | 25 December 2022 |
| **Relevant Organization** | FIEO, all EPCs |
| **Folder Link** | [Link](https://seetharamanassociates-my.sharepoint.com/:f:/g/personal/satish_sarvada_co_in/EiSBr9tTsGNJnnrTcqCWXpUBtY4Fw-6keOtqZu6MEIvxLA?e=Y9Ny5g) |

**Proposal in brief**

1. South Africa bureau of standards proposed guidelines on dual marking of products with ARSO Quality Marks & National Quality Marks.
2. The following African Conformity Assessment Programme (ACAP) issued by the African Organisation of Standardisation (ARSO).
   1. **ACAP 1-1:2022 - General requirements for the ACAP certification system,** describes the general structure of the African Conformity Assessment Programme (ACAP), its governance, functions and organization. It also describes the general rules to be followed by any party seeking to enter in the ACAP. Details on ACAP, common provisions applicable for all certification schemes included in the ACAP and rules for implementation, verification, certification and maintenance of the ACAP are included. More specific rules for certification schemes implementation, design of African Standards and management of ACAP are specified in the normative documents available for ACAP.
   2. **ACAP 1-2: 2022 - Special requirements for the certification schemes and standards design,** describes special requirements for the design and implementation of ACAP certification schemes. Further, the said document Specifies and describes the object of the conformity assessment (ex: products name, variety, status of final product, etc.) shall be included in the Standard.
   3. **ACAP 1-3: 2022 - Requirements for approval of certification bodies,** describes the procedure for the approval of National and International third party Certification Bodies (CB from now on) willing to be recognized as certifiers for the ACAP.

It summarizes the requirements which shall be met by a CB, to be engaged in the verification and certification process for the ACAP and award of the ACAP Mark.

The ARSO Secretariat will grant approval or disapproval for the CB to become recognized CB for ACAP, based on the result of the assessment. The said document includes the rules to be complied with by National and International third party Certification Bodies seeking accreditation under ACAP.

* 1. **ACAP 1-4:2022 – specifies requirements and procedure for the approval of national and regional/continental testing and calibration laboratories for ACAP**. Further, specifies the conditions in which the licence of laboratory is surrendered or suspended.

1. Apart from these conformity assessments the following reference documents are indispensable for the application of the said measure.
   1. ISO/IEC 17000, Conformity assessment — Vocabulary and general principles
   2. ISO/IEC 17065, Conformity assessment — Requirements for bodies certifying products, processes and services3. Terms and definitions.
   3. The African Conformity Assessment Program (ACAP)- an African system that provides confidence to all interested third parties that a product or process fulfils certain specified requirements; to improve the quality and/or safety of goods produced within the ARSO member states .
   4. Eco Mark Africa (EMA) - certification system for sustainability standards for African products and services developed by the African Organization for Standardization (ARSO) and covered under Scheme D on Sustainability and eco-labelling of the ACAP
   5. ARSO Mark- A certification mark awarded by licensed Certification Body or a National Standards Body (NSB).
   6. Dual Marking -The marking of a product complying with the requirements of an adopted harmonized African standard with an ARSO mark and a notified mark of the member state.
   7. Product Certification- The provision of assessment and impartial third-party attestation that fulfilment of specified requirements of ISO/IEC 17065 or equivalent has been demonstrated.
   8. ARSO License - A signed document signed between ARSO and a Certification Body or designated member state authority or agent for the purpose of assessment and award of an ARSO quality mark.
   9. African standard- standard approved by the ARSO Council and adopted by the ARSO General Assembly.

**Analysis**

* The said African guideline describes the fundamentals of dual marking of products with the ARSO quality mark and a member state’s notified quality mark for products complying with African harmonized standards. As such marking requirements should not cause significant adverse impact on trade. However, Stakeholders may offer their comments on or before 25 December 2022.

**Action Points**

* **For MoC:** The MoC may write to the BIS to review the draft document, compare the same with the Indian system and offer their comments, if any.

1. **Volatile Organic Compounds (VOCs)- G/TBT/N/USA/1930 Dated 18-Oct-2022 and G/TBT/N/USA/1930/Corr.1 Dated 20-Oct-2022**

|  |  |
| --- | --- |
| **Notifying Member** | USA |
| **Type of Notification** | Regular notification |
| **Economic relevance** | Very High |
| **Technical Relevance** | Technical-New |
| **Last Date to offer comments** | 13th Dec’22 |
| **Relevant Organization** | Chemexcil |
| **Folder Link** | [Link](https://seetharamanassociates-my.sharepoint.com/:f:/g/personal/satish_sarvada_co_in/EvwtobfsJqxIpCVHeqyB3AkBbOI0gjWxDpKlHSnmQfIqUw?e=g6x933) |

**Proposal in brief**

1. The USA, Department of Public Health and Environment,issured Regulation Number 21 titled “Control of Volatile Organic Compounds from Consumer Products and Architectural and Industrial Maintenance Coatings”.
2. This part applies to any person who sells, supplies, offers for sale, distributes for sale, or manufactures for sale consumer products in the 8-hour Ozone Control Area, Beginning February 14, 2023, applicability in northern Weld County is no longer on a State Only basis and (State Only) Colorado. As marked by (State Only), the requirements are not federally enforceable.
3. Standards –
   * + 1. On or after May 1, 2020, no person can manufacture for sale in Colorado any consumer product with a VOC content in excess of the VOC limit specified in Table 1.
       2. No person can sell, supply, offer for sale, or distribute for sale in Colorado any consumer product that is manufactured on or after May 1, 2020, with a VOC content in excess of the VOC limit specified in Table 1.
       3. On or after May 1, 2021, no person can manufacture for sale in Colorado any consumer product registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA; 7 USC Section 136-136y (1996)) in excess of the VOC limits in Table 1.
       4. No person can sell, supply, offer for sale, or distribute for sale in Colorado any consumer product registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA; 7 USC Section 136-136y (1996)) and manufactured on or after May 1, 2021, with a VOC content in excess of the VOC limits in Table 1.
       5. Effective May 1, 2020, and until May 1, 2021, no person can manufacture for sale, sell, supply, or offer for sale any flammable or extremely flammable, as labeled or meeting the criteria in Title 16 CFR Section 1500.3(c)(6) (February 27, 2018), paint thinner or multipurpose solvent labeled as a clean-up solvent or paint clean-up product unless the product is clearly and prominently labeled with-
     1. “DANGER,” “WARNING,” or “CAUTION” and “Formulated to meet California VOC limits; see warnings on label”; or
     2. The common name of the chemical compound (e.g., acetone, methyl acetate, etc.) that results in the product meeting the criteria for flammable or extremely flammable.
        1. Charcoal lighter material products must be issued a certification in accordance with Subchapter 8.5, Article 2, Section 94509(h) (January 1, 2019) of Title 17 of the California Code of Regulations.
        2. For consumer products for which the label, packaging, or accompanying literature states that the product should be diluted with any VOC solvent prior to use, the limits specified in Table 1 apply to the product only after the maximum recommended dilution has taken place.
4. Container labeling-
   1. The label on energized electrical cleaners must clearly display “Energized equipment use only. Not to be used for motorized vehicle maintenance or their parts.”
   2. The label on non-aerosol floor wax strippers must specify a dilution ratio for light or medium build-up of polish that results in an as-used VOC concentration of 3 percent by weight or less. The label on a non-aerosol floor wax stripper that is also intended to be used for removal of heavy build-up of polish that results must specify a dilution ratio for heavy build-up of polish that results in an as-used VOC concentration of 12 percent by weight or less.
   3. The label on zinc rich primers must clearly display “for professional use only,” “for industrial use only,” or “not for residential use” or “not intended for residential use.”

**Analysis**

* On 20th Oct’22 USA issued a *Corrigendum* to this notification, in which Regulation Number 21 Control of Volatile Organic Compounds from Consumer Products and Architectural and Industrial Maintenance Coatings

The text in Relevant Documents (Box Number 8) is corrected to read as follows:

Colorado Register 25 September 2022: <https://www.coloradosos.gov/CCR/RegisterContents.do?publicationDay=09/25/2022&Volume=45&yearPublishNumber=18&Month=9&Year=2022>

* WTO Members and their stakeholders are asked to submit comments to the USA TBT Enquiry Point by or before 4pm Eastern Time on 13 December 2022.

**Action Points**

* **For Sarvada:** Sarvada is disseminating the information to the stakeholders in its list. The email/s are copied to EIC and DOC

1. **Food for special Medical Purposes- G/TBT/N/EU/931 dated 10-Oct-2022**

|  |  |
| --- | --- |
| **Notifying Member** | European Union |
| **Type of Notification** | Regular |
| **Economic relevance** | High |
| **Technical Relevance** | Technical-New |
| **Last Date to offer comments** | 09-December-22 |
| **Relevant Organization** | Pharmexcil/Chemexcil |
| **Folder Link** | [Link](https://seetharamanassociates-my.sharepoint.com/:f:/g/personal/satish_sarvada_co_in/EqhBb1Vm_iNIgJE5c6xvVNcBF8aA6yUj9nbgqE5gQ4SqmA?e=PSBGeU) |

**Proposal in brief**

1. European Union proposed amendment to the Regulation (EU) No. 609/2013 to allow the use of nicotinamide riboside chloride as a source of niacin in food for special medical purposes and total diet replacement for weight control.
2. The following key amendments are made in the regulation:
   1. Proposes to add nicotinamide riboside chloride as a source of niacin in food for special medical purposes and total diet replacement for weight control. Therefore, substance “nicotinamide riboside chloride” should be added within the category of substance “vitamins” under ‘Niacin’ in the list of substance referred in EU 609/2013.
   2. In accordance with EU 2015/2283 and Eu 2020/16 regulation authorising Nicotinamide Riboside Chloride in the market as a novel food for use in food supplements.
   3. Implementing regulation EU 2022/1160 to authorise use of nicotinamide riboside chloride among other products, food for special medical purposes and total diet replacement for weight control for adult population, excluding pregnant and lactating women subject to certain conditions.
3. The stakeholders may offer their comments on or before 09 December 2022

**Analysis**

* EU claims to have sufficient grounds to establish that nicotinamide riboside chloride is not of safety concern as a source of niacin when used in food for special medical purposes and total diet replacement for weight control, under the conditions set out in Commission Implementing Regulation (EU) 2022/1160.
* The measure would have no unfavourable effect on India’s exporters, as the proposed regulation does not prohibit any substance, but only allows its use in food for special medical purposes.
* The proposed measure shall enter into force on 20th day following its publication in the official journal of EU.

1. **Sanitary Towels - G/TBT/N/UGA/1671 dated 3-Oct-2022**

|  |  |
| --- | --- |
| **Notifying Member** | Uganda |
| **Type of Notification** | Regular Notification |
| **Economic relevance** | Low |
| **Technical Relevance** | CAP-Sampling |
| **Last Date to offer comments** | 3rd Dec’22 |
| **Relevant Organization** | Chemexcil |
| **Folder Link** | [Link](https://seetharamanassociates-my.sharepoint.com/personal/satish_sarvada_co_in/_layouts/15/onedrive.aspx?ct=1666170178823&or=Teams%2DHL&ga=1&id=%2Fpersonal%2Fsatish%5Fsarvada%5Fco%5Fin%2FDocuments%2F2021%2F2021%20TBT%2F2022%20TBT%2FOctober%2FWEEK%2040%2FLow%20Notifications%20Week%2040) |

**Proposal In brief**

1. Uganda has issued this notification in light of MHM for girls and women.
2. This Draft Uganda Standard specifies requirements, sampling, and test methods for reusable menstrual cups.
3. The documents provide for factors to be considered when determining a menstrual cup size.
4. Labelling requirements for the packaging are-
   1. name and address of the manufacturer.
   2. product name, i.e., reusable menstrual cup.
   3. volume of flow that can be collected.
   4. dimensions (i.e., cup length, stem length (where applicable), diameter and wall thickness).
   5. material composition (i.e., rubber or medical grade silicone).
   6. Warning concerning the hazards of menstrual related Toxic Shock Syndrome (TSS) such as, “Menstrual cup use is associated with the Toxic Shock Syndrome. The potentially fatal disease causes women to experience fever, shock, low blood pressure, skin rashes, liver, and kidney abnormalities”.
   7. country of origin/manufacture.
   8. care and use instructions, including the emphasis on the importance of personal hygiene, particularly the washing of hands before and after inserting the menstrual cup. (Pictorials are recommended).
   9. storage instructions.
   10. guidance and recommendations on selection of a suitable size for one’s flow and the range of other available sizes (see Annex A for more understanding of the factors affecting selection of sizes).
   11. instructions for IUD users
   12. date of manufacture
   13. Lot/batch number
5. The use of the UNBS Certification Mark is governed by the Standards Act.

**Analysis**

1. There are no mandatory requirements to be follow the said notification.
2. The said notification should be circulated to the stakeholders.
3. **Carcinogenic, mutagenic, or reproductive toxicant substances - G/TBT/N/EU/930 dated 5-Oct'2022**

|  |  |
| --- | --- |
| **Notifying Member** | European Union |
| **Type of Notification** | Regular Notification |
| **Economic relevance** | Low |
| **Technical Relevance** | Technical-New |
| **Last Date to offer comments** | 4th Dec’22 |
| **Relevant Organization** | Chemexcil |
| **Folder Link** | [Link](https://seetharamanassociates-my.sharepoint.com/personal/satish_sarvada_co_in/_layouts/15/onedrive.aspx?ct=1666170178823&or=Teams%2DHL&ga=1&id=%2Fpersonal%2Fsatish%5Fsarvada%5Fco%5Fin%2FDocuments%2F2021%2F2021%20TBT%2F2022%20TBT%2FOctober%2FWEEK%2040%2FLow%20Notifications%20Week%2040) |

**Proposal In brief**

1. This draft Commission Regulation aims to include within the scope of entries 28 to 30 of Annex XVII to Regulation (EC) No 1907/2006 several substances, with the effect of restricting their placing on the market or use for supply to the general public as substances on their own, as constituents of other substances or in mixtures and to impose the requirement to mark packaging with the label "restricted to professional users".
2. This is consequent to the recent classification of these substances as CMR category 1A or 1B under Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, as amended by Commission Delegated Regulation (EU) 2022/692 (as corrected, OJ L 146, 25.5.2022, p. 150).

**Analysis**

1. The said notification is to be circulated to the concerned stakeholders.
2. **Cosmetics - G/TBT/N/EU/935 Dated 17-Nov-2022**

|  |  |
| --- | --- |
| **Notifying Member** | European Union |
| **Type of Notification** | Regular notification |
| **Economic relevance** | High |
| **Technical Relevance** | Technical - New |
| **Last Date to offer comments** | 16-January-2023 |
| **Relevant Organization** | Chemexcil |
| **Folder Link** | [Link](https://seetharamanassociates-my.sharepoint.com/:f:/g/personal/satish_sarvada_co_in/EqhGk9Ms6yFEr-PRvqh405oBeyphbi8PxWFtdApGYjQh5Q?e=8BzZ1M) |

**Proposal in brief**

1. EU has proposed a draft of commission regulation to amend Regulation No. 1223/2009 as regards to the use in cosmetic products of certain substances classified as carcinogenic, mutagenic or toxic for reproduction.
2. EU has classified the substances as classifiesd as carcinogenic, mutagenic or toxic for reporduction (CMR) substances of category 1A, category 1B or category 2 depending on the the level of evidence of their CMR properties.
3. CMR substances are chemicals identified as **carcinogenic, mutagenic, or toxic for reproduction**. They are divided into three hazard categories:

* **Category 1A** — substances that are known to be CMR mainly according to human evidence.
* **Category 1B** — substances presumed to be CMR based on data from animal studies.
* **Category 2** — substances suspected to be CMR derived from limited evidence from humans or animal studies. Category 2 is selected when there is insufficient evidence to classify a substance as CMR of category 1.[[1]](#footnote-2)

1. Substances which have been classified as above are prohibited to use as ingredients in the production of cosmetics.
2. For the uniform implementation of such prohibition of CMR substances Annex II, III to VI are amended accordingly.
3. The said regulation covers substances classified as CMR substances by Delegated Regulation (EU) 2022/6923 ‘the relevant substances’ which shall be applied from 1 December 2023.
4. Relevant substances are currently neither restricted in Annex III nor allowed in Annex IV to VI of regulation EC No. 1223/2009. However, the substance 2-ethylhexanoic acid (CAS No. 149-57-5) is currently listed in entry 1024 of Annex II to Regulation (EC) No 1223/2009. But the salts of that substance, which have been classified as CMR substances [of category 1B] by Delegated Regulation (EU) 2022/692, are not included in that entry. None of the other relevant substances are currently listed in Annex II to Regulation (EC) No 1223/2009. Therefore, those substances should be added to the list of substances prohibited in cosmetic products in Annex II to Regulation (EC) No 1223/2009 and the salts of the substance 2-ethylhexanoic acid should be added in entry 1024 of that Annex.
5. Entries amended in the Annex II are as follows:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Ref. No.** | **Substance identification** | | | | | |
| **Chemical name/INN** | | **CAS No.** | **EC No.** | |
| ʻ1024 | 2-ethylhexanoic acid and its salts with the exception of those specified elsewhere in Annex VI to Regulation (EC) No 1272/2008 | | 149-57-5/- | 205-743-6/-’ | |
| X | | Ammonium bromide | 12124-97-9 | | 235-183-8 | | |
| X | | Dibutyltin bis(2-ethylhexanoate) | 2781-10-4 | | 220-481-2 | | |
| X | | Dibutyltin di(acetate) | 1067-33-0 | | 213-928-8 | | |
| X | | Tellurium dioxide | 7446-07-3 | | 231-193-1 | | |
| X | | Barium diboron tetraoxide | 13701-59-2 | | 237-222-4 | | |
| X | | 2,2-dimethylpropan-1-ol,tribromo derivative; 3-bromo-2,2-bis(bromomethyl)propan-1-ol | 36483-57-5/  1522-92-5 | | 253-057-0/- | | |
| X | | 2,4,6-tri-tert-butylphenol | 732-26-3 | | 211-989-5 | | |
| X | | 4,4’-sulphonyldiphenol; bisphenol S | 80-09-1 | | 201-250-5 | | |
| X | | Benzophenone | 119-61-9 | | 204-337-6 | | |
| X | | Quinoclamine (ISO); 2-amino-3-chloro-1,4- naphthoquinone | 2797-51-5 | | 220-529-2 | | |
| X | | Perfluoroheptanoic acid; tridecafluoroheptanoic acid | 375-85-9 | | 206-798-9 | | |
| X | | methyl N-(isopropoxycarbonyl)-L-valyl- (3RS)-3-(4-chlorophenyl)-β-alaninate; valifenalate | 283159-90-0 | | 608-192-3 | | |
| X | | 6-[C12-18-alkyl-(branched, unsaturated)-2,5- dioxopyrrolidin-1-yl]hexanoic acid, sodium and tris(2-hydroxyethyl)ammonium salts | - | | 701-271-4 | | |
| X | | 6-[(C10-C13)-alkyl-(branched, unsaturated)- 2,5-dioxopyrrolidin-1-yl]hexanoic acid | 2156592-54-8 | | 701-118-1 | | |
| X | | 6-[C12-18-alkyl-(branched, unsaturated)-2,5- dioxopyrrolidin-1-yl]hexanoic acid | - | | 701-162-1 | | |
| X | | Theophylline; 1,3-dimethyl-3,7-dihydro-1H- purine-2,6-dione | 58-55-9 | | 200-385-7 | | |
| X | | 1,3,5-triazine-2,4,6-triamine; melamine | 108-78-1 | | 203-615-4 | | |
| X | | Fluopicolide (ISO); 2,6-dichloro-N-[3-chloro- 5-(trifluoromethyl)-2- pyridylmethyl]benzamide | 607-285-6 | | 239110-15-7 | | |
| X | | N-(2-nitrophenyl)phosphoric triamide | 874819-71-3 | | 477-690-9 | | |
| X | | N-(5-chloro-2-isopropylbenzyl)-N- cyclopropyl-3-(difluoromethyl)-5-fluoro-1- methyl-1H-pyrazole-4-carboxamide; isoflucypram | 1255734-28-1 | | 811-438-4 | | |
| X | | Reaction mass of 3-(difluoromethyl)-1-methyl- N-[(1RS,4SR,9RS)-1,2,3,4-tetrahydro-9-  isopropyl-1,4-methanonaphthalen-5- yl]pyrazole-4-carboxamide and 3- (difluoromethyl)-1-methyl-N-[(1RS,4SR,9SR)- 1,2,3,4-tetrahydro-9-isopropyl-1,4- methanonaphthalen-5-yl]pyrazole-4- carboxamide [>78% syn isomers <15% anti isomers relative content]; isopyrazam | 881685-58-1 | | 632-619-2 | | |
| X | | Margosa, ext. [from the kernels of Azadirachta indica extracted with water and further processed with organic solvents] | 84696-25-3 | | 283-644-7 | | |
| X | | Cumene | 98-82-8 | | 202-704-5 | | |
| X | | 2-ethyl-2-[[(1-oxoallyl)oxy]methyl]-1,3- propanediyl diacrylate; 2,2- bis(acryloyloxymethyl)butyl acrylate; trimethylolpropane triacrylate; | 15625-89-5 | | 239-701-3 | | |
| X | | Pentapotassium 2,2’,2’’,2’’’,2’’’’-(ethane-1,2- diylnitrilo)pentaacetate | 7216-95-7 | | 404-290-3 | | |
| X | | N-carboxymethyliminobis(ethylenenitrilo)tetra(a cetic acid); Pentetic Acid (INCI) | 67-43-6 | | 200-652-8 | | |
| X | | Pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)te traacetate; Pentasodium Pentetate (INCI) | 140-01-2 | | 205-391-3 | | |
| X | | Acetamiprid (ISO); (1E)-N-[(6-chloropyridin- 3-yl)methyl]-N'-cyano-N- methylethanimidamide; (E)-N1-[(6-chloro-3- pyridyl)methyl]-N2-cyano-N1- methylacetamidine | 135410-20-7/  160430-64-8 | | 603-921-1/  682-791-8 | | |
| X | | Pendimethalin (ISO); N-(1-ethylpropyl)-2,6- dinitro-3,4-xylidene | 40487-42-1 | | 254-938-2 | | |
| X | | Bentazone (ISO); 3-isopropyl-2,1,3- benzothiadiazine-4-one-2,2-dioxide | 25057-89-0 | | 246-585-8’ | | |

**Analysis**

* EU has introduced prohibition on many substances to be used in production of cosmetics. These CMR substances could earlier be utilised in consmetics if the conditions laid down in Article 15(1), second sentence, of Regulation (EC) No 1223/2009 or in Article 15(2), second subparagraph of that Regulation are fulfilled. However, pursuant to this proposed amendment, all CMR substances are to be moved to the list of prohibited substances.
* India may have been using the substances prohibited by the EU. Hence, stakeholders must go through the list of prohibited substances and offer their comments on or before 16 January 2023. Based on the comments EIC and DoC may like to take up the issues with the appropriate authorities.
* Stakeholders may offer their comments on or before 16 January 2023.

**Action Points**

* **For Sarvada:** Sarvada is disseminating the information to the stakeholders in its list. The email/s are copied to EIC and DOC.

1. **Chemical and Petroleum Products- G/TBT/N/USA/1944 Dated 17-Nov-2022**

|  |  |
| --- | --- |
| **Notifying Member** | USA |
| **Type of Notification** | Regular notification |
| **Economic relevance** | Indeterminable |
| **Technical Relevance** | Technical-New |
| **Last Date to offer comments** | 17 January 2023 |
| **Relevant Organization** | FIPI / Chemexcil |
| **Folder Link** | [Link](https://seetharamanassociates-my.sharepoint.com/:f:/g/personal/satish_sarvada_co_in/ErLaVoehk9lBnPa1Gun8HbABuhBfBkmPEJlxDIwCZN7gQw?e=6VNh8H) |

**Proposal in brief**

1. USA EPA has proposed a draft regualation to modify and supplement its proposed rule issued on 11 January 2021 in which the Agency updated fee adjustments to the 2018 Fee Rule established under the [Toxic Substances Control Act (TSCA)](https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act).
2. The said regulation shall affect the following:
   * 1. Chemical manufacturers (NAICS code 325).
     2. Petroleum and coal products (NAICS code 324).
     3. Chemical, Petroleum and Merchant Wholesalers (NAICS code 424).
3. Proposed fee amounts described in the tables as follows:

|  |  |  |  |
| --- | --- | --- | --- |
| **Fee Category** | **2018 Fee Rule** | **Current Fees** | **2022 Supplemental proposed rule** |
| Test Order | $9800 | $11,650 |  |
| Test rules | $29,500 | $35,080 |  |
| Enforceable consent agreement | $22,800 | $27,110 |  |
| PMN PMN and consolidated PMN, SNUN, MCAN and consolidated MCAN. | $16,000 | $19,020 |  |
| PMN and consolidated PMN, SNUN, MCAN and consolidated MCAN. | $4,700 | $5,590 |  |
| EPA-initiated risk evaluation | $1,350,000 | Two payments resulting in $2,560,000. | Two payments resulting in $5,081,000. |
| Manufacturer-requested risk evaluation on a chemical included in the TSCA Work Plan. | Initial payment nitial payment of $1.25M, with final invoice to recover 50% of actual costs. | Two payments of $945,000, with final invoice to recover 50% of actual costs. | Two payments of $1,497,000, with final invoice to recover 50% of actual costs |
| Manufacturer-requested risk evaluation on a chemical not included in the TSCA Work Plan. | Initial payment of $2.5M, with final invoice to recover 100% of actual costs | Two payments of $1.89M, with final invoice to recover 100% of actual costs. | Two payments of $2,993,000, with final invoice to recover 100% of actual costs. |

1. EPA is proposing to refund 20 percent of the user fee to the submitter if a notice is withdrawn after 10 business days after the beginning of the applicable review period, but prior to EPA initiating risk management on the chemical substance.
2. Manufacturers of a chemical substance subject to risk evaluation under section 6(b) of the Act are exempted from fee payment requirements in this section, if they meet one or more of the following exemptions for the five-year period preceding publication of the preliminary list and do not conduct manufacturing outside of those exemptions during the five-year period preceding publication of the preliminary list:
   * 1. import articles containing that chemical substance;
     2. produce that chemical substance as a byproduct that is not later used for commercial purposes or distributed for commercial use;
     3. manufacture (including import) that chemical substance as an impurity as defined in § 704.3;
     4. manufacture that chemical substance as a non-isolated intermediate as defined in § 704.3;
     5. manufacture (including import) small quantities of that chemical substance solely for research and development, as defined in § 700.43; and/or
     6. manufacture (including import) that chemical substance in quantities below a 2,500 lbs annual production volume as described in § 700.43, unless all manufacturers of that chemical substance manufacture that chemical in quantities below a 2,500 lbs annual production volume as described in § 700.43, in which case this exemption is not applicable.
3. EPA request comments on all other aspects of this proposed rule.

**Analysis**

* Stakeholders may offer their comments stating whether the revision in the fees is justifiable or not. Comments can be submitted to EPA through the Federal e-Rulemaking Portal at <https://www.regulations.gov> by following the instructions on or before 17 January 2022.

**Action Points**

* **For Sarvada:** Sarvada is disseminating the information to the stakeholders in its list. The email/s are copied to EIC and DOC.

1. **Varnish used in electrical Insulation- G/TBT/N/EGY/332 dated 17-Nov-2022**

|  |  |
| --- | --- |
| **Notifying Member** | Egypt |
| **Type of Notification** | Regular Notification |
| **Economic relevance** | Indeterminable |
| **Technical Relevance** | Technical-New |
| **Last Date to offer comments** | 16-January-2023 |
| **Relevant Organization** | Chemexcil |
| **Folder Link** | [Link](https://seetharamanassociates-my.sharepoint.com/:f:/g/personal/satish_sarvada_co_in/EkGO8P2AoEtFkslQmqPekgoB-QdcShfcSb5RscJR5Q1pUQ?e=ukv2ca) |

**Proposal in brief**

* 1. Egypt proposed a draft of Eqyptian standard “Varnishes used for electrical insulation – Part 2: Methods of test”.
  2. The said draft of Egyptian standard specifies methods of test to be used for testing varnishes used for electrical insulation. This includes methods of test to be applied before and others to be applied after drying and/or curing of the varnish.

**Analysis**

* Egypt claims that the said standard is technically identical with IEC 60464-2:2014. But the same cannot be verified as Egypt has not shared the copy of regulation in the notification.

**Action Points**

* **For Sarvada:** Sarvada is disseminating the information to the stakeholders in its list. The email/s are copied to EIC and DOC.
* **For EIC and DOC:** EIC may like to write to Egyptian Organisation for Standardization and Quality to get the copy of the technical document to further review the technicalities of the regulation.

1. **Chemical and Petroleum Products- G/TBT/N/USA/1944 Dated 17-Nov-2022**

|  |  |
| --- | --- |
| **Notifying Member** | USA |
| **Type of Notification** | Regular notification |
| **Economic relevance** | Indeterminable |
| **Technical Relevance** | Technical-New |
| **Last Date to offer comments** | 17 January 2023 |
| **Relevant Organization** | FIPI / Chemexcil |
| **Folder Link** | [Link](https://seetharamanassociates-my.sharepoint.com/:f:/g/personal/satish_sarvada_co_in/ErLaVoehk9lBnPa1Gun8HbABuhBfBkmPEJlxDIwCZN7gQw?e=6VNh8H) |

**Proposal in brief**

1. USA EPA has proposed a draft regualation to modify and supplement its proposed rule issued on 11 January 2021 in which the Agency updated fee adjustments to the 2018 Fee Rule established under the [Toxic Substances Control Act (TSCA)](https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act).
2. The said regulation shall affect the following:
   * 1. Chemical manufacturers (NAICS code 325).
     2. Petroleum and coal products (NAICS code 324).
     3. Chemical, Petroleum and Merchant Wholesalers (NAICS code 424).
3. Proposed fee amounts described in the tables as follows:

|  |  |  |  |
| --- | --- | --- | --- |
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| Test rules | $29,500 | $35,080 |  |
| Enforceable consent agreement | $22,800 | $27,110 |  |
| PMN PMN and consolidated PMN, SNUN, MCAN and consolidated MCAN. | $16,000 | $19,020 |  |
| PMN and consolidated PMN, SNUN, MCAN and consolidated MCAN. | $4,700 | $5,590 |  |
| EPA-initiated risk evaluation | $1,350,000 | Two payments resulting in $2,560,000. | Two payments resulting in $5,081,000. |
| Manufacturer-requested risk evaluation on a chemical included in the TSCA Work Plan. | Initial payment nitial payment of $1.25M, with final invoice to recover 50% of actual costs. | Two payments of $945,000, with final invoice to recover 50% of actual costs. | Two payments of $1,497,000, with final invoice to recover 50% of actual costs |
| Manufacturer-requested risk evaluation on a chemical not included in the TSCA Work Plan. | Initial payment of $2.5M, with final invoice to recover 100% of actual costs | Two payments of $1.89M, with final invoice to recover 100% of actual costs. | Two payments of $2,993,000, with final invoice to recover 100% of actual costs. |

1. EPA is proposing to refund 20 percent of the user fee to the submitter if a notice is withdrawn after 10 business days after the beginning of the applicable review period, but prior to EPA initiating risk management on the chemical substance.
2. Manufacturers of a chemical substance subject to risk evaluation under section 6(b) of the Act are exempted from fee payment requirements in this section, if they meet one or more of the following exemptions for the five-year period preceding publication of the preliminary list and do not conduct manufacturing outside of those exemptions during the five-year period preceding publication of the preliminary list:
   * 1. import articles containing that chemical substance;
     2. produce that chemical substance as a byproduct that is not later used for commercial purposes or distributed for commercial use;
     3. manufacture (including import) that chemical substance as an impurity as defined in § 704.3;
     4. manufacture that chemical substance as a non-isolated intermediate as defined in § 704.3;
     5. manufacture (including import) small quantities of that chemical substance solely for research and development, as defined in § 700.43; and/or
     6. manufacture (including import) that chemical substance in quantities below a 2,500 lbs annual production volume as described in § 700.43, unless all manufacturers of that chemical substance manufacture that chemical in quantities below a 2,500 lbs annual production volume as described in § 700.43, in which case this exemption is not applicable.
3. EPA request comments on all other aspects of this proposed rule.

**Analysis**

* Stakeholders may offer their comments stating whether the revision in the fees is justifiable or not. Comments can be submitted to EPA through the Federal e-Rulemaking Portal at <https://www.regulations.gov> by following the instructions on or before 17 January 2022.

**Action Points**

* **For Sarvada:** Sarvada is disseminating the information to the stakeholders in its list. The email/s are copied to EIC and DOC.

1. **Organic Chemicals- G/TBT/N/BRA/1453 dated 01-Nov-2022**

|  |  |
| --- | --- |
| **Notifying Member** | Brazil |
| **Type of Notification** | Regular Notification |
| **Economic relevance** | Very High |
| **Technical Relevance** | Technical -New |
| **Last Date to offer comments** | Not Applicable |
| **Relevant Organization** | Chemexcil |
| **Folder Link** | [Link](https://seetharamanassociates-my.sharepoint.com/:f:/g/personal/satish_sarvada_co_in/Er4mW62kl35Cr0IslqUI5wcBJIJ1vnX407VhjkFv0Npg0Q?e=sQvUtn) |

**Proposal in brief**

1. Brazil has issued safety requirements.
2. Procedures and requirements for registration of remediated products, renewal, prior consent for import , authorization for research and experimetation and provides other measures.

**Analysis**

1. The said observations are based on the WTO notification, as the relevant technical document is not available, due to technical error.

**Action Points**

* **For Sarvada:** Sarvada is disseminating the information to the stakeholders in its list. The email/s are copied to EIC and DOC.
* **For EIC and DOC-** Are to request for techinical documents, so that Sarvada can offer comments based technical document.

1. **Organic Chemicals- G/TBT/N/BRA/1454 dated 01-Nov-2022**

|  |  |
| --- | --- |
| **Notifying Member** | Brazil |
| **Type of Notification** | Regular Notification |
| **Economic relevance** | Very High |
| **Technical Relevance** | Technical -New |
| **Last Date to offer comments** | Not Applicable |
| **Relevant Organization** | Chemexcil |
| **Folder Link** | [Link](https://seetharamanassociates-my.sharepoint.com/:f:/g/personal/satish_sarvada_co_in/EkB21t63EehDqnH-3HefbAYBJ5c3z8iJeOrsojNEUyskOw?e=ROnsYl) |

**Proposal in brief**

1. Brazil has issued procedures for the control and supervision of chemicals and defines the chemicals to be controlled by the federal police.
2. As per Article 15, operating licence must be renewed annually from the date of their release, the revocation required in the period covering the last sixty days of validity of the certificate of licence a operating and the application must be sent until date of expiration even if not useful.
3. The central unit for the control of chemical products of the federal police has issed notification to the multilateral in compliance with the agreements and the international agreements of which Brazil is a signataory.
4. For the purpose of greater control and taxation of foreign trade activities and the federal police have been able to establish by ,means of their own act, points and entry and exit allowed in national territory for the chemical products listed in Annex l.
5. Articles 34- 41 Articles, talks about the general rules of control , for the quantification of the chemical product, the unit of measure shall be considered in kilogram or liter using three decimal places, in the respect of rounding rules. The packaging rule must contain, in a visible and easily identified place information about the cncentration of each chemical products.
6. Final, disposal to comply with the provisions of the ordinance, the federal police made available the computerized system of control of chemical produdcts. Certificates, authorizations, control maps and the formulations listed in the Annexes to this Ordinance may, at any time, be replaced by others that allow the mechanisms of control and fiscalization of chemical products through issue of Normative Rules for the role of the Federal Police.

**Analysis**

1. Relevant technical document was not available in English language and proper translation was not obtained through MS Translate feature hence observations are based on the notification document only. An English translation of the relevant technical documents were sought from the concerned TBT Enquiry point and awaiting their response.
2. The notification was issued on 01-November -22 but it came into force from 24 October 2022. Prima facie, Brazil appears to have not complied with the following WTO provisions:

* Brazil failed to publish a notice in a publication at an early appropriate stage, in such a manner as to enable interested parties in other Members to become acquainted with it, that they propose to introduce a particular technical regulation (**Art.2.9.1 of the Agreement on Technical Barriers to Trade**).
* The failure of Brazil to allow, without discrimination, reasonable time for other Members to make comments in writing, discuss these comments upon request, and take these written comments and the results of these discussions into account (**Article 2.9.4 of the Agreement on Technical Barriers to Trade**).

**Action Points**

* **For Sarvada:** Sarvada is disseminating the information to the stakeholders in its list. The email/s are copied to EIC and DOC.
* **For EIC/DOC:** Brazil notifies regulations only after they have come into force or just a few days before. DOC should consider raising this issue with Brazil through appropriate channels and impress upon them the need to grant sufficient time for the Indian exporters to prepare themselves to comply with the new regulations. In any such interaction, several notifications issued by Brazil without providing adequate time may be clubbed together.

1. **Chemical Substances - G/TBT/N/USA/1936 dated 01-Nov-2022**

|  |  |
| --- | --- |
| **Notifying Member** | United States of America |
| **Type of Notification** | Regular Notification |
| **Economic relevance** | Very High |
| **Technical Relevance** | Technical -Amendment |
| **Last Date to offer comments** | 30-Nov-22 |
| **Relevant Organization** | Chemexcil |
| **Folder Link** | [Link](https://seetharamanassociates-my.sharepoint.com/:f:/g/personal/satish_sarvada_co_in/EoNzrrCFEnJDiwBRGNK3TGQB-XhJCG1Yl6FMQtHOZiDfwQ?e=fGOsAZ) |

**Proposal in brief**

1. USA’s Environmental Protection Agency (EPA) is proposing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for chemical substances that were the subject of premanufacture notices (PMNs) and are also subject to Orders issued by EPA pursuant to TSCA.
2. These proposed SNURs would require persons to notify EPA at least 90 days before commencing the manufacture or processing of any of these chemical substances for an activity proposed as a significant new use. Receipt of such notices would allow EPA to assess risks and, if appropriate, to regulate the significant new use before it may occur.
3. Once EPA receives a SNUN and before the manufacture or processing for the significant new use can commence.
4. EPA must either determine that the use is not likely to present an unreasonable risk of injury under the conditions of use for the chemical substance or take such regulatory action as is associated with an alternative determination.
5. EPA is proposing these SNURs for specific chemical substances which have undergone premanufacture review because the Agency wants:

* To identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying TSCA Orders, consistent with TSCA section 5(f)(4).
* To have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing a listed chemical substance for the described significant new use.
* To be able to either determine that the prospective manufacture or processing is not likely to present an unreasonable risk, or to take necessary regulatory action associated with any other determination before the described significant new use of the chemical substance occurs.

1. SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on the following:

* Human exposure and environmental release that may result from the significant new use of the chemical substances.
* Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

**Analysis**

* EPA is proposing significant new use and record keeping requirements for certain chemical substances in 40 CFR part 721, subpart E. In this unit, EPA provides the following information for each chemical substance that is identified in this unit as subject to this proposed rule:

1. PMN number (the proposed CFR citation assigned in the regulatory text section of the proposed rule).
2. Chemical name (generic name, if the specific name is claimed as CBI).
3. Chemical Abstracts Service (CAS) Registry number (if assigned for nonconfidential chemical identities).
4. Effective date of and basis for the TSCA Section 5I Order.
5. Potentially Useful Information.

* To establish a significant new use, EPA must determine that the use is not ongoing. The chemical substances subject to this proposed rule have undergone premanufacture review. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no person may commence such activities without first submitting a PMN. Therefore, for chemical substances for which an NOC has not been submitted EPA concludes that the designated significant new uses are not ongoing.
* Effect on Importes - This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import provisions promulgated at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and Orders under TSCA, which would include the SNUR requirements should these proposed rules be finalized. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B.

**Action Points**

* **For Sarvada:** Sarvada is disseminating the information to the stakeholders in its list. The email/s are copied to EIC and DOC.

1. **Hazardous Substances - G/TBT/N/SGP/66 dated 04-Nov-2022**

|  |  |
| --- | --- |
| **Notifying Member** | Singapore |
| **Type of Notification** | Regular Notification |
| **Economic relevance** | Very High |
| **Technical Relevance** | Technical -New |
| **Last Date to offer comments** | 3-Jan-23 |
| **Relevant Organization** | Chemexcil |
| **Folder Link** | [Link](https://seetharamanassociates-my.sharepoint.com/:f:/g/personal/satish_sarvada_co_in/ErnJXepGwqxOu-dhSG0DXJcBMEuL9TiME1XqlJBfaWtyJA?e=GclySG) |

**Proposal in brief**

1. Singapore's National Environment Agency (NEA) is proposing to regulate 26 new chemicals and chemical groups (see Section 4 above) as hazardous substances under the Environmental Protection and Management Act (EPMA) and the Environmental Protection and Management (Hazardous Substances) Regulations (EPM (HS) Regs).
2. These 26 chemicals and chemical groups have been identified as toxic chemicals and precursors under the Chemical Weapons Convention (CWC), and are currently regulated by Singapore Customs, as the National Authority for the Chemical Weapons Convention (NA(CWC)), through the Chemical Weapons (Prohibition) Act (CWPA) and the Chemical Weapons (Prohibition) Regulations. Under the CWPA, depending on the CWC Schedule that the chemicals belong to, companies are required to apply for a NA(CWC) licence from Singapore Customs if they are engaged in activities including the import, export, production, processing, consumption and local sale and distribution of these chemicals.
3. From July 2023, NEA will also be regulating these 26 chemicals and chemical groups under the EPMA and EPM (HS) Regs. Once the regulations take effect, companies will be required to apply for a Hazardous Substances (HS) licence/permit from NEA for the import, export, manufacture, sale, transport, storage and/or use of these chemicals and of products containing these chemicals. Accordingly, companies engaged in activities involving any of these chemicals would have to comply with the requirements on the import, export, manufacture, offer for sale, transport, storage and/or use of hazardous substances, that are stipulated in the EPMA and EPM (HS) Regs. These include, inter alia, labelling and other requirements for the containers/tanks and vehicles that are used to store or transport the chemicals, as well as other specific safety and documentational requirements.

**Analysis**

1. While Singapore Customs currently regulates the 26 chemicals and chemical groups under the CWPA, the focus of the CWPA is on counter-proliferation measures in the fulfilment of Singapore's international obligations to the CWC and is limited in addressing the domestic security and safety risks posed by these chemicals.
2. The regulation of these chemicals under the EPMA and the EPM (HS) Regs will therefore fill this gap, through the stipulation of requirements on the import, export, manufacture, sale, transport, storage and/or use of hazardous substances. This will minimise the domestic security and safety risks posed by these chemicals and serve the objectives of safeguarding public health and safety and protecting the environment. ; Protection of human health or safety; Protection of the environment

**Action Points**

* **For Sarvada:** Sarvada is disseminating the information to the stakeholders in its list. The email/s are copied to EIC and DOC.

1. **Color Additive - G/TBT/N/USA/1937 dated 03-Nov-2022**

|  |  |
| --- | --- |
| **Notifying Member** | United States of America |
| **Type of Notification** | Regular notification |
| **Economic relevance** | Low |
| **Technical Relevance** | Technical-Amendment |
| **Last Date to offer comments** | 3-Jan-23 |
| **Relevant Organization** | Chemexcil / APEDA |
| **Folder Link** | [Link](https://seetharamanassociates-my.sharepoint.com/:f:/g/personal/satish_sarvada_co_in/Errpz5E06ZxOgqwl_IPvFbQBFeju7qaiN4pnxZfAiOq1Yw?e=g6Bzxw) |

**Proposal in brief**

1. USA’s Food and Drug Administration (FDA or we) is proposing to amend the color additive regulation to increase the fee for certification services.
2. The change in fees will allow FDA to continue to maintain an adequate color certification program as required by the Federal Food, Drug, and Cosmetic Act (FD&C Act). The fees are intended to recover the full costs of operation of FDA’s color certification program.
3. This proposed rule, if finalized, would amend the color additive regulation to increase the fees for certification services. The fees for straight colors including flakes would be $0.45 per pound ($0.10 per pound increase) with a minimum fee of $288. There would be similar increases in fees for repacks of certified color additives and color additive mixtures

**Analysis**

* 1. The FDA is marginally increasing the fee for certification services from $0.35 per pound to $0.45. This would lead to only a marginal increase in costs for the exporters.

**Action Points**

* **For Sarvada:** Sarvada is disseminating the information to the stakeholders in its list. The email/s are copied to EIC and DOC.

1. **Organic Chemicals- G/TBT/N/BRA/1453 dated 01-Nov-2022**

|  |  |
| --- | --- |
| **Notifying Member** | Brazil |
| **Type of Notification** | Regular Notification |
| **Economic relevance** | Very High |
| **Technical Relevance** | Technical -New |
| **Last Date to offer comments** | Not Applicable |
| **Relevant Organization** | Chemexcil |
| **Folder Link** | [Link](https://seetharamanassociates-my.sharepoint.com/:f:/g/personal/satish_sarvada_co_in/Er4mW62kl35Cr0IslqUI5wcBJIJ1vnX407VhjkFv0Npg0Q?e=sQvUtn) |

**Proposal in brief**

1. Brazil has issued safety requirements.
2. Procedures and requirements for registration of remediated products, renewal, prior consent for import , authorization for research and experimetation and provides other measures.

**Analysis**

1. The said observations are based on the WTO notification, as the relevant technical document is not available, due to technical error.

**Action Points**

* **For Sarvada:** Sarvada is disseminating the information to the stakeholders in its list. The email/s are copied to EIC and DOC.
* **For EIC and DOC-** Are to request for techinical documents, so that Sarvada can offer comments based technical document.

1. **Organic Chemicals- G/TBT/N/BRA/1454 dated 01-Nov-2022**

|  |  |
| --- | --- |
| **Notifying Member** | Brazil |
| **Type of Notification** | Regular Notification |
| **Economic relevance** | Very High |
| **Technical Relevance** | Technical -New |
| **Last Date to offer comments** | Not Applicable |
| **Relevant Organization** | Chemexcil |
| **Folder Link** | [Link](https://seetharamanassociates-my.sharepoint.com/:f:/g/personal/satish_sarvada_co_in/EkB21t63EehDqnH-3HefbAYBJ5c3z8iJeOrsojNEUyskOw?e=ROnsYl) |

**Proposal in brief**

1. Brazil has issued procedures for the control and supervision of chemicals and defines the chemicals to be controlled by the federal police.
2. As per Article 15, operating licence must be renewed annually from the date of their release, the revocation required in the period covering the last sixty days of validity of the certificate of licence a operating and the application must be sent until date of expiration even if not useful.
3. The central unit for the control of chemical products of the federal police has issed notification to the multilateral in compliance with the agreements and the international agreements of which Brazil is a signataory.
4. For the purpose of greater control and taxation of foreign trade activities and the federal police have been able to establish by ,means of their own act, points and entry and exit allowed in national territory for the chemical products listed in Annex l.
5. Articles 34- 41 Articles, talks about the general rules of control , for the quantification of the chemical product, the unit of measure shall be considered in kilogram or liter using three decimal places, in the respect of rounding rules. The packaging rule must contain, in a visible and easily identified place information about the cncentration of each chemical products.
6. Final, disposal to comply with the provisions of the ordinance, the federal police made available the computerized system of control of chemical produdcts. Certificates, authorizations, control maps and the formulations listed in the Annexes to this Ordinance may, at any time, be replaced by others that allow the mechanisms of control and fiscalization of chemical products through issue of Normative Rules for the role of the Federal Police.

**Analysis**

1. Relevant technical document was not available in English language and proper translation was not obtained through MS Translate feature hence observations are based on the notification document only. An English translation of the relevant technical documents were sought from the concerned TBT Enquiry point and awaiting their response.
2. The notification was issued on 01-November -22 but it came into force from 24 October 2022. Prima facie, Brazil appears to have not complied with the following WTO provisions:

* Brazil failed to publish a notice in a publication at an early appropriate stage, in such a manner as to enable interested parties in other Members to become acquainted with it, that they propose to introduce a particular technical regulation (**Art.2.9.1 of the Agreement on Technical Barriers to Trade**).
* The failure of Brazil to allow, without discrimination, reasonable time for other Members to make comments in writing, discuss these comments upon request, and take these written comments and the results of these discussions into account (**Article 2.9.4 of the Agreement on Technical Barriers to Trade**).

**Action Points**

* **For Sarvada:** Sarvada is disseminating the information to the stakeholders in its list. The email/s are copied to EIC and DOC.
* **For EIC/DOC:** Brazil notifies regulations only after they have come into force or just a few days before. DOC should consider raising this issue with Brazil through appropriate channels and impress upon them the need to grant sufficient time for the Indian exporters to prepare themselves to comply with the new regulations. In any such interaction, several notifications issued by Brazil without providing adequate time may be clubbed together.

1. **Chemical Substances - G/TBT/N/USA/1936 dated 01-Nov-2022**

|  |  |
| --- | --- |
| **Notifying Member** | United States of America |
| **Type of Notification** | Regular Notification |
| **Economic relevance** | Very High |
| **Technical Relevance** | Technical -Amendment |
| **Last Date to offer comments** | 30-Nov-22 |
| **Relevant Organization** | Chemexcil |
| **Folder Link** | [Link](https://seetharamanassociates-my.sharepoint.com/:f:/g/personal/satish_sarvada_co_in/EoNzrrCFEnJDiwBRGNK3TGQB-XhJCG1Yl6FMQtHOZiDfwQ?e=fGOsAZ) |

**Proposal in brief**

1. USA’s Environmental Protection Agency (EPA) is proposing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for chemical substances that were the subject of premanufacture notices (PMNs) and are also subject to Orders issued by EPA pursuant to TSCA.
2. These proposed SNURs would require persons to notify EPA at least 90 days before commencing the manufacture or processing of any of these chemical substances for an activity proposed as a significant new use. Receipt of such notices would allow EPA to assess risks and, if appropriate, to regulate the significant new use before it may occur.
3. Once EPA receives a SNUN and before the manufacture or processing for the significant new use can commence.
4. EPA must either determine that the use is not likely to present an unreasonable risk of injury under the conditions of use for the chemical substance or take such regulatory action as is associated with an alternative determination.
5. EPA is proposing these SNURs for specific chemical substances which have undergone premanufacture review because the Agency wants:

* To identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying TSCA Orders, consistent with TSCA section 5(f)(4).
* To have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing a listed chemical substance for the described significant new use.
* To be able to either determine that the prospective manufacture or processing is not likely to present an unreasonable risk, or to take necessary regulatory action associated with any other determination before the described significant new use of the chemical substance occurs.

1. SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on the following:

* Human exposure and environmental release that may result from the significant new use of the chemical substances.
* Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

**Analysis**

* EPA is proposing significant new use and record keeping requirements for certain chemical substances in 40 CFR part 721, subpart E. In this unit, EPA provides the following information for each chemical substance that is identified in this unit as subject to this proposed rule:

1. PMN number (the proposed CFR citation assigned in the regulatory text section of the proposed rule).
2. Chemical name (generic name, if the specific name is claimed as CBI).
3. Chemical Abstracts Service (CAS) Registry number (if assigned for nonconfidential chemical identities).
4. Effective date of and basis for the TSCA Section 5I Order.
5. Potentially Useful Information.

* To establish a significant new use, EPA must determine that the use is not ongoing. The chemical substances subject to this proposed rule have undergone premanufacture review. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no person may commence such activities without first submitting a PMN. Therefore, for chemical substances for which an NOC has not been submitted EPA concludes that the designated significant new uses are not ongoing.
* Effect on Importes - This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import provisions promulgated at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and Orders under TSCA, which would include the SNUR requirements should these proposed rules be finalized. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B.

**Action Points**

* **For Sarvada:** Sarvada is disseminating the information to the stakeholders in its list. The email/s are copied to EIC and DOC.

1. **Hazardous Substances - G/TBT/N/SGP/66 dated 04-Nov-2022**

|  |  |
| --- | --- |
| **Notifying Member** | Singapore |
| **Type of Notification** | Regular Notification |
| **Economic relevance** | Very High |
| **Technical Relevance** | Technical -New |
| **Last Date to offer comments** | 3-Jan-23 |
| **Relevant Organization** | Chemexcil |
| **Folder Link** | [Link](https://seetharamanassociates-my.sharepoint.com/:f:/g/personal/satish_sarvada_co_in/ErnJXepGwqxOu-dhSG0DXJcBMEuL9TiME1XqlJBfaWtyJA?e=GclySG) |

**Proposal in brief**

1. Singapore's National Environment Agency (NEA) is proposing to regulate 26 new chemicals and chemical groups (see Section 4 above) as hazardous substances under the Environmental Protection and Management Act (EPMA) and the Environmental Protection and Management (Hazardous Substances) Regulations (EPM (HS) Regs).
2. These 26 chemicals and chemical groups have been identified as toxic chemicals and precursors under the Chemical Weapons Convention (CWC), and are currently regulated by Singapore Customs, as the National Authority for the Chemical Weapons Convention (NA(CWC)), through the Chemical Weapons (Prohibition) Act (CWPA) and the Chemical Weapons (Prohibition) Regulations. Under the CWPA, depending on the CWC Schedule that the chemicals belong to, companies are required to apply for a NA(CWC) licence from Singapore Customs if they are engaged in activities including the import, export, production, processing, consumption and local sale and distribution of these chemicals.
3. From July 2023, NEA will also be regulating these 26 chemicals and chemical groups under the EPMA and EPM (HS) Regs. Once the regulations take effect, companies will be required to apply for a Hazardous Substances (HS) licence/permit from NEA for the import, export, manufacture, sale, transport, storage and/or use of these chemicals and of products containing these chemicals. Accordingly, companies engaged in activities involving any of these chemicals would have to comply with the requirements on the import, export, manufacture, offer for sale, transport, storage and/or use of hazardous substances, that are stipulated in the EPMA and EPM (HS) Regs. These include, inter alia, labelling and other requirements for the containers/tanks and vehicles that are used to store or transport the chemicals, as well as other specific safety and documentational requirements.

**Analysis**

1. While Singapore Customs currently regulates the 26 chemicals and chemical groups under the CWPA, the focus of the CWPA is on counter-proliferation measures in the fulfilment of Singapore's international obligations to the CWC and is limited in addressing the domestic security and safety risks posed by these chemicals.
2. The regulation of these chemicals under the EPMA and the EPM (HS) Regs will therefore fill this gap, through the stipulation of requirements on the import, export, manufacture, sale, transport, storage and/or use of hazardous substances. This will minimise the domestic security and safety risks posed by these chemicals and serve the objectives of safeguarding public health and safety and protecting the environment. ; Protection of human health or safety; Protection of the environment

**Action Points**

* **For Sarvada:** Sarvada is disseminating the information to the stakeholders in its list. The email/s are copied to EIC and DOC.

1. **Color Additive - G/TBT/N/USA/1937 dated 03-Nov-2022**

|  |  |
| --- | --- |
| **Notifying Member** | United States of America |
| **Type of Notification** | Regular notification |
| **Economic relevance** | Low |
| **Technical Relevance** | Technical-Amendment |
| **Last Date to offer comments** | 3-Jan-23 |
| **Relevant Organization** | Chemexcil / APEDA |
| **Folder Link** | [Link](https://seetharamanassociates-my.sharepoint.com/:f:/g/personal/satish_sarvada_co_in/Errpz5E06ZxOgqwl_IPvFbQBFeju7qaiN4pnxZfAiOq1Yw?e=g6Bzxw) |

**Proposal in brief**

1. USA’s Food and Drug Administration (FDA or we) is proposing to amend the color additive regulation to increase the fee for certification services.
2. The change in fees will allow FDA to continue to maintain an adequate color certification program as required by the Federal Food, Drug, and Cosmetic Act (FD&C Act). The fees are intended to recover the full costs of operation of FDA’s color certification program.
3. This proposed rule, if finalized, would amend the color additive regulation to increase the fees for certification services. The fees for straight colors including flakes would be $0.45 per pound ($0.10 per pound increase) with a minimum fee of $288. There would be similar increases in fees for repacks of certified color additives and color additive mixtures

**Analysis**

* 1. The FDA is marginally increasing the fee for certification services from $0.35 per pound to $0.45. This would lead to only a marginal increase in costs for the exporters.

**Action Points**

* **For Sarvada:** Sarvada is disseminating the information to the stakeholders in its list. The email/s are copied to EIC and DOC.

1. https://www.coslaw.eu/what-do-you-need-to-know-about-cmr-substances-in-cosmetics/ [↑](#footnote-ref-2)