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视点

尊敬的 AICM 会员,本期区域间法规交流 平台快讯将为您带来以下内容:

韩国

本季韩国官方持续修订《化学品分类及标签规定》、《化学物质危害性评估结果》,建议企业持续关注其化学物质是否被新增进入《毒性化学物质清单》或其毒性物质的官方分类在清单里的变化,因而采取及时的合规措施,如更新分类、MSDS和标签。

另外,企业应重点关注近期发布的 K-REACH下修订,对于无需 CSR 风险评估报告的化学物质,在信息传递时,可以仅在MSDS 中体现注册与否;此次危害化学物质的分类有很大变动,这有可能要求企业对原有的物质分类重新管理;新化学物质申报的吨位量调整至 1 吨。K-CCA 与 K-REACH 法规同步,也更新了危害化学物质的分类。

近期,韩国为了更好地实施生物杀灭物质 批准和生物杀灭剂批准制度,发布一系列 相关的指南文件,建议生物杀灭物质、生 物杀灭剂和生产生活化学产品的企业持续 关注相关的批准规定。

日本

此前日本对《化审法》实施条例进行了部分修订,将"PFHXS(全氟己烷基磺酸)及其异构体或其盐类"指定为第1类特定化学物质,因此日本对相关化学物质的进口清关手续也进行了相应的修改。另外,日本要求在化学物质的 SDS 中不仅要体现适用法律法规的名称,还需明确体现相关的法规要求。

台湾地区

台湾地区化学品管理局 (CHA) 发布通知, 提醒注册人不要多次注册同一物质:食品 药品监督管理局 (FDA) 计划在化妆品禁 用成分清单中增加9种物质, 并重组限制 化妆品成分清单,清单重组将使台湾地区 与欧盟、美国和东盟国家使用的化妆品成 分清单保持一致;台湾地区环境部 (MoE):台湾地区台中劳动局发布了 《工厂处理和使用危险物品的安全注意事 项》的指导意见,协助工厂安全使用和处 置有害物质,以保障工人操作安全。台湾 地区卫生福利部将对《管制药品分级及品 项》进行修订, 增列三种药品为第四级管 制药品原料药:台湾地区化学品管理局督 促企业在 2024 年上半年提交既有物质第 一阶段标准登录资料。

菲律宾

菲律宾化学品和化学物质名录 (PICCS) 新增 162 个物质;食品和药物管理局 (FDA)发布《签发玩具及儿童保育用品 授权的规则及条例》草案和《产品召回指南》修订草案;菲律宾环境和自然资源部环境管理局 (DENR-EMB)发布了化学品 豁免和机密商业信息 (CBI)申请指南草案;菲律宾通过了《禁止化学武器法》,同时公布了禁化武清单。

印度

印度化学和石化部(DCPC)近期发布多项通告,发布或推迟多项质量控制令的实施日期。为不影响企业的贸易进程,建议企业时刻关注印度官方发布的公告,及时应对相应的产品质量控制令的要求。印度发布 ChemIndia 的用户手册。

Viewpoint

Distinguished AICM members: this issue of Regional Regulatory Exchange Platform will bring you the following:

South Korea

Korean officials revised the *Regulations on Classification and Labeling of Chemicals* and the *Results of Hazard Assessment of Chemical Substances. Enterprises* are advised to continuously verify whether their chemical substances are added to the *List of Toxic Chemical Substances* or whether their official classification of toxic substances has changed in the List, so that they can take compliance measure in time (e.g. update classification, MSDS and label).

In addition, enterprises shall focus on the recently released revision under K-REACH. Regarding the chemical substances that do not require a CSR risk assessment report, their register status can only be displayed in MSDS when transmitting information. There are significant changes in the classification of hazardous chemical substances this time, which may require enterprises to re-manage the original classification of substances; the tonnage of new chemical substances to be declared is adjusted to 1 ton. K-CCA has also updated the classification of hazardous chemical substances in synchronization with the K-REACH regulation.

Recently, Korea has issued a series of relevant guidance documents for better implementation of the biocidal substance approval and biocide approval system. It is recommended that enterprises producing biocidal substances, biocides and household chemical products shall pay continuous attention to the relevant approval regulations.

Japan

Previously, Japan partially revised the implementing regulations of the *Chemical Substance Control Law* and designated "PFHxS (perfluorohexylsulfonic acid) and its isomers or salts" as the class 1 specified chemical substance. As a result, Japan has revised its customs clearance procedures for the import of related chemical substances accordingly. In addition, Japan requires that not only the names of applicable laws and regulations but also the related regulatory requirements be clearly reflected in the SDS of chemical substances.

Taiwan

The Chemicals Administration (CHA) of Taiwan issued a notice warning registrants not to register the same substance more than once. The Food and Administration (FDA) plans to add nine substances to the list of banned cosmetic ingredients and reorganize the list of restricted cosmetic ingredients. This list reorganization will bring the cosmetic ingredient list used in Taiwan Region in line with that used in the European Union (EU), the United States (U.S.), and ASEAN countries. The Ministry of the Environment (MoE) of Taiwan and the Taichung Bureau of Labor Affairs (TBLA) have issued guidance on Safety Precautions for Handling and Use of Hazardous Substances in Factories to assist factories in the safe use and disposal of hazardous substances in order to ensure the safety of workers' operations. The Ministry of Health and Welfare (MOHW) of Taiwan will revise the Classification and Items of Controlled Drugs to add three additional drugs as level 4 controlled drug ingredients. CHA urges companies to register priority chemicals by midyear.

Philippines

162 new substances are added to the Philippine Inventory of Chemicals and Chemical Substances (PICCS); Food and Drug Administration (FDA) released the Draft Rules and Regulations for Issuance of Authorizations for Toys and Childcare Items and the draft revisions to the Guidance on Product Recalls; the Philippine Department of Environment and Natural Resources Environmental Management Bureau (DENR-EMB) released the draft guideline for chemicals exemption and confidential business information (CBI) applications; and

the Philippines approved the *Chemical Weapons Prohibition Act* (CWPA), along with the publication of the CWC chemicals list.

India

The Department of Chemicals and Petrochemicals (DCPC) of India has recently issued a number of notices, releasing or postponing the implementation date of a number of quality control orders. In order not to affect the trade process of enterprises, it is recommended that enterprises always pay attention to the official announcements issued by India, and respond to the requirements given in the corresponding product quality control order in time. India released the user's manual of ChemIndia.



韩国·《化学物质的注册与评估法案》施行令部分修订案

2023年12月12日,根据33952号公告,韩国环境部发布了《化学物质的注册与评估法案》施行令的部分修订案,主要内容包括:

- 1. 在 化 学 物 质 信 息 处 理 系 统 (https://kreach.me.go.kr/repwrt/index.do) 中,针对含优先管控化学物质的产品的变更申报和化学物质的注册/申报相关继承事宜申报,创建了处理、委任和委托等模块。(第 21 条、第 22 条、第 31 条)
- (1) 针对第 33 条"含优先管控化学物质的产品的变更申报"和第 45 条第 2 项"化学物质的注册/申报相关继承事宜申报",被国外生产商/制造商委任的唯一代理人(OR)被允许申请以上申报。
- (2) 针对第 33 条"含优先管控化学物质的产品的变更申报"和第 45 条第 2 项"化学物质的注册/申报相关继承事宜申报",可通过化学物质信息处理系统(https://kreach.me.go.kr/repwrt/index.do)完成。
- (3) 第33条"含优先管控化学物质的产品的变更申报"的接收工作委托给流域/ 地方环境局,第45条第2项"化学物质

的注册/申报相关继承事宜申报"的接收 工作委托给韩国环境工团(KECO)。

- 2. 针对未履行"含优先管控化学物质的产品的变更申报"和"化学物质的注册/申报相关继承事宜申报",规定了罚款标准(附表 6)
- (1) 按照第 33 条 "含优先管控化学物质的产品的变更申报", 企业未申报或者虚假申报和按照第 45 条第 2 项 "化学物质的注册/申报相关继承事宜申报",企业未申报时,根据违反次数进行罚款,首次违反时,6,000,000 韩币,第二次违反时,8,000,000 韩币,3次及以上违反时,10,000,000 韩币。

点评:对于在韩国境内生产或进口化学产品的企业,需要关注环境部更新的优先管控化劳场清单,如果产品中含指定优先管控物质,并且法规规定对其产品进行申报时,需在生产或进口产品前完成申报后申报后如有发生上述变更事宜,需进一步申请变更。另外,上述的继承事宜人多种,涉及原申报人死亡、业务转让、公司合并等,如有发生继承事宜则根据该修订案也需要进行申报。

详情请点击以下链接:

https://www.me.go.kr/home/web/law/list.do?pagerOffset=10&maxPageItems=10&maxIndexPages=10&searchKey=&searchValue=&menuId=10525&orgCd=&condition.typeCode=law号)

South Korea · Amendment to the *Act on Registration and Evaluation of Chemical Substance*

On December 12, 2023, in accordance with Announcement No. 33952, the Ministry of the Environment of Korea issued a partial amendment to the *Act on Registration and Evaluation of Chemical Substance of Korea*, which includes the following main points:

- 1. In the Chemical Substance Information Processing System, modules for processing, appointment and delegation have been created for notification of changes in products containing preferentially controlled chemical substances and notification of succession matters related to the registration/declaration of chemical substances. (Articles 21, 22, and 31) (https://kreach.me.go.kr/repwrt/index.do)
- (1) Regarding Article 33 "Notification of Changes in Products Containing Preferentially Controlled Chemical Substances" and Article 45-2 "Notification of Succession Matters Relating to Registration/Declaration of Chemical Substances", the sole agent (OR) appointed by the foreign producer/manufacturer is permitted to apply for the declarations.
- (2) Regarding Article 33 "Notification of Changes **Products** Containing Preferentially Controlled Chemical Substances" and Article 45-2 "Notification of Succession Related to Registration/Declaration of Chemical Substances", the notifications can be done through the Chemical Substances Information Processing System can be used. (https://kreach me.go.kr/repwrt/index.do).
- (3) Receipt of Article 33 "Notification of Changes in Products Containing Preferentially Controlled Chemical Substances" is entrusted to basin/local environment bureaus, and receipt of Article 45-2 "Notification of Succession Matters

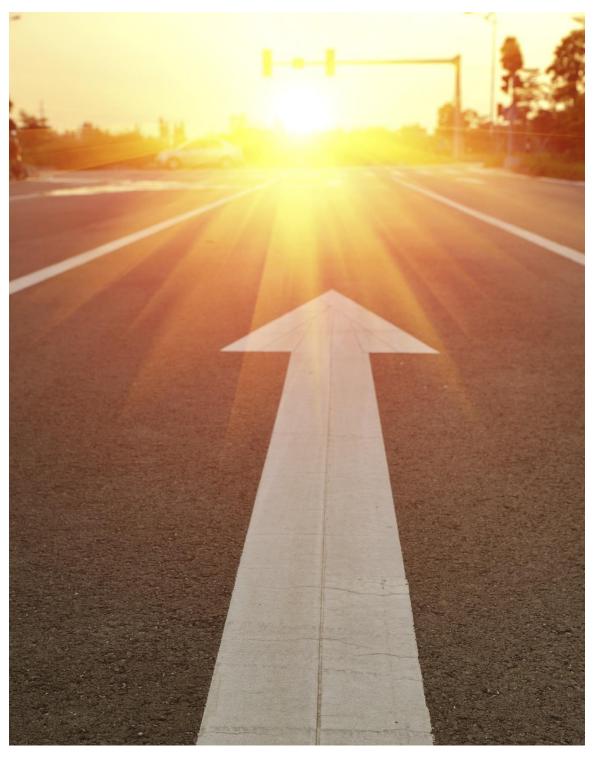
Related to Registration/Declaration of Chemical Substances" is entrusted to the Korea Environmental Corporation (KECO).

- 2. Fines for failure to comply with "Notification of Changes in Products Containing Preferentially Controlled Chemical Substances" and "Notification of Succession Related to Registration/Declaration of Chemical Substances" have been stipulated (Table 6).
- (1) If a company fails to make a notification in accordance with Article 33 "Notification of Changes in **Products** Containing Preferentially Controlled Chemical Substances" or Article 45-2 "Notification of Succession Related to Registration/Declaration of Chemical Substances", or even makes a false notification, a fine is imposed depending on the number of violations. A fine of 6,000,000 won is imposed for the first offense, 8,000,000 won for the second offense, and 10,000,000 won for three or more offenses.

Comments: Enterprises that manufacture or import chemical products in Korea need to pay attention to the list of preferentially controlled chemical substances updated by the Ministry of the Environment. If a product designated preferentially contains controlled chemical substance and the regulations require that the product be notified, the notification must be completed prior to manufacturing or importing the product. If any of the above changes occur after the product has been declared, a further application for change is required. In addition, there are various types of succession mentioned above, including death of the original notifier, transfer of business, and merger of enterprises, which need to be notified according to the amendment in case of succession.

For details, please visit the link below:

 $\frac{https://www.me.go.kr/home/web/law/list.do?pagerOffset=10\&maxPageItems=10\&maxIndexPages=10\&searchKey=\&searchValue=\&menuId=10525\&orgCd=\&condition.typeCode=law(No. 184)$



韩国·《化学物质的注册与评估法案》施行细则的部分修订案

2023 年 12 月 18 日,根据 1064 号公告, 韩国环境部发布了《化学物质的注册与评估法案》施行细则的部分修订案,主要内容包括:

1. 转让化学物质时,将信息传递资料简化 (第36条第1项)

现行法规要求完成注册但未提交风险评估 资料的化学物质在被转让时,应在化学品 安全技术说明书 (MSDS) 上记载化学物 质的注册证号或者申报证号。但这可能暴 露企业的商业机密,所以,法规修订为仅 需记载是否注册或者申报。

- 2. 新增含优先管控化学物质的产品的变更申报 (第42条)
- (1)产品所含优先管控化学物质的总量增加50%以上,以及含优先管控化学物质的产品的进口商/委托商发生变更时,可进行变更申请。
- (2)产品所含优先管控化学物质的总量变更后为30%以内时,无需变更申请。
- 3. 化学物质的注册/申报相关继承事宜的 相关程序(第55条第3项)
- (1) 化学物质的注册/申报的企业涉及原申报人死亡、业务转让、公司合并等,规定了相关程序,使继承人、受让人或者合并后的法人实体能够继承注册/申报企业的合法权益。

- 4. 规定了"含优先管控化学物质的产品的申报/变更申报"和"化学物质的注册/申报相关继承事宜申报"的手续费(附表11)
- (1) 现行 50,000 韩币的含优先管控化学物质的产品的申报的手续费降为 20,000 韩币,新增了含优先管控化学物质的产品的变更申报的手续费为 15,000 韩币、化学物质的注册/申报相关继承事宜申报的手续费为 2,000 韩币。

点评:根据已有数据判断化学物质没有危害分类,同时化学物质在韩国供应链上,并且没有消费者用途时,可以在注册卷宗中省略风险评估报告,在法规生效后,这类已完成注册但未提交风险评估资料的化学物质和无需提交风险评估报告的新、现有化学物质在被转让时,仅需在化学品安全技术说明书(MSDS)上记载是否注册或者申报。

对于在韩国境内生产或进口化学相关产品的企业,需要关注环境部更新的优先管控化学物质清单,如果产品中含指定优先申控物质,并且法规规定对其产品进行申报时,需在生产或进口产品前完成申报,需在生产或进口产品前完成申报,需在生产或进口产品的继承事宜,步时,涉及原申报人死亡、业务转让、方多种,涉及原申报人死亡、业务转让、该修订案也需要进行申报。

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https://www.me.go.kr/home/web/law/list.do?pagerOffset=10&maxPageItems=10&maxIndexPages=10&searchKey=&searchValue=&menuId=10525&orgCd=&condition.typeCode=law号)

South Korea · Amendment to enforcement rules the *Act on Registration and Evaluation of Chemical Substance*

On December 18, 2023, in accordance with Announcement No. 1064, the Ministry of the Environment of Korea issued a partial amendment to enforcement rules of the *Act on Registration and Evaluation of Chemical Substance*, which includes the following main points:

1. Simplification of transmitted information when transferring chemical substances (Article 36, item 1)

Current regulations require that when a chemical substance for which registration has been completed but for which no risk assessment information has been submitted is transferred, the registration certificate number or notification certificate number of the chemical substance shall be recorded on the material safety data sheets (MSDS). However, this may expose the business secrets of the company. Therefore, the regulation is revised to: only need to document whether it is registered or declared.

- 2. New declaration of changes in products containing preferentially controlled chemical substances (Article 42)
- (1) When the total amount of preferentially controlled chemical substances contained in products is increased by more than 50% and the importer/consignor of products containing preferentially controlled chemical substances is changed, an application for change can be made.
- (2) An application for change is not required when the total amount of preferentially

controlled chemical substances contained in products is decreased to 30% or less.

- 3. Procedures concerning succession matters related to registration/declaration of chemical substances (Article 55, Item 3)
- (1) In the event of the death of the original filer, transfer of business, or merger of in enterprises involved the registration/declaration of chemical substances, corresponding procedures are stipulated to enable the successor, transferee, or merged legal entity to inherit the legal rights and interests of the enterprises involved the in registration/declaration.
- 4. The handling fee for "Notification/Notification of Changes in Products Containing Preferentially Controlled Chemical Substances" and "Notification of Succession Related to Registration/Declaration of Chemical Substances" has been stipulated (Table 11)
- (1) The current handling fee of 50,000 won for the notification of products containing preferentially controlled chemical substances will be reduced to 20,000 won, and the handling fee for the notification of change of products containing preferentially controlled chemical substances will be 15,000 won, and the handling fee for the notification of succession related to the registration/declaration of chemical substances will be 2,000 won.

Comments: If there is no hazard classification of a chemical substance based on available data and the chemical

substance has no consumer use in the supply chain of Korea, a risk assessment report can be omitted from the registration dossier. After the entry into force of the Regulation, when such chemical substances that have been registered without submitting the risk assessment information, and new or existing chemical substances that do not need to submit a risk assessment report are transferred, it is only necessary to document whether the chemical is registered or declared on the MSDS.

Enterprises that manufacture or import chemistry-related BD products in Korea need to pay attention to the list of preferentially controlled chemical substances updated by the Ministry of the Environment. If a product contains a designated preferentially controlled chemical substance and the regulations require that the product be notified, the notification must be completed prior to manufacturing or importing the product. If any of the above changes occur after the product has been declared, a further application for change is required. In addition, there are various types of succession mentioned above, including death of the original notifier, transfer of business, and merger of enterprises, which need to be notified according to the amendment in case of succession.

For details, please visit the link below:

https://www.me.go.kr/home/web/law/list.do?pagerOffset=10&maxPageItems=10&maxIndexPages=10&searchKey=&searchValue=&menuId=10525&orgCd=&condition.typeCode=law (No. 190)



韩国·获得批准缓冲期的现有生物杀灭物质名录更新

2023年12月18日,根据第2023-74号公告,韩国环境科学院(NIER)发布了获得批准缓冲期的现有生物杀灭物质名录的修正案,主要内容包括:

- 1. 缩短了 1 种生物杀灭物质的批准缓冲期
- 2. 延长了 246 种生物杀灭物质的批准缓冲 期
- 3. 修改了编号"353"至"460"

2024 年 1 月 25 日,根据第 2024-8 号公告,韩国环境科学院(NIER)发布了获得批准缓冲期的现有生物杀灭物质名录的修正案,主要内容包括:

- 1. 新增了 5 种生物杀灭物质及其批准缓冲 期
- 2. 新增了 6 种生物杀灭剂类型及其批准缓 冲期
- 3. 撤销了 203 种生物杀灭物质及其批准缓 冲期
- 4. 将编号"13"至"460"修正为"13"至 "360"

点评: 企业应关注其在韩国境内生产、进口、销售的生物杀灭剂是否涉及相应的缓冲期的更改、撤销,以及时的采取相应的应对措施。

详情请点击以下链接:

https://www.nier.go.kr/NIER/cop/bbs/selectNoLoginBoardList.do (第 1532 和 1556 号)

South Korea · South Korea updated the list of existing biocidal substances with approved buffer periods

On December 18, 2023, in accordance with Announcement No. 2023-74, the National Institute of Environmental Research, Republic of Korea (NIER) issued an amendment to the list of existing biocidal substances with approved buffer periods, which includes the following main points:

- 1. The approved buffer period of one biocidal substance is reduced
- 2. The approved buffer period of 246 biocidal substances is extended
- 3. The number is revised from "353" to "460"

On January 25, 2024, in accordance with Announcement No. 2024- 8, the National Institute of Environmental Research, Republic of Korea (NIER) issued an amendment to the list of existing biocidal substances with approved buffer periods, which includes the following main points:

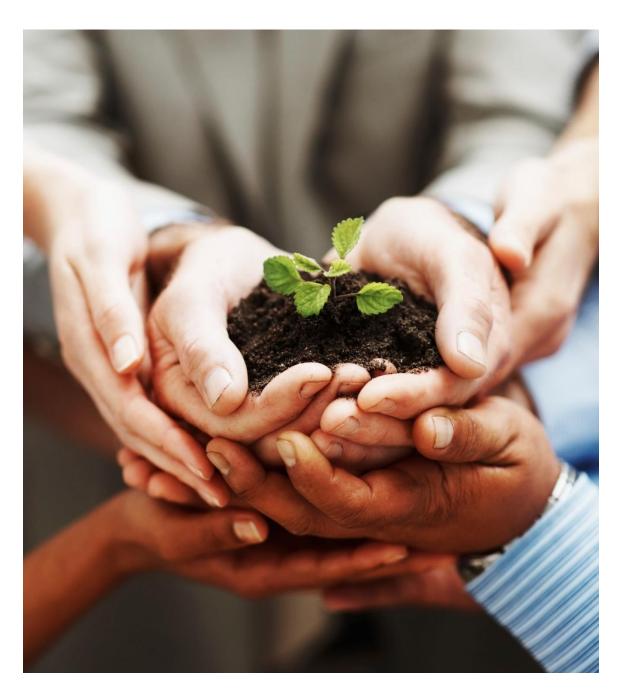
- 1. 5 biocidal substances and their approved buffer periods are added
- 2. 6 biocide types and their approved buffer periods are added
- 3. 203 biocidal substances and their approved buffer periods are canceled

4. Number "13-460" is modified to "13-360".

Comments: Enterprises shall check whether the biocides they manufacture, import, or sell in Korea are involved in the change or withdrawal of the corresponding buffer period, and take appropriate countermeasures in a timely manner where necessary.

For details, please visit the link below:

https://www.nier.go.kr/NIER/cop/bbs/selectNoLoginBoardList.do (No. 1532&1556)



韩国 · 化学物质危害评估结果公布

2023年12月21日,根据第2023-77号公告,韩国环境科学院(NIER)发布了《化学物质危害性评估结果》,附表中更新了10种新化学物质的名称,删除了1种新化学物质,修正了66种新化学物质和1种现有化学物质的危害分类,并新增了124种新化学物质和85种现有化学物质的危害分类。

2024年1月12日,根据第2024-2号公告,韩国环境科学院(NIER)发布了《化学物质危害性评估结果》,修正了第2023-77号公告内容,更改为"2017-371"栏。

点评:对于在韩国境内生产或进口供应 给下游的企业,需要关注 NIER 更新的危 害评估/分类结果,及时更新 MSDS 和标 签.并和 NIER 的结果保持一致。

详情请点击以下链接:

https://www.nier.go.kr/NIER/cop/bbs/selectNoLoginBoardList.do (第 1534 和 1554 号)

South Korea · South Korea announced results of chemical substance hazard assessment

On December 21, 2023, in accordance with Announcement No. 2023-77, NIER published the *Results of Hazard Assessment of Chemical Substances*. In the table attached, the names of 10 new chemical substances are updated, 1 new chemical substance is deleted, the hazard classifications of 66 new chemical substances and 1 existing chemical substance are amended, and the hazard classifications of 124 new chemical substances and 85 existing chemical substances are added.

On January 12, 2024, in accordance with Announcement No. 2024-2, NIER published the *Results of Hazard Assessment of Chemical Substances*, in which the contents of Announcement No. 2023-77 are modified and it is changed to the "2017-371" column.

Comments: Enterprises manufacturing or importing chemicals for downstream use in Korea need to pay attention to NIER's updated hazard assessment/classification results and update the MSDS and label in a timely manner to be consistent with NIER's results.

For details, please visit the link below:

https://www.nier.go.kr/NIER/cop/bbs/selectNoLoginBoardList.do (No. 1534&1554)

韩国·《生物杀灭物质及生物杀灭剂的批准资料的编写范围及编写方法 规定》修正案

2023年12月28日,根据第2023-78号公告,韩国环境科学院(NIER)发布了《生物杀灭物质及生物杀灭剂的批准资料的编写范围及编写方法规定》的修正案,主要内容包括:

- 1. 规定了生物杀灭剂的具体定义和批准资料编写范围
- 新增了定义和【附表 1】生物杀灭物质 及生物杀灭剂批准资料编写范围:各种生 物杀灭剂的批准资料清单
- 各种生物杀灭剂批准相关指南文件 (2023年3月发行)
- 【附表 5】细化了生物杀灭物质及生物 杀灭剂的成分分析资料的编写方法

- 生物杀灭物质及杂质的规格设定时,需要考虑的事项
- 生物杀灭物质的成分分析测试报告的要求
- 生物杀灭物质(2021年9月发行)及生物杀灭剂(2022年9月发行)批准相关指南文件
- 3. 【附表 10】修订了生物杀灭剂功效测 试项目豁免程序
- 完善了生物杀灭物质功效测试项目的豁 免程序

详情请点击以下链接:

https://www.nier.go.kr/NIER/cop/bbs/selectNoLoginBoardList.do (第 1537 号)

South Korea · Amendment to *Provisions on the Scope and Methodology for the Preparation of Approved Information on Biocidal Substances and Biocides*

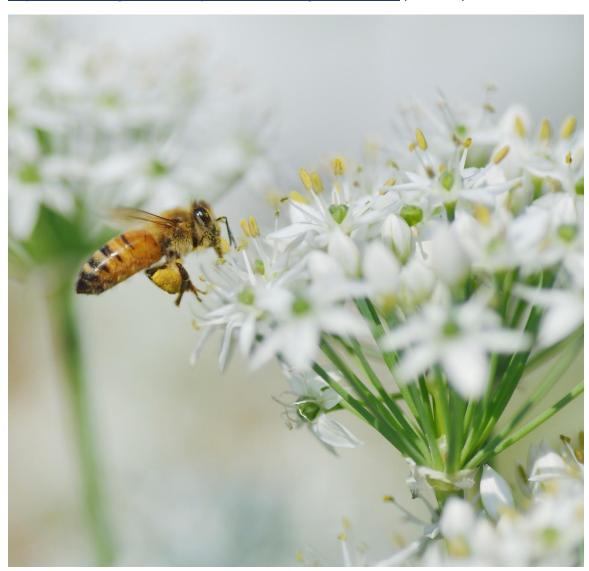
On December 28, 2023, in accordance with Announcement No. 2023-78, NIER issued an amendment to the *Provisions on the Scope and Methodology for the Preparation of Approved Information on Biocidal Substances and Biocides*, which includes the following main points:

- 1. Specify the specific definitions of biocides and the scope of preparation of approved information.
- Add new definitions and [Table 1] scope of preparation of approved information on biocidal substances and biocides: list of approved information on various biocides
- Guidance documents related to the approval of various biocides (issued in March 2023)

- 2. [Table 5] refines the preparation method of information on analysis of components of biocidal substances and biocides
- Matters to be considered when setting specifications for biocidal substances and impurities
- Requirements for composition analysis test reports for biocidal substances
- Guidance documents related to the approval of biocidal substances (issued in September 2021) and biocides (issued in September 2022)
- 3. [Table 10] revises the exemption procedures for biocide efficacy test items
- Improve the exemption procedure for biocidal efficacy test items.

For details, please visit the link below:

https://www.nier.go.kr/NIER/cop/bbs/selectNoLoginBoardList.do (No. 1537)



韩国·《化学物质的注册与评估法案》部分修订案

2024年1月9日,根据19964号公告, 韩国环境部发布了《化学物质的注册与评估法案》的部分修订案,主要内容包括:

允许环境部向获得毒理数据使用权限的企业收取数据使用费,并制定减免全部或部分数据使用费制度。

2024 年 2 月 6 日,根据 20232 号公告, 韩国环境部发布了《化学物质的注册与评估法案》的部分修订案,主要内容包括:

将原毒性物质类别区分为对人体有急性危害的物质、对人体有慢性危害的物质、对 生态有危害的物质;新增了危害性不明确 物质的定义;在确认物质无危害性之前, 假定物质有危害,并采取适当措施,防止 对人体健康或环境造成损害。

新化学物质申报的生产或者进口量将从每年100公斤调整为1吨,环境部将审查新

化学物质申报时提交的数据,生产同物质的企业都可以向环境部附上公开化学物质信息的证明文件,要求任何人发现数据泄露(例如受保护数据泄露)应立即向环境部通报相关事宜。

点评:注册申请人向环境部购买数据时,可提前确认申请人是否时小企业,是否购买脊椎动物替代试验数据等,之后也可向环境部确认数据使用费。

此次危害化学物质的分类有很大变动,这有可能要求企业对原有的物质分类重新管理,并赋予对应的新的物质识别编码。因新化学物质申报的吨位量调整至1吨,增加申请资料要求,如危害分类相关证明资料等。

详情请点击以下链接:

https://www.law.go.kr/nwRvsLsPop.do?pg=2&chrldx=0&lsKndCd=&cptOfi=1480000&searchType=lsNm&lsNm=&pspubdt=&pepubdt=&pspubno=&pepubno=(第22号和第38号)

South Korea · Amendment to the *Act on Registration and Evaluation of Chemical Substance*

On January 09, 2024, in accordance with Announcement No. 19964, the Ministry of the Environment of Korea issued a partial amendment to the *Act on Registration and Evaluation of Chemical Substance*, which includes the following main points:

The Ministry of the Environment is allowed to collect data use fees from companies that have been granted access to toxicological data, and establish a system to reduce or waive all or part of the data use fees.

On February 06, 2024, in accordance with Announcement No. 20232, the Ministry of the Environment of Korea issued a partial amendment to the *Act on Registration and Evaluation of Chemical Substance*, which includes the following main points:

The former categories of toxic substances are distinguished into substances that are acutely hazardous to human beings, substances that are chronically hazardous to human beings, and substances that are ecologically hazardous. A new definition of substances with unclear hazards is added. Substances are presumed to be hazardous until they are confirmed to be non-hazardous and appropriate measures are taken to prevent damage to human health or the environment.

The declared production or import volume of new chemical substances will be adjusted from 100 kg to 1 ton per year. The Ministry of the Environment will review the data submitted in the declaration of new chemical substances, and any company that produces the same substance can submit to the Ministry of the Environment a document certifying the disclosure of information on chemical substances. Anyone who becomes aware of a data breach (e.g. a breach of protected data) shall immediately notify the Ministry of the Environment of the matter.

Comments: When an applicant for registration purchases data from the Ministry of the Environment, it is possible to confirm in advance whether the applicant is a small business, and whether he wants to purchase the data of vertebrate substitution test. Afterwards, it is also possible to confirm the data usage fee from the Ministry of the Environment.

The classification of hazardous chemical substances has changed significantly this time, which may therefore require companies to re-manage the original classification of substances and assign corresponding new substance identification codes. Due to the adjustment of the declared tonnage amount for new chemical substances to 1 ton, the requirements for application documents, such as hazard-classification-related supporting documents, have been added.

For details, please visit the link below:

https://www.law.go.kr/nwRvsLsPop.do?pg=2&chrldx=0&lsKndCd=&cptOfi=1480000&searchType=lsNm&lsNm=&pspubdt=&pspubdt=&pspubno=&pepubno= (No. 22&38)



韩国·《毒性物质清单公告》更新

2024年1月10日,根据第2024-3号公告,韩国环境科学院(NIER)发布了《毒性物质清单公告》更新,修正了3种毒性物质的化学物质名称,并新增了39种毒性物质。

2024年2月13日,根据第2024-15号公告,韩国环境科学院(NIER)发布了《毒性物质清单公告》更新,修正了第2024-3

号公告内容, 更改为"2024-1-1174"栏 至"2024-1-1212"栏。

点评:在韩国境内生产或进口供应化学品给下游的企业,需要关注 NIER 更新的毒性物质清单,按照《化学物质管理法案》,及时提交化学物质明细表,办理毒性物质的进口申报、危险化学物质经营许可等。

详情请点击以下链接:

https://www.nier.go.kr/NIER/cop/bbs/selectNoLoginBoardList.do?bbsId=BBSMSTR 000000000 031&menuNo=13001(第 1549 和 1567 号)

South Korea · Update of the *Announcement of List of Toxic Substances*

On January 10, 2024, in accordance with Announcement No. 2024- 3, the National Institute of Environmental Research, Republic of Korea (NIER) issued an update to the *Announcement of List of Toxic Substances*, in which the chemical substance names of 3 toxic substances are modified and 39 new toxic substances are added.

On February 13, 2024, in accordance with Announcement No. 2024-15, NIER issued an update to the *Announcement of List of Toxic Substances*, in which the contents of Announcement No. 2024-3 are modified and

the column "2024-1-1174" is changed to the column "2024-1-1212".

Comments: enterprises manufacturing or importing chemicals for downstream use in Korea need to pay attention to NIER's updated list of toxic substances, and submit the detailed list of chemical substances in a timely manner in accordance with the *Chemical Substances Control Act*, and handle the import notification of toxic substances, hazardous chemical substance business license, and so on.

For details, please visit the link below:

https://www.nier.go.kr/NIER/cop/bbs/selectNoLoginBoardList.do?bbsId=BBSMSTR 000000000 031&menuNo=13001 (No. 1549&1567)

韩国、《化学品分类及标签规定》更新

2024年1月10日,根据第2024-4号公告,韩国环境科学院(NIER)发布了《化学品分类及标签规定》部分修订案,修正了4种毒性物质和3种事故应急物质,删除了1种毒性物质,同时新增了39种毒性物质的分类信息。

2024年1月12日,根据第2024-6号公告,韩国环境科学院(NIER)发布了《化学品分类及标签规定》部分修订案,修正了第2023-65号公告内容,修正了毒性物质"97-1-119"的危害分类信息。

2023 年 2 月 13 日,根据第 2024-16 号公告,韩国环境科学院(NIER)发布了《化学品分类及标签规定》部分修订案,修正了第 2024-4 号公告内容,更改为"2024-1-1174"栏至"2024-1-1212"栏。

点评:在韩国境内生产或进口供应毒性物质或含有毒性物质的化学品 给下游的企业,需要关注 NIER 更新的危害分类及标签结果,及时更新 MSDS 和标签,并和NIER 的结果保持一致。

详情请点击以下链接:

South Korea · Update of the *Regulations on Classification and Labeling of Chemicals*

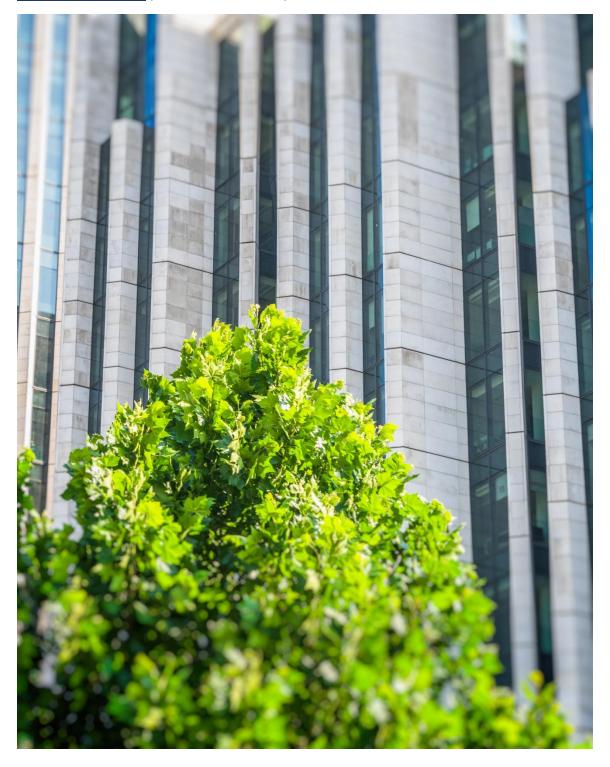
On January 10, 2024, in accordance with Announcement No. 2024- 4, NIER issued a partial amendment to the *Regulations on Classification and Labeling of Chemicals*, in which 4 toxic substances and 3 accident-response substances are amended, 1 toxic substance is deleted, and categorized information for 39 toxic substances is added.

On January 12, 2024, in accordance with Announcement No. 2024-6, NIER issued a partial amendment to the *Regulations on Classification and Labeling of Chemicals*, in which the contents of Announcement No. 2023-65 and the hazard classification information of toxic substance "97-1-119" are amended.

On February 13, 2023, in accordance with Announcement No. 2024-16, NIER issued a partial amendment to the *Regulations on Classification and Labeling of Chemicals*, in which the contents of Announcement No. 2024-4 are amended and the column "2024-1-1174" is changed to column "2024-1-1212".

Comments: Enterprises that produce or import toxic substances or chemicals containing toxic substances for downstream supply in South Korea need to pay attention to the hazard classification and labeling results updated by NIER, update MSDS and labeling in time, and keep consistent with the results of NIER.

For details, please visit the link below:



韩国·《化学物质管理法案》施行细则部分修订案

2024年2月6日,根据20231号公告, 韩国环境部发布了《化学物质管理法案》 施行细则的部分修订案,主要内容包括:

危险化学品操作设施及其相关检验结果的报告主体变更为进行检验的检验机构;对于仅被归类为对人体有慢性危害的危险化学品的操作设施,将免于定期检验;经营被指定的危险化学品的企业需向环境部申报。在国外生产并进口到韩国的化学品可以指定满足一定的要求的国内唯一代理人,代替进口商完成化学物质确认申请、许可证申请等业务。

点评:此次危害化学物质的分类有很大变动,这有可能要求企业对原有的物质分类重新管理,并赋予对应的新的物质识别编码。全量出口的化学物质和化学试剂会被简化注册/申报资料。在此法案下也新增了境内唯一代理人制度,化学物质确认申请和许可证办理可以通过被指定的境内代理人来完成。

详情请点击以下链接:

https://www.me.go.kr/home/web/law/list.do?pagerOffset=10&maxPageItems=10&maxIndexPages=10&searchKey=&searchValue=&menuId=10525&orgCd=&condition.typeCode=law (第 225 号)

South Korea · Amendment to enforcement rules of the *Chemical Substances Control Act*

On February 06, 2024, in accordance with Announcement No. 20231, the Ministry of the Environment of Korea issued a partial amendment to enforcement rules of the *Chemical Substances Control Act*, which includes the following main points:

The former categories of toxic substances are distinguished into substances that are acutely hazardous to human beings, substances that are chronically hazardous to

human beings, and substances that are ecologically hazardous. Hazardous chemical substances are categorized as: substances that pose an acute hazard to humans, substances that pose a chronic hazard to humans, substances that pose an ecological hazard, and accident response substances. It is expressly specified that waste under the *Waste Management Act* is excluded from the application of this Act. Hazardous

chemicals used in the daily lives of consumers are exempt from their general operating and regulatory duties. Prohibited, restricted or license-required chemical substances that do not circulate domestically and are exported in full quantities, as well as chemical reagents used for experimental, research and testing may be subject purposes, registration/declaration system for special

The reporting entity for hazardous chemical operation facilities and their related test results will be changed to the testing organization that conducts the test. Operation facilities for hazardous chemicals categorized only as chronic hazards to human beings will be exempted from periodic testing. Companies dealing with the designated hazardous chemicals will be required to report to the Ministry of the Environment. Importers of chemicals

manufactured abroad and imported into Korea can appoint a sole domestic agent who meets certain requirements to complete chemical substance confirmation applications, license applications, etc. on behalf of the importer.

Comments: The classification of hazardous chemical substances has changed significantly this time, which may therefore require companies to re-manage the original classification of substances and assign corresponding new substance identification codes. Chemical substances and chemical reagents exported in full volume will be subject to simplified registration/declaration information. A new domestic sole agent system has also been introduced under this Act, and chemical substance confirmation applications and license processing can be completed through a designated domestic agent.

For details, please visit the link below:

https://www.me.go.kr/home/web/law/list.do?pagerOffset=10&maxPageItems=10&maxIndexPages=10&searchKey=&searchValue=&menuId=10525&orgCd=&condition.typeCode=law (No. 225)



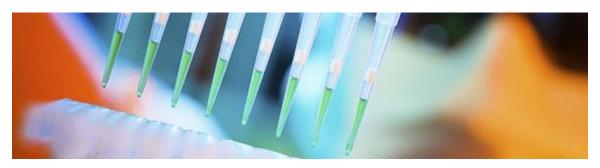
韩国·毒性物质、限制物质、禁止物质及授权类物质的规定吨位量更新

2024年2月16日,根据第2024-38号公告,韩国环境部发布了毒性物质、限制物质、禁止物质及授权类物质的允许吨位量的部分修订案,规定了新增毒性物质(56种)的允许吨位量的上下限。

点评: 对于在韩国境内生产或进口供应 给下游的企业,需要关注环境部更新的毒 性物质的规定吨位量相关规定,在生产、 使用、储存时严格遵守规定吨位量。

详情请点击以下链接:

https://www.me.go.kr/home/web/law/list.do?maxPageItems=10&maxIndexPages=10&searchKey=&searchValue=&menuId=10525&condition.typeCode=admrul&condition.ruleType=&order=&pagerOffset=20(第 1493 号)



South Korea · Update of the specified tonnage quantity of toxic substances, restricted substances, banned substances and authorized class substances

On February 16, 2024, in accordance with Announcement No. 2024-38, the Ministry of the Environment of Korea issued the partial amendment to the specified tonnage quantity of toxic substances, restricted substances, banned substances and authorized class substances, stipulating the upper and lower limits of the permissible tonnage amounts of the newly added toxic substances (56 types).

Comments: enterprises manufacturing or importing chemicals for downstream use in Korea need to pay attention to the regulations related to the specified tonnage of toxic substances updated by the Ministry of the Environment, and strictly comply with the specified tonnage during manufacture, use and storage.

For details, please visit the link below:

https://www.me.go.kr/home/web/law/list.do?maxPageItems=10&maxIndexPages=10&searchKey=&searchValue=&menuId=10525&condition.typeCode=admrul&condition.ruleType=&order=&pagerOffset=20 (No. 1493)

韩国·现有化学物质注册相关公告

2023 年 12 月 18 日,韩国发布了政府支援现有化学物质注册咨询服务和危害性测试数据的现有化学物质清单。

2024 年 1 月 5 日,韩国发布了风险评估报告的暴露场景示例(DB)和 Use-map示例。

2023年1月16日,韩国环境部公布了第18次现有化学物质预注册的结果。

2024年1月18日、2月1日、2月26日, 环境部举办了 K-REACH 和 K-CCA 修订案说 明会。 2024年1月24日和2月27日,韩国征集了需要政府支援现有化学物质的注册咨询服务、危害性测试数据和安全评估报告编写服务,以及需要新化学物质的危害性测试数据的韩国中小型企业。

2024年1月29日,韩国发布了中小企业支援项目指南文件。

2024年2月29日,韩国化学物质管理协会(KCMA)发布了指定为2024年度K-REACH和K-BPR相关政府支援项目的执行机构。

详情请点击以下链接:

https://www.chemnavi.or.kr/chemnavi/spboard/notice.do

South Korea · Announcement on registration of existing chemical substances

On December 18, 2023, Korea released the List of Existing Chemical Substances for which the government supports the registration consulting service, as well as the list of existing chemical substances containing hazard testing data.

On January 5, 2024, Korea published the exposure scenarios (DB) example and the Use-map example for risk assessment report.

On January 16, 2023, the Ministry of Environment of Korea announced the results of the 18th pre-registration of existing chemical substances.

On January 18, February 1, and February 26, 2024, the Ministry of the Environment held

explanatory meetings on K-REACH and K-CCA amendments.

On January 24 and February 27, 2024, Korea called up Korean small and medium-sized enterprises in need of government support for registration consulting services, hazard test data, and safety assessment report preparation services for existing chemical substances, as well as hazard test data for new chemical substances.

On January 29, 2024, Korea released a guideline document for SME support programs.

On February 29, 2024, the Korea Chemicals Management Association (KCMA) unveiled

the designated executing agency for the government support projects related to K-REACH and K-BPR for the year 2024.

For details, please visit the link below:

https://www.chemnavi.or.kr/chemnavi/spboard/notice.do



韩国·生物杀灭剂相关公告

2023 年 12 月 21 日,韩国征集了需要政府支援(批准缓冲期至 2022 年)的"现有生物杀灭物质批准"咨询服务的韩国中小型企业。

2024年1月11日,韩国征集了需要政府 支援生物杀灭物质相关生产危害性测试的 韩国中小型企业。

2024 年 2 月 6 日,韩国征集了需要政府 支援的"2024 年度现有生物杀灭物质批 准"咨询服务的韩国中小型企业。 2024年2月23日,韩国环境部发布了汽车相关生物杀灭处理产品的安全管理指南文件。

2024年2月29日,韩国化学物质管理协会(KCMA)发布了指定为2024年度 K-REACH和 K-BPR 相关政府支援项目的执行机构。

详情请点击以下链接:

https://chemp.me.go.kr/cop/bbs/selectBoardList.do?bbsId=BBSMSTR 000000000001

South Korea · Announcement on biocides

On December 21, 2023, Korea called up its small and medium-sized enterprises (SMEs) that need government support in approving consulting services for the existing biocidal substances with a buffer period until 2022.

On January 11, 2024, Korea called up its small and medium-sized enterprises (SMEs) requiring government support for the production hazard tests related to biocidal substances.

On February 6, 2024, Korea called up its small and medium-sized enterprises (SMEs)

that need government support in approving consulting services for the existing biocidal substances in 2024.

On February 23, 2024, the Ministry of the Environment of Korea issued a safety management guideline for biocidal treatment products related to automobiles.

On February 29, 2024, the Korea Chemicals Management Association (KCMA) unveiled the designated executing agency for the government support projects related to K-REACH and K-BPR for the year 2024.

For details, please visit the link below:

https://chemp.me.go.kr/cop/bbs/selectBoardList.do?bbsId=BBSMSTR 00000000001

日本·日本修改《化审法》相关的化学物质的进口清关手续

随着《化审法》实施条例的部分修订,日本经济产业省于2023年12月4日发布修改"《化审法》相关的化学物质的进口清关手续"(以下称为"通知"),具体修改内容如下:

- 1. 附录 1 的"第 1 类特定化学物质"新增全氟已烷基磺酸(也称为 PFHx S) (仅限于具有 6 个碳原子的支链结构)及其异构体、盐类(PFHxS 或其异构体,或其盐类)。
- 2. 在附录 2 的"使用第 1 类特定化学物质时禁止进口的产品与关税法附录的对比"表格中,使用全氟辛烷磺酸或其盐的"用于电镀的表面处理剂或其制备添加剂"。

- 3. 新增以下使用 PFHxS 及其异构体或其盐 类的产品禁止进口
- 经过处理以具有水性或油性能的织物
- 用于金属加工的蚀刻剂
- 用于制造半导体的蚀刻剂
- 电镀用表面处理剂及其制备添加剂
- 用于制造半导体的抗反射剂
- 半导体用的光刻胶
- 水添加剂、油添加剂和纺织品保护剂
- 灭火器、灭火器用灭火剂及泡沫灭火剂
- 经过水性或油性处理的服装
- 经过处理以具有水或油性能的地板覆盖 物

详情请点击以下链接:

https://www.meti.go.jp/policy/chemical management/kasinhou/todoke/tsukan 231204.pdf

Japan · Japan revises the customs clearance procedures for the import of chemical substances listed in the *Chemical Substance Control Law*

Along with the partial revision of the implementing regulations of the *Chemical Substance Control Law*, the Ministry of Economy, Trade and Industry (METI) of Japan issued a notice on December 4, 2023 (hereinafter referred to as the "Notice") regarding the revision of "customs clearance procedures for the import of chemical substances listed in the *Chemical Substance*

Control Law". The details of the revision are as follows:

1. The perfluorohexylsulfonic acid (also known as PFHx S) (limited to branched chain structure with 6 carbon atoms) and its isomers or salts (PFHxS, its isomers, or its salts) is added to "Class 1 Specified Chemical Substances" in Appendix 1.

- 2. In the table of "comparison of products containing class 1 specific chemical substances, the import of which is prohibited, with the Appendix to the Tariff Law" in Appendix 2, the "surface treatment agents for plating or additives for their preparation" containing perfluorohexylsulfonic acid or its salts is amended as: "surface treatment agents for plating or additives for their preparation".
- 3. The following products containing PFHxS and its isomers or salts are prohibited from import:
- Fabrics treated to have aqueous or oily properties
- Etchant for metal processing

- Etchant for manufacturing semiconductors
- Surface treatment agents for plating or additives for their preparation
- Antireflective agents for the manufacture of semiconductors
- Photoresists for semiconductors
- Water additives, oil additives, and textile protection agents
- Fire extinguishers, extinguishing agents for fire extinguishers, and foam extinguishing agents
- Clothing treated with water or oil properties
- Floor coverings treated to have water or oil properties

For details, please visit the link below:

https://www.meti.go.jp/policy/chemical_management/kasinhou/todoke/tsukan_231204.pdf



日本·日本要求在 SDS 中明确体现适用的法规信息

日本厚生劳动省在 2024 年 1 月 9 日发布一项修订通知,规定了化学物质等相关产品的 SDS 在体现化学物质适用的法律法规名称的同时,还需明确法规要求。适用法律法规除了《工业安全与健康法实施令》的第 18 条(标签对象)和第 18-2 条(通知对象)以外,还包括实施令的附录 1 (危险品)、附录 3 (特定化学物质和允许制造的物质)和附录 6-2 (有机溶剂),《铅中毒预防规则》(附录 4 第 6 项规定的铅和铅化合物),《四烷基铅中毒预防规则》(附录 5 第 1 项规定的四烷基铅)

和第 577-2 条(致癌物质)和第 594-2 条(损害皮肤等的化学物质)。

此外,如果发现已交付 SDS 的产品成分中含有适用于新的法律法规的物质(组分),应尽快更新 SDS,并将记载有新的适用法律法规名称,适用于新规的成分名称及法规的相关要求的 SDS 传递给接收方,同时在传递更新后的 SDS 之前,应努力通过在网站上发布或其他方式将新的适用法律法规以及所涉及的成分名称通知接收方。

详情请点击以下链接:

https://www.mhlw.go.jp/content/11300000/001187657.pdf

$\label{lem:continuous} \textbf{Japan requires applicable regulatory information to be clearly reflected in SDSs}$

The Ministry of Health, Labor and Welfare (MHLW) of Japan issued a revision notice on January 9, 2024, stipulating that SDS of chemical substances and other related products must clearly reflect the names of laws and regulations applicable to the chemical substances, as well as regulatory requirements. In addition to Article 18 (Labeling Objects) and Article (Notification Objects) of the Enforcement Decree of the Industrial Safety and Health Law, the applicable laws and regulations include Appendices 1 (Dangerous Goods), 3 (Specified Chemical Substances Substances Permitted to be Manufactured), and 6-2 (Organic Solvents) of the Enforcement Decree, the Rules for the Prevention of Lead Poisoning (lead and lead compounds specified in Item 6 of Appendix 4), and the *Tetraalkyl Lead Poisoning Prevention Rule* (tetraalkyl lead specified in Item 1 of Appendix 5), and Articles 577-2 (carcinogenic substances) and 594-2 (chemical substances damaging the skin, etc.).

In addition, if it is found that a substance (component) applicable to the new law or regulation is contained in the ingredient of a product whose SDS has been delivered, the SDS shall be updated as soon as possible, and the SDS with the name of the new applicable law or regulation, the name of the ingredient to which the new regulation applies, and the relevant requirements of the regulation shall be transmitted to the recipient. Before

transmitting the updated SDS, efforts shall be made to notify the recipient of the new applicable laws and regulations and the names of the ingredients involved through posting on the website or other means.

For details, please visit the link below:

https://www.mhlw.go.jp/content/11300000/001187657.pdf



日本·化审法数据库(J-CHECK)等多个数据平台更新

CHECK)、日本化学物质风险信息平台数据库(AJCSD)均发布了数据更新。

2024年1月30日,日本化审法数据库(J- (NITECHRIP)和日本东盟化学物质管理

详情请点击以下链接:

J-CHECK(English) (nite.go.jp)

Update history - NITE-CHRIP (NITE Chemical Risk Information Platform)

ASEAN-Japan Chemical Safety Database (ajcsd.org)



Japan · Updates to various data platforms including the Japan Chemical Substance Control Law Database (J-CHECK)

On January 30, 2024, the Japan Chemical Substance Control Law Database (J-CHECK), the Japan Chemical Risk Information

Platform (NITECHRIP), and the ASEAN -Japan Chemical Safety Database (AJCSD) released data update notices.

For details, please visit the link below:

J-CHECK(English) (nite.go.jp)

Update history - NITE-CHRIP (NITE Chemical Risk Information Platform)

ASEAN-Japan Chemical Safety Database (ajcsd.org)

台湾地区·化学品管理局(CHA)发布通知提醒注册人不要多次注册同一物质

台湾地区化学品管理局(CHA)发布了一份通知,提醒单一注册人不要就同一物质提交多次注册以试图通过拆分吨位而降低数据要求。该通知规定,注册人必须将一年内进口或制造的同一种物质的总量合并,包括同一物质在不同货物中出现或进口自不同国外企业制造的物质。CHA要求之前

多次注册同一物质的企业尽快提交合并注册申请,并取消额外的注册编号。必要时,还必须按照有关规定重新申请注册或补充提交的资料。今后,企业应在年度报告中准确记录制造和进口数量。CHA 在注册平台上增加了一个验证机制,以防止同一企业重复提交同一物质的注册申请。

详情请点击以下链接:

https://tcscachemreg.epa.gov.tw/Epareg/content/login/NewsDetail.aspx?k=n&enc=DD03C67FE E74E58B6B21FA9EEE335EE1020368536D17576F

Taiwan · CHA issued a notice warning registrants not to register the same substance more than once

CHA issued a notice warning single registrants not to submit multiple registrations for the same substance in an attempt to reduce data requirements by splitting tonnage. The notice requires registrants to consolidate the total amount of a substance imported or manufactured within a one-year period, including the same substance present in different shipments or the same substance imported from different foreign companies. CHA requires companies that have previously registered the same substance multiple times to submit an

application for consolidated registration as soon as possible and cancel the additional registration numbers. If necessary, they must also reapply for registration or submit additional information in accordance with the relevant regulations. In the future, enterprises shall accurately record the quantities manufactured and imported in their annual reports. CHA has added a verification mechanism to the registration platform to prevent companies from repeatedly submitting registration applications for the same substance.

For details, please visit the link below:

https://tcscachemreg.epa.gov.tw/Epareg/content/login/NewsDetail.aspx?k=n&enc=DD03C67FE E74E58B6B21FA9EEE335EE1020368536D17576F

台湾地区·食品药品监督管理局 (FDA) 提议在化妆品禁用成分清单中增加 9 种物质

台湾地区食品药品监督管理局(FDA)发布了草案,计划将全氟辛烷磺酸(PFOS)、全氟辛酸(PFOA)和其他七种物质列入化妆品禁用成分清单,并修订另外两项内容,目前正在征求反馈意见。

- (1) 氨基己酸及其盐类:
- (2) 3- and 4-(4-Hydroxy-4-methylpentyl) cyclohex-3-ene-1-carbaldehyde;
- (3) 2, 6-Dihydroxy-4-methylbenzaldehyde (苔黑醛);
- (4) 3-Chloro-2 6-Dihydroxy-4methylbenzaldehyde (氯化苔黑醛);
- (5) 全氟辛烷磺酸 (PFOS) 及其盐类, 全氟辛烷磺酸钾、全氟辛烷磺酸二乙醇胺、 全氟辛烷磺酸铵和全氟辛烷磺酸锂:

- (6) 十五氟辛酸铵盐;
- (7) 全氟辛酸 (PFOA);
- (8) 十一氟癸酸(PFDA)及其盐十一氟癸酸铵和十一氟癸酸钠;
- (9) 全氟壬酸及其钠盐和铵盐。

修订后的清单于2023年12月13日公布, 预计将于2024年7月1日生效。

该草案还建议增加豁免以便允许使用经FDA批准的人类细胞、组织和产品。

该草案还将禁止在所有化妆品中使用锆及 其化合物。这些物质目前已被禁止用于喷 雾化妆品。

FDA 在 2 月 15 日前接受评论。

详情请点击以下链接:

https://www.fda.gov.tw/tc/newsContent.aspx?cid=5072&id=30290

Taiwan · Food and Drug Administration (FDA) proposes to add 9 substances to the list of banned cosmetic ingredients

FDA of Taiwan has released a draft that plans to add perfluorohexylsulfonic acid (PFOS), perfluorooctanoic acid (PFOA), and seven other substances to the list of banned cosmetic ingredients, and to revise two other items. Feedback is currently being sought.

(1) Aminocaproic acid and its salts;

- (2) 3- and 4-(4-Hydroxy-4-methylpentyl) cyclohex-3-ene-1-carbaldehyde;
- (3) 2, 6-Dihydroxy-4-methyl-benzaldehyde (atranol)
- (4) 3-Chloro-2 6-Dihydroxy-4-methylbenzaldehyde (chloroatranol)
- (5) Perfluorohexylsulfonic acid (PFOS) and its salts, potassium perfluorooctane sulfonate,

perfluorooctane sulfonate diethanolamine, perfluorooctane sulfonate ammonium and perfluorooctane sulfonate lithium;

- (6) Ammonium pentadecafluorooctanoate;
- (7) Perfluorooctanoic acid (PFOA);
- (8) Undecafluorodecanoic acid (PFDA) and its salts, ammonium undecafluorodecanoate and undecafluorodecanoic acid sodium;
- (9) Perfluorononanoic acid (PFNA) and its sodium and ammonium salts.

The revised list was published on December 13, 2023 and is expected to enter into force on July 1, 2024.

The draft also proposes to add exemptions to allow the use of FDA-approved human cells, tissues, and products.

The draft would also ban the use of zirconium and its compounds in all cosmetics. These substances are currently banned for use in aerosol cosmetics.

The FDA is accepting comments until February 15th.

For details, please visit the link below:

https://www.fda.gov.tw/tc/newsContent.aspx?cid=5072&id=30290



台湾地区·氢氟碳化物管理加强

台湾地区环境部(MoE)已根据《斯德哥尔摩公约》制定持久性有机污染物(POPs)管理计划,包括全氟辛烷磺酸(PFOS)、全氟辛酸(PFOA)和全氟已烷磺酸(PFHXS)等全氟烷基物质(PFAS)。

MOE 将与其他十个部门和委员会合作, 实现五个主要目标:管理污染源、控制污染扩散、整合国际法规、控制这些物质在 工业中的使用、发布可能产生的风险。

各部门将对相关规定进行滚动审查和修改。 MoE 表示,还将制定抽样和检测方法, 以监测和了解环境、产品和食品中 PFAS 的存在。

此外,MoE 将鼓励业界自愿减少使用 PFAS 或使用 PFAS 的替代品,并加强与各 利益相关方的沟通,以保护人类健康。

2023 年 11 月 21 日, MoE 公布了《氢氟碳化物管理办法》草案及《蒙特利尔议定书列管之高温暖化潜势温室气体氢氟碳化物种类》草案。根据公告, 从 2024 年起,

台湾地区将严格控制氢氟碳化物的消费量,确保其低于设定的基准量。该基准量定为24,523.8642 千公吨二氧化碳当量。之后这一限制将逐渐加严,自2045年1月1日起,每年不得超过基准量的20%。并且自2024年1月1日起氢氟碳化物禁止生产。

厂商应在取得氢氟碳化物核配资格及核配量后,自行或委托供应商向主管机关申请核发输出入许可证,办理输出(出口)或输入(进口)作业。当年累计输入量扣除输出量大于核配量者,主管机关应驳回该次输入许可申请。

持有核配量的厂商应于每年1月、4月、7月、10月底前,向主管机关申报上一季执行实绩,并提交相关证明文件,如采购的氢氟碳化物品名、数量、来源、使用量、用途说明、库存量、使用情形等。供应商应申报输入与输出的氢氟碳化物品名、数量、来源、销售量、库存量等资料。

公告还详细列出了蒙特利尔议定书新加入 管理的 18 种氢氟碳化物。

详情请点击以下链接:

https://enews.moenv.gov.tw/Page/3B3C62C78849F32F/d7a89e44-5ee7-44c6-b834-d1607eaef527

https://enews.moenv.gov.tw/DisplayFile.aspx?FileID=76763464AE1E1257

Taiwan · Strengthening of HFC management

MoE has developed a management plan for persistent organic pollutants (POPs), including perfluoroalkylated substances (PFAS) such as perfluorohexylsulfonic acid (PFOS), perfluorooctanoic acid (PFOA), and

perfluorohexanesulfonic acid (PFHxS), in accordance with the *Stockholm Convention*.

MoE will work with ten other departments and commissions to accomplish five main goals: Manage sources of pollution; Control the spread of pollution; Integrate international regulations; Control the use of these substances in industry; Publish the risks that may arise.

The departments will review and revise the relevant regulations on a rolling basis. MoE indicated that sampling and testing methods will also be developed to monitor and understand the presence of PFAS in the environment, products and food.

In addition, MoE will encourage industry to voluntarily reduce the use of PFAS or use alternatives to PFAS, and enhance communication with various stakeholders to protect human health.

On November 21, 2023, the MoE published the Draft *HFC Management Approach* and the Draft *Types of High-temperature Warming Potential Greenhouse Gases (i.e. HFCs) Regulated under the Montreal Protocol.* According to the announcement, starting from 2024, Taiwan will strictly control the consumption of HFCs to ensure that it is below a set baseline amount. The baseline is set at 24,523.8642 kilo metric tons of carbon dioxide equivalent. This limit will be gradually tightened to 20% of the baseline from January 1, 2045 onwards. As of January 1, 2024, HFC production was banned.

After obtaining the qualification authorized quantity of HFCs, the manufacturer shall apply to the competent authority for the issuance import/export license by itself or commissioning a supplier. Then, he can undertake the export or import businesses. The competent authority shall reject the application for an import license if the cumulative imported quantity minus the exported quantity is greater than the authorized quantity in the same year.

The manufacturer holding the authorized quantity shall declare to the competent authority the actual performance of the previous quarter before the end of January, April, July and October of each year, and submit relevant supporting documents, such as the name, the quantity, the source, the amount used, the description of the use, the inventory, and the use situation of the purchased HFCs. Suppliers shall declare the name, quantity, source, sales volume, inventory, and so on of the imported and exported HFCs.

The announcement also lists in detail the 18 HFCs newly added to the Montreal Protocol for management.

For details, please visit the link below:

https://enews.moenv.gov.tw/Page/3B3C62C78849F32F/d7a89e44-5ee7-44c6-b834-d1607eaef527

https://enews.moenv.gov.tw/DisplayFile.aspx?FileID=76763464AE1E1257



台湾地区·食品药品监督管理局计划重组限制化妆品成分清单

台湾地区食品药品监督管理局(FDA)正在计划修订化妆品限制成分清单、创建允许使用的紫外线吸收剂清单、废除特殊用途和抗菌成分清单,并正在进行公众咨询。如果该计划生效,新的清单将使台湾地区与欧盟、美国和东盟国家使用的化妆品成分清单保持一致。

在1月4日的公告中,FDA 提议废除化妆品特定用途成分清单——染发剂例如酸性红91、防晒霜和止汗除臭剂,如氯化铝。防晒剂将被转移到新制定的化妆品紫外线吸收剂草案清单中,二氧化钛也将添加进这个清单。特殊用途化妆品清单上的其他122 种物质将转移到修订后的化妆品限制成分清单中。目前列入化妆品抗菌清单的物质也将移至限制成分清单,并取消抗菌清单。

FDA 还提议对以下物质的使用限制进行修改:

- (1) 尿囊素:
- (2) 无机亚硫酸盐和重亚硫酸盐;
- (3) 巯基乙酸及其盐类;
- (4) 氢氧化钾或氢氧化钠;
- (5) 氢氧化锂:
- (6) 1,3-苯二酚。

FDA 还对限制成分清单提出了许多其他修订,包括删除重复条目和更正成分名称。

征求意见的截止日期为2024年3月5日。 修订后的清单预计将于2024年7月1日 生效。

详情请点击以下链接:

https://www.fda.gov.tw/tc/newsContent.aspx?cid=5072&id=30314

https://www.fda.gov.tw/tc/newsContent.aspx?cid=5072&id=30315

https://www.fda.gov.tw/tc/newsContent.aspx?cid=5072&id=30316

https://www.fda.gov.tw/tc/newsContent.aspx?cid=5072&id=30317

Taiwan · FDA plans to reorganize the list of restricted cosmetic ingredients

FDA of Taiwan is planning to revise the list of restricted cosmetic ingredients, create a list of permitted ultraviolet absorbers, and abolish the list of special-use and antimicrobial ingredients, and is conducting a public consultation. If the plan goes into effect, the new list will bring the cosmetic ingredient list used in Taiwan Region in line

with that used in the European Union (EU), the United States (U.S.), and ASEAN countries.

In the January 4 announcement, FDA proposed to repeal the list of cosmetic ingredients for specific uses - hair dyes such as acid red 91, sunscreens and antiperspirant deodorants such as aluminum chloride.

Sunscreens will be transferred to the newly developed draft list of UV absorbers for cosmetics, and titanium dioxide will also be added to this list. The other 122 substances on the list of special-use cosmetics will be moved to the revised list of restricted cosmetic ingredients. Substances currently on the list of cosmetics antimicrobial ingredients would also be moved to the list of cosmetics antimicrobial ingredients would be eliminated.

FDA is also proposing to revise the restrictions on the use of the following substances:

(1) Allantoin;

(2) Inorganic sulfites and bisulfites;

- (3) Mercaptoacetic acid and its salts;
- (4) Potassium hydroxide or sodium hydroxide;
- (5) Lithium hydroxide;
- (6) 1, 3-benzenediol.

FDA is also proposing numerous other revisions to the list of restricted ingredients, including deletion of duplicate entries and correction of ingredient names.

The deadline for comments is March 05, 2024. The revised list is expected to take effect on July 1, 2024.

For details, please visit the link below:

https://www.fda.gov.tw/tc/newsContent.aspx?cid=5072&id=30314

https://www.fda.gov.tw/tc/newsContent.aspx?cid=5072&id=30315

https://www.fda.gov.tw/tc/newsContent.aspx?cid=5072&id=30316

https://www.fda.gov.tw/tc/newsContent.aspx?cid=5072&id=30317



台湾地区·对使用危险化学品的工厂的指导意见发布

台湾地区台中劳动局发布了指导意见《工厂处理和使用危险物品的安全注意事项》,协助工厂安全使用和处置有害物质,为工人安全操作和保护提供指导。

该指南对公司的要求如下:

- (1)向有关监管部门申报使用的化学品 和有害物质;
- (2) 入库时检查物品的名称和数量:
- (3) 确保包装密封完好。

劳动局建议,为了减少现场储存的有害物质的数量,在工作场所的有害物质的数量 应该只够半天的使用。储存地点应独立于 厂房,容器应由不与有害物质发生化学反 应的材料制成。有机过氧化物应单独存放,不得与易燃物质存放在一起。具有危险特性的化学品应相应地贴上标签,并将相关的安全数据表(SDS)放在易于获取的位置,并至少每三年更新一次。

工厂在引进或修改使用危险化学品的工艺前,应当对职业事故风险进行评估并采取预防措施,确保工人接受相关培训。此外,雇主应分析和评估使用的原材料的危害和反应特性,并采取必要的预防措施,包括为工人提供个人防护装备。还应设置检漏仪,用于预防液体有害物质泄漏。有火灾和爆炸危险的工序和场所应纳入工厂的职业安全卫生管理计划,由公司定期检查设备和操作标准,并进行安全演习。

详情请点击以下链接:

https://www.doli.taichung.gov.tw/3271951/post

Taiwan · Guidance for factories using hazardous chemicals is issued

The Taichung Bureau of Labor Affairs (TBLA) has issued the *Safety Precautions for Handling and Using Hazardous Materials in Factories* to assist factories in the safe use and disposal of hazardous substances and to provide guidance for the safe operation and protection of workers.

The guideline requires companies to do the following:

(1) Declare chemicals and hazardous substances used to the relevant regulatory authorities;

- (2) Check the names and quantities of items during warehousing;
- (3) Ensure that packaging is well sealed.

TBLA recommends that in order to reduce the amount of hazardous substances stored on site, the amount of hazardous substances in the workplace shall be sufficient for only half a day's use. The storage location shall be independent of the plant and the containers shall be made of materials that do not react chemically with the hazardous substances. Organic peroxides shall be stored separately and not together with flammable substances. Chemicals with hazardous characteristics

shall be labeled accordingly and the relevant Safety Data Sheets (SDS) shall be kept in an easily accessible location and updated at least once every three years.

Factories shall assess the risk of occupational accidents, take precautionary measures and ensure workers receive relevant trainings before introducing or modifying processes that use hazardous chemicals. In addition, employers shall analyze and assess the hazard and reaction characteristics of the raw materials used and take the necessary

precautions, including the provision of personal protective equipment for workers. Leak detectors shall also be installed for the prevention of leakage of liquid hazardous substances. Processes and locations with fire and explosion hazards shall be included in the factory's occupational safety and health management program, with regular inspections of equipment and operating standards and safety drills conducted by the company.

For details, please visit the link below:

https://www.doli.taichung.gov.tw/3271951/post



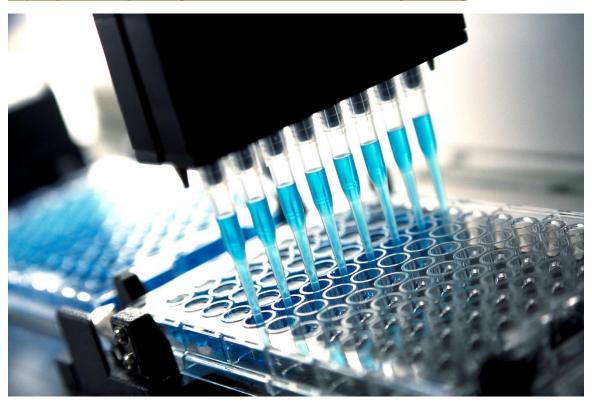
台湾地区·台湾地区拟增列三种药品为第四级管制药品原料药

2024年2月26日,台湾地区卫生福利部对《管制药品分级及品项》进行修订,增列三种药品为第四级管制药品原料药,包

括 3-Oxo-2-phenylbutanamide 、 N-Methylpseudoephedrine 和 MDP2P methyl glycidic acid。

详情请点击以下链接:

https://gazette.nat.gov.tw/egFront/detail.do?metaid=147626&log=detailLog



Taiwan · Taiwan proposes to add three additional drugs as level 4 controlled drug ingredients

On February 26, 2024, MOHW of Taiwan revised the *Classification and Items of Controlled Drugs* to add three additional drugs as level 4 controlled drug ingredients,

including 3-Oxo-2-phenylbutanamide, N-Methylpseudoephedrine, and MDP2P methyl glycidic acid.

For details, please visit the link below:

https://gazette.nat.gov.tw/egFront/detail.do?metaid=147626&log=detailLog

台湾地区·既有物质标准登录即将达到截止日期

2021 年 11 月 23 日,《新化学物质及既有化学物质资料登录办法》正式发布,登录办法最大的变化就是延长了既有物质标准登录的截止期。第一批既有物质所有吨位段的标准登录截止期为 2024 年 12 月 31 日。

台湾化学品管理局称:由于主管机构需要时间来审查提交的材料,以确保它们在年底前注册,所以建议登录人"不晚于2024年上半年"提交标准登录档案。

详情请点击以下链接:

https://www.tcsb.gov.tw/cp-21-5578-1eb9d-1.html

https://product.enhesa.com/1015942/taiwan-chemicals-administration-urges-companies-to-register-priority-chemicals-by-midyear



Taiwan · Approaching registration deadline of priority existing chemicals (PECs)

On November 23, 2021, the *New Chemicals* and *Existing Chemicals Registration Management Approach* was issued. The biggest change in the registration management approach is to extend the deadline for the registration of existing chemicals. The deadline of priority existing chemicals (PECs) registration is December 31, 2024.

According to CHA, the government needs time to review submissions to ensure they are registered before the end of the year. Because of this, the administration is recommending that registrants submit their dossiers no later than the first half of 2024.

For details, please visit the link below:

https://www.tcsb.gov.tw/cp-21-5578-1eb9d-1.html

https://product.enhesa.com/1015942/taiwan-chemicals-administration-urges-companies-to-register-priority-chemicals-by-midyear

菲律宾·化学品和化学物质名录 (PICCS) 新增 162 个物质

菲律宾化学品和化学物质名录(PICCS)列出了在菲律宾使用、进口、分销、加工、制造、储存、出口、处理或运输的所有现有物质。进口和生产列入 PICCS 的化学品的公司不需要注册或取得许可证。菲律宾环境和自然资源部环境管理局(DENR-EMB)公布了从 2022 年开始增加的 96 种化学品和从 2023 年开始增加的 66 种化学品的清单。PICCS 上的化学品总数达到

22,439。DENR-EMB 正在就将 162 种物质添加到菲律宾化学物质名录 (PICCS) 征求意见, 但没有给出最后期限。

点评:请企业及时关注 PICCS 的增补,一旦列入 PICCS,物质不需要注册或许可申请就可以进入菲律宾市场,将极大地节省产品进入菲律宾的合规成本和时间。

详情请点击以下链接:

https://chemical.emb.gov.ph/wp-content/uploads/2023/11/PICCS2023Final 13102023-Final.pdf

https://chemical.emb.gov.ph/wp-content/uploads/2023/11/PICCS2022Final_26072023-DAO.pdf

Philippines · 162 new substances are added to the Philippine Inventory of Chemicals and Chemical Substances (PICCS)

PICCS lists all existing substances used, imported, distributed, processed, manufactured, stored, exported, handled, or transported in the Philippines. Companies importing or manufacturing the chemicals in PICCS are not required to register for the substance or obtain a license. DENR-EMB has published a list of 96 chemicals added since 2022 and 66 chemicals added since 2023. A total of 22,439 chemicals are listed in the PICCS. DENR-EMB is seeking

comments on the addition of 162 substances to the PICCS, but no deadline has been given.

Comments: Enterprises are requested to keep an eye on the additions to the PICCS. Once included in the PICCS, the substances do not need to be registered or licensed before entering the Philippine market, which will greatly save compliance costs and time for products to enter the Philippines.

For details, please visit the link below:

https://chemical.emb.gov.ph/wp-content/uploads/2023/11/PICCS2023Final_13102023-Final.pdf

 $\frac{\text{https://chemical.emb.gov.ph/wp-content/uploads/2023/11/PICCS2022Final_26072023-DAO.pdf}{\text{DAO.pdf}}$

菲律宾·菲律宾提出玩具和儿童保育用品授权新规则

菲律宾食品和药品管理局(FDA)正在征求公众对玩具和儿童保育用品授权规则草案的意见。《签发玩具及儿童保育用品授权规则及条例》(临时标题)旨在:

- (1) 更新并符合适当的法律、当地和国际标准;
- (2) 建立产品通报程序;
- (3) 确定豁免产品的认证程序;
- (4) 更新标签要求, 使之与国家规则保持一致;
- (5) 规定持有上市许可的公司的责任和 义务,以确保物品在整个生命周期内的安 全性、有效性和质量。

规则草案适用于生产、包装、进出口、销售、分销、使用、测试、推广、广告和赞助产品的企业,其分类如下:

(1) 目标人群在14岁以下儿童的玩具:

- (2) 家庭室内、室外用秋千、滑梯及类似活动玩具;
- (3) 专为促进睡眠、喂食和卫生而设计或用于直接接触口腔,或帮助儿童吸吮或出牙的儿童保育用品。

征求意见的截止日期为 2024 年 1 月 15 日。 新规定将在官方公报或其他全国性公报公 布 15 天后生效。在条例生效后 6 个月内 会发布指导意见或实施细则。过渡期不超 过 6 个月,从指导意见或实施细则生效之 日起算。

另外,FDA 通过其化妆品和消费类有害物质管理和研究中心(CCHUHSRR)表示,目前正在研究和测试市场上玩具和儿童用品中的邻苯二甲酸盐/酯。FDA 表示,将利用调查结果更新这些产品中某些邻苯二甲酸盐/酯的限值。

FDA 补充将在 2024 年将其许可申请(以及其他 CCHUHSRR 监管服务)迁移到 FDA服务门户网站。

详情请点击以下链接:

https://www.fda.gov.ph/draft-for-comments-rules-and-regulations-governing-the-issuance-of-authorizations-for-toys-and-childcare-articles/

Philippines · Philippines proposed new rules for authorization of toys and childcare products

The Food and Drug Administration (FDA) of the Philippines is seeking public comments on the draft rule for the authorization of toys and childcare articles. *Rules and Regulations for Issuance of Authorizations for Toys and Childcare* (interim title) seek to:

- (1) Update and conform to appropriate legal, local, and international standards;
- (2) Establish product notification procedures;
- (3) Establish certification procedures for exempted products;

- (4) Update labeling requirements to be consistent with national rules;
- (5) Establish the responsibilities and obligations of companies holding marketing authorizations to ensure the safety, efficacy and quality of articles throughout their life cycle.

The draft rules apply to companies that manufacture, package, import, export, sell, distribute, use, test, promote, advertise, and sponsor products in the following categories:

- (1) Toys whose target population is children under 14 years of age;
- (2) Swings, slides and similar movable toys for indoor (at home) and outdoor use;
- (3) Childcare items designed to promote sleep, feeding, and hygiene or for direct contact with the mouth or to assist children in sucking or teething.

For details, please visit the link below:

The deadline for comments is January 15, 2024. The new regulation will come into force 15 days after its publication in the official bulletin or other national bulletin. Guidance or implementing regulations will be issued within 6 months of the regulations coming into force. The transition period will not exceed 6 months from the effective date of the guidance or implementing regulations.

In addition, FDA, through its Center for Cosmetic and Consumer Hazardous Substances Regulation and Research (CCHUHSRR), said it is currently researching and testing phthalates/esters in toys and children's products on the market. FDA has claimed that it will use the results of the survey to update the limits for certain phthalates/esters in these products.

The FDA added that it would migrate its permit applications (and other CCHUHSRR regulatory services) to the FDA Services Portal in 2024.

https://www.fda.gov.ph/draft-for-comments-rules-and-regulations-governing-the-issuance-of-authorizations-for-toys-and-childcare-articles/



菲律宾·《产品召回指南》修订

菲律宾食品和药品管理局(FDA)提议更 新其一系列健康、个人护理和消费品的召 回指导方针。

FDA 表示, 鉴于自 2016 年 9 月《产品召回指南》生效以来全球贸易和监管格局的变化, 召回系统需要进一步加强。

涵盖的产品类别包括:

- (1) 人用药品和兽药,包括疫苗、生物制品、草药和家庭秘方;
- (2) 预包装加工食品、食品补充剂、添加剂和原料;
- (3) 化妆品、消费类有害物质、日常消费者使用的农药、玩具和儿童保育用品、烟草制品;

(4) 医疗和健康相关设备、辐射发射设备和体外诊断设备。

该制度适用于制造商、贸易商、进口商/ 出口商和零售商,涵盖由上市许可持有人 发起的自愿召回,以及FDA的强制召回。 根据草案,FDA将设立一个产品召回委员 会。上市许可持有人必须在召回后 24 小 时内向FDA提交一份详细报告,监督召回 的有效性,并建立一个追踪受影响产品的 系统。他们还必须每年进行一次模拟召回, 以评估该系统的有效性。

新指南于12月15日以草案形式发布,将在官方公报或其他全国性公报发表后15天生效。FDA将在实施的三年内审查和评价该指南,以确定是否已经实现了预定的目标、并评估其影响和有效性。

详情请点击以下链接:

https://files.chemicalwatch.com/Philippines-

draft_guidance_for_product_recalls.pdf? gl=1*1anasd0* gcl_au*OTUzOTY5MzlyLjE3MDk2OTE_4ODAuMTc0Njk1ODQyNy4xNzA5NzAzOTgxLjE3MDk3MDM5ODU.*_ga*MTQyODlwMjMyMy4xNjk5ODQ1MjMy* ga_SQ9PWWQ2T2*MTcwOTcxMTYxNy45LjEuMTcwOTcxMTYzMC40Ny4wLjA.

Philippines · Revised Guidance on Product Recalls

FDA has proposed to update its recall guidelines for a range of health, personal care and consumer products.

FDA said that the recall system needed to be further strengthened in light of changes in the global trade and regulatory landscape since the *Product Recall Guidelines* came into effect in September 2016.

The product categories covered include:

- (1) Human and veterinary drugs, including vaccines, biologics, herbal remedies, and family recipes;
- (2) Prepackaged processed foods, food supplements, additives and ingredients;
- (3) Cosmetics, consumer hazardous substances, pesticides for everyday consumer use, toys and childcare products, and tobacco products;

(4) Medical and health-related equipment, radiation emitting equipment and in vitro diagnostic equipment.

The system applies to manufacturers, traders, importers/exporters and retailers, and covers voluntary recalls initiated by marketing authorization holders, as well as mandatory recalls by FDA. According to the draft, FDA will establish a product recall committee. Marketing authorization holders must submit a detailed report to the FDA within 24 hours of a recall, monitor the

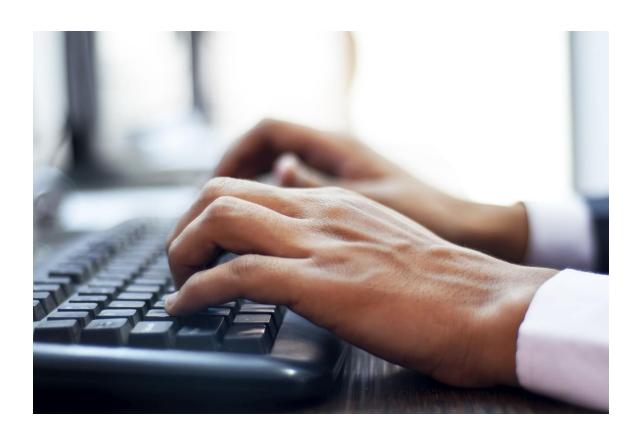
effectiveness of the recall, and set a system to track affected products. They must also conduct an annual mock recall to assess the effectiveness of the system.

The new guidance was released in draft form on Dec. 15 and will take effect 15 days after publication in the official bulletin or other national bulletin. FDA will review and evaluate the guidance within three years of implementation to determine whether the intended goals have been achieved and to assess its impact and effectiveness.

For details, please visit the link below:

https://files.chemicalwatch.com/Philippines-

draft_guidance_for_product_recalls.pdf?_gl=1*1anasd0*_gcl_au*OTUzOTY5MzlyLjE3MDk2OTE_4ODAuMTc0Njk1ODQyNy4xNzA5NzAzOTgxLjE3MDk3MDM5ODU.*_ga*MTQyODlwMjMyMy4xNjk5ODQ1MjMy*_ga_SQ9PWWQ2T2*MTcwOTcxMTYxNy45LjEuMTcwOTcxMTYzMC40Ny4wLjA.



菲律宾 · 化学品豁免指南草案发布

菲律宾环境和自然资源部环境管理局 (DENR-EMB) 发布了《DENR 行政命令 1992-29 (RA 6969) 第 II 章下杂质、副产物、非分离中间体豁免指南》草案。

要申请豁免,需要支付 1,500 比索的费用,公司还必须提供以下材料:

- (1) 签名的请求书;
- (2) 100%混合成分;
- (3) 安全数据表;
- (4) 制造工艺流程:
- (5) 签署的证明信及构成豁免基础的所 有证明文件。

所有申请均应透过网上许可及监察系统 (OPMS) 提交,并会在收到申请后 15 个 工作日内进行审核及评估。 一旦获得批准,这些化学品将不受 RA 6969第II章的限制,不再需要获得许可,但化学品管制令(CCOs)中指定的某些化学品除外。

优先化学品清单(PCL)上不属于草案范围的物质也可以选择申请豁免,但它们必须符合低于或等于混合物浓度 1%的阈值限制。

此外,草案将建立FDA上市后监测系统。

草案将在官方公报或其他全国性公报发表 后 15 天生效。

点评: 相关产品满足豁免条件的企业应及时关注草案的进展,一旦草案生效,应及时递交相关豁免申请资料。

详情请点击以下链接:

https://urldefense.com/v3/ https://chemical.emb.gov.ph/?attachment_id=856 ;!!le6nUkZk!s05Ka6kZWzIZyB76uV1bPR6Ndhi6i3cNbcQxWpzjqv5h0sO8s2m31mYI7HlhXe7NRMDvMM1Ps4ZHz80llBw\$

Philippines · Draft guidance on chemicals exemption was issued

DENR-EMB has issued the Draft *Guideline for Exemption of Impurities, Byproducts, and Non-Separated Intermediates under Chapter II of DENR Administrative Order 1992-29* (RA 6969).

To apply for an exemption, a fee of P1,500 is required and the company must also provide the following:

(1) Signed request form;

- (2) 100% blended ingredients;
- (3) Safety data sheet;
- (4) Manufacturing process flow;
- (5) A signed letter of certification and all supporting documents that form the basis of the exemption.

All applications shall be submitted through the online permitting and monitoring system (OPMS) and will be reviewed and evaluated within 15 working days of receipt.

Once approved, these chemicals will be exempt from Chapter II of RA 6969 and will no longer require a permit, with the exception of certain chemicals designated in Chemical Control Orders (CCOs).

You can also apply for exemptions for substances on the priority chemicals list (PCL) that are not covered by the draft, but they must meet a threshold limit of less than or equal to 1% of the mixture concentration.

In addition, the draft proposed to establish an FDA post-market surveillance system.

The draft will take effect 15 days after publication in the official bulletin or other national bulletin.

Comments: Enterprises whose products meet the exemption conditions shall pay attention to the progress of the draft, and submit the relevant exemption application information in time once the draft comes into effect.

For details, please visit the link below:

https://urldefense.com/v3/_https://chemical.emb.gov.ph/?attachment_id=856_;!!le6nUkZk!s05Ka6kZWzIZyB76uV1bPR6Ndhi6i3cNbcQxWpzjqv5h0sO8s2m31mYI7HlhXe7NRMDvMM1Ps4ZHz80llBw\$



菲律宾·《机密商业信息(CBI)申请指南》草案发布

菲律宾环境和自然资源部环境管理局 (DENR-EMB)发布了一份行政命令草案, 明确了在RA 6969要求的化学评估中要求 提供机密商业(CBI)信息保护的程序。

该草案涵盖涉及保密化学成分的条例和下 列许可的申请:

- (1) PMPIN 及其豁免;
- (2) 优先化学品清单(PCL) 合规认证或 豁免:

(3) 化学品管制令(CCOs)

草案将在官方公报或其他全国性公报发表后 15 天生效。

点评:涉及 CBI 的企业应及时关注草案的进展以及 CBI 保护申请程序的变动,一旦草案落实,及时按照草案调整 CBI 保护申请的材料和流程。

详情请点击以下链接:

https://urldefense.com/v3/_https://chemical.emb.gov.ph/?attachment_id=854_;!!le6nUkZk!s05Ka6kZWzIZyB76uV1bPR6Ndhi6i3cNbcQxWpzjqv5h0sO8s2m31mYI7HlhXe7NRMDvMM1Ps4ZHPGhvP1A\$

Philippines · Draft *Guideline for Chemicals Exemption and Confidential Business Information (CBI) Applications* was released

DENR-EMB has issued a draft administrative order clarifying the process for requesting confidential business (CBI) information protection in chemical assessments required by RA 6969.

The draft covers regulations involving confidential chemical compositions and applications for the following permits:

- (1) PMPIN and its exemptions;
- (2) Priority chemical list (PCL) compliance certifications or exemptions;

For details, please visit the link below:

(3) Chemical control orders (CCOs)

The draft will take effect 15 days after publication in the official gazette or other national bulletin.

Comments: Enterprises involved in CBI shall keep an eye on the progress of the draft and the changes in the CBI protection application process, and adjust the materials and process of CBI protection application in accordance with the draft in a timely manner once the draft is implemented.

https://urldefense.com/v3/ https://chemical.emb.gov.ph/?attachment_id=854 ;!!le6nUkZk!s05Ka6kZWzIZyB76uV1bPR6Ndhi6i3cNbcQxWpzjqv5h0sO8s2m31mYI7HlhXe7NRMDvMM1Ps4ZHPGhvP1A\$

菲律宾·禁化武清单公布

2024年1月23日,菲律宾通过第9571号 法案(HB9571),即《禁止化学武器 法》,旨在履行《化学武器公约》(CWC),禁止开发、生产、获取、储备或保留任何化学武器。HB9571 除罗列了化武相关的禁止行为外,附件同时包含了禁化武清单(Schedule 1,Schedule 2,Schedule 3)。HB9571 涉及义务内容与联合国化学武器公约(CWC)一致。

主要规定如下:

- (1) 禁止向 CWC 公约非缔约国出口和进口 Schedule 1 中的化学品;
- (2) 禁止生产、获取、保留、转让和使用 Schedule 1 中的化学品;
- (3) 禁止大量生产 Schedule 2 中的化学品;

- (4) 对 Schedule 1, Schedule 2, Schedule 3 中的化学品进行现场检查和现场仪器监测等。
- (5) 禁化武清单中的化学品和设施需进行申报,并提供所要求的年度报告。

违法者将面临 12 年至终身监禁的处罚,以及 200 万至 500 万菲律宾比索的罚款。根据该法案,任何违规的化学武器及与之相关的其他工具均应没收归政府所有,销毁或处理的费用应由违规的个人或公司承担。

该法案指定反恐委员会(ATC)为菲律宾 国家化学武器公约机构(PNA-CWC), 后续 PNA-CWC 将发布实施细则和条例, 以确保该法案条款的有效实施。

详情请点击以下链接:

https://www.congress.gov.ph/press/details.php?pressid=12856

Philippines · Publication of the CWC chemicals list

On January 23, 2024, the Philippines approved HB 9571, or the Chemical Weapons Prohibition Act (CWPA), which implements the Chemical Convention (CWC) by prohibiting the development, production, acquisition, stockpiling, or retention of any chemical weapon. In addition to listing the prohibited acts related to CW, HB9571 contains the CWC chemicals list (Schedule 1, Schedule 2, and Schedule 3) through its annex. HB9571 lists the obligations consistent with the

United Nations Chemical Weapons Convention (CWC).

The main provisions are as follows:

- (1) Prohibit the export and import of Schedule 1 chemicals to non-States Parties to the CWC;
- (2) Prohibit the production, acquisition, retention, transfer, and use of Schedule 1 chemicals;

- (3) Prohibit the mass production of Schedule 2 chemicals;
- (4) Perform on-site inspection and on-site instrument monitoring, etc. of chemicals in Schedule 1, Schedule 2, and Schedule 3.
- (5) Declarations shall be made for the chemicals and facilities in the CWC chemicals list, and the required annual reports shall be provided.

Violators face penalties ranging from 12 years to life imprisonment and a fine of PhP 2 million to PhP 5 million. Under the act, any offending chemical weapons and other

instrumentalities associated with them shall be forfeited to the government and the cost of destruction or disposal shall be borne by the offending individual or company.

The act designates the Anti-Terrorism Commission (ATC) as the Philippine National Chemical Weapons Convention Authority (PNA-CWC), which will issue the implementing rules and regulations to ensure the effective implementation of the provisions of the act.

For details, please visit the link below:

https://www.congress.gov.ph/press/details.php?pressid=12856



印度·推迟执行三种物质的质量控制令

1,2023年12月19日,DCPC发布甲苯质量控制令(公报号:CG-DL-E-19122023-250753)。此控制令可称为《2023年甲苯(质量控制)第二次修订令》,是对2021年甲苯质量控制令的修订。生效日期为2024年12月22日。

2,2024年1月31日,DCPC发布通告(公报号:CG-DL-E-31012024-251664), 推迟4种物质的质量控制令的生效日期。 新的生效日期如下:

Morpholine: 2024年8月1日

Methanol: 2024年8月3日

Aniline: 2024年8月3日

Acetic Acid: 2024年8月3日

3,2024年2月27日,DCPC发布通告 (公报号:CG-DL-E-27022024-252419), 发布3种石化产品的质量控制令。自官方 公报公布之日起一百八十天后生效。这3种类型的产品及其实施标准为:

货物或	印度标准号	标准名称
物品		
聚氯乙	IS 17658:2021	聚氯乙烯均
烯均聚		聚物技术规
物		范
聚丙烯	IS 10951: 2020	模塑和挤压
(PP) 材		用聚丙烯
料		(PP)材料
用于模		技术规范
塑和挤		
压		
柴油发	IS 17042 (Part-	柴油发动机
动机-	1): 2018	- NOx 还原
NOx 还		剂 AUS 32 -
原 剂		技术规格
AUS 32		

4,2024年2月27日,DCPC发布通告(公报号:CG-DL-E-27022024-252416),推迟实施3种物质的质量控制令。这三种物质为醋酸乙烯单体,丙烯酸甲酯和丙烯酸乙酯。新的生效日期为2025年3月31日。

详情请点击以下链接:

https://egazette.gov.in/(S(wcfjylab3dtw45fk0fwan4g3))/SearchMenu.aspx



India · India delayed the implementation of quality control orders for three substances

1. On December 19, 2023, DCPC issued the Quality Control Order for Toluene (bulletin No. CG-DL-E-19122023-250753). This control order may be cited as *2023 Second Revision Order of Toluene (Quality Control)*, and is a revision of 2021 Toluene Quality Control Order. The effective date is December 22, 2024.

2. On January 31, 2024, DCPC issued a notice (bulletin No. CG-DL-E-31012024-251664) postponing the effective date of the quality control order for four substances. The new effective dates are listed below:

Morpholine: August 1, 2024

Methanol: August 3, 2024

Aniline: August 3, 2024

Acetic Acid: August 3, 2024

3. On February 27, 2024, DCPC issued a notice (bulletin No. CG-DL-E-27022024-252419) issuing the quality control order for three petrochemical products. It will take effect one hundred and eighty days from the date of publication in the official bulletin. The 3 types of products and their implementation criteria are as follows:

Goods	or	Indian	Name	of
articles		Standard	standard	
		No.		

Polyvinyl chloride homopolym er	IS 17658:202 1	Technical specification for polyvinyl chloride homopolym er
Polypropyle ne (PP) materials For molding and extrusion	IS 10951. 2020	Technical Specification for Polypropyle ne (PP) Materials for Molding and Extrusion
Diesel engine - NOx reducing agent AUS 32	IS 17042 (Part-1): 2018	Diesel engine - NOx reducing agent AUS 32-Technical Specification

4. On February 27, 2024, DCPC issued a notice (bulletin No. CG-DL-E-27022024-252416) postponing the implementation of the quality control order for three substances. The three substances are vinyl acetate monomer, methyl acrylate, and ethyl acrylate. The new effective date is March 31, 2025.

For details, please visit the link below:

https://egazette.gov.in/(S(wcfjylab3dtw45fk0fwan4g3))/SearchMenu.aspx



印度·印度发布 ChemIndia 用户手册

"Chemindia"门户网站是为 DCPC 设计的一个基于网络的综合数据管理系统。其目的是简化相关数据的收集、存储、分析和报告,以利于企业做出决策并监管对于相关法规的合规性。为了便于企业了解此平

台的使用方法,PCPC 发布 ChemIndia 平台的用户手册。此手册对 Chemindia 平台的使用给予了详细指导。ChemIndia 平台和用户手册的链接如下。

详情请点击以下链接:

https://chemindia.chemicals.gov.in/

https://files.chemicalwatch.com/ChemIndia User Manual (PDF).pdf? gl=1*o8c06d* gcl au*NzAzNzkwMDM1LjE3MDk2OTEyMDkuOTkxMzUxMDluMTcwOTY5MTlyNC4xNzA5NjkxMjl4* ga* MjAxMDM2NjMzNS4xNzA5NjkxMjA5* ga SQ9PWWQ2T2*MTcwOTY5MTlwOC4xLjEuMTcwOTY5MjYxNS42MC4wLjA.



India · India released the User's Manual of ChemIndia

The Chemindia portal is a web-based integrated data management system designed for DCPC. It is designed to simplify the collection, storage, analysis and reporting of relevant data, so that businesses can make decisions and monitor compliance with relevant regulations more

easily. To help organizations understand how to use the platform, PCPC has released the user's manual for the ChemIndia platform. This manual provides detailed guidance on the use of the ChemIndia platform. Links to the ChemIndia platform and the user's manual are provided below.

For details, please visit the link below:

https://chemindia.chemicals.gov.in/

https://files.chemicalwatch.com/ChemIndia User Manual (PDF).pdf? gl=1*o8c06d* gcl au*N zAzNzkwMDM1LjE3MDk2OTEyMDkuOTkxMzUxMDluMTcwOTY5MTlyNC4xNzA5NjkxMjl4* ga* MjAxMDM2NjMzNS4xNzA5NjkxMjA5* ga SQ9PWWQ2T2*MTcwOTY5MTlwOC4xLjEuMTcwOTY 5MjYxNS42MC4wLjA.

近期会议活动

2024 第 25 届上海环博会, 2024 年 4 月 18 - 20 日, 上海

https://www.ie-expo.cn/#/home?bd_vid=11414971064912142407

2024 中国无锡生物医药产业博览会,2024年4月18-20日,江苏无锡

www.bmte-expo.com

2024 上海国际农药助剂展览会, 2024 年 4 月 24 - 26 日, 上海

www.rhbyexpo.com

国际(广州)涂料工业展览会,2024年5月15-17日,广东广州

http://www.coatexpo.cn/

2024 上海国际环保展, 2024 年 6 月 3 - 5 日, 上海

http://www.ecotechchina.com/

2024 日本国际制药原料展览会, 2024 年 4 月 17 - 19 日, 日本东京

https://www.cphi.com/japan/en/home.html

KOREA CHEM/KOREA PHARM&BIO 2024, 2024年4月23-26日, 韩国

https://www.koreachem.org/eng/main.asp

2024 欧洲精细化工展览会, 2024 年 6 月 19 - 20 日, 德国杜塞尔多夫

https://www.chemspeceurope.com/#/

Food Contact Regulations Europe 2024, 2024 年 4 月 22 - 23 日, 比利时布鲁塞尔+线上

https://events.chemicalwatch.com/854819/food-contact-regulations-europe-2024

Regulatory Summit Europe 2024, 2024 年 4 月 25 - 26 日, 比利时布鲁塞尔+线上

https://events.chemicalwatch.com/868404/regulatory-summit-europe-2024

Biocides Symposium 2024, 2024 年 6 月 3 - 4 日, 捷克布拉格+线上

https://events.chemicalwatch.com/868608/biocides-symposium-2024

PFAS Global 2024, 2024年6月13日, 线上

https://events.chemicalwatch.com/868407/pfas-global-2024

Upcoming Events

IE expo 2024, 2024.4.18 – 2024.4.20, Shanghai

https://www.ie-expo.cn/#/home?bd_vid=11414971064912142407

China Wuxi biomedicine Industry Expo, 2024.4.18 – 2024.4.20, Jiangsu, Wuxi

www.bmte-expo.com

2024 Shanghai International pesticide Additives Exhibition, 2024.4.24 – 2024.4.26, Shanghai

www.rhbyexpo.com

ICIE 2024, 2024.5.15-2024.5.17, Guangdong, Guangzhou

http://www.coatexpo.cn/

ECOTECH CHINA 2024, 2024.6.3- 2024.6.5, Guangdong, Guangzhou

http://www.ecotechchina.com/

CPHI Japan 2024, 2024.4.17 – 2024.4.19, Japan, Tokyo

https://www.cphi.com/japan/en/home.html

KOREA CHEM/KOREA PHARM&BIO 2024, 2024.4.23 - 2024.4.26, South Korea

https://www.koreachem.org/eng/main.asp

ChemSpecEurope 2024, 2024.6.19 – 2024.6.20, German, Dusseldorf

https://www.chemspeceurope.com/#/

Food Contact Regulations Europe 2024, 2024.4.22 – 2024.4.23, Belgium, Brussels + virtual

https://events.chemicalwatch.com/854819/food-contact-regulations-europe-2024

Regulatory Summit Europe 2024, 2024.4.25 – 2024.4.26, Belgium, Brussels + virtual

https://events.chemicalwatch.com/868404/regulatory-summit-europe-2024

Biocides Symposium 2024, 2024.6.3 – 2024.6.4, Czechia, Prague + virtual

https://events.chemicalwatch.com/868608/biocides-symposium-2024

PFAS Global 2024, 2024.6.13, virtual

https://events.chemicalwatch.com/868407/pfas-global-2024

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