

# 区域间 法规交流快讯

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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

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 下现有化学物质部分修订案中 201 个公开原始的化学物质名称的现有化学物质。

近期，韩国为了更好的实施生物杀灭物质批准和生物杀灭剂批准制度的实施，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。

同时企业应关注韩国环境科学院（NIER）正在修订人体健康的相关测试方法，并已发布一些草案，这些方法均为最新 OECD 测试方法的转化，企业可以适当关注，若正式发布意味着在未来注册过程中和国际接轨的测试方法将被韩国认可。

### 日本

日本《化审法》新增 6 种优先评估化学物质和 8 种被列入数量监测的优先评估化学物质，同时 6 种优先评估化学物质被取消指定，建议企业及时确认并更新信息。

日本发布关于通报一般化学物质、优先评估化学物质及监测化学物质、第二类特定

化学物质及使用第二类特定化学物质产品的制造数量的通知，建议相关企业按照规定在期限内完成通报。

随着需要管理的化学物质数量不断增加，缺乏化学物质的测试结果无法充分进行 GHS 分类的情况也随之增多，为此，日本官方机构联合 JNIOH 和 NITE 合作开展 GHS 分类信息收集项目，并开始接收民间企业提供的用于 GHS 分类项目的测试报告等资料。

### 台湾地区

台湾环保署已经发布了新化学物质和既有物质登记的指南以及危害及暴露评估指南，旨在帮助企业履行《有毒和相关化学物质控制法》（TCSCCA）规定的登记义务。

### 菲律宾

菲律宾环境和自然资源部（DENR）呼吁公司注册塑料包装废物的生产者责任延伸（EPR）计划，敦促相关生产企业负责塑料废物的整个生命周期。

菲律宾固体废物管理委员会近期批准了 54 个州的固体废物管理计划，高度关注固体废物的处理。

### 印度

印度化学和石化部（DCPC）于 2023 年上半年持续发布通告，推迟多种物质质量控制令的实施日期，有的物质是再次推迟执行日期。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。

## Viewpoint

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

### South Korea

South Korean authority revised the *Regulations on Classification and Labeling of Chemicals* and *Results of Hazard Assessment of Chemical Substances*. Companies should pay sustained attention to check whether chemicals involved have been included into the *Toxic Chemicals List* or whether the official classification of the toxic substances has changed in the list, thus taking timely compliance measures, such as updating classifications, MSDS and labels. In addition, companies should focus on the 201 existing chemical substances with the original chemical substance names disclosed in the recently-released partial revision of existing chemical substances under K-REACH.

Recently, in order to effectively implement the approval system of biocidal substances and biocides, South Korea authority has issued a series of guidance documents, suggesting that companies that produce biocidal substances, biocides and domestic chemical products should pay constant attention to relevant approval requirements.

Meanwhile, companies should pay attention to that the National Institute of Environmental Research (NIER) is revising relevant test methods for human health, and has released some drafts. These methods are transformed from the latest OECD test methods, requiring due attentions. Their official release represents that test methods in line with international standards will be recognized by South Korea authority.

### Japan

6 new chemical substances are added in the *Chemical Substance Control Law* of Japan for priority assessment and 8 new chemical substances for the quantity monitoring. Meanwhile, 6 chemical substances are removed from the priority assessment. Companies should confirm and update the information in a timely manner.

The Japanese authority issued a circular on the notification of general chemical substances, chemical substances for priority assessment and monitored chemical substances, Class II specific chemical substances and the manufacturing quantity of products Class II specific chemical substances. Companies concerned should implement the circular within the prescribed time limit.

As the number of chemical substances that need to be managed continues to increase, the failure case regarding GHS classification due to the lack of test results of chemical substances is also increasing. Considering that, the Japanese authority has cooperated with JNIOH and NITE to carry out the GHS classification information collection project and began to receive test reports and other materials provided by private companies for GHS classification projects.

### Taiwan

The Environmental Protection Administration (Taiwan) has issued the guidelines for the registration of new chemical substances and existing substances, as well as the guidelines for hazard and exposure assessment, aiming to help companies fulfill their registration



obligations under the *Toxic and Chemical Substances of Concern Control Act* (TSCCA).

### Philippines

The Department of Environment and Natural Resources (DENR) of the Philippines calls on the companies to register the extended producer responsibility (EPR) program for plastic packaging waste, urging the relevant production companies to be responsible for the entire life cycle of plastic waste.

The National Solid Waste Management Council recently has approved the solid waste management plan of 54 states with a strong focus on solid waste disposal

### India

The Department of Chemicals and Petrochemicals (DCPC) of India continued to issue circulars in the first half of 2023, postponing the implementation date of quality control orders for various substances. For some substances, the implementation date was postponed again. In order not to affect the trade process, companies should pay attention to the official announcements issued by the authorities, and respond to the requirements of the product quality control orders in a timely manner.



## 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

2023 年 3 月 6 日，根据第 2023-47 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（14 种）的允许吨位量的上下限。同时，因原指定毒性物质的浓度限值发生变化，而当这类毒性物质（3 种）同为应急事故

物质，在应急事故物质下的浓度限值也同步修订，以保持一致。

**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：

<http://www.me.go.kr/home/web/index.do?menuId=71>（第 1394 号）

## South Korea · Update of specified tonnage of toxic substances, restricted substances, prohibited substances and authorized substances

On March 6, 2023, according to Announcement No. 2023-47, the Ministry of Environment issued a partial amendment to the allowable tonnage of toxic substances, restricted substances, prohibited substances and authorized substances, stipulating the upper and lower limits of allowable tonnage of new toxic substances (14 types). In addition, due to changes in the concentration limits of the originally-designated toxic substances, if such toxic substances (3 types) are also emergency substances, the concentration limits of

emergency substances will be also revised synchronously for consistency.

**Comments:** For companies producing or importing substances and supplying to the downstream in South Korea, they need to pay attention to the regulations on the specified tonnage of toxic substances updated by the Ministry of Environment, and strictly abide by the tonnage during the production, use, and storage.

For details, please visit the link below:

<http://www.me.go.kr/home/web/index.do?menuId=71> (No. 1394)

## 韩国 · 指定“安全确认对象生活化学产品”和安全及标签标准部分修订案

2023 年 3 月 29 日，根据第 2023-59 号公告，韩国环境部发布了指定“安全确认对象生活化学产品”和安全及标签标准部分

修订案，主要包括：为了解决行业难题，根据风险评估结果，允许在喷雾类产品中添加可使用的防腐物质（70 种）。

详情请点击以下链接：

<https://law.go.kr/admRulInfoP.do?admRulSeq=2100000221394&chrClsCd=010202&urlMode=admRulRvsInfoR>



## South Korea · Designated "Domestic Chemical Products Subject to Safety Confirmation" and partial amendments to safety and labeling standards

On March 29, 2023, according to Announcement No. 2023-59, the Ministry of Environment issued the designated "Domestic Chemical Products Subject to Safety Confirmation" and partial amendments to safety and labeling

standards, as follows: In order to solve industry problems, it is allowed to add usable preservative substances (70 types) to spray products according to the risk assessment results.

For details, please visit the link below:

<https://law.go.kr/admRulInfoP.do?admRulSeq=2100000221394&chrClsCd=010202&urlMode=admRulRvsInfoR>

## 韩国 · 《韩国促进资源节约和回收利用法案修订案》发布

2023 年 3 月 28 日，根据 19311 号公告，韩国环境部发布了《韩国促进资源节约和回收利用法案修订案》，主要内容包括：

(1) 为了减少包装废弃物和塑料废弃物的产生，在包装材料的材质、结构等标准及回收利用简易性评价标准中增加了颜色及重量标准；(2) 限制使用及禁止免费提供一次性用品的行业中，增加了拥有 50 间以上客房的住宿业；(3) 通过电子

商务或无人售卖终端提供、销售、配送食物时，顾客有义务选择是否使用一次性用品；(4) 为了促进再生原料的使用，再生原料使用比例超过一定比例的产品，容器的制造商等可以标识其使用比例；(5) 地方自治团体的负责人应当首先努力研究购买使用再生原料的产品和容器；(6) 关于回收利用附加税的缴纳，新设了延期征收及分期缴纳，缴纳期限前征收，缴纳义务的继承等规定。

详情请点击以下链接：

[Release of Amendment to the Korean Act on Promoting Resource Conservation and Recycling](#)

## South Korea · Release of *Amendment to the Korean Act on Promoting Resource Conservation and Recycling*

On March 28, 2023, the Ministry of Environment of the Republic of Korea issued the *Amendment to the Korean Act on Promoting Resource Conservation and Recycling* according to Announcement No. 19311, of which the main contents include:

(1) In order to reduce the generation of packaging waste and plastic waste, color and weight standards are added to the standards of packaging materials and structure, as well as the evaluation standards of recycling simplicity. (2) The accommodation industry with more than 50 rooms is added to the industries that restrict the use and prohibit the provision of disposable articles free of charge. (3) For food provision, selling and distribution through e-commerce or

unmanned sales terminals, the customers have the obligation to choose whether to use the disposable articles. (4) In order to promote the use of recycled raw materials, the manufacturer of containers and products with the use ratio of recycled raw materials exceeding a certain proportion can identify the use ratio in their products. (5) The person in charge of the local self-government organization shall firstly make efforts to study and purchase the products and containers made from recycled raw materials. (6) With regard to the payment of surtax on recycling, new regulations have been set up, such as the deferred collection and installment payment, collection before the payment deadline, and inheritance of payment obligations, etc.

For details, please visit the link below:

[Release of Amendment to the Korean Act on Promoting Resource Conservation and Recycling](#)



## 韩国 · 韩国化学物质安全信息豁免批准的相关规定的部分修订案

2023 年 4 月 18 日，根据 2023-187 号公告，韩国环境科学院（NIER）发布了化学物质的试验方法相关规定的部分修订案草案，主要包括：

### 1. 【附表】化学物质的试验方法

第五章 9 项人体健康试验项目的部分修订

第 4 条 眼刺激/腐蚀试验

第 5 条 皮肤致敏试验

第 14 条 毒代动力学试验

第 27 条 体外皮肤刺激试验（人类皮肤模型试验）

第 33 条 皮肤致敏试验（局部淋巴结试验，LLNA）

第 34 条 皮肤致敏试验（局部淋巴结试验，LLNA: DA）

第 36 条 化学性皮肤致敏试验（肽结合试验、氨基酸衍生物结合试验）

第 54 条 雌激素受体转录活性测试

第 68 条 利用 Vitrigel 的眼刺激试验

### 2. 【附表】化学物质的试验方法

新增了第五章 2 项人体健康试验项目

第 71 条 皮肤致敏试验（Defined Approach : 2 out of 3 methods）

第 72 条 体外人类皮肤模型（RhE）光毒性试验

详情请点击以下链接：

<https://opinion.lawmaking.go.kr/gcom/admpp>（第 241 号）

## South Korea · Draft partial amendments to regulations on test methods for chemical substances

On April 18, 2023, the National Institute of Environmental Research (NIER) released partial amendments to regulations on test methods for chemical substances according to Announcement No. 2023-187, as follows:

### 1. [Schedule] Test Methods for Chemical Substances

Partial revision of 9 human health test items in Chapter V

Article 4 Eye irritation/corrosion test

Article 5 Skin sensitization test

Article 14 Toxicokinetics test

Article 27 In-vitro skin irritation test (human skin model test)

Article 33 Skin sensitization test (local lymph node test, LLNA)

Article 34 Skin sensitization test (local lymph node test, LLNA: DA)



Article 36 Chemical skin sensitization test (peptide binding test, and amino acid derivative binding test)

Article 54 Estrogen receptor transcriptional activity test

Article 68 Eye irritation test using Vitrigel

2. [Schedule] Test Methods for Chemical Substances

2 human health test items added in Chapter V

Article 71 Skin sensitization test (Defined Approached: 2 out of 3 methods)

Article 72 In-vitro human skin model (RhE) phototoxicity test

For details, please visit the link below:

<https://opinion.lawmaking.go.kr/gcom/admpp> (No. 241)



## 韩国·资料保密申请书的编写方法及资料保密管理方法相关规定的部分修订案草案

2023 年 4 月 26 日，根据第 2023-269 号公告，韩国环境部发布了资料保密申请书的编写方法及资料保密管理方法相关规定的部分修订案草案，主要包括：

1. 对于使用通用名称而保护利益相关者的商业秘密，根据 K-REACH 第 29 条和 K-REACH 实施细则第 35 条新规传递化学品安全信息的人员也可以使用被批准的通用名称，以使得商业保密的通用名称的使用更加完备。（第 2 条）
2. 如果将根据 K-REACH 第 10 条将化学物质注册和通报时提交的化学物质的原始名

称原封不动地传递给下游用户，则存在因泄漏混合物和聚合物的组成成分而损害企业商业秘密的风险，所以，部分改进了通用名称的编写方法。（第 8 条和附表）

**点评：**虽说随着 K-REACH 的修订，通用名称的申请/使用，对于商业保密的条款愈加完善，但企业需注意资料保密期限申请是可以每 5 年申请一次，最多延期申请 2 次，但在此期间如果所申请资料保密的化学物质被全球任何一个国家列入名录时，将无法继续申请保密，并由环境部予以公布。

详情请点击以下链接：

<https://opinion.lawmaking.go.kr/gcom/admpp> （第 254 号）

## South Korea · Draft partial amendments to the regulations on the preparation method of the application form for data confidentiality and the management method concerning data confidentiality

On April 26, 2023, according to Announcement No. 2023-269, the Ministry of Environment released partial amendments to the regulations on the preparation method of the application form for data confidentiality and the management method concerning data confidentiality, as follows:

1. For the use of generic names to protect the trade secrets of stakeholders, personnel who transmit chemical safety information according to Article 29 of K-REACH and Article 35 of K-REACH Implementation Rules

may use approved generic names, to facilitate the completeness. (Article 2)

2. If the original name of the chemical substance submitted at the time of chemical substance registration and notification under Article 10 of K-REACH is transmitted to downstream users, there is a risk of impairing company's trade secrets due to the leakage of the composition of mixtures and polymers. Given that, the method of writing generic names is partially improved. (Article 8 and Schedule)

**Comments:** Although with the revision of K-REACH, the application/use of generic names and the terms concerning commercial confidentiality are becoming more and more perfect, companies should pay attention to the application period (once every 5 years) of data confidentiality, which

can be extended for 2 times at most. During the period, if the chemical substance applied for confidentiality is included in the list by any country in the world, it is impossible to apply for confidentiality and will be disclosed by the Ministry of Environment.

For details, please visit the link below:

<https://opinion.lawmaking.go.kr/gcom/admpp> (No. 254)





## 韩国 · 《化学物质危害性评估结果》草案公布

2023 年 5 月 9 日，根据第 2023-228 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》草案，附表中更新了 30 种新化学物质的危害分类，并新增了 37 种新化学物质。

**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://opinion.lawmaking.go.kr/gcom/admpp>（第 274 号）

## South Korea · South Korea authority publishes the draft of *Chemical Substance Hazard Assessment Results*

On May 9, 2023, according to Announcement No. 2023-228, the National Institute of Environmental Research (NIER) released the draft of *Chemical Substances Hazard Assessment Results*, updated the hazard classification of 30 new chemical substances in the schedule, and added 37 new chemical substances.

**Comments:** For companies producing substances in Korea or importing and supplying to the downstream, they should pay attention to the hazard assessment /classification results updated by NIER, update MSDS and labels in a timely manner, and keep them consistent with the results of NIER.



For details, please visit the link below:

<https://opinion.lawmaking.go.kr/gcom/admpp> (No. 274)

## 韩国 · 获得批准缓冲期的现有生物杀灭物质名录草案更新

2023 年 5 月 26 日，根据第 2023-264 号公告，韩国环境部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草案，主要包括：

1. 更新了 4 种生物杀灭剂类型及其批准缓冲期

2. 撤销了 3 种生物杀灭物质及其批准缓冲期

3. 将编号“333”至“355”修正为“330”至“352”

**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，以及及时的采取相应的应对措施。

详情请点击以下链接：

<https://opinion.lawmaking.go.kr/gcom/admpp> （第 310 号）



## South Korea · South Korea authority updates the draft list of existing biocidal substances with approval buffer periods

On May 26, 2023, the Ministry of Environment issued a draft amendment to the list of existing biocidal substances with approval buffer periods according to Announcement No. 2023-264, as follows:

1. Updated 4 types of biocides and their approval buffer periods

2. Canceled 3 biocidal substances and their approval buffer periods

4. Amended numbers "333"-"355" to "330"-"352"

**Comments:** Companies should pay attention to check whether the biocides produced, imported and sold in South Korea involve the change or cancellation of the buffer period, and take countermeasures in a timely manner.

For details, please visit the link below:

<https://opinion.lawmaking.go.kr/gcom/admpp> (No. 310)



## 韩国 ·安全确认对象生活化学产品的批准相关规定草案

2023 年 5 月 26 日，根据第 2023-269 号公告，安全确认对象生活化学产品的批准相关规定草案，主要包括：

1. 批准用于表面使用的消毒剂时，要求强制标识“如使用雾化消毒、高压喷雾消毒等消毒设备时，不得向空气喷洒消毒剂”的警示语。

- [附表 1] 编写使用方法中，新增了“不得向空气喷洒消毒剂”的警示语。

详情请点击以下链接：

[https://www.nier.go.kr/NIER/cop/bbs/selectNoLoginBoardList.do?bbsId=BBSMSTR\\_000000000241&menuNo=13002](https://www.nier.go.kr/NIER/cop/bbs/selectNoLoginBoardList.do?bbsId=BBSMSTR_000000000241&menuNo=13002)（第 358 号）

2. 明确了消毒、杀虫剂等使用注意事项中作业防护服的规范。

- [附表 1] 使用注意事项中，要求明确防护服的规范。

**点评：**企业应关注出口到韩国的产品是否被指定为“安全确认对象生活化学产品”，并按照法规要求完成产品相关测试和申报。

## South Korea · Draft of regulations on the approval of domestic chemical products subject to safety confirmation

On May 26, 2023, the draft of regulations on the approval of domestic chemical products subject to safety confirmation according to Announcement No. 2023-269, as follows:

1. When sanitizers are approved for use on the surface, a mandatory warning "When using the atomization disinfection, high-pressure spray disinfection and other disinfection equipment, do not spray sanitizers to air" shall be marked.

- [Schedule 1] A new warning "Do not spray sanitizers to air" is added into the preparation method.

2. The specifications for work protective clothing in precautions for the use of disinfectants and insecticides are clarified.

- [Schedule 1] In the precautions for use, it is required to clarify the specifications of protective clothing.

**Comments:** Companies should pay attention to check whether the products exported to South Korea are designated as "domestic chemical products subject to safety confirmation", and complete product-related testing and reporting in accordance with regulations.

For details, please visit the link below:

[https://www.nier.go.kr/NIER/cop/bbs/selectNoLoginBoardList.do?bbsId=BBSMSTR\\_000000000241&menuNo=13002](https://www.nier.go.kr/NIER/cop/bbs/selectNoLoginBoardList.do?bbsId=BBSMSTR_000000000241&menuNo=13002) (No. 358)

## 韩国 · 《韩国现有化学物质名录》公示部分修订案

2023年6月1日，根据2023-122号公告，韩国环境部发布了《韩国现有化学物质名录》公示部分的修订案，主要内容包括：

1. 针对201个资料保密期限已过的化学物质，将通用名称（Generic name）更新为原始化学物质名称；删除了重复的4个化学物质（KE 号码分别为：2015-3-6233、2015-3-6256、2016-3-7172、2017-3-7250）
2. 此前公布的名单中，分配了5个CAS号码，并对应着CAS号码新增了化学名称

（KE 号码分别为：99-3-1196、99-3-1197、99-3-1198、2000-3-1648、2011-3-5262）

3. 另修改了3个化学物质（KE 号码分别为：2009-3-3854、2010-3-4297、2011-3-4949）

**点评：**企业应关注出口到韩国的现有化学物质名录，每年生产和进口1吨以上已有化学物质的企业，需提前完成晚预注册来获得注册缓冲期，并截至到2030年，基于吨位量级完成正式注册。

详情请点击以下链接：

<http://www.me.go.kr/home/web/index.do?menuId=71>（第1491号）

## South Korea · Amendments to disclosed part of *List of Existing Chemical Substances in South Korea*

On June 1, 2023, the Ministry of Environment issued amendments to disclosed part of the *List of Existing Chemical Substances in South Korea* according to Announcement No. 2023-122, as follows:

1. For 201 chemical substances with data confidentiality period expired, the generic name (Generic name) was updated to the original name; 4 duplicate chemical substances were deleted (KE numbers: 2015-3-6233, 2015-3-6256, 2016-3-7172 and 2017-3-7250)
2. In the previously announced list, 5 CAS numbers were allocated, and chemical names were added for the CAS numbers (KE

numbers: 99-3-1196, 99-3-1197, 99-3-1198, 2000-3-1648 and 2011-3-5262)

3. Another 3 chemical substances were modified (KE numbers: 2009-3-3854, 2010-3-4297 and 2011-3-4949)

**Comments:** Companies should pay attention to the list of existing chemical substances exported to South Korea. Companies that produce and import more than 1 ton of existing chemical substances each year should complete the pre-registration in advance for a registration buffer period (expiring in 2030), and complete the formal registration according to the tonnage level.

For details, please visit the link below:

<http://www.me.go.kr/home/web/index.do?menuId=71> (No. 1491)

## 韩国 · 《毒性物质清单公告》更新

2023 年 6 月 1 日，根据第 2023-21 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 7 种毒性物质的化学物质名称，并新增了 6 种毒性物质。

**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、危险化学品物质经营许可等。

详情请点击以下链接：

[https://www.nier.go.kr/NIER/cop/bbs/selectNoLoginBoardList.do?bbsId=BBSMSTR\\_000000000031&menuNo=13001](https://www.nier.go.kr/NIER/cop/bbs/selectNoLoginBoardList.do?bbsId=BBSMSTR_000000000031&menuNo=13001)（第 1461 号）

## South Korea · South Korea authority updates *Announcement on List of Toxic Substances*

On June 1, 2023, the National Institute of Environmental Research (NIER) issued an update of the *Announcement on List of Toxic Substances* according to Announcement No. 2023-21, correcting the chemical substance names of 7 toxic substances and adding 6 new toxic substances.

**Comments:** Companies that produce or import chemicals and supply to the

downstream in South Korea should pay attention to the list of toxic substances updated by NIER, submit the list of chemical substances in a timely manner according to the Chemicals Control Act, and handle the import declaration and business licenses of toxic substances and hazardous chemical substances.

For details, please visit the link below:

[https://www.nier.go.kr/NIER/cop/bbs/selectNoLoginBoardList.do?bbsId=BBSMSTR\\_000000000031&menuNo=13001](https://www.nier.go.kr/NIER/cop/bbs/selectNoLoginBoardList.do?bbsId=BBSMSTR_000000000031&menuNo=13001) (No. 1461)

## 韩国 · 《化学品分类及标签规定》更新

2023 年 6 月 1 日，根据第 2023-22 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 28 种毒性物质、2 种事故应急类物质的分类，同时新增了 6 种毒性物质的分类信息。

**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：

[https://www.nier.go.kr/NIER/cop/bbs/selectNoLoginBoardList.do?bbsId=BBSMSTR\\_000000000031&menuNo=13001](https://www.nier.go.kr/NIER/cop/bbs/selectNoLoginBoardList.do?bbsId=BBSMSTR_000000000031&menuNo=13001)（第 1462 号）

## South Korea · South Korea authority updates *Regulations on Classification and Labeling of Chemicals*

On June 1, 2023, the National Institute of Environmental Research (NIER) issued a partial amendment to the *Regulations on Classification and Labeling of Chemicals* according to Announcement No. 2023-22, amending the classification of 28 toxic substances and 2 emergency substances, and adding the classification information of 6 types of toxic substances.

**Comments:** For companies producing toxic substances or chemicals containing toxic substances in Korea or importing and supplying to the downstream, they should pay attention to the hazard classification and labeling results updated by NIER, update MSDS and labels in a timely manner, and keep them consistent with the results of NIER.

For details, please visit the link below:

[https://www.nier.go.kr/NIER/cop/bbs/selectNoLoginBoardList.do?bbsId=BBSMSTR\\_000000000031&menuNo=13001](https://www.nier.go.kr/NIER/cop/bbs/selectNoLoginBoardList.do?bbsId=BBSMSTR_000000000031&menuNo=13001) (No. 1462)

## 韩国 · 现有化学物质注册相关公告发布

2023 年 3 月 7 日，韩国征集了需要政府支援编写风险评估资料的韩国中小型企业。

2023 年 3 月 28 日，韩国环境科学院（NIER）正在推动“使用 OECD QSAR toolbox 评估皮肤致敏的案例研究和评论”的项目，以制定使用 QSAR 的危害评估指南文件，并向正在使用 QSAR toolbox 的企业和期望使用的企业发起调查问卷，以了解 QSAR toolbox 的使用现状。

2023 年 3 月 30 日、5 月 30 日，韩国发布了政府所有危害性测试数据目录及其阅览和使用方法。

2023 年 4 月 12 日，韩国环境部公布了第 15 次现有化学物质预注册的结果。

2023 年 4 月 17 日、5 月 2 日、5 月 24 日，韩国征集了需要政府支援现有化学物质注册咨询服务及危害性测试数据的韩国中小型企业。

2023 年 5 月 15 日，韩国环境部发布了现有化学物质注册相关的问答集。

2023 年 5 月 24 日，韩国发布了政府支援现有化学物质注册咨询服务的现有化学物质清单。

详情请点击以下链接：

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

## South Korea · South Korea authority issues an announcement related to the registration of existing chemical substances

On March 7, 2023, South Korea authority solicited opinions from small and medium-sized companies that require government assistance in compiling risk assessment materials.

On March 28, 2023, the National Institute of Environmental Research (NIER) was promoting the project "Case Studies and Reviews of Assessment of Skin Sensitization Using OECD QSAR toolbox", to prepare a hazard assessment guidance document using QSAR, and distributed questionnaires to the companies using QSAR toolbox and those expecting to use it, so as to learn the current application status of QSAR toolbox.

On March 30 and May 30, 2023, South Korea authority released a catalog of hazard test data and its reading and use methods.

On April 12, 2023, the Ministry of Environment announced the results of the 15th pre-registration of existing chemical substances.

On April 17, May 2, and May 24, 2023, South Korea authority solicited opinions from small and medium-sized companies that require government assistance in existing chemical substance registration consulting services and hazard test data.

On May 15, 2023, the Ministry of Environment released a collection of



questions and answers related to the registration of existing chemical substances.

On May 24, 2023, South Korea authority released a list of existing chemical substances, for which the government provides consulting service supports.

For details, please visit the link below:

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



## 韩国 · 生物杀灭剂和经生物杀灭处理产品相关公告

2023 年 6 月 1 日，韩国环境部（MOE）发布了生物杀灭剂和经生物杀灭处理产品的区分方法、购买及使用的注意事项相关的指南文件。

2023 年 3 月 10 日，韩国环境科学院（NIER）发布了批准缓冲期至 2024 年的现有生物杀灭物质的申报及批准计划书的提交截止日期。

2023 年 3 月 14 日、5 月 8 日、5 月 24 日，韩国环境部（MOE）发布了生物杀灭剂批准相关的指南文件和资料。

2023 年 3 月 28 日，韩国环境科学院（NIER）发布了生物杀灭剂类型之一木材防腐剂的功效试验指南文件。2023 年 5 月 16 日，韩国环境科学院（NIER）发布了生物杀灭剂类型之一木材防腐剂的功效试验的豁免条件。

2023 年 4 月 12 日，韩国环境科学院（NIER）发布了生物杀灭剂关于保质期的产品品质的相关试验，如长期贮存试验、加速贮存试验、低温稳定性试验的指南文件。

2023 年 4 月 14 日，韩国环境部发（MOE）布了生物杀灭剂批准相关的问答集。

2023 年 4 月 24 日，韩国环境科学院（NIER）发布了生物杀灭剂的急性毒性吸入试验相关的注意事项。

2023 年 4 月 28 日，韩国环境科学院（NIER）发布了生物杀灭剂物质识别相关测试数据和申请流程相关的指南文件。韩国环境科学院（NIER）发布了环境风险评估指南文件和环境暴露评估 BPEAT 使用说明文件。

2023 年 5 月 16 日，韩国环境科学院（NIER）发布了生物杀灭剂类型之二消毒剂 and 杀虫剂的功效评估指南文件。

2023 年 5 月 25 日，韩国环境科学院（NIER）发布了申请生物杀灭剂批准时，除生物杀灭物质以外的成分的人体毒理、风险资料的提交范围及豁免条件相关指南文件。



详情请点击以下链接：

<https://ecolife.me.go.kr/ecolife/bbs/notice>

[https://chemp.me.go.kr/cop/bbs/selectBoardList.do?bbsId=BBSMSTR\\_000000000001](https://chemp.me.go.kr/cop/bbs/selectBoardList.do?bbsId=BBSMSTR_000000000001)

## South Korea · Announcement on biocides and biocidal-treated products in South Korea

On June 1, 2023, the Ministry of Environment (MOE) released guidance documents related to the method of distinguishing biocides from biocidal-treated products, and precautions for purchase and use.

On March 10, 2023, the National Institute of Environmental Research (NIER) announced the deadline for submission of reporting and approval proposals for existing biocidal substances with an approval buffer period extended to 2024.

On March 14, May 8, and May 24, 2023, the Ministry of Environment (MOE) released guidance documents and materials concerning the approval of biocides.

On March 28, 2023, the National Institute of Environmental Research (NIER) released guidance documents for efficacy testing of wood preservative, one of the biocides. On May 16, 2023, the National Institute of Environmental Research (NIER) released the exemption conditions for the efficacy testing of wood preservative, one of the biocides.

On April 12, 2023, the National Institute of Environmental Research (NIER) released guidance documents on biocides related to product quality tests during the shelf life, including the long-term storage tests, accelerated storage tests, and low-temperature stability tests.

On April 14, 2023, the Ministry of Environment (MOE) released a collection of questions and answers related to the approval of biocides.

On April 24, 2023, the National Institute of Environmental Research (NIER) issued precautions related to the acute toxicity inhalation test of biocides.

On April 28, 2023, the National Institute of Environmental Research (NIER) released guidance documents related to test data for identification and application procedures of biocidal substances. The National Institute of Environmental Research (NIER) issued guideline documents for environmental risk assessment and instruction documents for the environmental exposure assessment of BPEAT.

On Tuesday, May 16, 2023, the National Institute of Environmental Research (NIER) released guidance documents for efficacy testing of the sanitizer and insecticide (biocides).

On May 25, 2023, the National Institute of Environmental Research (NIER) issued guidance documents related to the submission scope and exemption conditions for human toxicology and risk data of ingredients other than biocidal substances in the process of applying for the approval of biocides.

For details, please visit the link below:

<https://ecolife.me.go.kr/ecolife/bbs/notice>

[https://chemp.me.go.kr/cop/bbs/selectBoardList.do?bbsId=BBSMSTR\\_000000000001](https://chemp.me.go.kr/cop/bbs/selectBoardList.do?bbsId=BBSMSTR_000000000001)

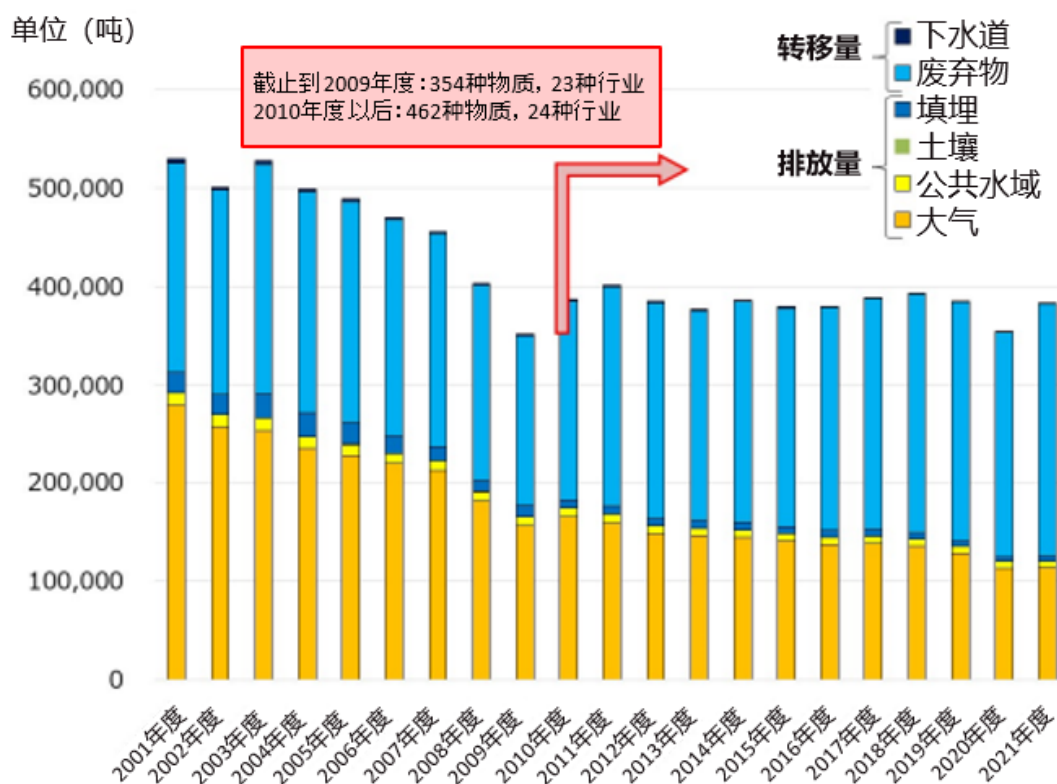
## 日本 · 2021 年度 PRTR 通报数据的统计结果公布

为了掌握环境中特定化学物质的排放量，促进改善企业经营者对化学物质的自主管理从而达到保护环境并防患于未然的目的，日本于 1999 年 7 月推出《化管法》，并引入化学物质排放和转移通报制度（PRTR 制度）。日本经济产业省（METI）和环境省（MOE）根据《化管法》（又称 PRTR 法）的要求，对企业通报的 2021 年度（2021 年 4 月 1 日-2022 年 3 月 31 日）化学物质的环境排放量和转移量进行了汇总，并于 2023 年 3 月 3 日公布了统计结果。

根据日本全国 3 万多家企业通报的排放量和转移量，2021 财政年度的环境排放量为 12.5 万吨（比上年度增长 0.5%），转移量为 25.9 万吨（比上年度增长 12.3%），排放和转移总量为 38.4 万吨（比上年度增长 8.2%）。其中，位列已通报的环境排放和转移总量前三名的化学物质分别是甲苯，锰及其化合物和二甲苯。

另外，对目标行业未通报的排放量、非目标行业的排放量、家庭排放量和交通运输工具（汽车，火车，飞机，船舶等）排放量进行估算，日本全国的总量为 18.8 万吨。

（下图为化学物质年度环境排放量和转移量的推移情况）



详情请点击以下链接：

[https://www.meti.go.jp/policy/chemical\\_management/law/prtr/r3kohyo/gaiyou.html](https://www.meti.go.jp/policy/chemical_management/law/prtr/r3kohyo/gaiyou.html)



## Japan · Japanese authority announces the statistical results of the PRTR circular data in 2021

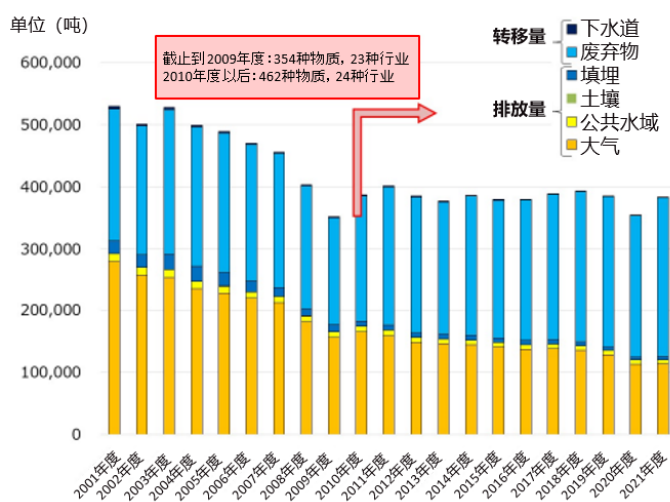
In order to learn the emissions of specific chemical substances in the environment and promote the voluntary improvement of management of chemical substances by enterprise operators, Japanese authority promulgated the *Chemical Substances Control Act* in July 1999 and introduced the Pollutant Release and Transfer Register System (PRTR), so as to protect the environment and prevent the hidden problems. The Ministry of Economy, Trade and Industry (METI) and the Ministry of the Environment (MOE) of Japan summarized the environmental emissions and transfers of chemical substances in 2021 (April 1, 2021-March 31, 2022) from companies in accordance with the requirements of the *Chemical Substances Control Act* (also known as the PRTR Law), and announced the statistical results on March 3, 2023.

According to the emissions and transfers reported by more than 30,000 companies across Japan, the environmental emissions

in the fiscal year 2021, were 125,000 tons (an increase of 0.5% over the previous year), and the transfers were 259,000 tons (an increase of 12.3% over the previous year), the total emissions and transfers reached 384,000 tons (an increase of 8.2% over the previous year). Among them, toluene, manganese and its compounds and xylene rank the top three chemical substances in the total environmental emissions and transfers reported.

In addition, the unreported emissions from target industries, emissions from non-target industries, household emissions, and emissions from transportation vehicles (automobiles, trains, airplanes, ships, etc.) were estimated, which is 188,000 tons.

(The figure below shows the changes in the annual environmental emissions and transfers of chemical substances)



For details, please visit the link below:

[https://www.meti.go.jp/policy/chemical\\_management/law/prtr/r3kohyo/gaiyou.html](https://www.meti.go.jp/policy/chemical_management/law/prtr/r3kohyo/gaiyou.html)



## 日本 · 关于 2021 年度既有化学物质的实际生产和进口量的公告发表

2023 年 3 月 28 日，日本经济产业省（METI）公布 2021 年度不同类别的既有化学物质的实际年度生产和进口量。根据《化审法》及实施条例的相关规定，每个

财政年度内，总生产和进口量为 100 吨或以上的优先评估化学物质，总生产和进口量为 1 吨或以上的监测化学物质，必须向公众公布其总量。

详情请点击以下链接：

[一般化学物质的总生产和进口量 2021FY.pdf \(meti.go.jp\)](#)

[第二类特定化学物质的总生产进口出货量 2021FY.pdf \(meti.go.jp\)](#)

[优先评估化学物质的总生产和进口量 2021FY.pdf \(meti.go.jp\)](#)

[监测化学物质的总生产和进口量 2021FY.pdf \(meti.go.jp\)](#)

## Japan · Japanese authority issues an announcement on the actual production and import volume of existing chemical substances in 2021

On March 28, 2023, the Ministry of Economy, Trade and Industry (METI) announced the actual annual production and import volumes of different categories of existing chemical substances in 2021. According to the relevant provisions of the *Chemical Substance Control Law* and the implementation regulations, in each fiscal

year, the total quantity of the priority assessment chemical substances with the total production and import volume of 100 tons or above and the monitored chemical substances with the total production and import volume of 1 ton or above shall be disclosed to the public.

For details, please visit the link below:

[Total Production and Import Volume of General Chemical Substances 2021FY.pdf \(meti.go.jp\)](#)

[Total Production, Import, and Shipment of Class II Specific Chemical Substances 2021FY.pdf \(meti.go.jp\)](#)

[Total Production and Import Volume of Priority Assessment Chemical Substances 2021FY.pdf \(meti.go.jp\)](#)

[Total Production and Import Volume of Monitored Chemical Substances 2021FY.pdf \(meti.go.jp\)](#)

## 日本·日本发布目前为数量监测对象的优先评估化学物质名单

根据《化审法》的《优先评估化学物质风险评估基本方法》[修订第3版]的要求，对在评估年度内总生产和进口量为10吨以下或预计排放量为1吨以下的优先评估化学物质，其生产和进口量应该接受监测（以下简称“数量监测”），并且对连续三年以上接受数量监测，并被判定为“不大可能因环境污染对人体健康造成损害或者对环境中动植物的栖息地或生长造成损害”的优先评估化学物质，根据《化审法》第11条的规定对其取消优先评估化学物质的指定。

基于这种方法，日本厚生劳动省（MHLW），经济产业省（METI）和环境省（MOE）发布2022年度在数量监测后被取消优先评估化学物质指定的物质，以及目前被列入数量监测对象的物质，具体结果如下：

1. 在数量监测后被取消优先评估化学物质指定的物质：2022年度无物质在数量监测后被取消优先评估化学物质的指定。

2. 被列入数量监测对象的物质

序列号	物质名称	优先指定理由	2019 年度通报 (2018 年度实绩)	2020 年度通报 (2019 年度实绩)	2021 年度通报 (2020 年度实绩)
37	次氨基三乙酸	影响人类健康	-	-	生产进口量 10 吨以下
54	苯胺	影响人类健康 影响生态	-	-	排放量 1 吨 以下
160	2-叔丁基氨基-4-环丙基氨基-6-甲硫基-1, 3, 5-三嗪	影响生态	-	排放量 1 吨以下	生产进口量 10 吨以下
219	磷酸三腈酯	影响生态	-	-	排放量 1 吨 以下
237	三辛胺	影响生态	-	排放量 1 吨以下	排放量 1 吨 以下
243	N, N-二乙基-N-甲基-2-[(2-甲基丙-2-烯酰基)氧基]乙烷-1-铵盐	影响生态	-	生产进口量 10 吨以下	生产进口量 10 吨以下

255	4, 4'-二氨基-3, 3'-二氯二苯基甲烷(别名: 4, 4'-亚甲基双(2-氯苯胺))	影响人类健康	-	-	排放量 1 吨以下
256	双环[2.2.1]庚烷-2, 5(或 2, 6)-二基=二氯化物的混合物	影响人类健康	-	-	排放量 1 吨以下

详情请点击以下链接:

[https://www.meti.go.jp/policy/chemical\\_management/kasinhou/files/information/ra/pacs\\_sur\\_yokanshi\\_2022fy.pdf](https://www.meti.go.jp/policy/chemical_management/kasinhou/files/information/ra/pacs_sur_yokanshi_2022fy.pdf)

## Japan · Japanese authority releases the list of priority assessment chemical substances currently subject to quantity monitoring

According to the requirements of the *Basic Measures for Priority Risk Assessment of Chemical Substances* [Revision 3] of the *Chemical Substance Control Law*, in terms of the priority assessment chemical substances with the total production and import volume of less than 10 tons or the estimated emissions of less than 1 ton in the assessment year, their production and import volumes should be monitored (hereinafter referred to as "quantity monitoring") for more than three consecutive years; if they are identified as the chemical substances that are "unlikely to cause damage to human health or to the habitat or growth of animals and plants due to environmental pollution", they will be removed from the priority assessment list in accordance with the provisions of Article 11 of the *Chemical Substance Control Law*.

In this way, the Ministry of Health, Labor and Welfare (MHLW), the Ministry of Economy, Trade and Industry (METI) and the Ministry of the Environment (MOE) released the substances that have been removed from the priority assessment list according to the quantity monitoring results in 2022, and those currently listed as quantity monitoring objects, as follows:

1. Substances removed from the priority assessment list according to the quantity monitoring results

Substances remaining in the priority assessment list in 2022

2. Substances listed as quantity monitoring objects

No.	Substance name	Priority assessment reasons	Circular in 2019 (Results in 2018)	Circular in 2020 (Results in 2019)	Circular in 2021 (Results in 2020)
37	Nitrilotriacetic acid	Affecting human health	-	-	Production and import volume Less than 10 t
54	Phenylamine	Affecting human health Affecting ecology	-	-	Emissions less than 1 t
160	2-tert-butylamino-4-cyclopropylamino-6-methylthio-1, 3, 5-triazine	Affecting ecology	-	Emissions below 1 t	Production and import volume Less than 10 t
219	Trinitrile phosphate	Affecting ecology	-	-	Emissions less than 1 t
237	Trioctylamine	Affecting ecology	-	Emissions less than 1 t	Emissions less than 1 t
243	N, N-Diethyl-N-methyl-2-[(2-methylprop-2-enoyl)oxy] ethane-1-ammonium salt	Affecting ecology	-	Production and import volume Less than 10 t	Production and import volume Less than 10 t
255	4, 4'-Diamino-3,3'-dichlorodiphenylmethane (alias: 4, 4'-methylenebis (2-chloroaniline))	Affecting human health	-	-	Emissions less than 1 t
256	Bicyclo [2,2,1] heptane-2, 5 (or 2, 6) -diyl=mixture of dicyanides	Affecting human health	-	-	Emissions less than 1 t

For details, please visit the link below:

[https://www.meti.go.jp/policy/chemical\\_management/kasinhou/files/information/ra/pacs\\_sur\\_yokanshi\\_2022fy.pdf](https://www.meti.go.jp/policy/chemical_management/kasinhou/files/information/ra/pacs_sur_yokanshi_2022fy.pdf)

## 日本 · 最新的优先评估化学物质的风险评估（初级）的结果公布

日本根据《化审法》的相关规定，对优先评估化学物质实施了风险评估（初级）评估Ⅰ（以下简称“评估Ⅰ”），并于2023年3月31日公布了评估结果。本次评估Ⅰ是使用2020年度的实际生产和进口量以及按用途划分的详细出货量来进行的。目标物质首先是在2020年度被通报为优先评估化学物质的物质并且目前仍然被指定为优先评估化学物质，同时，除去这些物质中被划为“风险评估（初级）评估Ⅱ”（以下简称“评估Ⅱ”）和“风险评估（初级）评估Ⅲ”的物质，剩余的主要就是“评估Ⅰ”。此外，日本国内总生产和进口量为10吨或以下的物质也被排除在评估Ⅰ之外。

根据评估Ⅰ的结果，本年度没有新进入评估Ⅱ的物质。此外，本次评估Ⅰ中也没有出现当初估计排放量为1吨或以下的物质，但在过去两年的监测中判定为“不存在因环境污染对人类健康或者对生活环境中动植物的栖息或生长造成损害的风险”的物质，因此无物质被撤销优先评估化学物质的指定；从而评估Ⅰ的目标物质将继续是97种影响人类健康的物质和73种影响生态的物质。

对于此次评估Ⅰ中的物质，日本将在下一年度继续使用2021年度的实际生产和进口量以及按用途等划分的详细出货量等再次实施评估Ⅰ，并根据结果决定是否移至评估Ⅱ。

详情请点击以下链接：

[https://www.meti.go.jp/policy/chemical\\_management/kasinhou/information/ra\\_230331.html](https://www.meti.go.jp/policy/chemical_management/kasinhou/information/ra_230331.html)

## Japan · Japanese authority announces the results of the latest risk assessment (preliminary) results of priority chemical substances

In accordance with the relevant provisions of the *Chemical Substance Control Law*, Japanese authority carried out risk assessment (primary) assessment I (hereinafter referred to as "Assessment I") for priority chemical substances, and announced the results on March 31, 2023. Assessment I was executed using actual production and import volumes in 2020 and detailed shipments by use. The target substances are those that were notified as chemical substances for priority assessment in 2020 and are still identified as chemical substances for priority assessment. Except

for substances subject to "Risk Assessment (preliminary) II" and "Risk Assessment (preliminary) III", the remainder is mainly subject to "Assessment I". In addition, substances with a total domestic production and import volume of 10 tons or less in Japan are also excluded from Assessment I.

Based on the results of Assessment I, there are no new substances included into Assessment II this year. Moreover, during Assessment I, there were no substances with the emissions originally estimated to be 1 ton or less, but through the past two years of



monitoring, they were identified as chemical substances that are "unlikely to cause damage to human health or to the habitat or growth of animals and plants due to environmental pollution". Therefore, no substance has been removed from the priority assessment list. In other words, the target substances of Assessment I still include 97 substances affecting human health and 73 substances affecting ecology.

For the substances in Assessment I, Japanese authority will continue to carry out Assessment I again in the next year using the actual production and import volumes in 2021 and detailed shipments by use, and determine whether they need to be included into Assessment II according to the results.

For details, please visit the link below:

[https://www.meti.go.jp/policy/chemical\\_management/kasinhou/information/ra\\_230331.html](https://www.meti.go.jp/policy/chemical_management/kasinhou/information/ra_230331.html)



## 日本 · 最新被取消及被指定为优先评估化学物质的物质名单发布

2023 年 4 月 3 日，日本厚生劳动省（MHLW），经济产业省（METI）和环境省（MOE）根据《化审法》第 11 条的规定，发布了截至 2023 年 3 月 31 日被取消优先评估化学物质指定的最新物质名单，分别是：

- 甲基=十二烷醇
- 邻二氯苯

- 乙胺
- 苯甲酸苄酯
- 蒎烯
- 二氟氯甲烷

同时，日本还公布了截至 2023 年 4 月 1 日被新指定为优先评估化学物质的物质名单以及优先评估化学物质的最新一览表。

详情请点击以下链接：

[https://www.meti.go.jp/policy/chemical\\_management/kasinhou/information/pacs\\_announcement.html](https://www.meti.go.jp/policy/chemical_management/kasinhou/information/pacs_announcement.html)

## Japan · Japanese authority releases the latest list of substances that have been removed from and included into the priority assessment list

On April 3, 2023, the Ministry of Health, Labor and Welfare (MHLW), the Ministry of Economy, Trade and Industry (METI) and the Ministry of the Environment (MOE) issued the latest list of substances that have been removed from the priority assessment list as of March 31, 2023 in accordance with the provisions of Article 11 of the *Chemical Substance Control Law*, including:

- Methyl = dodecanol
- Orthodichlorobenzene

- Ethylamine
- Benzyl benzoate
- Camphene
- Difluorochloromethane

Meanwhile, Japanese authority also announced the list of substances newly identified as chemical substances for priority assessment as of April 1, 2023, and the latest list of chemical substances for priority assessment.

For details, please visit the link below:

[https://www.meti.go.jp/policy/chemical\\_management/kasinhou/information/pacs\\_announcement.html](https://www.meti.go.jp/policy/chemical_management/kasinhou/information/pacs_announcement.html)

## 日本・日本要求通报第二类特定化学物质及使用第二类特定化学物质产品的制造数量

2023年4月3日，日本经济产业省（METI）发布了 2023 年度版通报第二类特定化学物质及使用第二类特定化学物质的产品的制造数量等的通知。根据《化审法》规定，若在一个财年（4月-下一年的3月）制造进口超过 1kg 的第二类特定化学物质时，必须在制造或进口日期前至少一个月通报计划的制造和进口数量。如果在一个财年制造进口的第二类特定化学物质超过 1kg，则必须在有过制造进口活动年份的次年报告实际制造和进口的数量。在进口使用含有第二类特定化学物质的产品（目前被认定可使用第二类特定化学物质的产品只有

含有三丁基锡化合物的涂料）时，不是整个产品，而是产品中所含的第二类特定化学物质的数量在一个财年内达到 1kg 或更多，需要进行上述的通报。此外，还规定了未进行通报或虚假通报，或实际制造进口量超过通报计划数量的都将会受到相应处罚。

对于上一年度实际制造进口数量的书面通报，要求在 2023 年 6 月 30 日前将书面资料邮寄到经济产业省，而通过电子系统或者邮寄光盘进行通报的，则放宽期限至 7 月 31 日。

详情请点击以下链接：

[https://www.meti.go.jp/policy/chemical\\_management/kasinhou/files/todoke/2toku/2toku\\_manual\\_2023fy.pdf](https://www.meti.go.jp/policy/chemical_management/kasinhou/files/todoke/2toku/2toku_manual_2023fy.pdf)

## Japan・Japanese authority requires the reporting of the Class II specific chemical substances and the manufacturing quantity of products using the Class II specific chemical substances

On April 3, 2023, the Ministry of Economy, Trade and Industry (METI) issued the notification of the Class II specific chemical substances and the manufacturing quantity of products using the Class II specific chemical substances in 2023. According to the *Chemical Substance Control Law*, if the Class II specific chemical substances manufactured and imported are more than 1kg in a fiscal year (April to March), the planned manufacturing and import volumes shall be reported at least one month before the manufacturing or import date. If Class II

specific chemical substances manufactured and imported are more than 1kg in a fiscal year, the actual manufacturing and import volumes shall be reported in the year following the year in which the manufacturing and importing activities occurred. If the product containing Class II specific chemical substances (currently, the only product that is approved to use Class II specific chemical substances is the paint containing tributyltin compounds) is imported and used, and the Class II specific chemical substances contained in the

product other than the total product reaches 1kg or more in a fiscal year, the above-mentioned volumes shall be reported. In addition, the failure to report or false reporting, or the case that the actual manufacturing and import volumes exceed the planned volumes will be punished accordingly.

For the written reporting of the actual manufacturing and import volumes in the previous year, it is required to mail the written information to the Ministry of Economy, Trade and Industry before June 30, 2023. If the report is made through the electronic system or by mailing a CD, the deadline will be extended to July 31.

For details, please visit the link below:

[https://www.meti.go.jp/policy/chemical\\_management/kasinhou/files/todoke/2toku/2toku\\_manual\\_2023fy.pdf](https://www.meti.go.jp/policy/chemical_management/kasinhou/files/todoke/2toku/2toku_manual_2023fy.pdf)





## 日本・日本要求通报一般化学物质、优先评估化学物质及监测化学物质的制造数量等

2023 年 4 月 3 日，日本经济产业省（METI）发布了 2023 年度版通报一般化学物质、优先评估化学物质及监测化学物质的制造数量等的通知。根据 2011 年 4 月 1 日发布的修订版《化审法》，从 2010 年度起每年制造或进口一般化学物质、优先评估化学物质和监测化学物质（以下简称“一般化学物质等”）的数量为 1 吨或以上（监测化学物质为每年 1kg 或以上），必

须将数量等通报给经济产业大臣。此外，还规定了未通报或虚假报告的会根据《化审法》第 60 条和第 62 条受到相应处罚。

在 2022 年度（2022 年 4 月 1 日-2023 年 3 月 31 日）有制造或进口一般化学物质等的企业有通报义务，通报方法及期限如下：

通报方法	通报期限	受理方式
电子申请	4 月 1 日~7 月 31 日	e-Gov（官方系统）
光盘	4 月 1 日~7 月 31 日（必须送达）	邮寄
书面	4 月 1 日~6 月 30 日（必须送达）	邮寄

详情请点击以下链接：

[https://www.meti.go.jp/policy/chemical\\_management/kasinhou/files/ippantou/manual\\_2023FY.pdf](https://www.meti.go.jp/policy/chemical_management/kasinhou/files/ippantou/manual_2023FY.pdf)

## Japan · Japanese authority requires the reporting of general chemical substances, priority-assessment chemical substances and manufacturing quantity of monitored chemical substances

On April 3, 2023, the Ministry of Economy, Trade and Industry (METI) issued the notification of reporting general chemical substances, priority-assessment chemical substances, and manufacturing quantity of monitored chemical substances in 2023. According to the revised version of the *Chemical Substance Control Law* issued on

April 1, 2011, if the annual production or import volumes of general chemical substances, priority-assessment chemical substances and monitored chemical substances (hereinafter referred to as "general chemical substances") from 2010 are 1 ton or more (monitored chemical substances: 1kg or more per year), the

volumes shall be reported to the Minister of Economy, Trade and Industry. In addition, the failure to report or false reporting will be punished according to Articles 60 and 62 of the *Chemical Substance Control Law*.

Companies that manufacture or import general chemical substances in 2022 (April 1, 2022 to March 31, 2023) are obliged to report by following the method and deadline below:

Reporting method	Time limit	Acceptance method
Electronic application	April 1 - July 31	e-Gov (official system)
CD	April 1 - July 31 (deadline)	By post
Written	April 1 - June 30 (deadline)	By post

For details, please visit the link below:

[https://www.meti.go.jp/policy/chemical\\_management/kasinhou/files/ippantou/manual\\_2023FY.pdf](https://www.meti.go.jp/policy/chemical_management/kasinhou/files/ippantou/manual_2023FY.pdf)



## 日本・日本发表关于全氟己烷磺酸（PFHxS）等相关措施（草案）的意见征集的结果

日本厚生劳动省（MHLW）、经济产业省（METI）、环境省（MoE）三省在 2023 年 2 月 18 日曾就《化审法》中关于全氟己烷磺酸（PFHxS）等相关措施（草案）发起意见征集。该措施（草案）规定从 2024 年春季开始，原则上禁止制造和进口 PFHxS 及其盐类，禁止进口使用 PFHxS 及其盐类的产品（批准的特殊用途除外），

还制定了废弃处理/处置 PFHxS 或某些含有 PFHxS 盐类的产品的技术标准。

此次公开征集共收到 2 条意见，厚生劳动省（MHLW），经济产业省（METI），环境省（MoE）三省对这些意见做出了回复并于 2023 年 4 月 26 日将结果进行了公示。

详情请点击以下链接：

<https://public-comment.e-gov.go.jp/servlet/Public?CLASSNAME=PCM1040&id=595223011&Mode=1>

## Japan · Japanese authority publishes the results of the collected opinions on measures (draft) related to perfluorohexane sulfonic acid (PFHxS)

The Ministry of Health, Labor and Welfare (MHLW), the Ministry of Economy, Trade and Industry (METI), and the Ministry of the Environment (MoE) have solicited opinions on measures (draft) for perfluorohexane sulfonic acid (PFHxS) in the *Chemical Substance Control Law* on February 18, 2023. According to the Measures (draft), from the spring of 2024, the manufacture and import of PFHxS and its salts and the import of products using PFHxS and its salts will be prohibited (except for approved special

purposes), and technical standards for waste treatment/disposal of PFHxS or certain products containing PFHxS salts are formulated.

A total of 2 opinions were received, and were replied by the Ministry of Health, Labor and Welfare (MHLW), the Ministry of Economy, Trade and Industry (METI), and the Ministry of the Environment (MoE). Results were published on April 26, 2023.

For details, please visit the link below:

<https://public-comment.e-gov.go.jp/servlet/Public?CLASSNAME=PCM1040&id=595223011&Mode=1>

## 日本·日本开始 2023 年度官民合作 GHS 分类信息收集项目的信息接收

2023 年 4 月 14 日，由日本厚生劳动省（MHLW）、经济产业省（METI）、环境省（MoE）、独立行政法人日本职业健康安全机构劳动安全卫生研究所（JNIOOSH）和 NITE 合作开展的接收民间企业提供的可用于 GHS 分类项目的测试报告等资料的项目正式启动。NITE 负责接受来自民间企业的信息。

自 2006 年度以来，厚生劳动省、经济产业省、环境省等相关政府部门合作进行化学物质的 GHS 分类项目，迄今为止已经公布了约 3,300 种物质的 GHS 分类结果。原则上，政府的 GHS 分类项目以国际组织和主要国家等公共机构完成的评估文件等作为分类依据，并根据专家的知识进行分类，但随着需要管理的化学物质数量不断增加，缺乏化学物质的测试结果无法充分进行 GHS 分类的情况也随之增多。为此，厚生劳动省、经济产业省、环境省、JNIOOSH 和 NITE 合作启动了 this 尝试利用民间企业拥有的化学物质危害信息进行分类的新项目。

此次接收信息的物质为：

- 日本政府实施 GHS 分类项目的物质
- 国际上没有可靠信息的物质

另外，此项目只收集被认为可靠且符合以下条件的测试报告。

### 1. 企业有所有权的报告（需符合某些标准）

（1）物理化学危害：按照 UNRTDG-test manual（联合国危险货物运输建议书-测试手册）、ISO（国际标准化组织）、JIS（日本工业标准）等国际组织和标准机构规定的测试方法进行的测试

（2）对人体健康的危害：根据 OECD 测试指南等国际公认的测试方法，测试物质具有一定的纯度（最好在符合 GLP 标准的测试机构进行）

（3）环境危害：根据 OECD 测试指南等国际公认的测试方法，测试物质具有一定的纯度（最好在符合 GLP 标准的测试机构进行）

### 2. 经过专业专家评审并公开发表在学术期刊的科研论文

用日语或英语撰写的报告，其内容涵盖 GHS 分类测试结果，论文发表在接受第三方同行评审的学术期刊，并在可访问的书籍，期刊，网站上公开。

提供的信息将由 NITE 接收并确认，然后与参与 GHS 分类项目的人员（厚生劳动省，经济产业省，环境部，JNIOOSH 和分类项目的受托人等）共享。基本上，政府会在该年度或下一年度将这些信息用于 GHS 分类项目，并发布在 NITE 网站上，同时，其分类依据会被描述为“民间提供的信息”。原则上，信息提供者（公司名称等）将被公布，但如果提供的信息是在符合 GLP 标准的测试机构中进行的，则可以匿名发表。

详情请点击以下链接：

[https://www.nite.go.jp/chem/ghs/ghs\\_govpro\\_apply.html](https://www.nite.go.jp/chem/ghs/ghs_govpro_apply.html)

[https://www.nite.go.jp/chem/ghs/ghs\\_govpro.html#2-6](https://www.nite.go.jp/chem/ghs/ghs_govpro.html#2-6)



## Japan · Japanese authority begins to receive information for the public-private cooperation GHS classification information collection project in 2023

On April 14, 2023, the Ministry of Health, Labor and Welfare (MHLW), the Ministry of Economy, Trade and Industry (METI), the Ministry of the Environment (MoE), the independent administrative institution, Japan National Institute of Occupational Health and Safety (JNIOH), and NITE officially initiated the project to receive test reports and other materials provided by private companies that can be used for GHS classification. NITE was responsible for receiving information from private companies.

Since 2006, the Ministry of Health, Labor and Welfare, the Ministry of Economy, Trade and Industry, and the Ministry of the Environment have cooperated in the GHS classification project of chemical substances. So far, they have announced GHS classification results of about 3,300 substances. In principle, the government's GHS classification project is based on assessment documents completed by international organizations and public institutions of major countries as well as the expert knowledge. However, as the number of chemical substances that need to be managed continues to increase, the failure case regarding GHS classification due to the lack of test results of chemical substances is also increasing. Considering that, the Ministry of Health, Labor and Welfare, the Ministry of Economy, Trade and Industry, the Ministry of the Environment, JNIOH and NITE have jointly initiated the new project, in which the hazard information of chemical substances from private companies is used for classification.

The substances received this time include:

- Substances subjected to the GHS classification projects by Japanese authority
- Substances without reliable information internationally

In addition, in this project, only test reports that are considered reliable and meet the following criteria are collected.

1. Reports owned by companies (subject to certain criteria)

(1) Physical and chemical hazards: tests carried out with the test methods specified by the “United Nations Recommendations on the Transport of Dangerous Goods - Test Manual” (UNRTDG-Test Manual), ISO (International Organization for Standardization), JIS (Japanese Industrial Standards), and other international organizations and standard bodies

(2) Hazards to human health: According to internationally-recognized test methods such as OECD test guidelines, the test substance has a certain degree of purity (preferably detected in a test institution that meets GLP standards)

(3) Environmental hazards: According to internationally-recognized test methods such as OECD test guidelines, the test substance has a certain degree of purity (preferably detected in a test institution that meets GLP standards)

2. Scientific research papers that have been reviewed by professional experts and published in academic journals

Reports written in Japanese or English, covering the GHS classification test results, published in academic journals that undergo third-party peer review, and published in accessible books, journals, and websites.

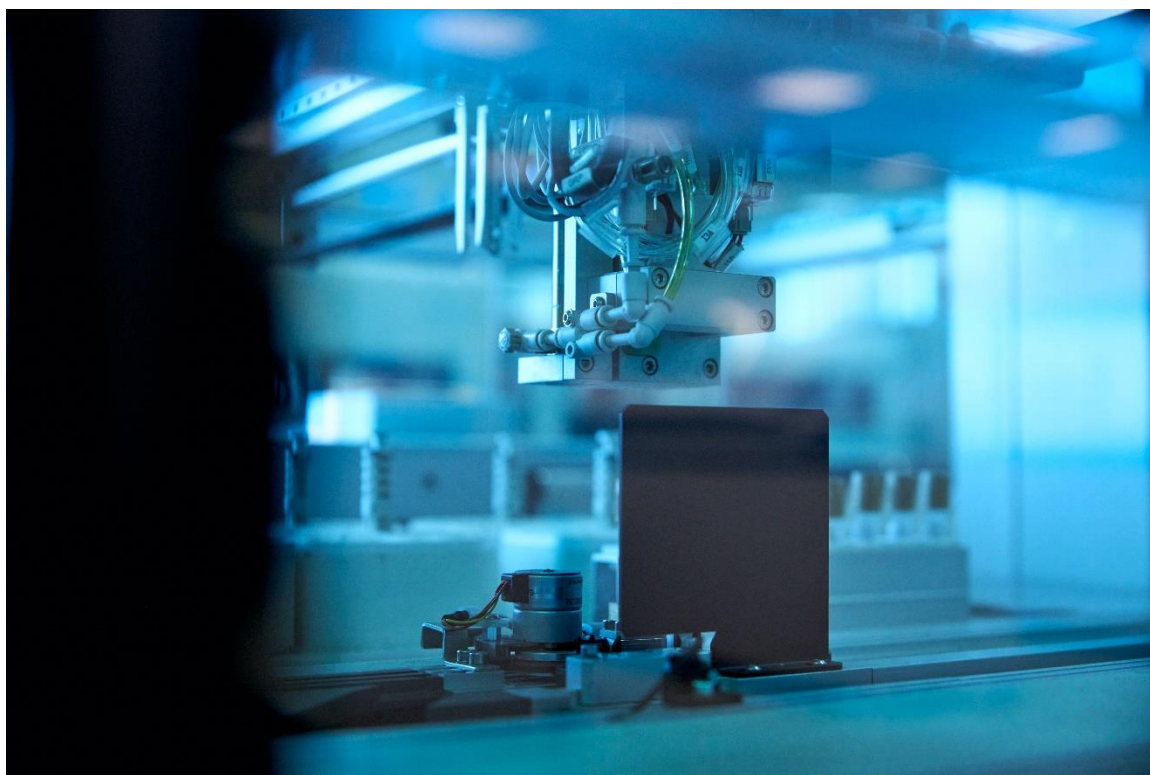
The provided information will be received and confirmed by NITE, and then shared with those involved in the GHS classification project (the Ministry of Health, Labor and Welfare, the Ministry of Economy, Trade and Industry, the Ministry of Environment,

JNIOOSH and trustees of the classification project). Normally, the authority will use this information for the GHS classification project in this year or the next year, and publish it on the NITE website, and describe the classification basis as "information provided by the private sector". In principle, the information provider (company name, etc.) will be published. The information, coming from a GLP-compliant testing facility, can be published anonymously.

For details, please visit the link below:

[https://www.nite.go.jp/chem/ghs/ghs\\_govpro\\_apply.html](https://www.nite.go.jp/chem/ghs/ghs_govpro_apply.html)

[https://www.nite.go.jp/chem/ghs/ghs\\_govpro.html#2-6](https://www.nite.go.jp/chem/ghs/ghs_govpro.html#2-6)



## 日本 · 日本部分修改并公开英文版 GHS 分类结果

日本对 2006 年度和 2018 年度的政府 GHS 分类结果进行了部分修改，添加了碳酸镉的一个 CAS 号，而 2023 年 3 月 29 日最新公布的 NITE 统合版 GHS 分类结果也反映了这一结果，同时还公开了统合版 GHS 分类结果的英文网页。

在日本，受《安卫法》、《化管法》和《有毒有害物质控制》等法规管控的物质需要制作 SDS 和标签。自 2006 年度以来，厚生劳动省、经济产业省、环境省等相关

部委一直在合作进行化学物质的 GHS 分类。最终分类结果以“政府 GHS 分类结果”的形式在 NITE 网站上按照每种物质的（1）危险项目分类（2）图片显示（3）警告词（4）危险信息（5）分类依据等进行公布，目前，大约有 3000 种物质被公布。另外，政府 GHS 分类结果旨在供企业在制作标签和 SDS 时作为参考，并非强制，企业还是应该对自己的 SDS 及标签负责，若企业有更可信的数据，则应该采信这些数据进行分类，并制作相应的 SDS 及标签。

详情请点击以下链接：

[NITE Japan-GHS | Chemical Management | National Institute of Technology and Evaluation \(NITE\)](https://www.nite.go.jp/chem/ghs/ghs_nite_all_fy.html)

[https://www.nite.go.jp/chem/ghs/ghs\\_nite\\_all\\_fy.html](https://www.nite.go.jp/chem/ghs/ghs_nite_all_fy.html)

## Japan · Japanese authority partially revises and releases the English version of GHS classification results

Japanese authority has partially revised the government GHS classification results in 2006 and 2018, adding a CAS number for cadmium carbonate, which is reflected in the latest NITE integrated version of the GHS classification results published on March 29, 2023. Besides, the authority has released the English web page of the consolidated version of GHS classification results.

In Japan, substances, subject to regulations such as the *Industrial Safety and Health control Law*, *Chemical Substances Control Act* and *Poisonous and Deleterious Substances Control Law*, require SDS and labels. Since 2006, relevant ministries

including the Ministry of Health, Labor and Welfare, the Ministry of Economy, Trade and Industry, and the Ministry of the Environment have been cooperating in the GHS classification of chemical substances. The final classification results are published on the NITE website in the form of “Government GHS Classification Results” according to (1) classification of hazardous items (2) picture (3) warning words (4) hazard information (5) classification basis. Up to now, about 3,000 substances have been published. In addition, the government GHS classification results are intended to be used as a non-mandatory reference for enterprises when making labels and SDSs.

Enterprises should be responsible for their own SDS and labels. They should use more

credible data (if any) for classification, and make SDS and labels.

For details, please visit the link below:

[NITE Japan-GHS | Chemical Management | National Institute of Technology and Evaluation \(NITE\)](#)

[https://www.nite.go.jp/chem/ghs/ghs\\_nite\\_all\\_fy.html](https://www.nite.go.jp/chem/ghs/ghs_nite_all_fy.html)





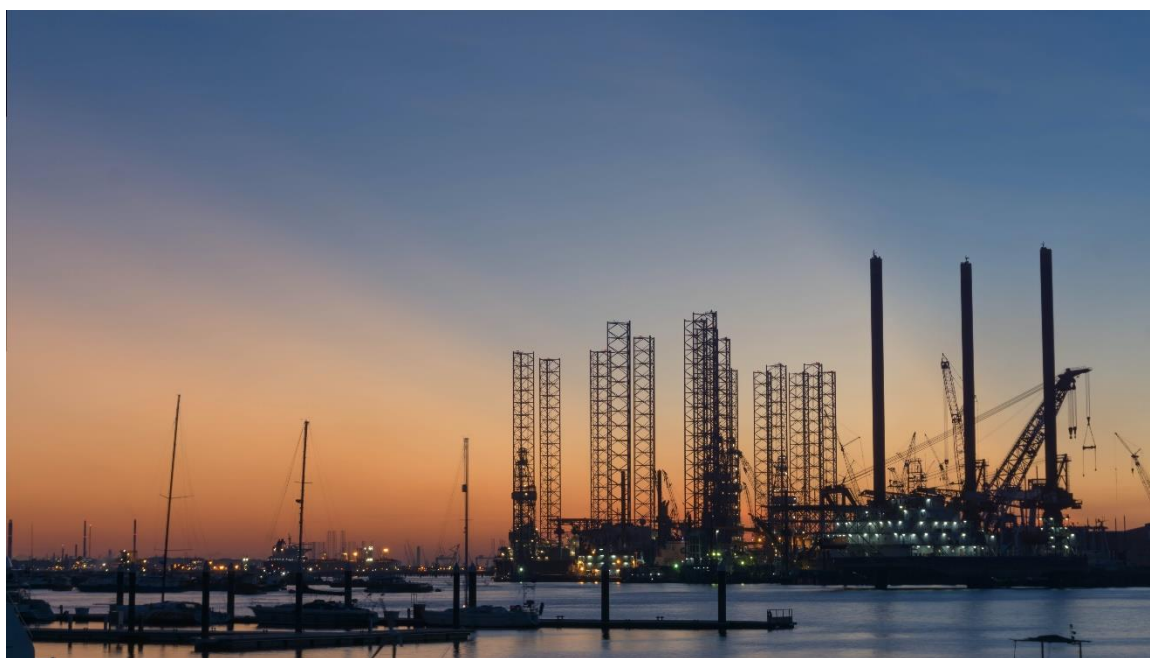
## 日本・危害评估支持系统综合平台（HESS）更新

2023 年 3 月 20 日，日本对危害评估支持系统综合平台（HESS: Hazard Evaluation Support System Integrated Platform）进行了更新，将化审法下新化学物质的重复剂

量毒性试验数据（56 种物质，56 种试验）添加到了数据平台。同时，也修改了重复剂量毒性数据库（HESS repeated dose toxicity）的数据。

详情请点击以下链接：

[https://www.nite.go.jp/en/chem/qsar/hess\\_update-e.html](https://www.nite.go.jp/en/chem/qsar/hess_update-e.html)



## Japan・Japanese authority updates the hazard evaluation support system integrated platform (HESS)

On March 20, 2023, Japanese authority updated the hazard evaluation support system integrated platform (HESS), to incorporate the repeated dose toxicity test data of new chemical substances under the

Chemical Substance Control Law (56 substances, and 56 tests) into the data platform. Meanwhile, the authority also revised data in the HESS repeated dose toxicity database.

For details, please visit the link below:

[https://www.nite.go.jp/en/chem/qsar/hess\\_update-e.html](https://www.nite.go.jp/en/chem/qsar/hess_update-e.html)



## 日本 · 日本化审法数据库（J-CHECK）等多个数据平台更新

2023 年 4 月 3 日，日本化学物质风险信息平台（NITECHRIP）和日本东盟化学物质管理数据库（AJCSD）均发布了数据更

新。2023 年 4 月 18 日，日本化审法数据库（J-CHECK）也发布了更新索引。

详情请点击以下链接：

[J-CHECK\(English\) \(nite.go.jp\)](https://nite.go.jp)

[Update history - NITE-CHRIP \(NITE Chemical Risk Information Platform\)](#)

[ASEAN-Japan Chemical Safety Database \(ajcsd.org\)](https://ajcsd.org)



## Japan · Japanese authority updates multiple data platforms such as the Japan Chemical Substance Control Law Database (J-CHECK)

On April 3, 2023, Japanese authority updated data in the NITE Chemical Risk Information Platform (NITECHRIP) and the Japan-ASEAN Chemical Safety Database

(AJCSD). On April 18, 2023, Japanese authority released an updated index of the Japan Chemical Substance Control Law Database (J-CHECK).

For details, please visit the link below:

[J-CHECK\(English\) \(nite.go.jp\)](https://nite.go.jp)

[Update history - NITE-CHRIP \(NITE Chemical Risk Information Platform\)](#)

[ASEAN-Japan Chemical Safety Database \(ajcsd.org\)](https://ajcsd.org)

日本・危险药物中含有的 7 种物质被新指定为“指定物质”

2023 年 3 月 10 日，日本厚生劳动省颁布了将危险药物中含有的下列 7 种物质新指定为“指定物质”的省令，并于 2023 年 3 月 20 日生效。

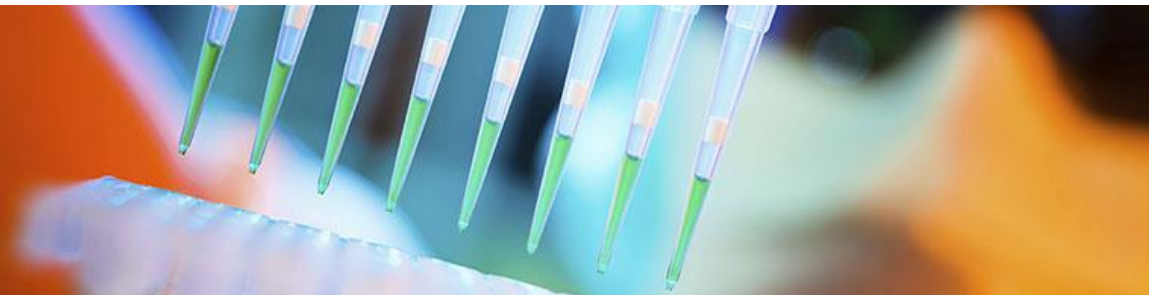
这项省令生效后，除医疗用途以外，这些物质以及含有这些物质的产品会被禁止制造、进口、销售、持有和使用。

由于这些物质是在进口时被新发现的或是目前仅在海外流通的物质，厚生劳动省计划加强边境（进口）措施，以防止危险药物从海外流入和滥用。此外，厚生劳动省还表示今后将根据《药机法》加强对包括通过互联网销售在内的未经批准和未经许可的药品监管和取缔。

序号	物质名称	通称
1	N-Ethyl-N-methyltryptamine	MET Methyl ethyl tryptamine
2	N,N-Diethyl-7-methyl-4-pentanoyl-4,6,6a,7,8,9-hexahydroindolo[4,3-fg]quinoline-9-carboxamide	1V-LSD
3	6a,7,8,10a-Tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo[b,d]pyran-1-yl=acetate	THC-O-acetate THC acetate Δ9 -THC-O THCO
4	6a,7,10,10a-Tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo[b,d]pyran-1-yl=acetate	THC-O-acetate THC acetate Δ8 -THC-O THCO
5	N-(4-Fluorophenyl)-N-(1-phenethylpiperidin-4-yl)furan-2-carboxamide	4F-Furanylfentanyl para-Fluorofuranylfentanyl
6	6a,7,8,9,10,10a-hexahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo[b,d]pyran-1-yl=acetate	HHC-O-acetate HHC acetate HHC-O HHCO
7	1-[1-(3-Methylphenyl)cyclohexyl]pyrrolidine	3-Me-PCPy 3-Methyl rolicyclidine

详情请点击以下链接：

[https://www.mhlw.go.jp/stf/houdou/0000212475\\_00037.html](https://www.mhlw.go.jp/stf/houdou/0000212475_00037.html)



## Japan · Japanese authority newly designates 7 substances contained in dangerous drugs as "designated substances"

On March 10, 2023, the Ministry of Health, Labor and Welfare issued a provincial order, which takes effect on March 20, 2023, to newly designate the following seven substances contained in dangerous drugs as "designated substances".

When this provincial order comes into effect, the manufacture, import, sale, possession and use of these substances and products containing them will be prohibited, except for medical purposes.

Since these substances are newly detected at the time of import or are currently only distributed overseas, the Ministry of Health, Labor and Welfare plans to strengthen border (import) control measures, to prevent the influx and abuse of dangerous drugs from overseas. In addition, the Ministry of Health, Labor and Welfare also stated that in the future, it would strengthen the supervision and suppression of unapproved and unlicensed drugs, including those sold through the Internet, in accordance with the *Pharmaceutical and Medical Device Act*.

No.	Substance Name	Common name
1	N-Ethyl-N-methyltryptamine	MET Methyl ethyl tryptamine
2	N,N-Diethyl-7-methyl-4-pentanoyl-4,6,6a,7,8,9-hexahydroindolo[4,3-fg]quinoline-9-carboxamide	1V-LSD
3	6a,7,8,10a-Tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo[b,d]pyran-1-yl=acetate	THC-O-acetate THC acetate Δ9 -THC-O THCO
4	6a,7,10,10a-Tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo[b,d]pyran-1-yl=acetate	THC-O-acetate THC acetate Δ8 -THC-O THCO
5	N-(4-Fluorophenyl)-N-(1-phenethylpiperidin-4-yl)furan-2-carboxamide	4F-Furanylfentanyl para-Fluorofuranylfentanyl
6	6a,7,8,9,10,10a-hexahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo[b,d]pyran-1-yl=acetate	HHC-O-acetate HHC acetate HHC-O HHCO
7	1-[1-(3-Methylphenyl)cyclohexyl]pyrrolidine	3-Me-PCPy 3-Methyl rolicyclidine

For details, please visit the link below:

[https://www.mhlw.go.jp/stf/houdou/0000212475\\_00037.html](https://www.mhlw.go.jp/stf/houdou/0000212475_00037.html)

## 日本·《医药部外品原料规格 2021 版》部分修订

2023 年 3 月 27 日，日本厚生劳动省公布修订后的《医药部外品原料规格 2021 版》，即日生效。主要修订的内容如下：

1. 对一般测试方法中的以下项目进行了修订：

- (1) 39.水分测定法（卡尔费休法）
- (2) 40.水溶性胶原蛋白试验方法
- (3) 80. 标准产品
- (4) 81. 试剂和测试溶液
- (5) 82. 体积分析的标准溶液
- (6) 83. 标准溶液

2. 对标准各条款的以下项目进行了修订

- (1) 牛脂脂肪酸
- (2) 环糊精-糖醇混合物
- (3) 脱氧核糖核酸
- (4) 羟基磷灰石
- (5) 黄素腺嘌呤二核苷酸二钠二水合物
- (6) 荷荷巴醇
- (7) 聚二甲基二亚甲基吡咯烷多氯液体
- (8) 芳樟醇
- (9) 核糖核酸 (1)

详情请点击以下链接：

<https://www.mhlw.go.jp/content/001077015.pdf>

## Japan · Japanese authority has partially revised the *Specifications for Quasi-Drug Raw Materials in 2021*

On March 27, 2023, the Ministry of Health, Labor and Welfare announced the revised *Specifications for Quasi-Drug Raw Materials in 2021*, which will take effect immediately. The main revisions are as follows:

1. The following items in the general test method have been revised

- (1) 39. Moisture determination (Karl Fischer method)
- (2) 40. Test methods for water-soluble collagen
- (3) 80. Standard products

(4) 81. Reagents and test solutions

(5) 82. Standard solutions for volumetric analysis

(6) 83. Standard solutions

2. The following items in each clause of the standards have been revised

- (1) Tallow fatty acid
- (2) Cyclodextrin-sugar alcohol mixture
- (3) DNA
- (4) Hydroxyapatite

(5) Flavin adenine dinucleotide disodium dihydrate

(6) Jojoba alcohol

(7) Polydimethyldimethylpyrrolidine polychlorinated liquid

(8) Linalool

(9) RNA (1)

For details, please visit the link below:

<https://www.mhlw.go.jp/content/001077015.pdf>





## 日本 · 日本将对 860 种物质实行工作场所接触限值

日本正计划根据《工业安全与健康法》（ISHL）分阶段引入 860 种化学物质的工作场所接触限值。根据该计划，企业将需要进行风险评估，并采取必要措施，将工

人接触这些物质的情况控制在允许的范围

内。  
日本厚生劳动省（MHLW）对剩余物质管理的日程表如下：

时间	物质数量
2023 年	约 170
2024 年	约 180
2025 年及之后	约 390

详情请点击以下链接：

<https://www.mhlw.go.jp/content/11201000/001024179.pdf>

<https://www.mhlw.go.jp/content/11201000/001024175.pdf>

## Japan · Japan will impose workplace exposure limits for 860 substances

Japan is planning to introduce workplace exposure limits of 860 chemical substances in stages according to *Industrial Safety and Health Law* (ISHL). According to the plan, enterprises need to conduct risk assessment and take necessary measures to control

workers' exposure to these substances within the allowable range.

MHLW's schedule for residual substance management is as follows:

Year	Quantity of substances
2023	About 170
2024	About 180
2025 and later	About 390

For details, please click the following link:

<https://www.mhlw.go.jp/content/11201000/001024179.pdf>

<https://www.mhlw.go.jp/content/11201000/001024175.pdf>

## 日本 · 日本修订关于 SDS 中化学物质的成分含量等的通知方法

2023 年 4 月 24 日，日本厚生劳动省发布省令第 70 号，对《工业安全与健康条例》进行了部分修订，即日生效。主要修订内容如下：

(1) 为了不损害经营者的财产利益，在保护商业秘密的同时又能传递必要的信息，省令第 70 号规定，如果该成分及其含量的信息属于商业秘密，可以在 SDS 中说明这一情况后省略成分及其含量的说明，并采取保密协议和其他一般保密措施单独提供成分及其含量。

(2) 该省令还规定浓度范围的差值为 10%，例如“10-20%”，当然浓度范围的差值也可以小于 10%。

(3) 如果交易另一方不能实施相关措施来保护商业机密，则无需提供进一步的详细

信息，而是以范围差值 10% 的方式提供即可。

(4) 如果交易另一方出于客观原因，比如数学模型需要输入含量信息，认为成分含量是实施风险评估所必须的信息，那么可以通过浓度范围差值小于 10% 或者重量百分比的方式提供。

(5) 《有机溶剂中毒预防规定》、《铅中毒预防规定》、《四烷基铅中毒预防规定》以及《特定化学物质危害预防规定》中的对象物质，不适用于本规定。

同时，还新增了对致癌物质 SDS 的要求，规定在转让或者提供由厚生劳动大臣指定的致癌物质（厚生劳动省告示第 371 号）时，无论风险评估对象的物质名称如何，SDS 中描述的成分名称必须是该致癌物质的名称。

详情请点击以下链接：

<https://www.mhlw.go.jp/content/11300000/001089979.pdf>

## Japan · Japan revised the notification method for the component and content of chemical substances in SDS

On April 24, 2023, the Ministry of Health, Labour and Welfare of Japan issued the Provincial Decree No. 70, to partially revise the *Regulations on Industrial Safety and Health*, which took effect on the same day. The main revision contents are as follows:

(1) In order not to damage the property interests of operators and to transmit the necessary information while protecting the trade secrets, Provincial Decree No. 70

stipulates that the information of the components and their contents that are taken as trade secrets can be omitted by explaining their property as trade secrets in SDS, and confidentiality agreements and other general confidentiality measures shall be taken to provide the components and their contents separately.

(2) The Provincial Decree also stipulates that the concentration range may vary within

10%, for example, "10-20%", and certainly the difference in the concentration range can be less than 10%.

(3) If the other party to the transaction is unable to implement the relevant measures to protect trade secrets, no further detailed information is required, but the concentration range can be provided with a difference of 10%.

(4) If the other party to the transaction considers that the component content is necessary for the risk assessment due to objective reasons, such as the need to input the content information in the mathematical model, the concentration range can be provided with a difference less than 10% or by weight percentage.

(5) The object substances in the *Regulations on Prevention of Organic Solvent Poisoning*, *Regulations on Prevention of Lead Poisoning*, *Regulations on Prevention of Tetraalkyl Lead Poisoning* and *Regulations on Prevention of Hazards of Specific Chemical Substances* are not applicable to the Provisions.

(6) At the same time, a new requirement of carcinogenic substance SDS has been added, which stipulates that when transferring or providing carcinogenic substance designated by the Minister of Health, Labour and Welfare (Notice No. 371 of the Ministry of Health, Labour and Welfare), regardless of the substance name of the risk assessment object, the component name described in SDS must be the name of the carcinogenic substance.

For details, please click the following link:

<https://www.mhlw.go.jp/content/11300000/001089979.pdf>



## 日本 · 《食品器具、容器和包装》最新正清单草案公布

2023 年 5 月 31 日，日本厚生劳动省公布《食品器具、容器和包装》最新版正清单草案，并且在 6 月 22 日，日本向世界贸易组织 WTO 通报了用于食品器具、容器

包装合成树脂规格标准的修订。最新版正清单草案由表 1（基础材料）和表 2（添加剂）组成，将于 2025 年 6 月 1 日正式实施。

详情请点击以下链接：

[https://www.mhlw.go.jp/stf/newpage\\_33383.html](https://www.mhlw.go.jp/stf/newpage_33383.html)

<https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/G/TBTN23/JPN773.pdf&Open=True>



## Japan · Japan published the latest draft positive list of *Food Utensils, Containers and Packaging*

On May 31, 2023, Japan's Ministry of Health, Labour and Welfare published the latest draft positive list of *Food Utensils, Containers and Packaging*, and on June 22, Japan notified WTO of the revision of the specifications and standards of synthetic

resins for food utensils and containers. The latest draft positive list consists of Table 1 (Basic Materials) and Table 2 (Additives), which will be officially implemented on June 1, 2025.

For details, please click the following link:

[https://www.mhlw.go.jp/stf/newpage\\_33383.html](https://www.mhlw.go.jp/stf/newpage_33383.html)

<https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/G/TBTN23/JPN773.pdf&Open=True>



## 日本・指定化学物质的浓度标准及其应用方法公布

2023 年 4 月 27 日，日本厚生劳动省制定并公布了“厚生劳动大臣基于《工业安全与健康条例》第 577-2 条第 2 款规定而指定的物质以及浓度标准”（浓度标准告示）和“化学物质预防健康危害浓度标准的应用技术指南”（技术指南），并将于 2024 年 4 月 1 日起正式实施。

浓度标准告示规定了厚生劳动大臣指定的物质及其浓度标准值，设定了丙烯酸乙酯等 67 种物质的浓度标准值，还规定了物质在 8 小时暴露期间的平均浓度（8 小时时间加权平均值）不应超过“8 小时浓度标准值”，和在预计浓度最高的 15 分钟暴

露期间的平均浓度（15 分钟时间加权平均值）不应超过“短时间浓度标准值”。

技术指南则规定了确认工人暴露程度低于浓度标准值的方法。根据该指南，企业应识别工作场所中所有风险评估对象的危害，了解工人的暴露程度，并预估风险。如果在估计风险的过程中，确定工人在室内工作中的暴露程度可能超过浓度标准值，则应进行测量以确认接触该物质的程度低于浓度标准值。对于具有明显致癌性的物质，由于很难设定不会对健康造成长期影响的安全阈值的浓度标准值，企业必须尽量减少这些物质的暴露程度。

详情请点击以下链接：

[https://www.mhlw.go.jp/stf/newpage\\_32871.html](https://www.mhlw.go.jp/stf/newpage_32871.html)

## Japan · Japan published the concentration standards of designated chemical substances and their application methods

On April 27, 2023, Japan's Ministry of Health, Labour and Welfare formulated and published the "Standards for the Substances and Concentration Designated by the Minister of Health, Labor and Welfare according to Article 577-2, Paragraph 2 of the *Regulations on Industrial Safety and Health* (Concentration Standard Notice) and the "Technical Guide for the Application of Concentration Standards for Preventing Health Hazards of Chemical Substances" (Technical Guide), which will be officially implemented on April 1, 2024.

The concentration standard notice stipulates the substances designated by the Minister of

Health, Labour and Welfare and their concentration standard values, sets the concentration standard values of 67 substances such as ethyl acrylate, and specifies that the average concentration (8-hour time-weighted average) of the substances during 8-hour exposure shall not exceed the "8-hour concentration standard value", and the average concentration (15-minute time-weighted average) during the 15-minute exposure period with the highest expected concentration shall not exceed the "short-time concentration standard value".

The technical guide stipulates the method to determine that the exposure of workers is



lower than the concentration standard value. According to the guide, enterprises shall identify the hazards of all risk assessment objects in the workplace, understand the exposure of workers, and estimate the risks. If it is determined during the risk assessment that the exposure of the worker during indoor work may exceed the concentration standard value, measurements shall be

made to confirm that the exposure to the substance is lower than the concentration standard value. For substances with obvious carcinogenicity, it is difficult to set the concentration standard value of safety threshold without long-term impact on health. Thus, the enterprises must minimize the exposure to these substances.

For details, please click the following link:

[https://www.mhlw.go.jp/stf/newpage\\_32871.html](https://www.mhlw.go.jp/stf/newpage_32871.html)



## 日本・日本加强对工作场所有机溶剂和特定化学物质等的的安全标准

2023 年 4 月 17 日，日本厚生劳动省公布了对工作环境有机溶剂等浓度测量方法进行修订的通知，规定在《个人取样法》的对象物质中添加了以下物质。该通知将于 2023 年 10 月 1 日正式实施。

- (a) 粉尘（游离二氧化硅含量极高的除外）
- (b) 特定化学物质中的丙烯腈等 15 种物质
- (c) 有机溶剂

详情请点击以下链接：

[https://www.mhlw.go.jp/web/t\\_doc?dataId=00tc7619&dataType=1&pageNo=1](https://www.mhlw.go.jp/web/t_doc?dataId=00tc7619&dataType=1&pageNo=1)



## Japan・Japan reinforced the safety standards for organic solvents and specific chemicals in workplaces

On April 17, 2023, the Ministry of Health, Labour and Welfare of Japan published a notice on revising the determination methods of organic solvents in the working environment, stipulating that the following substances are added to the object substances in the *Personal Sampling Method*. The notice will be officially implemented on October 1, 2023.

- (a) Dust (except those with extremely high content of free silica)
- (b) Fifteen substances such as acrylonitrile in specific chemicals
- (c) Organic solvent

For details, please click the following link:

[https://www.mhlw.go.jp/web/t\\_doc?dataId=00tc7619&dataType=1&pageNo=1](https://www.mhlw.go.jp/web/t_doc?dataId=00tc7619&dataType=1&pageNo=1)

## 日本・日本扩大需在工作场所张贴危险警告的物质范围

随着《工业安全与健康条例》的部分修订，日本厚生劳动省于 2023 年 4 月 21 日发布部分修改《有机溶剂中毒预防条例》等的省令，将《特定化学物质危害预防条例》第 38 条之 3 中规定的特别管制物质修改为所有特定化学物质，并删除了《有机溶剂中毒预防条例》第 24 条第 2 款关于张贴有机溶剂的危险警告内容和方法由厚生劳动大臣另行规定的规定。

前一项修订规定企业应在制造或处理特定化学物质的工作场所的显眼位置张贴包括特定化学物质的名称，特定化学物质可能引起的疾病类型及其症状和处理特定化学物质的注意事项等内容的危险警告。该修订将于 2023 年 10 月 1 日正式实施。

而后一项修订则是在预期使用最新数字技术的情况下，关于张贴方法应通过发布通知等方式来具体化，因此删除了这一款规定。该修订于公布日起正式生效。

详情请点击以下链接：

<https://www.nisseikyo.or.jp/gyousei/tsuuchi/images/2023/230424/230424-04.pdf>

## Japan・Japan expanded the scope of substances requiring to pose hazard warnings in workplaces

With the partial revision of the *Regulations on Industrial Safety and Health*, the Ministry of Health, Labour and Welfare of Japan issued a provincial decree on partial revision of the *Regulations on Prevention of Organic Solvent Poisoning* on April 21, 2023, revised the special controlled substances stipulated in Article 38, Paragraph 3 of the *Regulations on Prevention of Hazards of Specific Chemical Substances* to all specific chemical substances, and deleted the regulation in Article 24, Paragraph 2 of the *Regulations on Prevention of Organic Solvent Poisoning* that the contents and methods for posting hazard warnings for organic solvents shall be separately stipulated by the Minister of Health, Labour and Welfare.

The previous revision stipulates that the enterprises shall post hazard warnings, including the names of specific chemicals, the types of diseases that may be caused by the specific chemicals and their symptoms, as well as the precautions for handling the specific chemicals, in conspicuous places in workplaces where the specific chemicals are manufactured or handled. The revision will be officially implemented on October 1, 2023.

In the latter revision, the posting method shall be concretized by issuing notices under the condition that the latest digital technology is expected to be used. Therefore, this regulation is deleted. The revision came into effect on the date of promulgation.

For details, please click the following link:

<https://www.nisseikyo.or.jp/gyousei/tsuuchi/images/2023/230424/230424-04.pdf>



## 台湾地区·台湾环保署公布了新化学物质和既有物质的登记指南以及危害及暴露评估指南

台湾环保署于 3 月 24 日发布了新化学物质和既有物质的登记指南。最终的登记指南对草案做了以下修改：

(1) 通过基因编辑生产的蛋白质和其他大分子以及以家庭使用包装出售的进口化学品成品被豁免注册；

(2) 不需要对 1-辛醇和庚烷的水溶解度进行测试；

(3) 对皮肤刺激性、眼睛刺激性和皮肤过敏性，优先采用体外测试方法；

(4) 在眼睛刺激方面增加了更多的替代试验方法，包括荧光素渗漏试验方法（OECD TG460）、短时间暴露体外试验方法（OECD TG491）、重建人类角膜样上皮细胞（RhCE）试验方法（OECD TG 492）等；

(5) 增加了使用胸苷激酶（TK）基因的体外哺乳动物细胞基因突变试验（OECD TG490），作为遗传毒性的替代方法；

(6) 提供了更多测试数据的豁免标准。

该指南取代了 2015 年发布的现行技术指南，并提供了相关法律法规、术语定义、注册范围和数据提交规范，以及物质审查、注册申请完成后的管理和信息披露以及常见问题等信息。

### 《危害及暴露评估指南》

环保署还发布了物质危害和暴露评估指南的最终版本。该指南与草案相比未做较大修改。

该指南推荐了测量每种物质对工人和环境的暴露水平的方法，还规定了物质的物理化学性质对人类健康和环境的风险以及持久性和生物蓄积性的危害评估方法。

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### 最新消息 NEWS



#### 「登錄資料撰寫指引」「危害及暴露評估撰寫指引」已開放下載，提供業界先進參考

「新化學物質及既有化學物質第一階段登錄資料撰寫指引」「化學物質危害及暴露評估撰寫指引」及修正對照表已於化學物質登錄平臺開放下載，依據「新化學物質及既有化學物質資料登錄辦法」（以下稱登錄辦法）規定之新化學物質及既有化學物質第一階段、標準登錄等工作，提供業界先進閱覽。

「新化學物質及既有化學物質第一階段登錄資料撰寫指引」

除納入近年修法條文及細部規定變更外，亦納入登錄人相關常見疑問並增加整體易讀性，以期利於整體登錄作業順遂。

其內容共分五章：

第一章說明登錄制度相關法規及名詞定義

第二章講述登錄範圍及不適用之狀況

第三章解釋登錄類型以及資料繳交規範

第四章簡介登錄工具、表單以及系統內容

第五章說明登錄申請後之審查、管理及資訊公開等相關規定

详情请点击以下链接：

<https://tcscachemreg.epa.gov.tw/Epareg/content/login/NewsDetail.aspx?k=n&enc=FBE895E75338746C52C720EFD5FA97C5028BE297AB4EB929>

## Taiwan · The Environmental Protection Administration (Taiwan) publishes the guidelines for the registration of new chemical substances and existing substances, as well as *Guidelines for Hazard and Exposure Assessment*

On March 24, The Environmental Protection Administration (Taiwan) released the guidelines for the registration of new chemical substances and existing substances. In the final registration guidelines, the following changes were made to the draft:

(1) Proteins and other macromolecules produced through gene editing and imported finished chemicals sold in packaging for home use are exempt from the registration;

(2) No water solubility test is required for 1-octanol and heptane;

(3) For skin irritation, eye irritation and skin irritability, in-vitro test methods are preferred;

(4) More alternative test methods are added for eye irritation, including the fluorescein leakage test method (OECD TG460), short exposure in-vitro test method (OECD TG491), reconstructed human corneal epithelial cells (RhCE) test method (OECD TG 492), etc.;

(5) An in-vitro mammalian cell gene mutation test (OECD TG490) using the thymidine kinase (TK) gene is added as an alternative to genotoxicity test;

(6) Exemption criteria for more test data are provided.

The guidelines replaced the current technical guide released in 2015, and provided relevant laws and regulations, term definitions, registration scope and data submission specifications, as well as substance review, management and information disclosure after the registration application, and frequently-asked questions.

### *Guidelines for Hazard and Exposure Assessment*

EPA also released the final version of *Guidelines for Hazard and Exposure Assessment*. The guidelines have not been significantly revised from the draft.

The guidelines recommended methods for measuring the exposure levels of workers and the environment to each substance, and specified hazard assessment methods for the risks to human health and the environment due to the physicochemical properties of substances, as well as the hazard assessment methods for persistence and bioaccumulation.

For details, please visit the link below:

<https://tcscachemreg.epa.gov.tw/Epareg/content/login/NewsDetail.aspx?k=n&enc=FBE895E75338746C52C720EFD5FA97C5028BE297AB4EB929>



## 菲律宾 · 环境和自然资源部（DENR）敦促公司注册塑料包装废物的生产者责任延伸（EPR）计划

环境和自然资源部（DENR）敦促企业在发布共和国法案 RA 11898 或 2022 年生产者责任延伸（EPR）法案的实施细则和条例（IRR）后注册各自的 EPR 计划。EPR 法案中要求大型企业在法律生效后的六个月内建立塑料包装的 EPR 计划。RA 11898 修订了 RA 9003 并于 2022 年 8 月 13 日生效，通过制定和实施侧重于废物减少、回收和转移的 EPR 计划，将塑料废物的整个生命周期的责任置于其生产者身上。未注册 EPR 计划的企业将被依法罚款。

详情请点击以下链接：

[DENR urges companies to register EPR programs for plastic packaging waste](#)

**点评：** EPR 法案引导菲律宾逐步发展和过渡到循环经济，因为它有助于解决塑料废物管理不善的问题。EPR 要求有义务的企业制定和实施这一项计划来有效回收、处理及再利用塑料包装。DENR 再次提醒对于法案中要求的企业，需要及时注册塑料包装废物的 EPR 计划，否则可能会面临罚款。

## Philippines · DENR urges companies to register EPR programs for plastic packaging waste

The Department of Environment and Natural Resources (DENR) urged companies to register the EPR programs upon the issuance of *Republic Act (RA) 11898* or the *Implementing Rules and Regulations (IRR) of the Extended Producer Responsibility (EPR) Act of 2022*. According to the EPR Act, large companies were required to formulate an EPR program for plastic packaging within six months after the law takes effect. RA 9003, revised based on RA 11898, entered into force on August 13, 2022, specifying responsibility of producers for plastic wastes within the entire life cycle by developing and implementing EPR programs that focus on the waste reduction, recycling and

transferring. Companies that failed to register the EPR programs would be fined in accordance with the law.

**Comments:** The EPR Act guides the gradual development and the transition to a circular economy as it helps address the mismanagement of plastic wastes. According to the EPR Act, companies are obligated to develop and implement the program, to effectively recycle, treat and reuse plastic packaging wastes. DENR once again reminds companies involved to register the EPR program for plastic packaging waste in time, otherwise they will be fined.

For details, please visit the link below:

[DENR urges companies to register EPR programs for plastic packaging waste](#)

## 菲律宾 · NSWMC 批准了 54 个州的固体废物管理计划（SWMPs）

由环境和自然资源部（DENR）主持的国家固体废物管理委员会（NSWMC）近期批准了全国 54 个城市和直辖市的 10 年固体废物管理计划（SWMPs）。这使批准的 SWMPs 总数达到 1263 个，79% 的地方政府单位（LGUs）需要根据共和国法案 RA 9003 或 2000 年生态固体废物管理法提交和实施他们的计划。根据 RA 9003，LGUs 被授权制定符合 NSWMC 国家固体废物管理框架的 10 年的 SWMPs。LGUs 的 SWMPs 目标包括预计人口和废物产生量的信息，以及在 10 年内相应的收集、源

头分类、废物分流、物料回收设施合规性、收集车辆、处置设施和预算方面的目标。

DENR 还讨论了进一步改进 NSWMC 运营和系统的可能方法，包括加强端到端分析，提供有关固体废物及其管理、处理和处置方式的信息。

**点评：**固体废物管理计划（SWMPs）由菲律宾的地方政府单位（LGUs）制定，若有涉及，相关企业需配合完成相关的固体废物处理工作。

详情请点击以下链接：[NSWMC okays solid waste management plans of 54 LGUs](#)

## Philippines · NSWMC approves solid waste management plans of 54 LGUs

The National Solid Waste Management Council (NSWMC), chaired by the Department of Environment and Natural Resources (DENR), recently approved 10-year solid waste management plans (SWMPs) for 54 cities and municipalities in the Philippines. Consequently, the total approved SWMPs reached 1,263, and 79% of local government units (LGUs) were required to submit and implement their plans under the “Republic Act RA 9003” or the “Ecological Solid Waste Management Act in 2000”. Under RA 9003, LGUs were authorized to formulate 10-year SWMPs in line with the National Solid Waste Management Framework (NSWMC). The objectives of SWMPs by LGUs include the information on projected population and

wastes produced, and targets for the collection, source separation, waste diversion, material recovery facility compliance, collection vehicles, disposal facilities, and budget over a 10-year period. DENR also discussed possible ways to further improve NSWMC's operations and systems, including enhanced end-to-end analysis, providing information on solid waste and its management, treatment, and disposal methods.

**Comments:** Solid waste management plans (SWMPs) are formulated by local government units (LGUs) in the Philippines. Relevant companies should cooperate to complete the solid waste disposal work.

For details, please visit the link below: [NSWMC okays solid waste management plans of 54 LGUs](#)

## 印度 · 执行多项物质的质量控制令推迟

(1) 印度化学和石化部 (DCPC) 已将用于制造化妆品、油漆、圆珠笔、溶剂和液压制动液的乙二醇的质量控制令 (QCO) 推迟到 2023 年 6 月 28 日执行。

(2) DCPC 于 2023 年 3 月 31 日在官方公报上发布通告，再次推迟实施 6 种物质的 QCO。这 6 种物质及其控制令的强制实施日期分别变更为：

乙烯乙酸乙烯酯共聚物：2023 年 10 月 3 日

模塑和挤出用聚乙烯材料：2023 年 10 月 3 日

涤纶连续长丝全拉伸纱：2023 年 7 月 3 日

涤纶部分取向纱：2023 年 7 月 3 日

涤纶工业纱：2023 年 7 月 3 日

100%涤纶短纤灰白纱：2023 年 7 月 3 日

(3) DCPC 于 2023 年 4 月 19 日在印度公报上发布通告，推迟了 3 种物质的 QCO 的实施日期。这 3 种物质及其控制令的强制实施日期分别变更为：

苯乙烯（乙烯基苯）：2024 年 4 月 24 日

丙烯腈：2024 年 4 月 24 日

马来酸酐：2023 年 10 月 24 日

(4) DCPC 于 2023 年 4 月 24 日在印度公报上发布通告，再次推迟了 7 种物质实施的质量控制令。这 7 种物质控制令的实施日期曾在 2022 年 10 月发布的通告中被推迟到 2023 年 4 月或 5 月强制实施，目前是再次推迟。这 7 种物质及其控制令的强制实施日期分别变更为：

月桂酸：2023 年 10 月 24 日

酸油：2023 年 10 月 24 日

棕榈脂肪酸：2023 年 10 月 24 日

米糠脂肪酸：2023 年 10 月 24 日

椰子脂肪酸：2023 年 10 月 24 日

氢化米糠脂肪酸：2023 年 10 月 24 日

二氯甲烷：2023 年 11 月 20 日

(5) DCPC 于 2023 年 5 月 27 日在印度公报上发布通告，再次推迟了 2 项质量控制令的执行日期。醋酸乙烯单体和丙烯酸甲酯、丙烯酸乙酯质量控制令的执行日期变更为 2024 年 2 月 29 日。

**点评：**印度近期推迟了多项质量控制令，对于在印度涉及这些物质的公司可以推迟执行相应的质量控制要求，但企业还是应当关注相关质量控制令的最后截止日期，并按照要求尽早准备。

详情请点击以下链接：

<https://egazette.nic.in/WriteReadData/2023/244632.pdf>

<https://egazette.nic.in/WriteReadData/2023/244832.pdf>

<https://egazette.nic.in/WriteReadData/2023/245259.pdf>

<https://egazette.nic.in/WriteReadData/2023/245361.pdf>

<https://egazette.nic.in/WriteReadData/2023/246123.pdf>

## India · Indian authority postpones the implementation of the quality control order for several substances

(1) The Department of Chemicals and Petrochemicals (DCPC) of India has postponed the implementation of the quality control order (QCO) on ethylene glycols used in the manufacture of cosmetics, paints, ballpoint pens, solvents and hydraulic brake fluids to June 28, 2023.

(2) DCPC issued a circular in the Official Bulletin on March 31, 2023, postponing the implementation of QCO for 6 substances again. The mandatory implementation dates of these 6 substances and their control orders have been changed to:

- ethylene vinyl acetate copolymer: October 3, 2023
- polyethylene materials for molding and extrusion: October 3, 2023
- polyester continuous filament fully-drawn yarn: July 3, 2023
- polyester partially oriented yarn: July 3, 2023
- polyester industrial yarn: July 3, 2023
- 100% polyester staple grey yarn: July 3, 2023

(3) DCPC issued a circular in the Official Bulletin on April 19, 2023, postponing the implementation date of QCO for 3 substances. The mandatory implementation dates of these 3 substances and their control orders have been changed to:

- styrene (vinylbenzene): April 24, 2024
- acrylonitrile: April 24, 2024
- maleic anhydride: October 24, 2023

(4) DCPC issued a circular in the Official Bulletin on Monday, April 24, 2023, postponing the implementation date of QCO for 7 substances again. The implementation date of the quality control order for these 7 substances was postponed to April or May 2023 in the circular issued in October 2022, and it is currently postponed again. The mandatory implementation dates of these 7 substances and their control orders have been changed to:

- lauric acid: October 24, 2023
- acid oil: October 24, 2023
- palm fatty acids: October 24, 2023
- rice bran fatty acids: October 24, 2023
- coconut fatty acids: October 24, 2023
- hydrogenated rice bran fatty acids: October 24, 2023
- dichloromethane: November 20, 2023

(5) DCPC issued a circular in the Official Bulletin on May 27, 2023, postponing the implementation date of QCO for 2 substances again. The implementation date of the quality control order for vinyl acetate monomer and methyl acrylate and ethyl acrylate was changed to February 29, 2024.

**Comments:** For companies involving these substances in India, the requirements for implementing the quality control order can be postponed. However, companies should pay attention to the deadline for QCO and take measures as soon as possible.



For details, please visit the link below:

<https://egazette.nic.in/WriteReadData/2023/244632.pdf>

<https://egazette.nic.in/WriteReadData/2023/244832.pdf>

<https://egazette.nic.in/WriteReadData/2023/245259.pdf>

<https://egazette.nic.in/WriteReadData/2023/245361.pdf>

<https://egazette.nic.in/WriteReadData/2023/246123.pdf>





## 近期会议活动

第二十一届世界制药原料中国展（CPHI China 2023），2023 年 6 月 19 - 21 日，上海

<https://www.cphi-china.cn/>

2023 第 11 届上海国际生物发酵产品与技术装备展览会，2023 年 8 月 4 - 6 日，上海

[www.biozl-expo.com](http://www.biozl-expo.com)

2023 中国（兰州新区）国际精细化工产业博览会，2023 年 8 月 30 日-9 月 1 日，甘肃兰州

[www.highlandexpo.com](http://www.highlandexpo.com)

2023（第二十届）中国国际化工展览会（ICIF China 2023），2023 年 9 月 4 - 6 日，上海

<http://www.icif.cn>

2023 第 89 届中国医药原料药/中间体/包装/设备交易会（API China），2023 年 10 月 18 - 20 日，江苏南京

<https://www.apichina.com.cn/>

Chemical Watch Expo 2023，2023 年 6 月 15 - 16 日，荷兰阿姆斯特丹

<https://events.chemicalwatch.com/657283/chemical-watch-expo-2023>

Food Contact Regulations USA 2023，2023 年 6 月 29 - 30 日，美国华盛顿+线上

<https://events.chemicalwatch.com/657402/food-contact-regulations-usa-2023>

2023 日本国际制药原料及配料展览会（in-PHARMA JAPAN），2023 年 7 月 5 - 7 日，日本东京

<https://www.interphex.jp/hub/en-gb/about/pi.html>

菲律宾国际化工展览会（CHEMEXPO Philippines 2023），2023 年 8 月 1 - 3 日，菲律宾马尼拉

[www.philippinechem.com](http://www.philippinechem.com)

Chemical Watch Regulatory Summit Europe 2023，2023 年 10 月 16 - 17 日，比利时布鲁塞尔+线上

<https://events.chemicalwatch.com/712478/chemical-watch-regulatory-summit-europe-2023>

第 70 届欧洲洗涤剂、化妆品及香水原料展（SEPAWA Congress 2023），2023 年 10 月 25 - 27 日，德国柏林

<https://sepawa-congress.de/en/>

## Upcoming Events

CPHI China 2023, 2023.6.19 – 2023.6.21, Shanghai

<https://www.cphi-china.cn/>

BIO CHINA 2023, 2023.8.4 – 2023.8.6, Shanghai

[www.biozl-expo.com](http://www.biozl-expo.com)

Finechem China 2023, 2023.8.30 – 2023.9.1, Lanzhou, Gansu

[www.highlandexpo.com](http://www.highlandexpo.com)

ICIF China 2023, 2023.9.4 - 2023.9.6, Shanghai

<http://www.icif.cn>

API China 2023, 2023.10.18 – 2023.10.20, Nanjing, Jiangsu

<https://www.apichina.com.cn/>

Chemical Watch Expo 2023, 2023.6.15 – 16, Amsterdam, Netherlands

<https://events.chemicalwatch.com/657283/chemical-watch-expo-2023>

Food Contact Regulations USA 2023, 2023.6.29 – 2023, 2023.6.30, Washington, D.C., USA + Online

<https://events.chemicalwatch.com/657402/food-contact-regulations-usa-2023>

in-PHARMA JAPAN 2023, 2023.7.5 – 2023.7.7, Tokyo, Japan

<https://www.interphex.jp/hub/en-gb/about/pi.html>

CHEMEXPO Philippines 2023, 2023.8.1 – 2023.8.3, Manila, Philippines

[www.philippinechem.com](http://www.philippinechem.com)

Chemical Watch Regulatory Summit Europe 2023, 2023.10.16 – 2023.10.17, Brussels, Belgium + Online

<https://events.chemicalwatch.com/712478/chemical-watch-regulatory-summit-europe-2023>

SEPAWA Congress 2023, 2023.10.25 – 2023.10.27, Berlin, Germany

<https://sepawa-congress.de/en/>

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