NEWSLETTER

Global Environmental and Chemical Regulations, Policies, and Standards
July 2021

IAEG INTERNATIONAL AEROSPACE ENVIRONMENTAL GROUP
10-YEAR ANNIVERSARY

WHO IS IAEG?

The International Aerospace Environmental Group (IAEG) is a non-profit organization of global aerospace companies created to collaborate on and share innovative environmental solutions for the industry. The group works to promote the development of voluntary consensus standards and provide accessible solutions for key environmental issues.

Members of IAEG recognize that there are currently a wide variety of different laws and regulations impacting health and the environment in place worldwide. The complexity and variability of requirements and guidance has led to an increased burden for the industry and its supply chain.

IAEG work groups address such issues as chemical material declarations and reporting requirements, the development of alternative technologies and greenhouse gas reporting and management. They create a forum for diverse and often competitive businesses to come together and share information on industry-wide opportunities for the promotion and adoption of global environmental requirements. In addition, IAEG provides opportunities for wider education on environmental issues and the supply chain via its meetings agendas and bespoke seminars.

IAEG WORK GROUP 9 NEWSLETTER

The Aerospace and Defense (AD) industry is committed to developing an approach to help the AD industry evaluate emerging global environmental and chemical regulations and their impact on compliance and potential operational risk for companies and their supply chain. The objectives are to:
Maintain a list of global regulations, policies and standards considered and to be considered, including executive summaries of those regulations.
Develop a method to evaluate designated emerging regulation's potential impact on compliance and/or operational risk, business continuity and/or impact on supply chain.
Develop summaries of the associated timeline for regulations (e.g., deadlines) and highlight the specific impacts.
Develop communication materials and conduct informational webinars, as appropriate, for member companies and/or AD supply chain companies, as appropriate.

This Newsletter summarizes environmental and chemical regulations relevant to the AD industry. Contact Lisa Brown at myrna.l.brown@lmco.com or Lindsey Bean at lindsey.bean@ngc.com for question on this Newsletter. For general assistance on IAEG matters, contact Christer Hellstrand at chellstrand@iaeg.com or Amanda Myers at Amanda.Myers@sae.org.

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ASIA

China

Announcement No. 27 of 2021 on supplementing the "Inventory of Existing Chemical Substances in China"

Legal Status: In Force

On 8 July 2021, China's Ministry of Ecology and Environment released a list of substances to be added the Inventory of Existing Chemical Substances in China. This is the inventory of chemical substances that are produced or imported into China. Substances on this list do not need to be registered as new substances in China. If the substance is not included in the inventory, China New Chemical Substance Notification shall be required.

The following substances are added to the list:

- carbon oxysulfide; carbon oxide sulfide; carbonyl sulfide; carbonyl sulphide COS; (CAS # 463-58-1)
- cesium hydroxide; cesium hydroxide; anhydrous cesium hydroxide; caesium hydroxide; CsOH; (CAS# 21351-79-1)
- N -(3 -dodecyloxy -2- hydroxypropyl) triethylamine chloride; N-(3-dodecyloxy-2-hydroxypropyl) triethylammonium chloride; trialkylamine chloride; tri-alkyl ammonium chloride; C21H46NO2 ·Cl; (CAS # 32818-34-1)
- 1,8 -naphthalene lactimide; 1,8-naphthostyril; C11H7NO; (CAS # 130-00-7)
- 2 -azabicyclo [2.2.1] hept -5- en- 3 -one; 2-azabicyclo[2.2.1]hept-5-en-3-one; azabicyclo; vince lactam; C6H7NO; (CAS # 49805-30-3)
- 2, 2 , 3 , 3 -tetramethylcyclopropane carboxylic acid; 2,2,3,3-tetramethyl cyclopropanecarboxylic acid; fenproic acid; C8H14O2; (CAS # 15641-58-4)
- 10- methoxy -4 H - benzo [4,5] cyclohepta [1,2- B] thiophen -4- -one; 4 H -benzo[4,5]cyclohepta[1,2- b]thiophen-4-one, 10-methoxy-; 10-methoxy-4 H -benzo[4,5]
- cyclohepta[1,2- b]thiophen-4-one; C14H10O2S; (CAS # 59743-84-9)
- 2,6- dichloroquinoxaline; 2,6-dichloroquinoxaline; C8H4Cl2N2; (CAS # 18671-97-1)

There are no non-compliance provisions for this announcement.

More information can be found at:
https://www.iaeg.com/elements/pdf/CHN_Amendment_to_Inventory_of_Existing_Chemical_Substances_in_China_english.pdf

China officially accepts the "Kigali Amendment to the Montreal Protocol on Substances that Deplete the Ozone Layer"

Legal Status: Published

On 21 June 2021, the Ministry of Ecology and Environment announced that China will formally adopt the "Kigali Amendment to the Montreal Protocol on Substances that Deplete the Ozone Layer" on 15 September 2021. Used as refrigerants, solvents, fire suppressants, foam blowing agents, aerosols and propellants, there are currently 18

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hydrofluorocarbons (HFCs) listed under the Amendment. China, as a Group 1 developing country, is set to follow an HFC phase-out schedule:

- - 2024 – freeze baseline consumption to average annual levels from 2011–2013
- - 2029 – reduce to 90% or less of baseline consumption
- - 2035 – reduce to 70% or less of baseline consumption
- - 2040 – reduce to 50% or less of baseline consumption
- - 2045 – reduce to 20% or less of baseline consumption

In addition, China will establish a licensing system for the export and import of HFCs. This aims to prohibit unlicensed parties from trading in the substances.

More information can be found at (in Chinese):
http://mee.gov.cn/ywdt/hjywnews/202106/t20210621_841062.shtml

Notice on publicly soliciting opinions on the National Ecological Environment Standard "Pollution Discharge Permit Application and Issuance of Technical Specifications for Industrial Solid Waste (Trial)"

Legal Status: Draft amendment

In order to implement the "Law of the People's Republic of China on the Prevention and Control of Environmental Pollution by Solid Wastes " and " Regulations on the Management of Pollution Discharge Permits ", the Chinese Ministry of Ecology and Environment solicited opinions on the National Standard for Pollution Discharge Permit Application and Issuance of Technical Specifications for Industrial Solid Waste. The goal is to improve the technical support system for permits and standardize the application process for permits related to industrial solid waste.

All interested parties could provide comments by 22 July 2021.

More information can be found at (in Chinese):
http://www.mee.gov.cn/xxgk2018/xxgk/xxgk06/202106/t20210624_841662.html

Japan

Japan aligns to the restrictions set out by Stockholm Convention on persistent organic pollutants

Legal Status: Published

Japan has published a notice banning the export of perfluorooctanoic acid (PFOA), its salts and products containing them, and 2,2,2-trichloro-1-(2-chlorophenyl)-1-(4-chlorophenyl)ethanol, also known as o,p'-dicofol (or dicofol). Companies will be required to obtain permission from the Ministry of Trade, Economy, and Industry to export the persistent organic pollutants (POPs) and products containing them under the country's Export Control Ordinance. This announcement aligns to the country's approach with the global restrictions set out in the Stockholm Convention on POPs. PFOA (and its salts) and dicofol were added to Annex A of the Stockholm Convention as part of the 2019 amendment.

More information can be found at:
https://www.iaeg.com/elements/pdf/JPN_PFOA_and_Dicofol_ratification.pdf

Public comments on the revision of some of the items to be displayed regarding measures to prevent environmental pollution by specific chemical substances

Legal Status: Draft amendment

The Japanese Ministry of Environment solicited opinions on a proposal to revise some of the items to be displayed regarding measures to prevent environmental pollution by specific chemical substances. The proposal expands the definition of pollutant from just perfluorooctanesulfonic acid (PFOS) and its salts to also include perfluorooctanoic acid (PFOA) and its salts.

Interested parties could submit comments by 6 August 2021.

More information can be found at (in Japanese):
https://public-comment.e-gov.go.jp/servlet/Public?CLASSNAME=PCMMSTDETAIL&id=195210017&Mode=0

Part of the Ministerial Ordinance that stipulates technical standards for fire extinguishers, fire extinguishing agents for fire extinguishers, and foam fire extinguishing agents that use PFOS or its salt

Legal Status: Draft amendment

The Japanese Ministry of the Environment solicited opinions on the Ministerial Ordinance that stipulates technical standards for fire extinguishers that use perfluorooctanesulfonic acid (PFOS), which is a Class 1 Specified Chemical Substance. The proposal expands the scope of the technical standards to include fire extinguishers that use perfluorooctanoic acid (PFOA) and its salt in addition to PFOS and its salts.

Interested parties could submit comments by 6 August 2021.

More information can be found at (in Japanese):
https://public-comment.e-gov.go.jp/servlet/Public?CLASSNAME=PCMMSTDETAIL&id=195210016&Mode=0

Russia

On amending the federal law "On Environmental Protection" and Article 11 of the federal law "On Environmental Expertise"

Legal Status: Adopted

The Russian Federal Environmental Protection Act of 2002 (Act) has been amended. The amendments to Article 80.1 and 80.2 of the Act include:

- provisions of identifying objects of accumulated harm to the environment
- the survey and evaluation of facilities for assessment of accumulated harm to environment
- the records and categorization of the objects of accumulated harm
- the state registry of the objects of accumulated harm
- the order of work to eliminate the accumulated harm
- the reliability of the estimated cost

There are no non-compliance provisions associated with this Act.

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Furthermore, Article 11 of the Environmental Examination Law was amended. The changes were made to a supplement paragraph (7.11) that explains a project to eliminate accumulated environmental damage.

More information can be found at (in Russian):
https://regulation.gov.ru/projects#npa=117237

Saudi Arabia

Technical regulations for limiting hazardous substances in electrical and electronic equipment

Legal Status: Published

The Saudi Standard, Metrology and Quality Organization' Board of Directors approved a technical regulation for limiting hazardous substances in electrical and electronic equipment (EEE) and their spare parts.

The following EEE categories are in scope for products placed on the Saudi Arabia's market:

- household appliances
- information and communications equipment
- lighting equipment
- electrical and electronic tools and equipment
- games, entertainment, and sports equipment
- monitoring and control tools

The following substances are restricted in EEE to the amounts noted below:

- cadmium (0.01 % weight by weight [w/w])
- lead (0.1 % w/w)
- mercury (0.1 % w/w)
- hexavalent chromium (0.1 % w/w)
- polybrominated biphenyls (PBB) (0.1 % w/w)
- polybrominated diphenyl ethers (PBDE) (0.1 % w/w)

The following categories are exempt from this regulation:

- medical equipment
- weapons and military equipment
- equipment to be sent into space
- extensive industrial stationary tools
- extensive stationary equipment

Suppliers must obtain a certificate of conformity in accordance with ISO/IEC 17067 from an accepted body for their product in addition to providing a risk assessment document, and any necessary warnings/cautions and manuals for safe use of the EEE placed on the Saudi Kingdom market.

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The transitional period is 180 days for the suppliers to correct their situation in accordance with the new provisions and 365 days to trade in the products that do not meet the requirements. Penalties for non-compliance include removal of the product from the market, fines and/or imprisonment.

More information can be found at:
https://www.iaeg.com/elements/pdf/SAU_Technical_Regulations_for_Limiting_Hazardous_Substances_in_EEE_english.pdf

Technical regulation for glue and adhesive materials

Legal Status: Draft amendment

Saudi Arabia published a draft technical regulation for glue and adhesive materials which aims to set the basic requirements for the adhesive and glue substances covered in this regulation. This regulation applies to all products of adhesives and glue, in an any physical form, used for the purpose of adhesion. The following uses are out of scope:

- the use of glue and adhesives for construction purposes which are regulated under other technical standards
- adhesive materials used for medical and food purposes under the management of the General Authority for Drugs and Food

Suppliers must complete the declaration of conformity form found in Annex 5 of the regulation. Under the regulation, suppliers in the Saudi Arabia's markets must provide the following information before placing the product on the market:

- ingredients
- current and expected risks
- first aid methods
- methods of handling and storage
- methods for disposal

The regulation also contains packaging requirements for the products. Penalties for non-compliance include removal of the product from the market.

More information can be found at (in Arabic):
https://www.iaeg.com/elements/pdf/SAU_Technical_Regulation_for_Adhesives_and_Glue.pdf

South Korea

Labelling method for containers and packaging of chemical substances

Legal Status: In effect

The South Korea Ministry of Environment published a notice for the Labeling Method for Containers and Packaging of Chemical Substances. This notice aims to unify the labelling requirements for containers or packaging of chemical substances stipulated in the Chemicals Control Act and Dangerous Substances Safety Control Act, respectively. The Chemicals Control Act protects all citizens from the potential harm caused by the chemical substances by providing guidance for managing chemical substances safely. The Dangerous Substances Safety Control Act contains provisions for storage, handling, and transport of dangerous substances.

The chemical substances subject to labeling in accordance with this notice are:

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- hazardous chemical substances as classified by the Chemicals Control Act (means toxic substances, permitted substances, restricted, or prohibited substances, accident preparation substances, and other chemical substances that are harmful or risky)
- dangerous goods under the Dangerous Substances Safety Control Act (means goods prescribed by Presidential Decree as having flammable or ignitable properties)

The regulation contains provisions for labelling matters with details provided in Annex 1. The pictograms, hazard phrases, and precautionary statements in Annex 1 are the same pictograms, hazard phrases, and precautionary statements provided in the Chemicals Control Act.

Facilities and individuals in South Korea must ensure the labeling requirements for containers and packaging of chemical substances are complied with by 9 January 2022. Penalties for non-compliance include fines and/or imprisonment.

More information can be found at:
https://www.iaeg.com/elements/pdf/KOR_Labeling_Method_for_Containers_of_Chemical_Substances_english.pdf

Regulations on classification and labelling of chemical substances

Legal Status: In effect

The South Korea Ministry of Environment published an update to Annex 4 of the Regulations on Classification and Labeling of Chemical Substances. This regulation gives detailed information regarding the classification and labelling of chemicals for the implementation of GHS by suppliers in South Korea. Annex 4 contains the List of Classification and Indications for hazardous substances. The update includes a list of substances and the revised classification parameters such as hazard statement, signal words, GHS pictograms, and M-factors.

The list of substances can be found at the link provided along with the full Regulation on Classification and Labeling of Chemical Substances (additional hyperlink).

Penalties for non-compliance include fines and/or imprisonment.

More information can be found at:
https://www.iaeg.com/elements/pdf/KOR_Amendment_to_Classification_and_Labeling_of_Chemical_Substances_english.pdf

Update on regulated quantities of toxic substances, restricted substances, prohibited substances and permitted substances

Legal Status: Published

The South Korean Ministry of Environment has updated the regulations on regulated quantities of toxic substances, restricted substances, prohibited substances and permitted substances. This regulation is made in accordance with the Enforcement Regulations of the Chemical Control Act. The update includes the addition of 51 new substances that are now classified as toxic substances (Appendix 1), and their upper and lower prescribed quantities. Facilities and individuals using any of the newly designated toxic substances must comply with the transitional measures such as import declaration, a chemical accident prevention management plan, and a hazardous chemical business license if needed.

The update also states the review deadline as of the end of every 3 years starting on July 1, 2021, by the Minister of Environment for review of any improvement measures.
Penalties for non-compliance include fines and/or imprisonment.

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More information can be found at (in Korean):
https://www.law.go.kr/LSW/admRulLsInfoP.do?chrClsCd=&admRulSeq=2100000202607#AJAX

Designation notice of toxic substances, National Institute of Environmental Sciences Notice No. 2021-36, 2021. 6. 22., partially revised, National Academy of Environmental Sciences (Risk Assessment Research Division), 032-560-7242

Legal Status: Published

On June 22, 2021, South Korea's National Institute of Environmental Research (NIER) published the Notice on Designation of Toxic Substances (Notice). Following provisions of the Registration and Evaluation of Chemical Substances Act, the Notice revised several substances. It specified 19 new chemical substances that meet the criteria for designation and are added to the Toxic Chemicals Substances List. Refer to the attachment for the list of revised and newly designated toxic substances.

Manufacturers and importers of newly designated toxic substances must register, mark, label, and file an import declaration of toxic substances in accordance with the Act and implement handling standards for hazardous chemicals, established by the Enforcement Rules of Chemicals Control Act, by 1 January 2022.

By 1 July 2023, companies that manufacture, sell, store, transport, use or handle newly designated hazardous chemicals must obtain a hazardous chemical business license. Also, companies that install or operate hazardous chemicals handling facilities must prepare and submit a chemical accident prevention management plan.

In accordance with the enforcement of the Notice, companies handling newly designated hazardous chemicals must comply with the standards for installation and management of hazardous chemical handling facilities, described in the Enforcement Rules of the Chemicals Control Act, by 1 July 2025.

Penalties for non-compliance include fines and/or imprisonment.

More information can be found at (in Korean):
https://www.law.go.kr/LSW/admRulLsInfoP.do?admRulSeq=2100000202158

Results of hazard assessment of chemical substances

Legal Status: In force

The National Academy of Environmental Sciences, Risk Assessment research division conducted a hazard examination for some chemicals that have been tested for hazard in accordance with Article 21 (Publication of Result) of the Act on Registration and Evaluation, etc. of Chemical Substances (K-REACH) and Article 28 of the Enforcement Regulations of the same Act. The information included is the name of the chemical substance, its hazard, and whether or not it is a toxic substance. The results of the hazard examination for chemical substances that have completed the hazard examination can be found in the hazard assessment results link.

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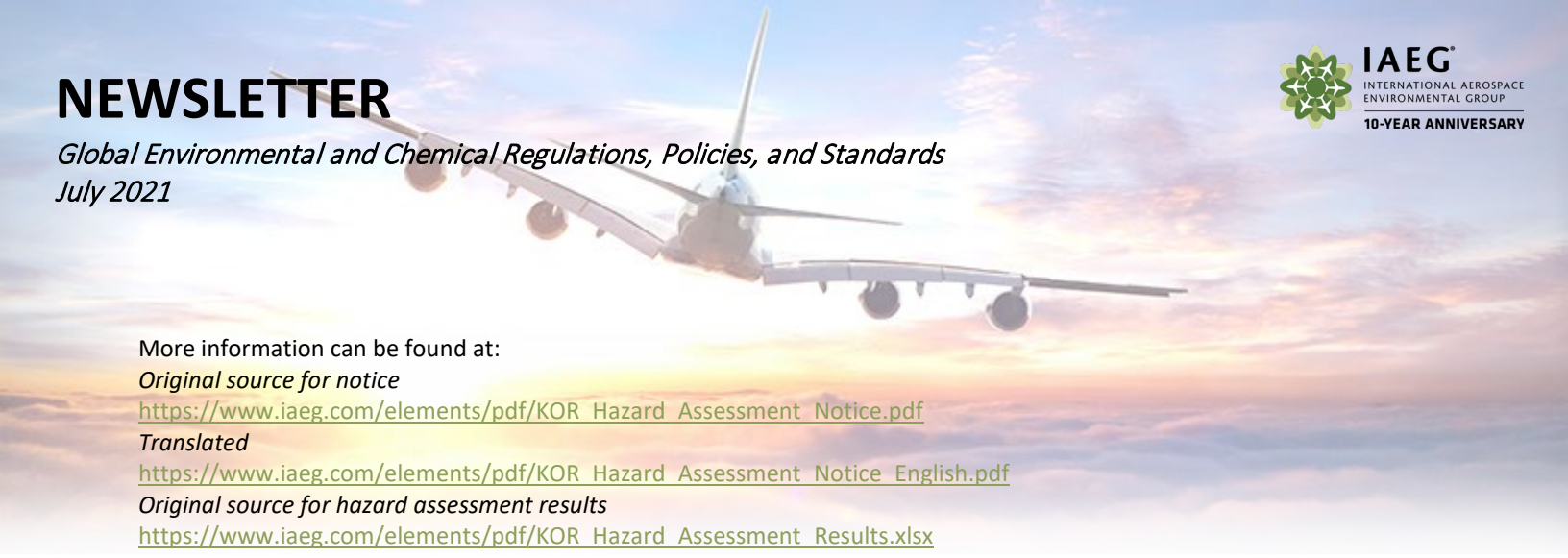

More information can be found at:
Original source for notice
https://www.iaeg.com/elements/pdf/KOR_Hazard_Assessment_Notice.pdf
Translated
https://www.iaeg.com/elements/pdf/KOR_Hazard_Assessment_Notice_English.pdf
Original source for hazard assessment results
https://www.iaeg.com/elements/pdf/KOR_Hazard_Assessment_Results.xlsx
Translated
https://www.iaeg.com/elements/pdf/KOR_Hazard_Assessment_Results_english.xlsx

Results of selection of support for all existing chemicals registration process

Legal Status: Published

The South Korea Ministry of Environment has published a list of 120 substances that will be supported through the K-REACH registration process. The substances were selected due to their importance to national industries that small and medium-sized enterprises (SMEs) focus on, and to their use in consumer products, meaning they require early acquisition of hazard information. The support will include:

- registration consulting
- hazard test data production
- support to write an exposure scenario
- support for the cost of co-registration of existing chemicals

The substances selected are manufactured or imported in South Korea in annual volumes of between 1 and 1,000 tonnes and must be registered between 2024 and 2030. The government's registration support program is designed to encourage registration by the end of 2022.

More information can be found at (in Korean):
https://www.iaeg.com/elements/pdf/KOR_Substances_selected_for_registration_support.pdf

Designation notice of toxic substances

Legal Status: Published

South Korea has amended the National Institute of Environmental Sciences' Notice "Designation of Toxic Substances" (Notice No. 2021-17, February 22, 2021) (the Notice). The purpose of this notice is to designate hazardous chemical substances as toxic substances in accordance with Article 3 of the Chemical Substances Control Act and Article 2 of the Enforcement Decree of the same Act. Substances included in the Notice's table are categorized as Toxic substances, and mixtures composed only of toxic substances present in the table are also considered toxic substances.

The amendments are as follows:

- Entries "97-1-9", "97-1-134", "97-1-250", "97-1-281", "97-1-297", "97-1-299", "97-1-309", "97-1-416", "97-1-423", "97-1-457", "97-1-466", "2002-1-529" and "2017-1-762" have been amended as shown in the Annex to the amendment
- Entries "2021-1-1038" to "2021-1-1056" have been added to the list of Toxic substances

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Transitional measures:

- Confirmation of chemical substances for the newly added toxic substances, in accordance with Article 9 of the Chemical Substances Control Act, must be made by 1 January 2022
- Labelling changes, in accordance with Article 16 of the Enforcement Decree of the Chemical Substances Control Act, must be made by 1 January 2022
- New import notifications of toxic substances, in accordance with Article 20 of the Enforcement Decree of the Chemical Substances Control Act, must be filed by 1 January 2022
- New chemical accident prevention management plans, in accordance with Article 28 of the Enforcement Decree of the Chemical Substances Control Act, must be filed by 1 July, 2023
- Hazardous chemical business licenses, in accordance with Article 28 of the Enforcement Decree of the Chemical Substances Control Act, must be obtained by 1 July 2023
- The handling of the newly added toxic substances must comply with the standards of Annex 1 of the Enforcement Rules of the Chemical Substances Control Act and the standards of Annex 5 of the Enforcement Rules of the Corolla Act by 1 July 2025

There are no non-compliance provisions specified.

More information can be found at:
Amendment text (in Korean)
https://www.iaeg.com/elements/pdf/KOR_Notice_Amendment_toxic_substances.pdf
Amendment text (in English)
https://www.iaeg.com/elements/pdf/KOR_Notice_Amendment_toxic_substances_english.pdf
Annex text (in Korean)
https://www.iaeg.com/elements/pdf/KOR_Notice_Amendment_toxic_substances_Annex.pdf
Annex text (in English)
https://www.iaeg.com/elements/pdf/KOR_Notice_Amendment_toxic_substances_Annex_english.pdf

Turkey

Regulation on control of packaging waste

Legal Status: Published

The Turkish Ministry of Environment and Urbanization has published a new regulation on packaging production and recycling. The new regulation establishes the provisions of production and placing on the market of packaging, deposit management and waste management systems, and recycling/recovery targets. This regulation determines the strategies and policies and administrative, financial, and technical procedures and principles.

More information can be found at (in Turkish):
https://www.resmigazete.gov.tr/eskiler/2021/06/20210626-18.htm

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EUROPE

European Union

Two substances added to registry of substances of very high concern (SVHC) intentions until outcome

Legal Status: Published

The following two substances were added to the registry of intention of substances of very high concern (SVHCs):

- tris(2-methoxyethoxy)vinylsilane | EC # 213-934-0 | CAS # 1067-53-4
- 6,6'-di-tert-butyl-2,2'-methylenedi-p-cresol | EC # 204-327-1 | CAS # 119-47-1

Substances that may have serious and often irreversible effects on human health and the environment can be identified as SVHCs. The registry of SVHC intentions until outcome aims to make interested parties aware of the substances for which an SVHC dossier is planned to be submitted to the European Chemical Agency (ECHA). If a substance is identified as an SVHC, it will be added to the Candidate List for eventual inclusion in the Authorisation List.

Next steps include submission of the dossier to ECHA, followed by multiple cycles of consultation to determine inclusion into the Candidate List.

More information can be found at:
https://echa.europa.eu/registry-of-svhc-intentions

Candidate List Updated with Eight Hazardous Chemicals

Legal Status: Published

On 8 July 2021 the Candidate List of substances of very high concern (SVHCs) for authorization was updated with 8 new entries bringing the total to 219 entries – some are group entries, so the number of substances is higher. Substances on the Candidate List may have serious effects on our health or the environment.

The 8 entries are noted below (note that the info below present a non-exhaustive list of CAS#):

- 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers (No EC/CAS available): used in cleaning agents, scented articles, polishes and wax blends
- orthoboric acid, sodium salt (EC # 237-560-2, CAS # 13840-56-7): may be used as solvent and corrosion inhibitor (not registered under REACH)
- 2,2-bis(bromomethyl)propane1,3-diol (BMP) (EC # 221-967-7, CAS # 3296-90-0): used in manufacture of polymer resins and in one component foam (OCPF) application
- 2,2-dimethylpropan-1-ol, tribromo derivative/3-bromo-2,2-bis(bromomethyl)-1-propanol (TBNPA) (EC # 253-057-0, CAS # 36483-57-5, 1522-92-5): used in polymer production manufacture of plastic products, including compounding and conversion and as an intermediate
- 2,3-dibromo-1-propanol (2,3-DBPA) (EC # 202-480-9, CAS # 96-13-9): registered as an intermediate
- glutaral (EC # 203-856-5, CAS # 111-30-8): used in biocides, leather tanning, x-ray film processing

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- medium-chain chlorinated paraffins (MCCP) (UVCB substances consisting of more than or equal to 80% linear chloroalkanes with carbon chain lengths within the range from C14 to C17) (No EC/CAS available): used as flame retardants, plasticizing additives in plastics, sealants, rubber and textiles
- phenol, alkylation products (mainly in para position) with C12-rich branched alkyl chains from oligomerization, covering any individual isomers and/ or combinations thereof (PDDP): (No EC/CAS available): used in preparation of lubricant additive materials and of fuel system cleaners
- 1,4-dioxane (EC # 204-661-8, CAS # 123-91-1): used as solvent
- 4,4'-(1-methylpropylidene)bisphenol (EC # 201-025-1, CAS # 77-40-7): may be used in manufacture of phenolic and polycarbonate resin (not registered under REACH)

The impact of this update is noted below:

- These substances may be placed on the REACH Authorisation List in the future which would require companies to apply for authorization to continue using them
- Any supplier of articles containing a Candidate List substance above a concentration of 0.1 % weight by weight – either on its own, in mixtures or in articles – must provide sufficient information to their customers and consumers to allow safe use
- Importers and producers of articles containing a Candidate List substance have six months from the date of its inclusion in the list (8 July 2021) to notify the European Chemical Agency (ECHA). Suppliers of substances on the Candidate List (supplied either on their own or in mixtures) have to provide their customers with a safety data sheet
- As of 5 January 2021, suppliers of articles on the European Union market containing Candidate List substances in a concentration above 0.1% weight by weight must notify these articles to ECHA's SCIP database. This duty comes from the Waste Framework Directive.

Penalties for non-compliance vary by member state.

More information can be found at:
https://echa.europa.eu/hu/-/candidate-list-updated-with-eight-hazardous-chemicals

RAC/57/2021 and SEAC/51/2021 Meeting. Concerns: Applications for Authorisation - Approach for evaluating review reports

Legal Status: Published

The European Chemical Agency (ECHA) committees for Risk Assessment (RAC) and Socio-Economic Analyses (SEAC) held 57th and 51st meetings, respectively, in which they discussed review reports. "Review report of an authorization" outlines to what extent the review process and the elements of the review report are identical to an application for authorization and what would be different or new. The meeting summary describes RAC and SEAC's approaches for assessing review reports to ensure consistency in the committees' evaluations. It outlines issues that should be considered by both RAC and SEAC, as well as specific considerations related to either committee.

The following items are elaborated in the meeting:

- what committees should do if the scope of the use in the review report is broader than the scope of the authorized use
- is the level of scrutiny for review reports the same as for the initial application
- should RAC and SEAC require and expect a more robust set of information in the review report than in the original application for authorization

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- actions to take if the additional conditions, monitoring arrangements or recommendations as per the authorization decision are not fulfilled in the review report
- early review reports treatment
- Committee for Risk Assessment (RAC) evaluation
- Committee for Scio-Economic Analysis (SEAC) evaluation, review period and actions to take in case of substitution activities delays

More information can be found at:
https://echa.europa.eu/documents/10162/13563/committee_approach_review_reports_en.pdf/9199c956-09cf-012d-983b-661bd13f0a2a?utm_source=echa-weekly&utm_medium=email&utm_campaign=weekly&utm_content=20210630&_cldee=ai5tYXR0aGV3QHlvcmRhc2dyb3VwLmNvbQ%3d%3d&recipientid=lead-6ca6f4e0c0e0e71180fa005056952b31-1e1fadc591fb40249c07060e9fa587c1&esid=7c4f1018-73d9-eb11-812c-005056b9310e

Simplification and digitalization of labelling requirements (classification, labelling, and packaging [CLP]; detergents; fertilizing products)

Legal Status: Draft amendment

The European Union proposed an action that will consider simplifying labelling requirements for some categories of chemicals and chemical products, and the use of digital labelling. The main objective is to increase the effectiveness of communicating essential information on chemicals, including safety and product use-instructions.

Policy decisions to realize this goal include:

- simplifying information; for example, by removing or adding information (relevant to the classification, labelling, and packaging [CLP] and detergents regulations only)
- changing the way in which specific information is currently provided; for example, from the physical label to digital (relevant to the CLP, detergents, and fertilizing products regulations)

Interested parties can provide comments until 20 September 2021.

More information can be found at:
https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12992-Chemicals-simplification-and-digitalisation-of-labelling-requirements_en

Proposed mercury exemption to Annex III of Directive 2011/65/EU

Legal Status: Draft amendment

Further changes have been proposed to the Restriction of Hazardous Substances (RoHS) regulation, which restricts the level of certain substances in electronics and electronic equipment. The amendment concerns an exemption for specified applications containing mercury in high pressure sodium lamps with improved color rendering index for general lighting purposes.

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Exemptions of entries 4(b), 4(b)-I, 4 (b)-II and 4(b)-III all have proposed updated conditions and can be found in the annex document.

More information can be found at:
https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13100-Electrical-equipment-Mercury-in-high-pressure-sodium-lamps-with-improved-colour-rendering-index-RoHS-exemption-_en

Draft Commission regulation amending Annexes VI to X to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning REACH

Legal Status: Proposed

The European Commission has amended certain provisions in Annexes VI to X to REACH 1907/2006. Annexes VI to X contain the standard information requirements for registration of substances manufactured or imported in varying quantities. The amendments cover the obligations for registrants, identification of the registered substances, as well as some provisions on toxicological information (mutagenicity, reproductive toxicity and developmental toxicity) and ecotoxicological information (aquatic toxicity, degradation and bioaccumulation). The amendments also include some changes in waiving options and the responsibilities of European Chemicals Agency.

More information can be found at:
Commission Regulation
https://www.iaeg.com/elements/pdf/EUR_Draft_Amendment_REACH_Regulation.pdf
Annex
https://www.iaeg.com/elements/pdf/EUR_Draft_Amendment_REACH_Regulation_Annex.pdf

Chemicals (REACH) regulation – amendment to the list of substances of very high concern in Annex XIV

Legal Status: Draft Amendment

The European Commission asked for feedback on a draft regulation amending Annex XIV of the REACH regulation (EC No. 1907/2006). Annex XIV contains the list of substances which are subject to authorization. The draft regulation is set to add 5 new substances to the Annex:

- tetraethyl lead | EC No: 201-075-4 | CAS No: 78-00-2
- 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol (with ≥ 0,1% of Michler's ketone (EC No 202-027-5) or Michler's base (EC No 202-959-2)) | EC No: 209-218-2 |CAS No: 561-41-1
- teaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP) (with ≥ 0,1% w/w 4-heptylphenol, branched and linear) | EC No: not available - | CAS No: not available-
- 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE) | EC No: 239-622-4 |CAS No: 15571-58-1
- reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE) | EC No: not available | CAS No: not available

For all of the substances, the latest application date and sunset date are set to be 18 and 36 months, respectively, after this amendment enters into force.

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Interested parties could provide feedback until 22 July 2021.

More information can be found at:
https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13092-Chemicals-REACH-regulation-amendment-to-the-list-of-substances-of-very-high-concern-in-Annex-XIV_en

Highlights from June RAC and SEAC meetings - REACH restrictions - Undecafluorohexanoic acid (PFHxA), its salts and related substances

Legal Status: Pre-draft

The Risk Assessment Committee (RAC) under the European Chemical Agency has acknowledged that undecafluorohexanoic acid (PFHxA) is a risk to human health and the environment and adopted its opinion on the matter. The Socio-economic Analysis Committee (SEAC) released its draft opinion on a restriction. SEAC could not conclude on whether or not the proposed measures were appropriate; however, it was able to conclude that the restriction was proportional for certain uses. This opinion will be open for comments for 60 days.

These two developments in June regarding PFHxA will move along its upcoming restriction under REACH.

PFHxAs are per- and polyfluoroalkyl substances (also known as PFAS) and are considered very persistent and mobile, which is why they are thought to contribute to environmental pollution.

A joint opinion on the matter is expected by the end of the year.

More information can be found at:
https://echa.europa.eu/hu/-/highlights-from-june-rac-and-seac-meetings

Austria

Battery Ordinance Amendment 2021

Legal Status: Published

On 7 July 2021, the Austrian Federal Minister published an amendment to the Battery Ordinance of 2008 (the Ordinance). The Ordinance applies to all types of batteries, regardless of shape, volume, weight, material composition or use. The Ordinance does not apply to batteries in equipment, weapons, ammunition, and war material specifically for military use or in equipment for use in space.

The major changes are highlighted below:

- added definition of manufacturer of batteries and accumulators
- clarified responsibility for final sellers of portable batteries to implement a system for collection of old batteries
- added responsibility for waste collector of device batteries to inform the Federal Minister regarding the export of batteries to another Member State on an annual basis
- added requirements for identifying an Authorized Representative in Austria for foreign persons placing batteries on the Austrian market

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The Authorized Representative requirements apply for batteries placed on the market in Austria from 1 January 2022, but the representative can be appointed from 1 October 2021.

There are no non-compliance provisions provided for this regulation.

More information can be found at (in German):
https://www.ris.bka.gv.at/Dokumente/BgblAuth/BGBLA_2021_II_311/BGBLA_2021_II_311.html

Norway

Amending the regulations on REACH

Legal Status: In force

Norway's government adopted a regulation to incorporate the European Union 2020/878 regulation into the Norwegian translation of REACH. Regulation (EU) 2020/878 is the amendment to Annex II of Regulation (EC) No 1907/2006 (REACH), it was published on 18 June 2020 and came into force on 1 January 2021. Annex II to Regulation (EC) No 1907/2006 lays down requirements for the compilation of safety data sheets, used to provide information on chemical substances and mixtures in the Union.

More information can be found at (in Norwegian):
https://lovdata.no/dokument/LTI/forskrift/2021-06-21-2219

Switzerland

Annexes 2 and 3 of the Ordinance on Protection against Dangerous Substances and Preparations (Chemicals O)

Legal Status: Published

The Swiss Chemical Ordinance on Protection against Dangerous Substances and Preparations (ChemO) specifies the requirements for placing on the market of substances and mixtures. This is the Swiss equivalent of the European Union (EU) REACH legislation because Switzerland is not part of the EU.

The update introduces the following changes in Annex 2 (List of applicable technical provisions) of the ChemO:

- The technical regulations for the classification, labeling and packaging of substances and preparations are updated and thus adapted to technical progress in the EU (16th and 17th ATP of the EU classification, labelling and packaging [CLP] regulation). The updated list of substances can be found in the Annex 3 document and consists of:
  - - New addition of 22 substances
  - - Modification of 41 existing entries
  - - Deletion of 1 entry
- The latest developments in test methods for substances and preparations have been adopted.

Two new substances are included in Annex 3 (List of substances of concern) of the ChemO, analogous to the Candidate List of substances for authorisation under EU-REACH:

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- dioctyltin dilaurate, stannane, dioctyl-, bis(coco acyloxy) derivs., and any other stannane, dioctyl-, bis(fatty acyloxy) derivs. wherein C12 is the predominant carbon number of the fatty acyloxy moiety
  - stannane, dioctyl-, bis(coco acyloxy) derivs. EC No.: 293- 901-5 | CAS No.: 91648-39-4
  - dioctyltin dilaurate; stannane, dioctyl-, bis(coco acyloxy) derivs. EC No.: not available | CAS No.: not available
  - dioctyltin dilaurate. EC No.: 222-883-3 | CAS No.: 3648-18-8
- bis(2-(2- methoxyethoxy)ethyl)ether EC No.: 205-594-7 | CAS No.: 143-24-8

This listing triggers information obligations along the supply chain.

The changes will come into effect September 2021. Penalties for non-compliance include fines and/or imprisonment.

More information can be found at (in German, French, and Italian):
https://www.anmeldestelle.admin.ch/chem/de/home/themen/recht-wegleitungen/revisionen-des-chemikalienrechts/anpassung-anhaenge-2-3-chemikalienverordnung.html

NORTH AMERICA

Canada

Canada Environmental Protection Act, 1999- Ministerial Condition No. 20654

Legal Status: In force

The Canadian Minister of the Environment and the Minister of Health (the ministers) have assessed information pertaining to the substance 1-propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-C8-18 acyl derivs., inner salts (CAS # 97862-59-4). The ministers suspect that the substance is toxic or capable of becoming toxic under Section 64 of Canadian Environmental Protection Act, CEPA, 1999.

The conditions restrict the manufacture or import of the substance unless:

- the concentration of 1,3-propanediamine, N,N-dimethyl- in the substance is less than 0.01% by weight, and
- the concentration of fatty acid amidopropyl dimethylamine (amidoamine) impurities is equal to or less than 1.5% by weight

This substance is used in the following products: washing & cleaning products, fillers, putties, plasters, modelling clay, and coating products. Other release to the environment of this substance is likely to occur from indoor use (e.g., automotive care products, paints and coating or adhesives, fragrances, and air fresheners) and outdoor use.

More information can be found at:
https://canadagazette.gc.ca/rp-pr/p1/2021/2021-07-03/html/notice-avis-eng.html#na2

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Order adding a toxic substance to Schedule 1 to the Canadian Environmental Protection Act, 1999

Legal status: Published

The Canada Minister of the Environment and the Minister of Health (the Ministers) are recommending to the Administrator in Council to make an order to add coal tars and their distillates to Schedule 1 of the Canadian Environmental Protection Act (CEPA) because they meet the ecological and human health criteria for a toxic substance. Schedule 1 of CEPA lists toxic substances subject to full, partial, or conditional prohibition.

The Order includes, but not limited to, the following six substances: (CAS RN; DSL Name; Common name)

- tar, coal; coal tar; CAS No. 8007-45-2
- tar oils, coal; coal tar oils; CAS No. 65996-82-9
- distillates (coal tar), upper; coal tar upper distillates; CAS No. 65996-91-0
- tar, coal, low-temperature; low-temperature coal tar CAS No. 65996-90-9
- tar, coal, high-temperature; high-temperature coal tar; CAS No. 65996-89-6
- pitch, coal tar, high-temperature; high-temperature coal tar pitch; CAS No. 65996-93-2

Coal tar is used in coatings and paint, as an adhesive, in aluminum industry, and coal tire oils are mainly used as feedstocks for industrial processes. Coal tars and their distillates may be released to air, water and soil from industrial activities associated with their production, transportation, consumption, and disposal of products containing them. All manufacturers/importers must inform themselves of the implications of these substances being listed on Schedule 1.

More information can be found at:
https://gazette.gc.ca/rp-pr/p1/2021/2021-06-26/html/reg2-eng.html

Draft federal environmental quality guidelines for certain substances

Legal status: Draft amendment

The Government of Canada published the draft federal environmental quality guidelines (FEQGs) for certain substances listed below:

- aluminum
- selenium
- siloxane-D4

More information can be found at:
https://gazette.gc.ca/rp-pr/p1/2021/2021-06-12/html/notice-avis-eng.html#ne1
FEQGs
https://www.canada.ca/en/health-canada/services/chemical-substances/fact-sheets/federal-environmental-quality-guidelines.html#a6

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United States

Per- and polyfluoroalkyl substances (PFAS) low volume exemption stewardship program

Legal Status: Published

The establishment of the per- and polyfluoroalkyl substances (PFAS) low volume exemptions (LVE) Stewardship Program by the US Environmental Protection Agency (EPA) follows an announcement in April that new LVE submissions for PFAS would likely be denied since a sufficiently robust safety review is unlikely to be possible in the 30 days the law allows given the potential hazards associated with various subclasses of PFAS and the need to consider their potential persistence in the environment.

EPA is renewing a program to work cooperatively with companies to voluntarily withdraw all previously granted LVEs for PFAS. This will build upon a 2016 outreach effort that resulted in companies withdrawing more than half of the 82 long-chain PFAS LVEs targeted for withdrawal at the time.

Through this program, EPA intends to work with trade associations, non-governmental organizations, and companies to encourage voluntary withdrawal of the LVEs.

More information can be found at:
https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/pfas-low-volume-exemption

EPA announces path forward for TSCA chemical risk evaluations

Legal Status: Published

The US Environmental Protection Agency (EPA) announced essential policy changes surrounding risk evaluations issued under the Toxic Substances Control Act (TSCA) and the plan for the first ten chemicals to undergo risk evaluation. Under TSCA, the EPA is responsible for reviewing the risks associated with high-priority chemicals already on the market and managing any determined unreasonable risks. The risk evaluation process is the second step, following prioritization and before risk management, in EPA's existing chemical process under TSCA. The purpose of risk evaluation is to determine whether a chemical substance presents an unreasonable risk to health or the environment under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation.

EPA plans to introduce the following changes into the risk evaluation process:

- expand consideration of exposure pathways and the fenceline community exposure screening level. The EPA intends to re-open and update the 1,4-dioxane risk evaluation to consider whether to include additional exposure pathways, like drinking water and ambient air and conditions of use, where 1,4-dioxane is generated as a byproduct excluded from the supplemental and final risk evaluations. The agency plans to take public comment on any potential revisions to the 1,4-dioxane risk evaluation before finalizing them
- for the methylene chloride, trichloroethylene, carbon tetrachloride, perchloroethylene, NMP, and 1-bromopropane, the EPA plans to examine additional exposure pathways to determine whether there are any unreasonable risks to fenceline communities
- introduce the review of information on personal protective equipment (PPE) use or other ways the industry protects its workers as a potential way to address unreasonable risk during the risk management process. Review could affect conclusions about the risk of use for methylene chloride, 1-bromopropane, hexabromocyclododecane (HBCD), 1-methyl-2-pyrrolidinone (NMP), perchloroethylene, and 1,4-dioxane

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- reissue the risk determinations that amend the approach to PPE and include a whole chemical risk determination for the first ten chemicals under TSCA and revise using the whole chemical approach. The whole chemical approach allows the agency to assess every condition of use and then issue one determination of unreasonable risk when most of the needs of use allow one determination

Existing risk evaluations for HBCD, Pigment Violet 29, and asbestos are deemed likely sufficient to inform the risk management approaches

EPA plans to make screening approaches and methods available for public comment and have them peer-reviewed by the Scientific Advisory Committee on Chemicals.

More information can be found at:
https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations

Health and safety data reporting; addition of 20 high-priority substances and 30 organohalogen flame retardants

Legal Status: Published

The US Environmental Protection Agency (EPA) has issued a rule requiring manufacturers and importers of 50 substances to submit unpublished health and safety studies to the agency to support its Toxic Substances Control Act (TSCA) activities. The chemical substances subject to this rule consist of the 20 designated by EPA as high-priority substances and the 30 organohalogen flame retardants being evaluated for risks by the Consumer Product Safety Commission (CPSC) under the Federal Hazardous Substances Act (FHSA). The EPA will use this information to inform the risk evaluations currently underway for 20 High-Priority Substances and for future prioritization.

Companies must submit relevant studies in their possession, as well as lists of studies under development.

More information can be found at:
General information
https://www.federalregister.gov/documents/2021/06/29/2021-13212/health-and-safety-data-reporting-addition-of-20-high-priority-substances-and-30-organohalogen-flame
Substance list
https://www.iaeg.com/elements/pdf/USA_H&S_Data_Reporting_substance_list.pdf

Development of tiered data reporting to inform TSCA prioritization, risk evaluation, and risk management

Legal Status: Draft

Currently, The US Environmental Protection Agency (EPA) primarily collects exposure-related data through the Toxic Substances Control Act (TSCA) Chemical Data Reporting process. EPA is interested in ensuring that data collection strategies provide information to better meet the Agency's basic chemical data needs, such as information related to exposure, health, and eco-toxicity.

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EPA is exploring a data reporting rule that is tiered to specific stages of the TSCA existing chemicals program:

- identifying a pool of substances as potential candidates for prioritization
- selecting candidate chemicals for and completing the prioritization process
- assessing high-priority substances through a robust risk evaluation, which may be followed by risk management actions (depending on the outcome of the risk evaluation)

Interested parties can provide comments until the 15 August 2021 deadline.

More information can be found at:
https://www.federalregister.gov/documents/2021/07/14/2021-14928/development-of-tiered-data-reporting-to-inform-tsca-prioritization-risk-evaluation-and-risk

Reporting and recordkeeping requirements for per- and polyfluoroalkyl substances (PFAS)

Legal Status: Notice

The Environmental Protection Agency (EPA) has published a proposal for the reporting and recordkeeping requirements regarding per- and polyfluoroalkyl substances (PFAS) under the Toxic Substances Control Act (TSCA). The proposal would require certain entities that manufacture (including import) or have manufactured these chemical substances in any year since January 1, 2011, to electronically report information regarding PFAS uses, production volumes, disposal, exposures, and hazards.

EPA is requesting public comment on all aspects of this proposed rule.

More information can be found at:
https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0549-0001

Oceania

Call for comments for Draft Evaluations on Industrial Chemicals

Legal Status: Draft amendment

The Australian government has extended its consultation on draft evaluations for 17 industrial chemicals or groups of chemicals from 25 June to 20 August. In each draft evaluation, the Australian Industrial Chemicals Introduction Scheme (AICIS) either makes recommendations to public health and/or workers, provides advice to industry on the potential risks to human health associated with the chemicals, or makes no recommendation.

Chemicals under evaluation and their uses:

- 1-butanone, 2-(dimethylamino)-1-[4-(4-morpholinyl)phenyl]-2-(phenylmethyl) (CAS # 119313-12-1) – used in inks, toners and colourants, paints and coatings, plastics/polymer products
- 1-propanone, 2-methyl-1-[4-(methylthio)phenyl]-2-(4-morpholinyl) (CAS # 71868-10-5) – used in inks, toners and colorants, paints and coatings, plastics/polymer products

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- alkyl pyridinium surfactants (CAS # 104-73-4, 104-74-5, 123-03-5, 140-72-7, 1155-74-4, 6004-24-6, 17342-21-1) – used as chemical intermediate
- carbamic acid, monoammonium salt (CAS # 1111-78-0) – used as chemical intermediate
- cashmeran (4H-inden-4-one, 1,2,3,5,6,7-hexahydro-1,1,2,3,3-pentamethyl-) (CAS # 33704-61-9) - used in air care products
- cesium salts (CAS # 3396-11-0, 534-17-8, 15519-28-5, 7787-69-1, 7647-17-8, 13400-13-0, 21351-79-1, 35103-79-8, 7789-17-5, 1068-63-9, 7789-18-6, 13454-83-6, 10294-54-9) – used as chemical intermediates, in electronic products, explosive materials and extractive products
- dichloromethane (methane, dichloro-) (CAS # 75-09-2) – used in paints and coatings
- ethanone, 1-[(3R,3aR,7R,8aS)-2,3,4,7,8,8a-hexahydro-3,6,8,8-tetramethyl-1H-3a,7-methanoazulen-5-yl]- (acetylcedrene) (CAS # 32388-55-9)– used in air care products
- maleic acid esters (short chain) (CAS # 105-76-0, 141-05-9, 624-48-6, 924-83-4, 925-21-3, 3052-50-4, 14234-82-3, 45022-27-3) – used in adhesives and sealants, construction chemicals, fabric, textile and leather products, inks, toners and colorants, paints and coatings
- nickel soaps (CAS # 4454-16-4, 2223-95-2, 13001-15-5, 4995-91-9, 75880-31-6) – used in lubricants and greases, paints and coating, plastic and polymer products
- nonanedioic acid (azelaic acid) (CAS # 123-99-9) – used in adhesives and sealants, chemical intermediates, construction chemicals, fabric, textile and leather products, inks, toners and colorants, lubricants and greases, paints and coatings, plastics/polymer products
- phenol, 4-(1,1-dimethylpropyl)- (4-tert-pentylphenol) (CAS # 80-46-6) – used in inks, toners and colorants, paints and coatings, plastic/polymer products
- pentabromodiphenyl ether (pentaBDE) (CAS # 32534-81-9) – a brominated flame retardant

Interested parties can provide comments until the 20 August deadline.

More information can be found at:
https://www.industrialchemicals.gov.au/consultations/draft-evaluations-have-your-say-closes-20-august

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