



Chemistry Shapes the Future

# 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：

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。近期，韩国修订了生活化学产品相关要求和批准规定等，建议生产生活化学产品的企业持续关注相关的批准规定。

日本当局为了提高工人的安全性，对 860 种物质实行工作场所接触限值并将 33 种物质认定为具有高度致突变性，同时将 200 种物质列为致癌性“第 1 类”并要求企业保存工作记录 30 年。为了减轻企业负担，日本当局计划根据《化审法》豁免 106 种物质的年度报告要求。日本还公布了《2021 年度化学物质环境调查的结果（概要）》，更新了《食品器具，容器和包装》正清单、药妆和染发剂的正清单。另外，日本就《全氟己烷磺酸（PFHxS）等的措施（草案）》和关于《工业安全与健康条例》指定物质及其标准浓度（草案）向公众发起了意见征集。

中国台湾环保署为强化化学物质管理，避免不当使用化学物质造成人体健康及环境危害，为此，台湾环保署在关注化学物质清单中增加 15 种物质及加强有机锡禁限用规定。

菲律宾环境和自然资源部（DENR）发布就位于或邻近受保护地区（PAs）及/或拉姆萨尔湿地的项目申请环保合格证书（ECC）的附加指南，进一步明确申请 ECCs 的流程及细节；DENR 通过全面实施生产者延伸责任法（EPR 法案），发布法案实施细则和条例（IRR），规定了企业在销售使用后的责任；菲律宾环境管理局（EMB）发布 2 个化学品管控指令（CCO）征求意见稿，将进一步对苯和氯乙烯进行管控。

## 法规动态

### 韩国

#### 1. 韩国《毒性物质清单公告》更新

2022年12月7日，根据第2022-80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15种毒性物质的化学物质名称，并新增了14种毒性物质。

详情请点击以下链接：

<https://www.nier.go.kr/NIER/cop/bbs/selectNoLoginBoardList.do>（第1421号）

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》，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。

#### 2. 韩国《化学品分类及标签规定》更新

2022年12月7日，根据第2022-81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15种毒性物质、3种限制物质、1种事故应急类物质的分类，同时新增了14种毒性物质的分类信息。

详情请点击以下链接：

<https://www.nier.go.kr/NIER/cop/bbs/selectNoLoginBoardList.do>（第1422号）

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。

#### 3. 民官联合制定毒性物质标识管理制度的改革方案

2022年12月8日，环境部长在以视频会议方式召开的第12次国事未决部长级会议上，发布了“毒性物质标识管理制度”的改革方案，内容是按照毒性物质<sup>①</sup>的危害性分级管理。

① 根据《化学物质的注册与评估法案》（K-REACH），有1,093种毒性物质（截至2022年11月30日）

2015年1月《化学物质的注册与评估法案》施行后，为了应对社会监管负担的增加<sup>②</sup>和提高管理的有效性，制定了本改革方案。

② 年均新增指定的毒性物质为约3倍：2014年722种 → 2021年1,082种



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因此，环境部自 2022 年 5 月以来一直与民间社会、行业、政府官员和专家一起举办“化学品安全政策论坛”，讨论改进方向并就合理的改革方案征求意见。

※ 网站 ([www.chemnavi.or.kr/forum](http://www.chemnavi.or.kr/forum)) 上公开了“化学安全政策论坛”的讨论内容

由此，对操作设施、操作人员和经营者进行区分管理，以便他们可以根据毒性物质的危害性，重点关注化学事故预防和响应管理，并最大限度地减少人体和环境的暴露，主要改革方向如下：

首先，指定“毒性物质”的体系细分成对人体/环境的影响和急性/慢性影响、“急性危害”、“慢性危害”和“生态危害”。

第二，根据《化学物质管理法案》(CCA)，考虑到化学物质的危险性和处理量不同，分级管理营业许可和操作设施标准。

根据本改革方案，环境部计划在 2023 年 8 月之前对 K-REACH 和 CCA 及相关子法规发布修正案。

详情请点击以下链接：

<https://www.me.go.kr/home/web/board/read.do?menuId=10525&boardMasterId=1&boardCategoryId=39&boardId=1566570>

#### 4. 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

2022 年 12 月 9 日，根据 2022-238 号公告，韩国环境部发布了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，主要包括：

1. 如果根据其他法案获得商业保密批准，该化学物质的注册号码和通报号码也被视为获得商业保密批准（第 7 条），注册人可以对其进行保密，但

- 在这种情况下，需要在沟通文件（如 MSDS 和《化学物质的注册与评估法案》实施细则附表 26 号文件）中注明该化学物质是否已注册/通报，以便下游用户核实该化学物质是否已合法注册或通报。

详情请点击以下链接：

<http://www.me.go.kr/home/web/law/list.do?maxPageItems=10&maxIndexPages=10&searchKey=&searchValue=&menuId=71&condition.typeCode=admrul&condition.ruleType=&order=&pageOffset=100>（第 1338 号）

点评：根据韩国《化学物质的注册与评估法案》第 29 条，转让该化学物质或含有该化学物质的混合物的企业，如果该化学物质为已注册/通报的化学物质或者为已预注册并享有缓冲期的危害化学物质（危害化学物质或含浓度限值及以上混合物），则向下游用户提供包含该化学物质的注册号码、名称、危害和风险信息等的信息。但是，根据《职业安全与健康法案》第 110 条第 1 项、第 3 项或第 111 条的规定编写和提供 MSDS 时，相关信息应记录在 MSDS 中，并向下游用户提供相关 MSDS 和《化学物质的注册与评估法案》实施细则附表 26 号文件。但，根据韩国化学物质安全信息豁免批准的相关规定，在其他法案如，《化学物质控制法案》，《职业安全与健康法案》已获得商业保密批准，可以向环境



部申请化学物质安全信息豁免批准，获得批准后，企业可以仅注明该化学物质是否已注册/通报，无需向下游用户提供该化学物质的注册号码和通报号码。

## 5. 安全确认对象生活化学产品的批准相关规定

2022年12月12日，根据第2022-82号公告，韩国环境科学院（NIER）发布了《安全确认对象生活化学产品的批准相关规定》，主要内容包括：

依据《生活化学产品及生物灭杀剂的安全管理法案》，“安全确认对象生活化学产品”需完成申报或者批准。用于加湿器的抗菌及消毒产品用途和形式的多样化，要求也不尽相同，修订内容如下：

### 1. 细分了加湿器抗菌及消毒剂等产品项目并明确了报批申请资料的要求

现有产品中，根据产品在水中的溶出特性，将加湿器抗菌及消毒剂细分为消毒剂和防腐剂两大类，并另外给定“加湿器防腐处理产品”的定义，并将其分类为其他产品类别，避免和防腐剂混为一谈。

### 2. 根据审批产品范围扩大，制定了编号标准

加湿器防腐处理产品：按项目类别的批准分类代码赋予编号

### 3. 明确了生物杀灭剂和经生物杀灭处理的产品的过渡措施、生产及销售的有效期限

详情请点击以下链接：

<https://www.nier.go.kr/NIER/cop/bbs/selectNoLoginBoardList.do>（第1424号）

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。

## 6. 生活化学产品风险评估的对象及方法相关规定

2022年12月19日，根据第2022-85号公告，韩国环境科学院（NIER）发布了《生活化学产品风险评估的对象及方法相关规定》，主要内容包括：

依据《生活化学产品及生物灭杀剂的安全管理法案》，为了完成生活化学产品用户的暴露及风险评估，针对一般消费者和职业消费者，按照产品种类和使用方式设置了暴露场景及暴露评估参数。按照产品的用户及用途的多样化，修订内容如下：

### 1. 新增了风险评估对象“专业用户”及其定义

### 2. 修正了不同暴露途径的暴露量计算公式《附表5》

按照产品类型细分了暴露场景，部分修正了吸入、经皮途径的算法

### 3. 新增及修正了一般暴露系数《附表6》及产品暴露系数《附表7》

一般暴露系数：部分修正和新增了面积/体积、浮动比和接触面积系数；



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产品暴露系数：针对一般/职业用户的杀菌产品和救援产品，新增了更为贴合真实使用情况下的暴露系数，修正了部分现有系数，并新增了针对专业用户（消毒专家）的产品暴露系数

详情请点击以下链接：

<https://www.nier.go.kr/NIER/cop/bbs/selectNoLoginBoardList.do>（第 1428 号）

点评：环境部对受调产品和国内外引起关注的产品等进行风险评估，评估后指定“安全确认对象生活化学产品”，企业可以通过此法规了解环境部指定“安全确认对象生活化学产品”的标准及方法。

## 7. 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

2022 年 12 月 20 日，根据第 2022-246 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（11 种）的允许吨位量的上下限。同时，因原指定为毒性物质的浓度限值发生变化，而当这类毒性物质（5 种）同为应急事故物质，在应急事故物质下被要求的浓度限值也同步修订，以保持一致。

详情请点击以下链接：

<http://www.me.go.kr/home/web/law/list.do?maxPageItems=10&maxIndexPages=10&searchKey=&searchValue=&menuId=71&condition.typeCode=admrul&condition.ruleType=&order=&pageOffset=90>（第 1374 号）

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。

## 8. 指定限制物质、禁止物质更新

2022 年 12 月 20 日，根据 2022-248 号公告，韩国环境部发布了指定限制物质、禁止物质公示的修订案，主要内容包括：

1. 限制物质 06-5-10（六价铬（Chromium(6+)）及含其 0.1% 或以上的混合物）：铬酸锶（Strontium chromate; CAS No. 7789-06-2）的用途为彩钢板、卷钢涂料时，限制标准的缓冲期限延长至 2025 年。

- 原先禁止生产和进口的日期“2023 年 1 月 1 日”改为“2025 年 7 月 1 日”
- 原先禁止使用、销售、存储和运输的日期“2023 年 7 月 1 日”改为“2025 年 1 月 1 日”

详情请点击以下链接：

<http://www.me.go.kr/home/web/law/list.do?maxPageItems=10&maxIndexPages=10&searchKey=&searchValue=&menuId=71&condition.typeCode=admrul&condition.ruleType=&order=&pageOffset=100>（第 1368 号）





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点评：此次对于含铬类产品的限制要求给予更长的缓冲期无疑对于企业是个非常好的消息，但鉴于全世界对于铬和含铬类物质的限制和禁止要求都越来越严，企业还是应该尽早研发替代物质，或者保证在新的截止日期之前提供的涂料含铬量低于 0.1%。

## 9. 韩国公布化学物质危害评估结果

2022 年 12 月 21 日，根据第 2022-87 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》，附表中修正了 5 种新化学物质的名称、3 种现有化学物质编码和 15 种毒性物质编码，删除了 1 种新化学物质危害性评估结果，**更新了 34 种新化学物质和 12 种现有化学物质的危害分类**，并新增了 56 种新化学物质和 27 种现有化学物质。

详情请点击以下链接：

<https://www.nier.go.kr/NIER/cop/bbs/selectNoLoginBoardList.do>（第 1429 号）

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。

## 10. 韩国更新获得批准缓冲期的现有生物杀灭物质名录

2022 年 12 月 30 日，根据第 2022-92 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，主要包括：

1. 更新了 5 种生物杀灭剂类型及其批准缓冲期
2. 撤销了 109 种生物杀灭物质及其批准缓冲期
3. 撤销了 106 种生物杀灭剂类型及其批准缓冲期
4. 将编号“2”至“452”修正为“1”至“343”
5. 调整了 6 个编号
6. 新增了 12 种生物杀灭物质及其批准缓冲期

详情请点击以下链接：

<https://www.nier.go.kr/NIER/cop/bbs/selectNoLoginBoardList.do>（第 1438 号）

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。

## 11. 韩国《化学物质的注册与评估法案》的部分修订案

2023 年 1 月 3 日，根据 19172 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，并于 2024 年 1 月 4 日施行，主要包括：

1. 生产或者进口含优先管控化学物质的产品的企业完成产品申报后，如果优先管控化学物质的暴露信息、含量、用途等重要事项发生变更时，应当向主管当局申请变更。





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2. 规范了化学物质注册、申报和含优先管控化学物质的产品申报相关权利、义务的继承事宜。法规要求继承人自继承之日起 1 个月内对继承事宜向主管当局进行申报。

详情请点击以下链接：

<https://www.law.go.kr/LSW/lsInfoP.do?lsiSeq=247281&viewCls=lsRvsDocInfoR#>

点评：对于在韩国境内生产或进口含优先管控化学物质的产品的企业，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，产品申报后如有发生上述变更事宜，需进一步申请变更。另外，上述所述的继承事宜有多种，涉及原申报人死亡、业务转让、公司合并，如有发生继承事宜则根据该修订案也需要进行申报。

## 12. 《化学品分类及标签和化学品安全技术说明书标准》的部分修订案

2023 年 2 月 15 日，根据第 2023-9 号公告，韩国雇佣劳动部（MOEL）发布了《化学品分类及标签和化学品安全技术说明书标准》的部分修订案，主要内容包括：

1. 以原始设备生产方式（Original Equipment Manufacturing, OEM）委托他人生产化学物质或混合物时，委托人或受托人可提交化学品安全技术说明书（MSDS）或申请商业机密批准。
2. 如由委托人提交化学品安全技术说明书（MSDS）或申请商业机密批准，委托人应向受托人传递相关结果。

详情请点击以下链接：

<https://law.go.kr/admRulInfoP.do?admRulSeq=2100000219530&chrClsCd=010202&urlMode=admRulRvsInfoR>

点评：《化学品分类及标签和化学品安全技术说明书标准》的目的是设定化学物质分类、化学品安全技术说明书（MSDS）、申请商业机密批准、警告标识和工人培训所需的事项。原法规要求化学物质、化学品的生产商/进口商/非韩国境内生产商委任的代理人可提交化学品安全技术说明书（MSDS）或申请商业机密批准，现新增了上述所述的申请的主体。

## 13. 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草案

2023 年 2 月 27 日，根据第 2023-112 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草案，主要内容包括：

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://chemp.me.go.kr/cop/bbs/selectBoardList.do?bbsId=BBSMSTR\\_00000000001](https://chemp.me.go.kr/cop/bbs/selectBoardList.do?bbsId=BBSMSTR_00000000001)



#### 14. 韩国发布现有化学物质注册相关公告

2022 年 12 月 27 日~28 日，韩国举办了风险评估软件（K-Chesar）的培训会。

2022 年 12 月 28 日，韩国环境部更新了“韩国 Use-map 案例手册”和暴露场景模板文件。

2023 年 1 月 4 日，韩国发布了政府支援开展危害性测试数据目录和预计生产的测试数据目录，要求已申请使用测试数据的企业在 1 月 13 日前完成系统确认。

2023 年 1 月 10 日，韩国环境部公布了第 14 次现有化学物质预注册的结果。

2023 年 2 月 6 日，韩国征集了 2023 年度 K-REACH 和 K-BPR 政府项目的执行机构。2023 年 2 月 28 日，韩国发布了 2023 年度 K-REACH 和 K-BPR 政府项目的执行机构的名单。

2023 年 2 月 10 日，根据 2023-84 号公告，韩国环境部发布延长授权类物质（候选物质清单）的征求意见，截止期限至 2023 年 2 月 28 日。

2023 年 2 月 15 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。

详情请点击以下链接：

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

#### 15. 韩国化学品安全技术说明书（MSDS）相关公告

2022 年 12 月 19 日，韩国雇佣劳动部（MOEL）在 MSDS IT 系统的编辑 MSDS 窗口中新增了提示混合物的危害分类的功能，在 MSDS IT 系统的提交 MSDS 窗口中区分了显示在 MSDS 的组分和未显示在 MSDS 的组分的录入区域。

2022 年 12 月 22 日，韩国雇佣劳动部（MOEL）在 MSDS IT 系统新增了 MSDS 管辖权的转移功能，企业信息变更功能和化学物质管理功能。

详情请点击以下链接：

<https://msds.kosha.or.kr/msds/BB00100M01.do>

#### 16. 韩国生物杀灭剂和经生物杀灭处理产品相关公告

2022 年 12 月 2 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。

详情请点击以下链接：

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

2022 年 12 月 2 日，根据《生活化学产品及生物灭杀剂的安全管理法案》和《生活化学产品的标签和宣称相关规定》，韩国环境部（MOE）发布了“安全确认对象生活化学产品”的种类和对象相关的问答集。



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2022年12月21日，根据《生活化学产品的标签和宣称相关规定》（2023年7月29日施行），韩国环境部（MOE）发布了相关问答集。

详情请点击以下链接：

[https://chemp.me.go.kr/cop/bbs/selectBoardList.do?bbsId=BBSMSTR\\_00000000001](https://chemp.me.go.kr/cop/bbs/selectBoardList.do?bbsId=BBSMSTR_00000000001)

## 日本

### 1. 日本认定 33 种物质具有高度致突变性

2022年12月12日，日本厚生劳动省（MHLW）在最近通报的 807 种新物质中，确定了 33 种新物质为高度致突变物质（高度致突变物质可导致 DNA 序列的永久性改变或突变）。其中几种物质和常见用途如下：

- 2-乙基-1-硝基蒽-9,10-二酮，用作染料中间体；
- 羟基-5-[(丙-2-基)氨基]蒽-9,10-二酮，也用作染料中间体；
- 二氟化氙 (II)，用于半导体绝缘膜的蚀刻；
- 用于粘合剂和密封剂的氧代烷-2, 5-二酮/{(氯甲基)环氧乙烷和(苯酚/甲醛的缩聚产物)的缩合产物}和 2-甲基丙-2-烯酸}的加成产物。

(详细清单见以下链接)

在 2022 年 12 月 7 日发给日本化学工业协会的通知中，厚生劳动省提醒生产和处理这些物质的企业需要遵守 MHLW 指南中规定的工作场所健康和安全措施，以防止致突变物质对健康的危害。这也适用于含有浓度超过 1%（重量百分比）的高度致突变物质的混合物。

详情请点击以下链接：

<https://www.toryo.or.jp/jp/anzen/news/files/MHLW20221212.pdf>

### 2. 日本发布了《2021 年度化学物质环境调查的结果（概要）》

2022 年 12 月 26 日，日本环境省（MoE）公布了《2021 年度化学物质环境调查的结果（概要）》。该化学物质环境调查分为“初期环境调查”，“详细环境调查”和“监测调查”。

在初期环境调查中，水质方面调查了 10 种物质（组），共检出 6 个物质组（伊维菌素、环己胺、N-(2, 3-二甲基苯基)邻氨基苯甲酸（又称甲芬那酸）、链霉素、2-羟基-4-甲氧基二苯甲酮（又称二苯甲酮-3）、2-乙基己基对甲氧基肉桂酸）；沉积物方面没有发现被调查的物质；大气层方面在 2 种调查物质中检测到一种物质（呔喃）。这些调查数据将在《化管法》特定化学物质的指定以及考虑与环境风险相关的措施时作为基本数据使用。

在详细环境调查中，为了对化审法规定的优先评估化学物质进行风险评估，对 6 种物质（群）展开调查，水质方面调查了 5 种物质（组），检测到了 3 种物质（组）（环状聚二甲基硅氧烷、四烷基铵盐、四甲基铵-氢氧化物）；沉积物调查中检测到了一种物质（组）（2-亚苄基辛醛）；生物体调查中检测到了一组物质（环状聚二甲基硅氧烷）；大气层方面没有发现被调查的物质。这些结果将成为用作考虑普通环境暴露评估的文件。



监测调查则对《持久性有机污染物公约》涵盖的下列 11 种物质进行了调查，目的在于监测《化审法》规定的第一类特定化学物质等在普通环境中的残留状况以及掌握《持久性有机污染物公约》中目标物质在普通环境中残留状况的变化情况。

- 多氯联苯
- 六氯苯
- 滴滴涕
- 全氟辛烷磺酸（PFOS）
- 全氟辛酸（PFOA）
- 五氯苯
- 硫丹
- 多氯萘
- 六氯-1, 3-丁二烯
- 短链氯化石蜡
- 全氟己烷磺酸（PFHxS）

根据调查结果，在水质、沉积物和大气层中检测到硫丹，在沉积物和生物体（仅限鱼类）和大气层中检测到六氯-1, 3-丁二烯。其他调查物质（组）在所有介质（水质、沉积物、生物和大气层）中均被检测到。

详情请点击以下链接：

[https://www.env.go.jp/press/press\\_01027.html](https://www.env.go.jp/press/press_01027.html)

### 3. 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>

#### 4. 日本将 200 种物质列为致癌性“第 1 类”

2022 年 12 月 26 日，日本厚生劳动省（MHLW）发布了根据《工业安全与健康法》（ISHL）修正案要求将 200 种物质列为致癌性“第 1 类”且分为两个阶段实施的通知，并规定企业必须保留生产或处理该类致癌物质工人的工作记录 30 年。

对 120 种物质的法规实施将于 2023 年 4 月 1 日开始，其中包括：

- 联苯-用于制造电子产品和汽车传动液；
- 2-硝基甲苯-用于染料生产；
- 1,2,3-三氯丙烷-用作聚合物生产中的化学中间体和交联剂和四氟乙烯 - 用作餐具涂层等。

(详细清单见以下链接)

对 80 种物质的法规实施将于 2024 年 4 月 1 日开始，其中包括：

- 氯霉素，用于治疗感染的药物；
- 甲基丙烯酸 2,3-环氧丙基酯-用于生产环氧聚合物、乙烯基和丙烯酸树脂；
- 缩水甘油胺，用于杀虫剂；
- 苯乙烯酸铅，用于炸药和 1-硝基茈，用于感光打印，如 3D 打印等。

(详细清单见以下链接)

但是以下物质，以及企业临时处理指定致癌物质的情况除外。

- 乙醇
- 特别管制物质（《特定化学物质危害预防条例》第 38-3 条规定的特别管制物质）

详情请点击以下链接：

[https://www.mhlw.go.jp/stf/newpage\\_29998.html](https://www.mhlw.go.jp/stf/newpage_29998.html)

#### 5. 日本更新《食品器具，容器和包装》正清单

2023 年 3 月 6 日，日本厚生劳动省（MHLW，以下简称“厚生省”）发布了食品接触材料（FCM）允许使用物质正清单的修订版草案。该正清单适用于合成树脂制成的食品接触用器具、容器和包装。此前，厚生省曾开放窗口向公众征求了对正清单的修改意见。

此次更新主要包括两个部分，一是针对 2022 年 4 月 26 日公开征集“表 2 添加剂正清单”中收到的意见，整理公布了最新修订版《20230306 表 2 的（新）整理案（20230306 New draft of Table2）》；二是针对 2022 年 12 月 26 日公布的表 1“基础材料正清单”，在听取相关企业的意见后再次整理更新了《20230306 表 1 的（新）整理案（20230306 New draft of Table1）》。

详情请点击以下链接：

[https://www.mhlw.go.jp/stf/newpage\\_05148.html](https://www.mhlw.go.jp/stf/newpage_05148.html)

## 6. 日本提议豁免 106 种物质的年度报告

日本当局计划根据《化审法》（CSCL）豁免 106 种物质的年度报告要求。根据化审法要求，每年一吨或以上的一般化学物质的制造商和进口商必须向日本经济产业省（METI）、厚生劳动省（MHLW）和环境省（MoE）提供年度报告，其中包括上一年度制造或进口的物质数量。

如果获得批准，物质清单草案将被添加到“免于通知制造/进口数量的化学物质清单”中。这意味着，从 2022 年 4 月开始的财政年度以及下一个财政年度，公司无需向三省提交这些物质的年度报告。

详情请点击以下链接：

<https://public-comment.e-gov.go.jp/servlet/PcmFileDownload?seqNo=0000246033>

## 7. 日本更新药妆和染发剂添加剂正清单

日本厚生劳动省（MHLW）于 2022 年 12 月 23 日将两种添加剂（硬脂基二甲胺和甲基玫瑰苯胺氯化物）从药妆添加剂的正清单中删除，意味着这两种添加剂将不再可以用于药妆。更新后的清单中有 2746 种添加剂，可用于药品、保健品和一些化妆品，如美白和抗衰老等。同时甲基玫瑰苯胺氯化物也被从染发剂正清单中删除。

详情请点击以下链接：

<https://www.mhlw.go.jp/content/001029257.pdf>

<https://www.mhlw.go.jp/content/001029219.pdf>

## 8. 日本化审法数据库（J-CHECK）等多个数据平台更新

2023 年 1 月 31 日，日本化审法数据库（J-CHECK），日本化学物质风险信息平台（NITE-CHRIP）以及日本东盟化学物质管理数据库（AJCSD）均发布了数据更新。其中 J-CHECK 的更新包括 MITI 编号和 CAS 号的组合和既有化学物质毒性数据库（JECDB）的链接。

详情请点击以下链接：

[https://www.nite.go.jp/chem/jcheck/top.action?request\\_locale=ja](https://www.nite.go.jp/chem/jcheck/top.action?request_locale=ja) (J-CHECK)

[https://www.nite.go.jp/chem/chrip/chrip\\_search/html/update.html](https://www.nite.go.jp/chem/chrip/chrip_search/html/update.html) (NITE-CHRIIP)

[https://www.nite.go.jp/chem/kanren/asia\\_kanren/aicsd.html](https://www.nite.go.jp/chem/kanren/asia_kanren/aicsd.html) (AJCSD)

## 9. 日本发起关于全氟己烷磺酸 (PFHxS) 等的措施 (草案) 的意见征集

2023年2月18日,日本厚生劳动省(MHLW),经济产业省(METI),环境省(MoE)三省就化审法(CSCL)中关于全氟己烷磺酸(PFHxS)等的措施(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,禁止使用批准用途以外的用途,还制定了处理PFHxS或某些含有PFHxS盐类的产品的技术标准。

详情请点击以下链接：

<https://public-comment.e-gov.go.jp/servlet/Public?CLASSNAME=PCMMSTDETAIL&id=595223011&Mode=0>

## 10. 日本发起关于《工业安全与健康条例》指定物质及其标准浓度 (草案) 的意见征集

2023年2月25日,日本厚生劳动省(MHLW)关于《工业安全与健康条例》中指定的物质及其标准浓度(草案)发起意见征集。根据修订后的《工业安全与健康条例》第577-2条第2项规定,对于接受风险评估的物质中由厚生劳动大臣指定的通过将暴露限制在一定水平而不太可能对工人造成健康问题的物质,在生产或处理这类物质的室内工作场所,工人接触这些物质的程度必须低于厚生劳动大臣规定的标准浓度。此次意见征集将于2023年3月26日截止。

详情请点击以下链接：

<https://public-comment.e-gov.go.jp/servlet/PcmFileDownload?seqNo=0000249503>

## 台湾地区

### 1. 台湾加强有机锡禁限用规定, 强化化学物质源头管理

台湾行政院环保署与行政院农业委员会为合作防堵伪农药, 加强有机锡化合物运作管理, 修正「列管毒性化学物质及其运作管理事项」, 依国际管制趋势禁止氧化三丁锡、氯化三苯锡等有机锡化合物用于制造生物杀灭剂、制造防污漆或防污系统, 并调整氧化三丁锡、氯化三苯锡等毒性分类, 更新化学文摘社登记号码(CAS号)。考察此次调整有机锡化合

物毒性分类，从业者应符合事故预防及应急响应的规定，分阶段给予半年至一年半的施行缓冲期。

为共同防范有机锡化合物滥用、濫用，环保署参考国际管制规定、调查国内运作情形并咨询专家学者建议，进一步调整氧化三丁锡、氯化三苯锡等 10 种有机锡化合物禁限用规定，禁止用于制造生物杀灭剂、制造防污漆或防污系统，以强化有机锡化合物管理。并依国际数据库及相关科学研究更新物质信息，增列三苯基- $\alpha$ -萘锡、氟化三丙锡、溴化三甲苯锡及参（三苯锡）甲烷的化学文摘社登记号码（CAS 号），及调整氧化三丁锡、氢氧化三苯锡等有机锡化合物的毒性分类。

首頁 > 新聞發布

### 加嚴有機錫禁限用規定 強化化學物質源頭管理

112-02-20 [行政院環境保護署毒物及化學物質局]

**毒物及化學物質管理**

行政院環境保護署與行政院農業委員會合作防堵偽農藥，加強有機錫化合物運作管理，修正「列管毒性化學物質及其運作管理事項」，依國際管制趨勢禁止氧化三丁錫、氯化三苯錫等有機錫化合物用於製造殺生劑、製造防污漆或防污系統，並調整氧化三丁錫、氯化三苯錫等毒性分類，更新化學文摘社登記號碼。考量此次調整加嚴有機錫化合物毒性分類，既有業者應符合事故預防及緊急應變規定，分階段給予半年至一年半的施行緩衝期。

111年雲林直轄地下農藥工廠，不法業者將毒性化學物質「氯化三苯錫」製成俗稱「白藥膏」之偽農藥，雲林縣環保局稽查發現違法業者108年至110年共輸入氯化三苯錫33.5公噸，未依毒性及關注化學物質管理法（下稱毒管法）申報運作紀錄，除依毒管法罰鍰及廢止其毒性化學物質核可文件，並就其申報不實、涉文書虛偽記載，移送檢察單位偵辦。

為共同防範有機錫化合物濫用、濫用，環保署參考國際管制規定、調查國內運作情形並經諮詢專家學者建議，進一步調整氧化三丁錫、氯化三苯錫等10種有機錫化合物禁限用規定，禁止用於製造殺生劑、製造防污漆或防污系統，以強化有機錫化合物管理。並依國際資料庫及相關科學研究更新物質資訊，增列三苯基- $\alpha$ -萘錫、氟化三丙錫、溴化三甲苯錫及參（三苯錫）甲烷之化學文摘社登記號碼，及調整氧化三丁錫、氫氧化三苯錫等有機錫化合物的毒性分類。

此次修正公告已於111年10月召開研商會，並考量有機錫化合物毒性分類調整，涉及運送、偵測警報設備、專業應變人員設置及證件變更等規定，分階段給予業者半年至一年半的施行緩衝期。另配合我國已全面禁用石綿，除研究、試驗、教育用途外，其他使用用途之登記或核可文件均已屆期，一併修正相關內容。

有關本次發布相關資料請參閱環保署新聞專區下載附加檔案([https://enews.epa.gov.tw/enewsfact\\_index.asp](https://enews.epa.gov.tw/enewsfact_index.asp))，或於隔日至行政院公報網站(<https://gazette.nat.gov.tw/egf/front/index.do>)下載參閱。

详情请点击以下链接：

<https://enews.epa.gov.tw/Page/3B3C62C78849F32F/6636204a-7dc9-4833-bc4a-9596106e9557>

## 2. 台湾环保署将 15 种物质列入关注化学品名单

环保署为强化化学物质管理，避免不当使用化学物质造成人体健康及环境危害，将食品安全疑虑化学物质（一氧化铅、四氧化三铅、硫化钠、硫氰酸钠及 $\beta$ -萘（茶）酚）、新兴精神类活性物质（1,4-丁二醇及海罌粟碱）及易制爆化学物质（硝酸钙、硝酸钠、硝酸铵钙、硝基甲烷、叠氮化钠、过氧酸铵、过氧酸钠及磷化铝）共 3 类 15 种物质列为关注化学物质。

首頁 > 新聞發布

### 顧食安 護健康 保安全 環保署新增列管3類15種關注化學物質

112-01-12 [行政院環境保護署毒物及化學物質局]

**毒物及化學物質管理**

環保署於112年1月12日新增列管3類15種關注化學物質，包含食安風險疑慮化學物質5種、爆製物先驅化學物質8種及新興精神活性物質2種，加強製造、輸入、販賣、使用、貯存及運送等管理作為，並評估運作風險，將爆製物先驅化學物質公告為具有危害性之關注化學物質，為降低不當使用導致人體健康及環境危害，運作人須於113年2月1日前取得核可文件。

環保署表示，本次公告具食安風險疑慮化學物質「四氧化三鉛」（俗稱鉛丹），109年8月臺中中醫診所曾將「四氧化三鉛」混入藥業砂，倘長期攝入，將累積於骨髓中造成鉛中毒，導致運動失調、癱瘓、昏迷、腦病等神經病變或腎臟、心臟、生殖系統及內分泌系統等多種器官損傷；為維護民眾健康，本次環保署將四氧化三鉛公告為關注化學物質，期能透過源頭管制，避免類此事件發生。

另本次公告具食安風險疑慮關注化學物質，包括為縮短皮膚製程曾大量添加之「一氧化鉛」、為冒充臭豆腐硫化物氣味所添加之「硫化鈉」及添加於乳製品或醬油以延長保存期限之「硫氰酸鈉」及「 $\beta$ -萘（茶）酚」。

環保署本次並順應曾被國際恐怖份子使用之硝油炸藥原料「硝酸銨鈣」，及國內爆炸犯罪案件曾拆解爆竹煙火類原料，製成土製炸彈，包括「過氧酸銨」、「過氧酸鈉」、「硝酸鈉」及「硝酸鈣」等；「硝基甲烷」及「疊氮化鈉」遇高熱或碰撞易發生猛烈爆炸；「磷化鋁」易與水或酸發生劇烈反應產生磷化氫，在高溫時會自然並與氧化劑反應引起爆炸，考量上述8種爆製物先驅化學物質恐造成公共安全风险及危害人體健康，依據物質特性列為具有危害性之關注化學物質。



详情请点击以下链接：

<https://enews.epa.gov.tw/Page/3B3C62C78849F32F/eb335faa-f91e-48e1-813b-36f401d3edf3>

## 菲律宾

### 1. 菲律宾发布受保护地区（PAs）和拉姆萨尔湿地的项目申请环保合格证书（ECC）的附加指南

菲律宾环境和自然资源部（DENR）发布备忘录 DMO-2023-01：就位于或邻近受保护地区（PAs）及/或拉姆萨尔湿地的项目申请环保合格证书（ECC）的附加指南。

为配合第 1586 号总统令（菲律宾环境影响报告体系）及其实施细则和条例（DAO 2003-30）的实施，确保受保护地区（PAs）和拉姆萨尔遗址得到相应的保护，作为适应和减缓气候变化的重要工具，菲律宾 DENR 发布了处理某些 ECCs 申请的附加指南，对申请 ECC 的一些流程进行了说明。

详情请点击以下链接：

<https://eia.emb.gov.ph/wp-content/uploads/2023/01/DENR-Memorandum-Order-2023-01.pdf>

点评：备忘录进一步阐明细化了申请 ECC 时的部分流程，Intertek 专家服务部在此提醒有相关项目的企业及时进行关注，按要求准备项目描述报告，以及相关材料供秘书办公室（OSEC）审核。

### 2. 菲律宾通过全面实施生产者延伸责任法（EPR 法案）

菲律宾环境和自然资源部（DENR）发布了第 11898 号共和国法案（又称“将塑料包装废弃物生产者责任延伸制度化法案”，也被称为 2022 年生产者扩展责任（EPR）法案）的实施细则和条例（IRR）。这项法律要求大型公司建立回收塑料包装的机制。EPR 法案中规定，公司有责任在产品被销售和使用后对其进行适当和有效地回收、处理、循环利用，以减少塑料废物的产生，并通过回收再利用或重复使用来延长塑料的寿命。EPR 法案还将有助于推进循环经济，避免或最大限度地减少污染，同时鼓励最大限度地利用材料，缓解气候变化，保护我们赖以生存的生态系统。

详情请点击以下链接：

<https://nswmc.emb.gov.ph/wp-content/uploads/2023/02/DENR-pushes-for-Circular-Economy-by-full-implementation-of-Extended-Producer-Responsibility-Act.pdf>

<https://apidb.denr.gov.ph/infores/uploads/DAO-2023-02.pdf>

点评：Intertek 专家服务部提醒相关的大型企业在该法律生效后的六个月内及时按照 EPR 法案的要求开展塑料回收和转移计划。企业应负责分配资源，以无环境危害的方式收集、回收、运输、加工和处置塑料包装废弃物。生产商、分销商和零售商根据 EPR 法案实施举措将有资格获得税收优惠。但是，未能遵守 EPR 法案规定的企业将被处以罚款。

### 3. 菲律宾发布苯和氯乙烯的化学品管控指令（CCO）的征求意见稿

菲律宾环境管理局（EMB）拟发布两个 CCO，分别对苯和氯乙烯进行管控，目前公布了草稿版，并处于向大众征求意见的阶段。一旦 CCO 正式发布，苯和氯乙烯的用途将被限制。

详情请点击以下链接：

<https://chemical.emb.gov.ph/>

[CO2022-FT5N36377-File\\_1.docx \(live.com\)](#)

[CO2022-FT5N36377-File\\_2.docx \(live.com\)](#)

点评：Intertek 专家服务部提醒有苯及氯乙烯相关业务的企业及时关注 CCO 的最新动向，必要时可以发表自己的意见（chemicals@emb.gov.ph），一旦 CCO 正式发布，若有相关用途需要按照 CCO 的要求申请注册再进行活动。

## 近期会议活动

中国毒理学会第十次全国毒理学大会，2023年4月8-11日，中国珠海

<https://chntox.org/newsmes.aspx?t=4&pid=35&cid=6174&id=31624>

第88届API China 中国国际医药原料药中间体包装设备交易会，2023年4月12-14日，中国青岛

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

第十届中国（上海）国际日用化学品原料及添加剂展览会，2023年4月26-28日，中国上海

<http://www.rhylexpo.com/>

上海国际表面活性剂和洗涤剂展览会，2023年4月26-28日，中国上海

<http://www.iesdexpo.com/>

2023第七届中国（淄博）化工科技博览会，2023年5月12-14日，山东淄博

<http://boftec.zibo.gov.cn/cec/exhibition/detail?id=55>

Food Contact Regulations Europe 2023，2023年4月17-18日，比利时布鲁塞尔+线上

<https://events.chemicalwatch.com/644951/food-contact-regulations-europe-2023>

2023韩国化工及制药原料展览会，2023年4月18-21日，韩国首尔

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

Regulatory Updates Europe 2023，2023年4月19-20日，比利时布鲁塞尔+线上

<https://events.chemicalwatch.com/618446/regulatory-updates-europe-2023>

PFAS Global 2023，2023年4月25日，线上

<https://events.chemicalwatch.com/651941/pfas-global-2023>

Biocides Symposium 2023，2023年5月2-3日，丹麦哥本哈根+线上

<https://events.chemicalwatch.com/655853/biocides-symposium-2023>

Regulatory Summit Asia 2023，2023年5月29-30日，新加坡+线上

<https://events.chemicalwatch.com/656236/regulatory-summit-asia-2023>

Food Contact Regulations Asia 2023，2023年5月31日，新加坡+线上

<https://events.chemicalwatch.com/654938/food-contact-regulations-asia-2023>

Cosmetics Regulations Asia 2023，2023年6月1日，新加坡+线上

<https://events.chemicalwatch.com/656285/cosmetics-regulations-asia-2023>

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本文件内容不代表 AICM 观点。

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## Viewpoint

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

In this quarter, the South Korean authority continues to revise the *Rules for Classification and Labelling of Chemicals* and *Hazard Assessment Results of Chemical Substances*, and suggests that enterprises continuously pay attention to whether any chemical substances are newly added to the *List of Toxic Chemical Substances* or the official classification of any toxic substances is changed in the list, and thus take timely compliance measures, such as updating the classification, MSDS and labelling. Recently, South Korea revised the relevant requirements and approval regulations for household chemical products and suggested that enterprises producing household chemical products continue to pay attention to the relevant approval regulations.

In order to improve the safety of workers, Japanese authority imposed workplace exposure limits on 860 substances and identified 33 substances as highly mutagenic. In addition, Japan listed 200 substances as “Class 1” carcinogenic and required enterprises to keep working records for 30 years. To reduce the burden on enterprises, Japanese authorities planned to exempt the requirement of submitting annual reports on 106 substances according to the CSCL. Moreover, Japan also released the *Results of 2021 Environmental Surveys of Chemical Substances (Summary)*, and updated the positive list of Food Utensils, Containers and Packaging, and the positive list for cosmeceuticals and hair dyes. Furthermore, Japan launched a public opinion collection on the *Measures for Perfluorohexane Sulfonate (PFHxS) (Draft) under CSCL* and the *Designated substances and their standard concentrations (Draft) under the ISHL*.

In order to strengthen the management of chemical substances and avoid the harm to human health and the environment caused by improper use of chemical substances, the Taiwan Environmental Protection Agency added 15 more concerned chemical substances and strengthened the prohibition and restriction of organic tin.

The Department of Environment and Natural Resources (DENR) of the Philippines released additional guidelines for applying for an Environmental Compliance Certificate (ECC) for projects located in or adjacent to protected areas (PAs) and/or Ramsar Wetlands, further clarifying the process and details of applying for ECCs. DENR fully implemented the Extended Producer Responsibility Act (EPR Act) and released the Implementing Rules and Regulations (IRR) of EPR Act, clarifying the responsibilities of enterprises after sales and use. The Environmental Management Bureau (EMB) of the Philippines released two Chemical Control Order (CCO) drafts for comments to further control benzene and vinyl chloride.

# Regulatory Updates

## South Korea

### 1. South Korea updated *Notice on List of Toxic Substances*

On December 7, 2022, the National Institute of Environmental Research (NIER) of Korea released the updated *Notice on List of Toxic Substances* in accordance with Announcement No.2022-80, amending the chemical substance names of 15 toxic substances and adding 14 new toxic substances.

For details, please click the following link:

<https://www.nier.go.kr/NIER/cop/bbs/selectNoLoginBoardList.do> (No.1421)

Comment: Enterprises that produce or import chemical substances for downstream supply in Korea should pay attention to the list of toxic substances updated by NIER, timely submit the list of chemical substances in accordance with the *Chemical Control Act*, handle the import declaration of toxic substances and obtain the business license of hazardous chemical substances.

### 2. South Korea updated *Regulations on Classification and Labelling of Chemical Substances*

On December 7, 2022, the National Institute of Environmental Research (NIER) of Korea released amendments to the *Regulations on Classification and Labelling of Chemical Substances* in accordance with Announcement No.2022-81, amending the classification of 15 toxic substances, 3 restricted substances and 1 accident emergency substance, and adding the classification information of 14 new toxic substances.

For details, please click the following link:

<https://www.nier.go.kr/NIER/cop/bbs/selectNoLoginBoardList.do> (No.1422)

Comment: Enterprises that produce or import toxic substances or chemical substances containing toxic substances for downstream supply in Korea should pay attention to the hazard classification and labeling results updated by NIER, and timely update the MSDS and labels to keep consistent with the results of NIER.

### 3. Reform Scheme on Toxic Substance Identification Management System Jointly Formulated by Private and Public Sectors

On December 8, 2022, the Minister of Environment released the reform scheme on the “Toxic Substance Identification Management System” in the 12th Pending National Affairs Ministerial Conference. The scheme contained administration by different degrees of hazards of toxic substances<sup>①</sup>.

① According to The Act on Registration and Evaluation of Chemicals (K-REACH), there are 1,093 types of toxic substances (as of November 30, 2022).

After The Act on Registration and Evaluation of Chemicals took effect in January 2015, this reform scheme was prepared to cope with the increasing social regulation burden<sup>②</sup> and improve management effectiveness.

② Designated toxic substances rise by 3 times annually on average: 722 types in 2014 → 1,082 types in 2021

Therefore, the Ministry of Environment has worked together with civil organizations, industries, government officials and experts to hold the “Chemical Safety Policy Forum” since May 2022, discussing the direction of improvement and asking for opinions to conclude a reasonable reform scheme.

※ Website ([www.chemnavi.or.kr/forum](http://www.chemnavi.or.kr/forum)) publishes the discussion content in the “Chemical Safety Policy Forum”.

For this reason, operating facilities, operators and businessmen should be regulated differently, so that they can focus on the prevention and response management of chemical accidents according to the hazards of toxic substances, and minimize exposure of human body and environment. The major reform orientations are as follows:

First of all, the designated “toxic substances” should be further divided into whether they influence human body/environment, and acute/chronic influence, “acute hazard”, “chronic hazard” and “ecological hazard”.

Secondly, in accordance with the Chemical Control Act (CCA) and considering the hazards and capacity of chemical substances, business permits and operating facility standards should be managed by different levels.

The Ministry of Environment plans to release an amendment to K-REACH, CCA and related sub-regulations prior to August 2023 according to this reform scheme.

For details, please click the following link:

<https://www.me.go.kr/home/web/board/read.do?menuId=10525&boardMasterId=1&boardCategoryId=39&boardId=1566570>

#### **4. Amendments to the relevant provisions on the exemption approval of chemical substance safety information in South Korea**

On December 9, 2022, the Ministry of Environment of Korea released amendments to the relevant provisions on the exemption approval of chemical substance safety information in Korea in accordance with Announcement No.2022-238, mainly covering:

1. If commercial confidentiality is approved under other acts, the registration number and declaration number of such chemical substances are also deemed to be approved for commercial confidentiality (Article 7), and the registrant can keep it confidential, provided that
  - In this case, it is necessary to indicate whether such chemical substances have been registered/declared in the communication documents (such as the MSDS and No.26 Schedule of the Implementation Rules of the K-REACH), so that downstream users can verify whether such chemical substances have been legally registered or declared.

For details, please click the following link:

<http://www.me.go.kr/home/web/law/list.do?maxPageItems=10&maxIndexPages=10&searchKey=&searchValue=&menuId=71&condition.typeCode=admrul&condition.ruleType=&order=&pageOffset=100> (No.1338)

Comment: According to Article 29 of K-REACH, if a chemical substance is a registered/declared chemical substance or a hazardous chemical substance (hazardous chemical substance or mixture containing the chemical substance with a concentration limit and above) that has been pre-registered and has a buffer period, enterprises transferring the chemical substance or mixture containing the chemical substance shall provide downstream users with safe use information including the registration number, name, hazard and risk information of the chemical substance. In addition, enterprises should record the relevant information in the MSDS when preparing and providing the MSDS according to the provisions of Items 1 or 3, Article 110, or Article 111 of K-OSHA, and provide downstream users with the relevant MSDS and No.26 Schedule of the Implementation Rules of the K-REACH. However, according to the relevant provisions of the exemption approval of chemical substance safety information in Korea, enterprises can apply to the Ministry of Environment of Korea for the exemption approval of chemical substance safety information after obtaining the commercial confidentiality approval of the chemical substance according to CCA, K-OSHA and other laws. After approval, enterprises can only indicate whether the chemical substance has been registered/declared, without providing the registration number and declaration number of the chemical substance to downstream users.

## 5. Regulations on the Approval of Household Chemical Products Subject to Safety Confirmation

On December 12, 2022, the National Institute of Environmental Research (NIER) of Korea released the *Regulation on Consumer Chemical Products subject to Safety Check Approval* according to the Announcement No.2022-82, mainly covering:

According to the K-BPR, “household chemical products subject to safety confirmation” should be declared or approved. Antibacterial and disinfectant products used for humidifiers have diverse uses and forms, and the requirements are also different. The amendments are as follows:

1. Antibacterial and disinfectant products used for humidifiers have been subdivided, and the requirements for application materials for approval have been clarified
  - According to the dissolution characteristics of products in water, existing antibacterial and disinfectant products used for humidifiers have been subdivided into disinfectants and preservatives. In addition, “anti-corrosion treatment products for humidifiers” have been defined and classified into other product categories to avoid confusion with preservatives.
2. Numbering standards have been formulated according to the expanded scope of approved products
  - Anti-corrosion treatment products for humidifiers have been numbered according to the approval classification code by item category
3. The transition measures, production and sales validity period of biocides and products treated by biocides have been clarified

For details, please click the following link:

<https://www.nier.go.kr/NIER/cop/bbs/selectNoLoginBoardList.do> (No.1424)

Comments: Enterprises should pay attention to whether products exported to Korea are designated as “household chemical products subject to safety confirmation” and complete the relevant test and declaration of products according to the requirements of laws and regulations.

## 6. Regulations on Risk Assessment Objects and Methods of Household Chemical Products

On December 19, 2022, the National Institute of Environmental Research (NIER) of Korea released the *Regulation on Subjects and Methods of Risk Assessment for Consumer Chemical Products* according to the Announcement No.2022-85, mainly covering:

According to K-BPR, in order to complete the exposure and risk assessment of users of household chemical products, exposure scenarios and exposure assessment parameters have been set for general consumers and professional consumers according to product types and use methods. According to user types and diversified uses of products, the amendments are as follows:

1. The risk assessment object “professional user” and its definition have been added
2. Exposure calculation formulas for different exposure routes in Schedule 5 has been revised  
Exposure scenarios have been subdivided according to product types, and the inhalation and percutaneous route algorithms have been partially modified.
3. General exposure coefficient in Schedule 6 and product exposure coefficient in Schedule 7 have been added and revised

Product exposure coefficient: The exposure coefficient of sterilization products and rescue products for general/professional users, which are more suitable for real use, and the product exposure coefficient for professional users (disinfection experts) have been added, and some existing coefficients have been revised.

For details, please click the following link:

<https://www.nier.go.kr/NIER/cop/bbs/selectNoLoginBoardList.do> (No.1428)

Comments: The Ministry of Environment of Korea conducted a risk assessment on products under investigation and products of concern at home and abroad, and after the assessment, designated “household chemical products subject to safety confirmation”. Through this regulation, enterprises can understand the standards and methods specified by the Ministry of Environment for “household chemical products subject to safety confirmation”.

## **7. Update of tonnage limits of toxic substances, restricted substances, prohibited substances and authorized substances**

On December 20, 2022, the Ministry of Environment of Korea released amendments to the allowable tonnage of toxic substances, restricted substances, prohibited substances and authorized substances according to Announcement No.2022-246, specifying the upper and lower allowable tonnage limits of (11) new toxic substances. The concentration limits of (5) chemical substances originally designated as toxic substances and also as emergency substances have changed, so their concentration limits required as emergency substances have also been revised synchronously to maintain consistency.

For details, please click the following link:

<http://www.me.go.kr/home/web/law/list.do?maxPageItems=10&maxIndexPages=10&searchKey=&searchValue=&menuId=71&condition.typeCode=admrul&condition.ruleType=&order=&pagerOffset=90> (No.1374)

Comment: Enterprises that produce or import chemical substances for downstream supply in Korea should pay attention to the regulations of the Ministry of Environment of Korea on the prescribed tonnage of toxic substances and strictly abide by the prescribed tonnage during production, use and storage.

## 8. Update of designated restricted substances and prohibited substances

On December 20, 2022, the Ministry of Environment of Korea released an amendment to the publicity of designated restricted substances and prohibited substances according to Announcement No.2022-248, mainly covering:

1. Restricted substances 06-5-10 (Chromium(6+)) and mixtures containing 0.1% Chromium(6+ or more): Strontium chromate (CAS No. 7789-06-2) is used as coating for color steel plates and coil steel, and the buffer period of its limit standard is extended to 2025.
  - The date “January 1, 2023” when strontium chromate is originally prohibited for production and import has been changed to “July 1, 2025”.
  - The date “July 1, 2023” when strontium chromate is originally prohibited for use, sales, storage and transportation has been changed to “January 1, 2025”.

For details, please click the following link:

<http://www.me.go.kr/home/web/law/list.do?maxPageItems=10&maxIndexPages=10&searchKey=&searchValue=&menuId=71&condition.typeCode=admrul&condition.ruleType=&order=&pageOffset=100> (No.1368)

Comment: It is undoubtedly good news for enterprises to provide a longer buffer period for the restriction of chromium-containing products. However, due to increasingly stringent global restrictions and prohibitions on chromium and chromium-containing substances, enterprises should develop alternative substances as soon as possible, or ensure that the chromium content of coatings provided before the new deadline is less than 0.1%.

## 9. South Korea released the Hazard Assessment Results of Chemical Substances

On December 21, 2022, the National Institute of Environmental Research (NIER) of Korea released *Hazard Assessment Results of Chemical Substances* according to Announcement No.2022-87, in schedules thereto amending the names of 5 new chemical substances and codes of 3 existing chemical substances and 15 toxic substances, deleting the hazard assessment results of 1 new chemical substance, **updating the hazard classification of 34 new chemical substances and 12 existing chemical substances**, and adding 56 new chemical substances and 27 existing chemical substances.

For details, please click the following link:

<https://www.nier.go.kr/NIER/cop/bbs/selectNoLoginBoardList.do> (No.1429)

Comment: Enterprises that produce or import chemical substances for downstream supply in Korea should pay attention to hazard assessment/classification results updated by NIER, and timely update MSDS and labels to keep consistent with the results of NIER.

## 10. South Korea updated the list of existing biocidal substances with approved buffer period

On December 30, 2022, the Ministry of Environment of Korea released an amendment to the list of existing biocidal substances with approved buffer period according to Announcement No.2022-92, mainly covering:

1. The types of 5 biocides and their approval buffer period have been updated
2. 109 biocidal substances and their approval buffer period have been revoked
3. The types of 106 biocides and their approval buffer period have been revoked
4. The numbers “2” to “452” have been amended to “1” to “343”
5. Six numbers have been adjusted
6. 12 biocidal substances and their approval buffer period have been added

For details, please click the following link:

<https://www.nier.go.kr/NIER/cop/bbs/selectNoLoginBoardList.do> (No.1438)

Comment: Enterprises should pay attention to whether biocides they produce, import and sell in Korea involve the corresponding buffer period that have been changed and cancelled to take corresponding response measures in time.

## 11. Partial amendments to K-REACH in South Korea

On January 3, 2023, the Ministry of Environment of Korea released amendments to K-REACH, which will be implemented on January 4, 2024, according to Announcement No.19172, mainly covering:

1. After completing the product declaration, enterprises that produce or import products containing preferentially controlled chemical substances shall apply to the competent authority for change if the exposure information, content, use and other important matters of such preferentially controlled chemical substances change.
2. The succession of rights and obligations related to the registration and declaration of chemical substances and the declaration of products containing preferentially controlled chemical substances has been regulated. According to K-REACH, successors shall declare their succession to the competent authority within one month from the date of succession.

For details, please click the following link:

<https://www.law.go.kr/LSW/lsInfoP.do?lsiSeq=247281&viewCls=lsRvsDocInfoR#>

Comment: Enterprises that produce or import products containing preferentially controlled chemical substances in Korea should pay attention to the list of preferentially controlled chemical substances updated by the Ministry of Environment of Korea. If products contain

designated preferentially controlled substances and such products should be declared according to the regulations, enterprises should complete the declaration before producing or importing such products. If the above changes occur after product declaration, enterprises shall further apply for changes. In addition, there are many types of succession mentioned above, involving the death of the original applicant, business transfer and merger. In case of succession, successors shall declare in accordance with the amendments.

## **12. Partial amendments to the Standards for Classification and Labelling of Chemicals and Material Safety Data Sheet of Chemicals**

On February 15, 2023, according to Announcement No. 2023-9, the Korean Ministry of Employment and Labor (MOEL) issued some amendments to the Standards for Classification and Labeling of Chemicals and Material Safety Data Sheet of Chemicals, which mainly include:

1. For entrusted manufacturing of chemical substances or mixtures in the form of Original Equipment Manufacturing (OEM), the entrusting party or the entrusted party may submit MSDS or apply for trade secret approval.
2. If the entrusting party submits the MSDS or applies for trade secret approval, the entrusting party shall transmit the relevant results to the entrusted party.

For details, please click the following link:

<https://law.go.kr/admRulInfoP.do?admRulSeq=2100000219530&chrClsCd=010202&urlMode=admRulRvsInfoR>

Comments: The purpose of the Standards for Classification and Labeling of Chemicals and Material Safety Data Sheet of Chemicals is to set the matters required for the classification of chemical substances, material safety data sheet (MSDS) of chemicals, application for trade secret approval, warning labels and worker training. The original regulation required that the manufacturer/importer/agent appointed by the non-Korean manufacturer of chemical substances and chemicals may submit a material safety data sheet or apply for trade secret approval, and now the subject of the above application is added.

## **13. Draft of partial amendments to the safety and labelling standards for designated “household chemical products subject to safety confirmation”**

On February 27, 2023, the Ministry of the Environment of Korea released draft amendments to the safety and labeling standards for designated “household chemical products subject to safety confirmation” according to Announcement No.2023-112, mainly covering:

In order to solve industry problems, (70) usable anti-corrosion substances have been allowed to be added to spray products according to the risk assessment results.

For details, please click the following link:

[https://chemp.me.go.kr/cop/bbs/selectBoardList.do?bbsId=BBSMSTR\\_00000000001](https://chemp.me.go.kr/cop/bbs/selectBoardList.do?bbsId=BBSMSTR_00000000001)

#### **14. South Korea released relevant announcements on the registration of existing chemical substances**

On December 27-28, 2022, a training meeting of risk assessment software (K-Chesar) was held in Korea.

On December 28, 2022, the Ministry of the Environment of Korea updated the “Korean Use-map Case Manual” and exposure scenario templates.

On January 4, 2023, Korea released a list of hazard test data supported by the government and a list of expected production test data, requiring enterprises that have applied for the use of test data to complete system confirmation before January 13.

On January 10, 2023, the Ministry of the Environment of Korea released the results of the 14<sup>th</sup> pre-registration of existing chemical substances.

On February 6, 2023, Korea enlisted implementing agencies of K-REACH and K-BPR government projects in 2023.

On February 28, 2023, Korea released a list of implementing agencies of K-REACH and K-BPR government projects in 2023.

On February 10, 2023, the Ministry of the Environment of Korea released a draft for an extension of authorized substances (list of candidate substances) for comments according to Announcement No.2023-84, subject to a deadline of February 28, 2023.

On February 15, 2023, Korea released a list of all government hazard test data and its reading and use methods.

For details, please click the following link:

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

#### **15. Relevant announcements of Material Safety Data Sheet (MSDS) in South Korea**

On December 19, 2022, the Ministry of Employment and Labor (MOEL) of the Republic of Korea added a function to prompt the hazard classification of mixtures in MSDS editing window of MSDS IT system, and distinguished input areas of components displayed in the MSDS and those not displayed in the MSDS in MSDS submission window of MSDS IT system.

On December 22, 2022, the Ministry of Employment and Labor (MOEL) of the Republic of Korea added functions of transfer MSDS jurisdiction, enterprise information change and chemical substance management in the MSDS IT system.

For details, please click the following link:

<https://msds.kosha.or.kr/msds/BB00100M01.do>

## 16. Relevant announcements on biocides and products treated by biocides in South Korea

On December 2, 2022, the Ministry of Environment (MOE) of Korea released guidance documents related to the differentiation method, purchase and use precautions of biocides and products treated by biocides.

For details, please click the following link:

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

On December 2, 2022, the Ministry of the Environment (MOE) of Korea released a Q&A set on the types and objects of “household chemical products subject to safety confirmation” in accordance with K-BPR and *Regulation on labeling and advertising of Consumer Chemical Products*.

On December 21, 2022, the Ministry of the Environment (MOE) of Korea released relevant Q&A sets in accordance with the *Regulation on labeling and advertising of Consumer Chemical Products* (to be implemented on July 29, 2023).

For details, please click the following link:

[https://chemp.me.go.kr/cop/bbs/selectBoardList.do?bbsId=BBSMSTR\\_00000000001](https://chemp.me.go.kr/cop/bbs/selectBoardList.do?bbsId=BBSMSTR_00000000001)

## Japan

### 1. Japan identified 33 substances as highly mutagenic

On December 12, 2022, the Ministry of Health, Labour and Welfare (MHLW) of Japan identified 33 new substances as highly mutagenic substances (highly mutagenic substances can cause permanent changes or mutations in DNA sequence) among 807 new substances recently reported. Several of these substances and their common uses are as follows:

- 2-ethyl-1-nitroanthracene-9,10-dione, used as dye intermediate;
- Hydroxy-5-[(pro-2-pyl)amino]anthracene-9,10-dione, used as dye intermediate;
- Xenon difluoride (II), used for etching semiconductor insulating films;
- Addition products of dimethyl-2,5-dione/[(chloromethyl) ethylene oxide and (condensation and polymerization product of phenol/methanal)] and 2-methacrylic-2-acid}, used for adhesives and sealants.

(Click the following link for a detailed list)

On December 7, 2022, MHLW sent a notice to the Japan Chemical Industry Association, reminding enterprises that produce and dispose of such substances to take workplace health and

safety measures specified in the MHLW guidelines to prevent the harm of mutagenic substances to health. This also applies to mixtures containing highly mutagenic substances in concentrations greater than 1% by weight.

For details, please click the following link:

<https://www.toryo.or.jp/jp/anzen/news/files/MHLW20221212.pdf>

## **2. Japan released the Results of 2021 Environmental Surveys of Chemical Substances (Summary)**

On December 26, 2022, the Ministry of Environment (MoE) of Japan released the *Results of 2021 Environmental Surveys of Chemical Substances (Summary)*, covering “preliminary environmental survey”, “detailed environmental survey” and “monitoring survey”.

In the preliminary environmental survey, 6 substance groups (ivermectin, cyclohexylamine, N-(2,3-dimethylphenyl) hydroxyanthranilic acid (also known as mefenamic acid), streptomycin, 2-hydroxy-4-methoxy-benzophenone (also known as benzophenone-3), 2-ethylhexyl-p-methoxycinnamate) were detected among 10 substances (groups) investigated in terms of water quality. No investigated substances were found in the sediments. One of the two investigated substances (furan) was detected in the atmosphere. These survey data will be used as basic data when specifying specific chemical substances in PRTR and considering measures related to environmental risks.

In the detailed environmental survey, 6 substances (groups) were investigated for a risk assessment on preferentially assessed chemical substances specified in CSCL. 3 substances (groups) (cyclic polydimethylsiloxane, tetraalkylammonium salt, tetramethylammonium hydroxide) were detected among 5 substances (groups) investigated in terms of water quality. One substance (group) (2-benzylidenecaprylaldehyde) was detected in the sediments. One substance (group) (cyclic polydimethylsiloxane) was detected in the biological survey. No investigated substances were found in the atmosphere. These results will be used in general environmental exposure assessments.

In the monitoring survey, the following 11 substances covered by *Convention on Persistent Organic Pollutants* were investigated to monitor the residual status of Class 1 specific chemical substances specified by CSCL in the ordinary environment and to master the change in residual status of target substances under *Convention on Persistent Organic Pollutants* in the ordinary environment.

- PCBs
- HCB
- DDT Classes

- Perfluorooctanesulfonic acid (PFOS)
- Perfluorooctanoic acid (PFOA)
- Pentachlorobenzene
- Endosulfan
- PCN
- Hexachloro-1, 3-butadiene
- SCCP
- Perfluorohexanesulfonic acid (PFHxS)

According to the survey results, endosulfan was detected in water, sediments and atmosphere, and hexachloro-1,3-butadiene was detected in sediments, organisms (only fishes) and atmosphere. Other investigated substances (groups) were detected in all media (water, sediments, organisms and atmosphere).

For details, please click the following link:

[https://www.env.go.jp/press/press\\_01027.html](https://www.env.go.jp/press/press_01027.html)

### 3. 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>

#### 4. Japanese lists 200 substances as “Class 1” carcinogenic

On December 26, 2022, the Ministry of Health, Labour and Welfare (MHLW) of Japan released a notice that 200 substances were classified as “Class 1” carcinogenic according to the ISHL amendment and implemented in two stages, and stipulated that enterprises must keep work records of workers who produce or dispose of such carcinogenic substances for 30 years.

Regulations on 120 substances will be implemented since April 1, 2023, covering:

- Biphenyl, used in the production of electronic products and automotive transmission fluid;
- 2-nitrotoluene, used for dye production;
- 1,2,3-trichloropropane, used as chemical intermediate and crosslinking agent in polymer production; and tetrafluoroethylene, used as tableware coating, etc.

(Click the following link for a detailed list)

Regulations on 80 substances will be implemented since April 1, 2024, covering:

- Chloramphenicol, a drug used to treat infection;
- Methacrylic acid 2,3-epoxy propyl esters, used to produce epoxy polymers, vinyl and acrylic resin;
- Glycidyl amine, used as insecticide;
- Lead styrene, used in explosives; and 1-nitropyrene, used for photosensitive printing, such as 3D printing.

(Click the following link for a detailed list)

However, the following substances and the temporary disposal of designated carcinogens by enterprises are excluded.

- Ethanol
- Specially controlled substances (specially controlled substances specified in Article 38-3 of the *Rules on the Prevention of Hazards from Special Chemical Substances*)

For details, please click the following link:

[https://www.mhlw.go.jp/stf/newpage\\_29998.html](https://www.mhlw.go.jp/stf/newpage_29998.html)

#### 5. Japan updated the positive list of Food Utensils, Containers and Packaging

On March 6, 2023, the Ministry of Health, Labour and Welfare (MHLW) of Japan released a revised draft of the positive list of substances allowed to be used in food contact materials (FCM). The positive list is applicable to food contact utensils, containers and packaging made of

synthetic resin. Previously, MHLW has publicly solicited the public's opinions on the revision of the positive list. This update mainly includes two parts.

1. According to the opinions publicly solicited for the "Positive List of Table 2 Additives" on April 26, 2022, the latest revision of the *20230306 New Draft of Table 2* was sorted and published.
2. According to the "Positive List of Table 1 Basic Materials" published on December 26, 2022, the *20230306 New Draft of Table 1* was re-sorted and updated after listening to the opinions of relevant enterprises.

For details, please click the following link:

[https://www.mhlw.go.jp/stf/newpage\\_05148.html](https://www.mhlw.go.jp/stf/newpage_05148.html)

## **6. Japan proposed to exempt 106 substances from annual reports**

Japanese authorities plan to exempt 106 substances from annual reports according to the CSCL. According to the requirements of CSCL, manufacturers and importers who manufacture/import general chemical substances 1t or more every year must provide annual reports to the Ministry of Economy, Trade and Industry (METI), the Ministry of Health, Labour and Welfare (MHLW) and the Ministry of the Environment (MoE), indicating the amount of substances manufactured or imported in the previous year.

If approved, the draft list of substances will be added to the "list of chemical substances exempted from notification of manufacturing/import quantities". This means that enterprises do not need to submit annual reports of these substances to METI, MHLW and MoE for a fiscal year since April 2022 and the next fiscal year.

For details, please click the following link:

<https://public-comment.e-gov.go.jp/servlet/PcmFileDownload?seqNo=0000246033>

## **7. Japan updated the list of additives for quasi-drugs and hair dyes**

On December 23, 2022, the Ministry of Health, Labour and Welfare (MHLW) of Japan deleted two additives (stearyl dimethylamine and methyl rosaniline chloride) from the list of additives for quasi-drugs, which means that these two additives would no longer be used in quasi-drugs. The updated list contains 2746 additives, which can be used in medicine, health care products and some cosmetics for whitening and anti-aging. Methyl rosaniline chloride was also removed from the list of additives for hair dyes.

For details, please click the following link:

<https://www.mhlw.go.jp/content/001029257.pdf>

<https://www.mhlw.go.jp/content/001029219.pdf>

## **8. Update of Japanese Chemical Substance Control Law database (J-CHECK) and other data platforms**

On January 31, 2023, Japanese Chemical Substance Control Law database (J-CHECK), NITE Chemical Risk Information Platform (NITE-CHRIP) and ASEAN-Japan Chemical Safety Database (AJCSD) released updated data. The updated data on J-CHECK includes combinations of MITI number and CAS number and a new link to the Japan Existing Chemical Toxicity Database (JECDB).

For details, please click the following link:

[https://www.nite.go.jp/chem/jcheck/top.action?request\\_locale=ja](https://www.nite.go.jp/chem/jcheck/top.action?request_locale=ja) (J-CHECK)

[https://www.nite.go.jp/chem/chrip/chrip\\_search/html/update.html](https://www.nite.go.jp/chem/chrip/chrip_search/html/update.html) (NITE-CHRIP)

[https://www.nite.go.jp/chem/kanren/asia\\_kanren/ajcsd.html](https://www.nite.go.jp/chem/kanren/asia_kanren/ajcsd.html) (AJCSD)

## **9. Japan initiated a solicitation of opinions on the Measures for Perfluorohexane Sulfonate (PFHxS) (Draft)**

On February 18, 2023, MHLW, METI, and MoE initiated a solicitation of opinions on the Measures for Perfluorohexane Sulfonate (PFHxS) (Draft) in the CSCL. These Measures (draft) stipulate that the production and import of PFHxS and its salts, the import of products using PFHxS and its salts, and the use other than approved uses are prohibited in principle from the spring of 2024, and also set out technical standards for the disposal of PFHxS or products containing PFHxS salts.

For details, please click the following link:

<https://public-comment.e-gov.go.jp/servlet/Public?CLASSNAME=PCMMSTDETAIL&id=595223011&Mode=0>

## **10. Japan initiated a solicitation of opinions on the Designated Substances and Their Standard Concentrations (Draft) in the ISHL**

On February 25, 2023, the Ministry of Health, Labour and Welfare (MHLW) of Japan launched a public opinion collection on the Designated Substances and Their Standard Concentrations (Draft) in the ISHL. According to Item 2, Article 577-2 of the revised ISHL, for substances that are not likely to cause health problems to workers by limiting their exposure to a certain level according to the instructions of the Minister of MHLW among substances subject to risk assessment, the level of workers' exposure to these substances must be lower than the standard concentration specified by Minister of MHLW in indoor workplaces where such substances are produced or disposed. The solicitation will end on March 26, 2023.

For details, please click the following link:

<https://public-comment.e-gov.go.jp/servlet/PcmFileDownload?seqNo=0000249503>

## Taiwan

### 1. Taiwan strengthened the prohibition and restriction of organic tin, and enhanced the source management of chemical substances

In order to cooperate in the prevention of fake pesticides and strengthen the operation and management of organotin compounds, the Taiwan Environmental Protection Agency and the Council of Agriculture, Executive Yuan revised the *Guidelines on Regulated Toxic Chemical Substances and the Management of Their Handling* and prohibited the use of tributyltin oxide, triphenyltin chloride and other organotin compounds in the production of biocides, antifouling paint or antifouling systems according to international control trend. Japan adjusted the toxicity classification of tributyltin oxide, triphenyltin chloride and other organotin compounds, and updated their CAS registration number (CAS number). In terms of this adjustment to the toxicity classification of organotin compounds, practitioners should follow the provisions of accident prevention and emergency response, and be given a buffer period of 1-1.5 years in stages.

In order to jointly prevent the abuse of organotin compounds, the Taiwan Environmental Protection Agency further adjusted the prohibition and restriction regulations of 10 organotin compounds, including tributyltin oxide and triphenyltin chloride, by referring to international regulations, investigating domestic operation and consulting experts and scholar, prohibiting their use in the production of biocides, antifouling paint or antifouling systems to strengthen the management of organotin compounds. According to international databases and relevant scientific research, the Taiwan Environmental Protection Agency updated the information of several organotin compounds, adding CAS numbers of triphenyl- $\alpha$ -naphthyl tin, tripropyltin fluoride, trimethyltin bromide, ginseng (triphenyltin) methane, and adjusted the toxicity classification of organotin compounds such as tributyltin oxide and triphenyltin hydroxide.



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### 加嚴有機錫禁用規定 強化化學物質源頭管理

112-02-20 [行政院環境保護署毒物及化學物質局]

毒物及化學物質管理

行政院環境保護署與行政院農業委員會合作防堵偽農藥，加強有機錫化合物運作管理，修正「列管毒性化學物質及其運作管理事項」，依國際管制趨勢禁止氧化三丁錫、氯化三苯錫等有機錫化合物用於製造殺生物劑、製造防污漆或防污系統，並調整氧化三丁錫、氯化三苯錫等毒性分類，更新化學文摘社登記號碼。考量此次調整加嚴有機錫化合物毒性分類，既有業者應符合事故預防及緊急應變規定，分階段給予半年至一年半的施行緩衝期。

111年雲林直轄地下農藥工廠，不法業者將毒性化學物質「氯化三苯錫」製成俗稱「白藥膏」之偽農藥。雲林縣環保局稽查發現違法業者108年至110年共輸入氯化三苯錫33.5公噸，未依毒性及關注化學物質管理法（下稱毒管法）申報運作紀錄，除依毒管法罰鍰及廢止其毒性化學物質核可文件，並就其申報不實、涉文書虛偽記載，移送檢察單位偵辦。

為共同防範有機錫化合物流用、濫用，環保署參考國際管制規定，調查國內運作情形並經諮詢專家學者建議，進一步調整氧化三丁錫、氯化三苯錫等10種有機錫化合物禁用規定，禁止用於製造殺生物劑、製造防污漆或防污系統，以強化有機錫化合物管理。並依國際資料庫及相關科學研究更新物質資訊，增列三苯基- $\alpha$ -萘錫、氯化三丙錫、溴化三甲苯錫及參（三苯錫）甲烷之化學文摘社登記號碼，及調整氧化三丁錫、氫氧化三苯錫等有機錫化合物的毒性分類。

此次修正公告已於111年10月召開研商會，並考量有機錫化合物毒性分類調整，涉及運送、偵測警報設備、專業應變人員設置及證件變更等規定，分階段給予業者半年至一年半的施行緩衝期。另配合我國已全面禁用石錫，除研究、試驗、教育用途外，其他使用用途之登記或核可文件均已屆期，一併修正相關內容。

有關本次發布相關資料請參閱環保署新聞專區下載附加檔案([https://news.epa.gov.tw/news/fact\\_index.asp](https://news.epa.gov.tw/news/fact_index.asp))，或於隔日至行政院公報網站(<https://gazette.nat.gov.tw/egFront/index.do>)下載參閱。

For details, please click the following link:

<https://enews.epa.gov.tw/Page/3B3C62C78849F32F/6636204a-7dc9-4833-bc4a-9596106e9557>

## 2. The Taiwan Environmental Protection Agency listed 15 substances in the list of chemicals of concern

In order to strengthen the management of chemical substances and avoid the harm to human health and the environment caused by improper use of chemical substances, the Taiwan Environmental Protection Agency listed 15 substances in 3 categories as chemical substances of concern, including chemical substances subject to food safety doubts (lead monoxide, lead tetraoxide, sodium sulfide, sodium thiocyanate and  $\beta$ -naphthol), emerging psychoactive substances (1,4-butanediol and glaucine), explosive chemical substances (calcium nitrate, sodium nitrate, calcium ammonium nitrate, nitromethane, sodium azide, ammonium perchlorate, sodium perchlorate and aluminum phosphide).



**顧食安 護健康 保安全 環保署新增列管3類15種關注化學物質**

環保署於112年1月12日新增列管3類15種關注化學物質，包含食安風險疑慮化學物質5種、爆裂物先驅化學物質8種及新興精神活性物質2種，加強製造、輸入、販賣、使用、貯存及運送等管理作為，並評估運作風險，將爆裂物先驅化學物質公告為具有危害性之關注化學物質，為降低不當使用導致人體健康及環境危害，運作人須於113年2月1日前取得核可文件。

環保署表示，本次公告具食安風險疑慮化學物質「四氧化三鉛」（俗稱鉛丹），109年8月臺中中醫師曾將「四氧化三鉛」混入藥材，倘長期攝入，將累積於骨髓中造成鉛中毒，導致運動失調、癱瘓、昏迷、腦病等神經病變或腎臟、心臟、生殖系統及內分泌系統等多種器官損傷；為維護民眾健康，本次環保署將四氧化三鉛公告為關注化學物質，期能透過源頭管制，避免類此事件發生。

另本次公告具食安風險疑慮關注化學物質，包括為縮短皮膚製程曾大量添加之「一氧化鉛」、為冒充與豆腐磷化物氣味所添加之「硫化鈉」及添加於乳製品或醬油以延長保存期限之「硫氰酸鈉」及「 $\beta$ -萘（業）酚」。

環保署本次並篩選曾被國際恐怖分子使用之硝油炸藥原料「硝酸銨鈣」，及國內爆炸犯罪案件曾拆解爆竹煙火類原料，製成土製炸彈，包括「過氧酸銨」、「過氧酸鈉」、「硝酸鈉」及「硝酸鈣」等；「硝基甲烷」及「疊氮化鈉」遇高熱或碰撞易發生猛烈爆炸；「碳化鈉」易與水或酸發生劇烈反應產生碳化氫，在高溫時會自然並與氧化劑反應引起爆炸，考量上述8種爆裂物先驅化學物質恐造成公共安全风险及危害人體健康，依據物質特性列為具有危害性之關注化學物質。

For details, please click the following link:

<https://enews.epa.gov.tw/Page/3B3C62C78849F32F/eb335faa-f91e-48e1-813b-36f401d3edf3>

## The Philippines

### 1. The Philippines released additional guidelines for applying for an Environmental Compliance Certificate (ECC) for projects in protected areas (PAs) and/or Ramsar Wetlands

The Department of Environment and Natural Resources (DENR) of the Philippines released a memo DMO-2023-01: additional guidelines for applying for an Environmental Compliance Certificate (ECC) for projects located in or adjacent to protected areas (PAs) and/or Ramsar Wetlands.

In order to coordinate with the implementation of Presidential Decree No.1586 (Philippine Environmental Impact Statement System) and its implementation rules and regulations (DAO 2003-30), and ensure that protected areas (PAs) and Ramsar Wetlands are protected accordingly, the DENR of the Philippines released additional guidelines for processing certain ECC applications as an important tool for adapting to and mitigating climate change, clarifying some processes of applying for an ECC.

For details, please click the following link:

<https://eia.emb.gov.ph/wp-content/uploads/2023/01/DENR-Memorandum-Order-2023-01.pdf>

Comment: The memo further clarifies and details some processes of applying for an ECC. The enterprises with relevant projects should pay attention to it in a timely manner and prepare project description reports and relevant materials as required for review by the Office of the Secretary for Environmental Compliance (OSEC).

## **2. The Philippines fully implemented the Extended Producer Responsibility Act (EPR Act)**

The Department of Environment and Natural Resources (DENR) of the Philippines released the implementation rules and regulations (IRR) of the Republic Act No.11898 (also known as an “Act Institutionalizing the Extended Producer Responsibility on Plastic Packaging Waste”, or the Extended Producer Responsibility (EPR) Act of 2022), requiring large companies to establish a mechanism for recycling plastic packaging. The EPR Act stipulates that enterprises have the responsibility to properly and effectively recycle, dispose of and reuse products after they are sold and used, so as to reduce plastic waste and extend the life of plastics through recycling or reuse. The EPR Act is conducive to promoting the circular economy, avoiding or minimizing pollution, encouraging the maximum use of materials, mitigating climate change, and protecting the ecosystem on which human beings depend.

For details, please click the following link:

<https://nswmc.emb.gov.ph/wp-content/uploads/2023/02/DENR-pushes-for-Circular-Economy-by-full-implementation-of-Extended-Producer-Responsibility-Act.pdf>

<https://apidb.denr.gov.ph/infores/uploads/DAO-2023-02.pdf>

Comment: The relevant large enterprises should carry out plastic recycling and transfer plan in time according to the requirements of the EPR Act within six months after it takes effect. Enterprises are responsible for allocating resources and collecting, recycling, transporting, processing and disposing plastic packaging waste in a way that is environmentally friendly.

Producers, distributors and retailers will be eligible for tax incentives if they take measures under the EPR Act. However, enterprises that fail to comply with the provisions of the EPR Act will be fined.

### **3. The Philippines released drafts for comments on Chemical Control Orders (CCO) of benzene and vinyl chloride**

The Environmental Management Bureau (EMB) of the Philippines proposed to release two Chemical Control Orders (CCO) to control benzene and vinyl chloride. Drafts have been released and public opinions have been solicited. Once CCOs are officially released, the use of benzene and vinyl chloride will be limited.

For details, please click the following link:

<https://chemical.emb.gov.ph/>

[CO2022-FT5N36377-File\\_1.docx \(live.com\)](#)

[CO2022-FT5N36377-File\\_2.docx \(live.com\)](#)

Comments: Enterprises with benzene and vinyl chloride related businesses should pay attention to the latest trends of CCO in time, and express their opinions when necessary (chemicals@emb.gov.ph). Once CCOs are officially released, it is necessary to apply for registration for relevant purposes according to the requirements of CCOs.

## **Upcoming Events**

The 10th National Toxicology Congress of CST, 8 - 11 April 2023, Zhuhai, China

<https://chntox.org/news/mes.aspx?t=4&pid=35&cid=6174&id=31624>

The 88th API China, 12 - 14 April, Qingdao, China

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

The 10th China (Shanghai) International Daily Chemicals Raw Materials and Additives Exhibition 2023, 26 - 28 April 2023, Shanghai, China

<http://www.rhylexpo.com/>

International Exhibition on Surfactant & Detergent, 26 - 28 April 2023, Shanghai, China

<http://www.iesdexpo.com/>

The 7th China (Zibo) International Chemical Technology Expo., 12 - 14 May 2023, Zibo, China

<http://boftec.zibo.gov.cn/cec/exhibition/detail?id=55>

Food Contact Regulations Europe 2023, 17 - 18 April 2023, Brussels, Belgium + Online

<https://events.chemicalwatch.com/644951/food-contact-regulations-europe-2023>

KOREA CHEM / KOREA PHARM&BIO 2023, 18 - 21 April 2023, Seoul, South Korea

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

Regulatory Updates Europe 2023, 19 - 20 April 2023, Brussels, Belgium + Online

<https://events.chemicalwatch.com/618446/regulatory-updates-europe-2023>

PFAS Global 2023, 25 April 2023, Online

<https://events.chemicalwatch.com/651941/pfas-global-2023>

Biocides Symposium 2023, 2 – 3 May 2023, Copenhagen, Denmark + Online

<https://events.chemicalwatch.com/655853/biocides-symposium-2023>

Regulatory Summit Asia 2023, 29 -30 May 2023, Singapore + Online

<https://events.chemicalwatch.com/656236/regulatory-summit-asia-2023>

Food Contact Regulations Asia 2023, 31 May 2023, Singapore + Online

<https://events.chemicalwatch.com/654938/food-contact-regulations-asia-2023>

Cosmetics Regulations Asia 2023, 1 June 2023, Singapore + Online

<https://events.chemicalwatch.com/656285/cosmetics-regulations-asia-2023>

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