1. **Synthetic Sulphur Dye- G/TBT/N/THA/593/Add.1 dated 07-September-22**

|  |  |
| --- | --- |
| **Notifying Member** | Thailand |
| **Type of Notification** | Addendum to Regular |
| **Economic relevance** | High |
| **Technical Relevance** | Technical-New |
| **Last Date to offer comments** | NA |
| **Relevant Organization** | Chemexcil |
| **Folder Link** | [Link](https://seetharamanassociates-my.sharepoint.com/:f:/g/personal/satish_sarvada_co_in/EnOd_ozOXOdDvFdjQ1DV2DgBZGGP_EeJ384_shbJQUX1bA?e=IcL0f8) |

**Proposal in brief:**

1. Thai Industrial Standards Institute (TISI) has proposed to revise the standards on synthetic dyestuffs: Sulphur dye. The said regulation covers the safety requirements for sulphur dye for textile and leather products, packaging, marking, labelling, sampling and testing of dye.
2. This Industrial Product Standard “Synthetic Color: Sulfur Color” covers the safety of sythethic dyes, sulfur dyes for products.
3. Sulfur paints must not dissociate to harmful aromatic amines. In case such dissociation it should exceeed 150 mg/k.

**Analysis**

* TISI claimed that the said regulation is amended in compliance with the following international standards:

1. ISO 14362-1:2017 Textiles – Methods for determination of certain aromatic amines derived from azo colorants
2. BEUC/X/110/2004 The EU Eco-label – less hazardous chemicals in everyday consumer products
3. EPA Method 3052 December 1996 Microwave assisted acid digestion of siliceous and organically based matrices
4. EPA Method 3060 December 1996 Alkaline digestion for hexavalent chromium
5. EPA Method 7199 December 1996 Determination of hexavalent chromium in drinking water, groundwater, and industrial wastewater effluents by ion chromatography
6. ISO 14362-1:2017 textiles, BEUC/X/110/2004 the EU Eco-label.

* In terms of Article 2.4 of TBT Agreement, when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems, then and only then, Members can deviate from the international standards. To examine this aspect, it is necessary to determine whether the proposed TISI standards deviate significantly from the international standards. For this purpose, we may seek inputs from the relevant stakeholders.
* Sarvada’s observations are based on the notification document as the relevant technical documents were not available in English langauge as per the response received from the concerned TBT Enquiry point.

**Action Points**

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

1. **Reactive Dye- G/TBT/N/THA/591/Add.1 dated 07-September-22**

|  |  |
| --- | --- |
| **Notifying Member** | Thailand |
| **Type of Notification** | Addendum to Regular |
| **Economic relevance** | High |
| **Technical Relevance** | Technical-New |
| **Last Date to offer comments** | Not Applicable |
| **Proposed date of Entry into force** | 19-August-2023 |
| **Relevant Organization** | Chemexcil |
| **Folder Link** | [Link](https://seetharamanassociates-my.sharepoint.com/:f:/g/personal/satish_sarvada_co_in/EjnawuTk0iZMhESAB53RI78Bknl4KRjOEiE8MB9N1Ujg6Q?e=LpR08a) |

**Proposal in brief:**

1. Thai Industrial Standards Institute (TISI) proposed a revise the standards on synthetic dyestuffs: reactive dye (TIS 740-2555(2012). The said regulation covers the safety requirements for synthetic dyestuffs: reactive dye for textile and leather products, packaging, marking, labelling, sampling and testing of dye.
2. The said amendment shall enter into force from 19 August 2023.

**Analysis**

* TISI claimed that the said regulation is amended in compliance with the following international standards:

1. ISO 14362-1:2017 Textiles – Methods for determination of certain aromatic amines derived from azo colorants
2. BEUC/X/110/2004 The EU Eco-label – less hazardous chemicals in everyday consumer products
3. EPA Method 3052 December 1996 Microwave assisted acid digestion of siliceous and organically based matrices
4. EPA Method 3060 December 1996 Alkaline digestion for hexavalent chromium
5. EPA Method 7199 December 1996 Determination of hexavalent chromium in drinking water, groundwater, and industrial wastewater effluents by ion chromatography
6. ISO 14362-1:2017 textiles, BEUC/X/110/2004 the EU Eco-label.

* In terms of Article 2.4 of TBT Agreement, when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems, then and only then, Members can deviate from the international standards. To examine this aspect, it is necessary to determine whether the proposed TISI standards deviate significantly from the international standards. For this purpose, we may seek inputs from the relevant stakeholders.
* Sarvada’s observations are based on the notification document as the relevant technical documents were not available in English langauge as per the response received from the concerned TBT Enquiry point.

**Action Points**

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

1. **Chemical Substances- G/TBT/N/EU/921 dated 12 Sep 2022**

|  |  |
| --- | --- |
| **Notifying Member** | EU |
| **Type of Notification** | Regular |
| **Economic relevance** | Very High |
| **Technical Relevance** | Technical -New |
| **Last Date to offer comments** | 11-Nov-2022 |
| **Relevant Organization** | Pharmexcil  Chemexcil  NCB |
| **Folder Link** | [Link](https://seetharamanassociates-my.sharepoint.com/:f:/g/personal/satish_sarvada_co_in/Emcbo8Hqz9JHlwoppqip9YABaR-oggKGEIYgIHwnVsentw?e=6J0jqy) |

**Proposal in brief**:

1. EU has issued draft Commission Regulation proposing to include certain drug precursors in the list of scheduled substances. Drug precursors are chemicals which may be used for the illicit manufacture of narcotic drugs or psychotropic substances. Regulation (EC) No 273/2004 of the European Parliament and of the Council1 lays down measures for monitoring trade in drug precursors within the EU, while Council Regulation (EC) No 111/20052 governs trade in drug precursors between the EU and third countries.
2. The scheduled substances listed in Annex I to Regulation (EC) No 273/2004 and in the Annex to Regulation (EC) No 111/2005 are divided into categories given below for which different measures apply. The strictest control and monitoring measures apply to substances of Category 1.

List of substances in Category 1-

|  |  |  |
| --- | --- | --- |
| **Substance** | **CN Code** | **CAS No.** |
| ‘Diethyl (phenylacetyl) propanedioate (DEPAPD) | 2918 30 00 | 20320-59-6’ |
| ‘Ethyl 3-(2H-1,3-benzodioxol-5-yl)- 2-methyloxirane-2-carboxylate (PMK ethyl gylcidate) | 2932 99 00 | 28578-16-7’ |
| ‘N-phenylpiperidin-4-amine (4-AP) | 2933 39 99 | 23056-29-3’ |
| ‘Tert-butyl 4-anilinopiperidine-1- carboxylate (1-boc-4-AP) | 2933 39 99 | 125541-22- 2’ |
| N-phenyl-N-(piperidin-4- yl) propenamide (norfentanyl) | 2933 39 99 | 1609-66-1’ |

List of substances in Category 2-

|  |  |  |  |
| --- | --- | --- | --- |
| **Substance** | **CN designation (if diff)** | **CN Code** | **CAS No.** |
| ‘N-phenyl-1-(2- phenylethyl) piperidin-4-amine | 4-anilino-N-phenethylpiperidine (ANPP) | 2933 36 00 | 21409-26-7’ |
| ‘1-(2-phenylethyl) piperidin-4-one | -phenethyl-4- piperidone (NPP) | 29333700 | 39742-60-4’ |

1. The stakeholders may offer their comments on or before 11 November 2022.

**Analysis**

* The purpose of the regulation is to monitor trade in drug precursors within the EU as well as trade between EU and third countries. The Commission is empowered to adopt delegated acts to add new substances to the list of scheduled substances in order to adapt to new trends in diversion of drug precursors, in particular substances which can be easily transformed into scheduled substances, and to follow any amendment to the tables in the Annex to the United Nations Convention.
* Upon adding the mentioned drugs in the category 1 and 2 of Annex 1 of EC 273/2004. The manufacturer shall possess a license and permitted only to supply with the license holders and have customer declaration prescribed in the decree.
* Operators wishing to place on the market scheduled substances of category 1 and 2 of Annex-I shall require appointing an officer responsible for trade in scheduled substances to ensure that the scheduled substances conducted by the operator takes place in compliance with the regulation.
* The regulation shall enter into force on the twentieth day following that of its publication in the official journal of the EU and shall be binding in its entirety & directly applicable in all Member States.
* India regulates manufacture, distribute, sell, purchase, possess, store, consume, offer for sale or distribution or mediation of narcotic, psychotrpic substances as well as drug precursors through the Narcotic Drugs and Psychotropic Substances (Regulation of Controlled Substances) Order, 2013[[1]](#footnote-1). The said order provides of Schedule-A (which relates to substances subject to controls) and Schedule-B (which regulates export of specified substances). It is worth considering whether the substances listed by the EU may also be included as part of controlled substances by India. If so, necessary action may be taken by Indian authorities as well.

**Action Points**

* **For EIC/DOC:** The notification may be shared with Narcotics Control Bureau for their inputs.
* **For Sarvada:** Sarvada is disseminating the information to the stakeholders in its list. The email/s are copied to EIC and DOC.

1. **Pesticide Active Substances- G/TBT/N/GBR/53 dated 13-September-22**

|  |  |
| --- | --- |
| **Notifying Member** | United Kingdom |
| **Type of Notification** | Regular |
| **Economic relevance** | Not Available |
| **Technical Relevance** | Technical-New |
| **Last Date to offer comments** | NA |
| **Relevant Organization** | Chemexcil |
| **Folder Link** | [Link](https://seetharamanassociates-my.sharepoint.com/:f:/g/personal/satish_sarvada_co_in/Ev_BtN4jm5lNmM3ciqFwbd0B5nIP3lbLX9m8jt4vNcb2Dg?e=78azDG) |

**Proposal in brief:**

1. The Great Britain is signopostig members to the public register providing list of approved active substaces to be included in plant protection products along with details on the specific conditions of the apporval.
2. List of active susbtances are as follows:

|  |  |  |  |
| --- | --- | --- | --- |
| **Substance Name** | **Date** | **Reg. update ref.** | **Changes Made** |
| N/A | Mar-22 | 2 | "Notes" column added to Register |
| Chitosan Hydrochloride | Mar-22 | 2 | Correct CAS number added to Notes column |
| Alpha-Cypermethrin (aka alphamethrin) | Mar-22 | 2 | Advance notice of WTO notification added to Notes column |
| Cinmethylin | Jun-22 | 3 | Added |
| Mefenpyr-diethyl | Jul-22 | 4 | Added to register as safener |
| Cloquintocet-mexyl | Jul-22 | 4 | Added to register as safener |
| Isoxadifen-ethyl | Jul-22 | 4 | Added to register as safener |
| Cyprosulfamide | Jul-22 | 4 | Added to register as safener |
| Piperonyl butoxide | Jul-22 | 4 | Added to register as synergist |
| Cinmethylin | Jul-22 | 4 | Relevant impurities added |
| Alpha-Cypermethrin (aka alphamethrin) | Jul-22 | 4 | Link to draft decision updated |
| Ampelomyces quisqualis strain AQ10 | Jul-22 | 4 | Low Risk Status added |
| ABE-IT 56 | Jul-22 | 4 | Added |
| Indoxacarb | 22-Aug | 5 | Notification of withdrawal proposal added |

**Analysis**

* The residues of the plant protection products, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, shall meet the following requirements:
  1. they shall not have any harmful effects on human health, including that of vulnerable groups, or animal health, taking into account known cumulative and synergistic effects where the scientific methods accepted by the Authority to assess such effects are available, or on groundwater;
  2. they shall not have any unacceptable effect on the environment.
* First Appproval shall be for a period of not exceeding 10 years.

**Action Points**

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

1. **Cosmetics- G/TBT/N/CHN/1699 dated 14-September-22**

|  |  |
| --- | --- |
| **Notifying Member** | China |
| **Type of Notification** | Regular |
| **Economic relevance** | Very High |
| **Technical Relevance** | Technical-New |
| **Last Date to offer comments** | 13-November-2022 |
| **Relevant Organization** | Chemexcil |
| **Folder Link** | [Link](https://seetharamanassociates-my.sharepoint.com/:f:/g/personal/satish_sarvada_co_in/Egsu6SMNpzxNssliSouRLbcBJfhUX4zDPP3XHcffw5FDkw?e=5fxUFD) |

**Proposal in brief:**

1. China issued a draft on “provisions for the supervision of cosmetics online distribution” to standardise the online cosmetics distribution.
2. The said regulation shall apply to the online business cosmetics operators withing the territory of the China, Provision of e-commerce platform services and their supervision and management.
3. The state drug administration is responsible for organising and guide the national cosmetic network operation and supervision & management of cosmetics e-commerce platform services management work.
4. The said regulation requires e-commerce platform operators to set up cosmetic quality and safety management institution or assign fulll time/part time personnel who is reponsible for organising the operations on the platform. Conduct daily checks and behaviour.
5. Every cosmetic operator is required to submit real information such as identity, address and contact information, conduct verification, registration maintain and update at least every months. And shall keep them for atleast 3 years.
6. Daily inspection shall be conducted and log shall be maintained and kept for not less than 2 years to check the following
   1. the cosmetic operators are not unregistered or using other people’s registarion certificate.
   2. Whether the cosmetic labels are consistent with the corresponding product information and not in prohibition of law, implying false medical effects, voilating social order and good customs.

**Analysis**

* The said measures do not apply on the cross-border E-commerce cosmetics business operators, as the relevant regulations of the state on the supervision of cross-border e-commerce retail imports shall be followed.
* The said regulations will not have any substantive effect on the Indian Exporters as the same is meant to be applied within the territories of China.

**Action Points**

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

1. **Cosmetics- G/TBT/N/EU/924 dated 15-September-22**

|  |  |
| --- | --- |
| **Notifying Member** | EU |
| **Type of Notification** | Regular |
| **Economic relevance** | Very High |
| **Technical Relevance** | Technical-New |
| **Last Date to offer comments** | 14-November-2022 |
| **Relevant Organization** | Chemexcil |
| **Folder Link** | [Link](https://seetharamanassociates-my.sharepoint.com/:f:/g/personal/satish_sarvada_co_in/EnmRcGiqhjFHrWIPUrJ8aT8B9U06_R-jAi-McvHy9gAjkA?e=394qpM) |

**Proposal in brief:**

1. EU has issued proposed amendment to Regulation 1223/2009 regarding labelling of fragrance allergens in cosmetic products. Annex III is amended as follows:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Ref. No,** | **Substance identification** | | **Restrictions** | | |
| **Chemical name/INN** | **Name of Common Ingredients Glossary** | **Max. conc.** | **Other** |
| ‘45 | Benzyl alcohol(6) | Benzyl Alcohol |  | The presence of the substance shall be indicated in the list of ingredients referred to in Article 19(1), point (g), when its concentration exceeds: -   0,001 % in leave-on products -  0,01 % in rinse-off products.’ |
| ‘46 | Methylcoumarin\* | 6-Methyl Coumarin | 0,003 % |
| ‘70 | 3,7-Dimethyl-2,6- octadienal | Citral | - |
| (E)-3,7-dimethylocta-2,6- dienal\* | Geranial |
| (Z)-3,7-dimethylocta-2,6- dienal\* | Neral |
| ‘73 | Phenol, 2- methoxy-4-(1- propenyl) | Isoeugenol |  |
| (E)-2-methoxy-4- (prop-1- enyl)phenol; (trans-Isoeugenol) | (b) 0,02 % |
| (Z)-2-methoxy-4- (prop-1- enyl)phenol;(cis-Isoeugenol) |  |
| ‘86 | Citronellol/ (±) 3,7-Dimethyl-6- octen-1-ol (3R)-3,7-dimethyloct-6-en- 1-ol (3S)-3,7-dimethyloct-6-en- 1-ol | Citronellol |  |
|  |
|  | |
|  | |
| ‘88 | 1-methyl-4-prop- 1-en-2-ylcyclohexene; dl- limonene (racemic); | Limonene |  |  | |
| Dipentene\* |  | |
| (R)-p-mentha-1,8- diene; (d- limonene) |  | |
| (S)-p-mentha-1,8- diene; (l- limonene)\* |  | |
| ‘109 | *Pinus mugo* leaf and twig oil and extract\*\* | Pinus Mugo Leaf Oil; Pinus Mugo Twig Leaf Extract; Pinus Mugo Twig Oil |  |  | |
|  | |
| ‘114 | *Pinus pumila* leaf and twig oil and extract\*\* | Pinus Pumila Needle Extract; Pinus Pumila Twig Leaf Extract; Pinus Pumila Twig Leaf Oil |  | -  0,001 % in leave-on products-  0,01 % in rinse-off products.The peroxide value shall be less than 10 mmoles/L(15)’ |  | |
| ‘122 | *Cedrus atlanticaoil and extract\*\** | Cedrus Atlantica Bark Extract; Cedrus Atlantica Bark Oil; Cedrus Atlantica Bark Water; Cedrus Atlantica Leaf Extract; Cedrus Atlantica Wood Extract; Cedrus Atlantica Wood Oil |  |  | |
| ‘124 | Turpentine gum (*Pinus* spp.); Turpentine oil and rectified oil; Turpentine, steam distilled (*Pinus* spp.)\*\* | Turpentine |  |  | |
|  | |
|  | |
| ‘131 | p-Mentha-1,3- diene\*\* | Alpha-Terpinene |  |  | |
| ‘133 | p-Mentha-1,4(8)- diene\*\* | Terpinolene |  |  | |
| ‘154 | *Myroxylon balsamum* var. *pereirae*; extracts and distillates; Balsam Peru oil, absolute and anhydrol (Balsam Oil Peru)\*\* | Myroxylon Balsamum Pereirae Balsam Extract; Myroxylon Balsamum Pereirae Balsam Oil; Myroxylon Pereirae Oil;Myroxylon Pereirae Resin Extract; Myroxylon Pereirae Oil;Myroxylon Pereirae Resin Extract; Myroxylon Pereirae Resin | 0,4 % |  | |
| ‘157 | 1-(2,6,6-trimethyl- 2-cyclohexen-1- yl)-2-buten-1- one(16) \*\* | Aalpha- Damascone;cis-Rose ketone 1 | (b) 0,02 % |  | |
| 1-(2,6,6-Trimethylcyclohe xa-1,3-dien-1-yl)- 2-buten-1- one(16)\*\* | trans-Rose ketone 1 Rose ketone 4 (Damascenone) |  |  | |
| 1-(2,6,6-Trimethyl-3- cyclohexen-1-yl)- 2-buten-1-one(16) | Rose ketone 3 (delta-Damascone) trans-Rose ketone 3 |  |  | |
| (Z)-1-(2,6,6-trimethyl-1- cyclohexen-1-yl)- 2-buten-1-one (16) | cis-Rose ketone 2 (cis-beta- Damascone) |  | |
| (E)-1-(2,6,6-Trimethyl-1- cyclohexen-1-yl)- 2-buten-1-one(16) | trans-Rose ketone 2 (trans-beta- Damascone) |  | |
| ‘175 | 3-Propylidene- 1(3H)-isobenzofuranone; 3-Propylidenephthal ide\*\* | 3-Propylidenephthali de | (b) 0,01 % |  | |
| ‘196 | Verbena absolute\*\* \*\*\* | Lippia citriodora absolute |  |  | |

**Analysis**

* Fragrance substances are organic compounds with characteristic, usually pleasant, odours. They are widely used in perfumes and other perfumed cosmetic products, but also in many other products such as detergents, fabric softeners and other household products. Contact allergy is a life-long, altered specific reactivity in the human immune system. Upon re-exposure to a sufficient amount of an allergen, eczema (allergic contact dermatitis) may develop. For the pruposes of primary prevention, amendment to existing regulation has been introduced, in respect of fragrance allergens.
* Cosmetic products containing that substance that do not comply with the restriction(s) may be placed on the Union market until 35th month after the date of entry into force of this Regulation and made available on the Union market until the last day of the 59th month after the date of entry into force of this Regulation. Cosmetics manufacturers must examine if their products are likely to be affected and share their technical inputs.
* The said measure shall enter into force 20 days from publication in the official journal of the EU.

**Action Points**

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

1. **Chemical Substances- G/TBT/N/USA/1918 dated 16-September-22**

|  |  |
| --- | --- |
| **Notifying Member** | USA |
| **Type of Notification** | Regular |
| **Economic relevance** | Not Available |
| **Technical Relevance** | Technical-Amendment |
| **Last Date to offer comments** | 17-October-2022 |
| **Relevant Organization** | Chemexcil |
| **Folder Link** | [Link](https://seetharamanassociates-my.sharepoint.com/:f:/g/personal/satish_sarvada_co_in/EuOmTedfAV9LqLNmwJkgsBoBhVoQjJwOXcLAW0x6Luesww?e=UfL3G8) |

**Proposal in brief:**

1. EPA has issued as proposed rule to amend the significant new use rules (SNURs) for certain chemical substances identified herein, which were the subject of one or more premanufacture notices (PMNs) and in some cases significant new use notices (SNUNs).
2. Chemicals subject to significant new uses are:
   1. 2-Propen-1-one, 1-(4-morpholinyl)
   2. oxirane, 2,2′-[1,6- naphthalenediylbis(oxymethylene)]bis-
   3. (1) The chemical substance identified as 1,3-propanediamine, N,N′- 1,2-ethanediylbis, polymer with 2,4,6- trichloro-1,3,5-triazine, reaction products with N-butyl-2,2,6,6- tetramethyl-4-piperidinamine
   4. Siloxanes and silicones, aminoalkyl, fluorooctyl, hydroxy-terminated salt (generic).
   5. Fatty acids, C14–18 and C16– 18-unsatd., polymers with adipic acid and triethanolamine, di-Me sulfate-quaternized.
   6. 1,2,4-Benzenetricarboxylic acid, mixed decyl and octyl triesters.
   7. 12-Hydroxystearic acid, reaction products with alkylene diamine and alkanoic acid (generic).
   8. 1,2,4-Benzenetricarboxylic acid, 1,2,4-trinonyl ester.
3. Stakeholders may offer their comments on or before 17 October 2022.

**Analysis**

* This action would amend the SNURs to allow certain new uses reported in the SNUNs or PMNs without additional notification requirements and modify the significant new use notification requirements based on the actions and determinations for the SNUN or PMN submissions or based on the examination of new test data or other information. EPA is proposing these amendments based on review of new and existing data for the chemical substances.

**Action Points**

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

1. <http://www.bareactslive.com/ACA/ACT2459.HTM> [↑](#footnote-ref-1)