CIRS

2020-2021

年度化学品法规展望

Prospects of Chemical Regulations for 2020-2021

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2020-2021 年度，许多国家的法规在持续更新中，也有更多的新的法规预计将出台，包括欧盟 REACH 评估，英国脱欧，纳米材料法规实施都将影响众多企业。

In 2020-2021, many countries are continuously updating their laws and regulations. More new laws and regulations are expected to be issued in the future which may affect many enterprises in every aspect, including the implementation of EU REACH evaluation, Brexit, nanomaterials regulations, etc.

除这些法规外，还有一些特别的法规，也将在接下来的 1-2 年实施，需要引起企业极大关注。以下将对这些法规进行逐一分析。

In addition to these regulations, enterprises also need give prominence to some special regulations which will be implemented in the next 1-2 years. We will analyze these regulations one by one in the following sections.

1. REACH 法规最新进展以及纳米材料法规

Updating development of REACH and nanomaterials regulation

作为 REACH 法规的重要组成部分 E（Evaluation）,在过去的一年中深刻影响到了多家注册企业。根据 ECHA 官方提供 2019 年的评估数据，80%以上要求补充额外的数据。根据 CIRS 2019 年度收到的欧盟注册 Draft Decision(DD)中，注册吨位为 100-1000 吨/年，相当高的比例需要补充 OECD 408 和 OECD 414 第一个物种；注册吨位为 1000+吨/年，相当高的比例需要补充 OECD 414 第二个物种以及 OECD 443。尤其是 OECD 443,单个实验室报价通常为 100 万欧元附近，即使分摊后，注册企业也需要分摊到 20-30 万欧元以上，造成企业无力应对卷宗或者物质评估，只能选择放弃注册号的方式。

Evaluation, as an important part of REACH Regulation, has deeply influenced many registered enterprises in the last year. In accordance with the evaluation data provided by ECHA in 2019, more than 80% of the substances require supplemental data. According to the draft decision (DD) of EU registration received by CIRS in 2019, a considerable proportion of substances in volumes of 100-1000 t/y need to supplement the data of OECD 408 and OECD 414 with first species; a considerable proportion of substances in volumes of 1000+ t/y need to supplement the data of the second species of OECD 414 and OECD 443. It is noteworthy that the quotation on OECD 443 is

usually around 1 million euros. Even after cost sharing, each registrant (enterprise) need to bear more than 200,000-300,000 euros. As a result, enterprises can't bear the cost of dossier or substance evaluation, and finally have to revoke the registration number.

在上述这些物质的注册卷宗里，大部分不合规的数据是因为采用了非测试方法比如 read-across, QSAR 或者一些公开文献数据，但缺乏相关细节。对于生殖/发育毒性以及重复剂量毒性这几个节点而言，ECHA 公布的数据，具有可靠的 GLP 测试报告的比例仅仅占 30%左右，意味着大部分高吨位的注册卷宗存在数据缺口，在后续评估过程中要求补充数据的可能性极大，而这几个节点测试的费用也是相当高，对已经完成注册的企业而言，是个巨大的负担。

In the registration dossiers of above mentioned substances, most of the data are not compliant due to the adoption of non-test methods such as read-across, QSAR. For public literatures, relevant details are not provided. According to the data published by ECHA, in terms of the reproductive and developmental toxicity and repeated dose toxicity, the proportion of data with reliable GLP test reports only accounts for about 30%, which means that most of the high tonnage registered dossiers are not completed enough and may be required for supplemental data in the subsequent evaluation process. However, the expensive test cost of those endpoints is a huge burden for the enterprises that have completed the registration.

2018 年 12 月，欧盟委员会通过了(EU) 2018/1881 号法规，称之为纳米材料法规，该法规自 2020 年 1 月 1 日起正式实施。法规主要是针对 REACH 法规的数据要求进行了更新，要求具有纳米形态的产品补充更多与纳米材料相关的信息。

The European Commission released Regulation (EU) No. 2018 / 1881 in December， 2018, which is also known as the nanomaterial regulation. It comes into force since January 1, 2020. The regulation mainly updates the data requirements of REACH regulation, requiring products with nanoforms to supplement more information related to nanomaterials.

自 2020 年 1 月 1 日起，如果客户向欧盟出口纳米材料物质，必须事先更新注册卷宗，添加和纳米材料有关的信息后，方能出口。对于通过联合提交方式完成 REACH 注册的企业而

言，其他新增加的数据要求主要是领头注册人 LR 的责任，其主要责任是及时更新和纳米材料有关的物质识别信息。企业也可以事先在该网站查询自己的产品是否可能具有纳米形式：

https://euon.echa.europa.eu/search-for-nanomaterials

From January 1, 2020, before exporting nanomaterials to the EU, the companies must update the registration dossier in advance and add information related to nanomaterials. For enterprises that complete REACH registration via joint submission, their main responsibility is to timely update the substance identification information related to nanomaterials. Enterprises can also check whether their products may have nanoforms on the website in advance:

https://euon.echa.europa.eu/search-for-nanomaterials

除了已经在之前注册卷宗中包括的通用物质识别信息外，对于纳米材料的物质识别信息具体规定有如下增加：

1、 物质的纳米形态或类似的纳米形态组的名称或其他标识符；

2、 基于数量的粒度分布，指示尺寸在 1 nm - 100 nm 范围内组成颗粒的分布；

3、表面功能化或处理的描述以及每种处理剂的标识，包括 IUPAC 名称和 CAS 或 EC 号；

4、形状，长宽比和其他形态特征：结晶度，组合结构信息，例如壳状结构或中空结构（如果适用）；

5、表面积（体积比表面积，质量比表面积，或两者兼有）；

6、本小节中信息的分析方法或适当的参考文献说明。

In addition to the general substance identification information already included in the previous registration dossier, the specific provisions for substance identification information of nanomaterials are added as follows:

1. Names or other identifiers of the nanoforms or sets of similar nanoforms of the substance;

2. Number based particle size distribution with indication of the number fraction of constituent

particles in the size range within 1 nm – 100 nm;

3. Description of surface functionalisation or treatment and identification of each agent including IUPAC name and CAS or EC number;

4. Shape, aspect ratio and other morphological characterisation: crystallinity, information on assembly structure including e.g. shell like structures or hollow structures, if appropriate;

5. Surface area (specific surface area by volume, specific surface area by mass or both);

6. Description of the analytical methods or the appropriate bibliographical references for the information elements in this sub-section.

2. 韩国修订后的 K-REACH 法规

The revised K-REACH Regulation

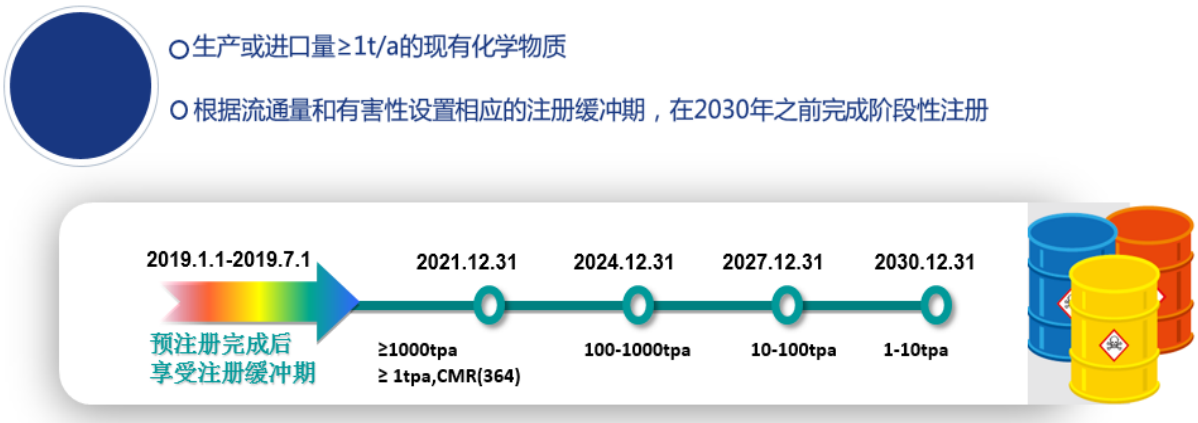
K-REACH 修订版于 2019 年 1 月 1 日正式实施，修订后的法规要求，新化学物质需要在生产或进口前完成注册或通报；现有化学物质（非 PEC 清单物质）在生产或进口量超过 1 吨/年的时需要完成注册，同时引入了预注册机制。原有的 PEC 清单中的 510 个物质注册不受影响，仍旧需要完成正式注册后，才能合法在韩国境内生产或进口。

The Korean K-REACH amendment was officially implemented on January 1, 2019. The revised regulation requires that new chemicals should be registered or notified before production or

import; existing chemicals (non-PEC substances) need to be registered when the production or import volume exceeds 1 t/y. The registration of 510 substances in the original PEC list will not be affected. It is still necessary to complete the registration before they can be legally produced or imported in South Korea.

修订后的 K-REACH 法规引入了预注册机制，要求所有超过 1 吨/年的现有化学物质（非 PEC 清单物质）必须在 2019 年 1 月 1 日至 2019 年 6 月 30 日期间完成预注册以获得相应的缓冲期。在缓冲期内，企业可以通过预注册号就申报的用途和吨位对韩进行正常合法的贸易。2019 年 6 月 30 日之后，对于 2016 年至今未对韩出口的新企业，可以通过完成后预注册以获得相应的缓冲期。预注册需要的信息及缓冲期如下：

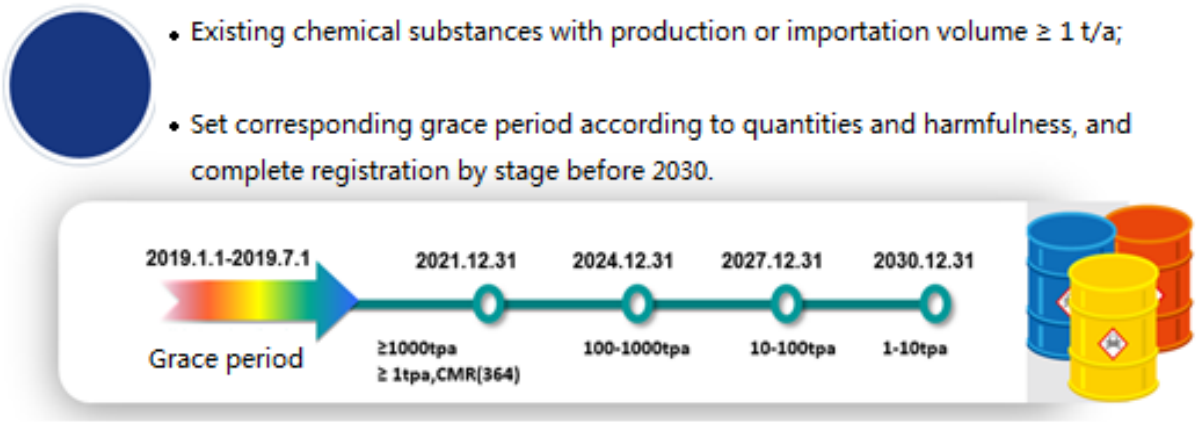
1. 生产商/进口商/OR 信息；
2. 物质信息；
3. 分类标签；
4. 进口商以及用途；
5. 吨位信息



The revised regulation also introduces pre-registration, requiring that all existing chemicals (non-PEC substances) manufactured or imported over 1 t/y must be pre-registered between January 1, 2019 to June 30, 2019 to obtain the corresponding grace period. During the grace period, enterprises can conduct normal and legal trade with South Korea on the notified purpose

and tonnage. After June 30, 2019, new enterprises that have not exported to South Korea since 2016 can completer late pre-registration to obtain the corresponding grace period. The information required for pre-registration and corresponding grace period are as follows:

1. Information of the manufacturer / importer / OR;
2. Identification information of the substance;
3. Classification and labelling;
4. Information of importers and the uses;
5. Information of the tonnage of the substance



截止目前为止，预注册完成了大概有 16,000 个物质，提交了约 170,000 份卷宗。值得注意的是，企业获得预注册号之后并非一劳永逸。缓冲期截止之后，企业必须使用正式注册号对韩进行正常合法的贸易，这意味着企业需在截止期前及时完成正式注册。

So far, about 16,000 substances have been pre-registered and about 170,000 dossiers have been submitted. However, the pre-registration number are not valid forever. After the end of the grace period, enterprises must use the registration number to conduct normal and legal trade with South Korea, which means that enterprises need to complete the registration in time before the deadline.

K-REACH 下现有化学物质正式注册采用联合注册的方式进行。想要加入联合体注册，企业需要先加入每个物质对应的 CICO (Chemical substance Information Communicative Organization，联合注册协议体)。加入 CICO 之后，有意向正式注册的 CICO 成员可以通过选举投票产生 LR（Lead Registrant，领头注册），组建注册联合体，提交联合注册。

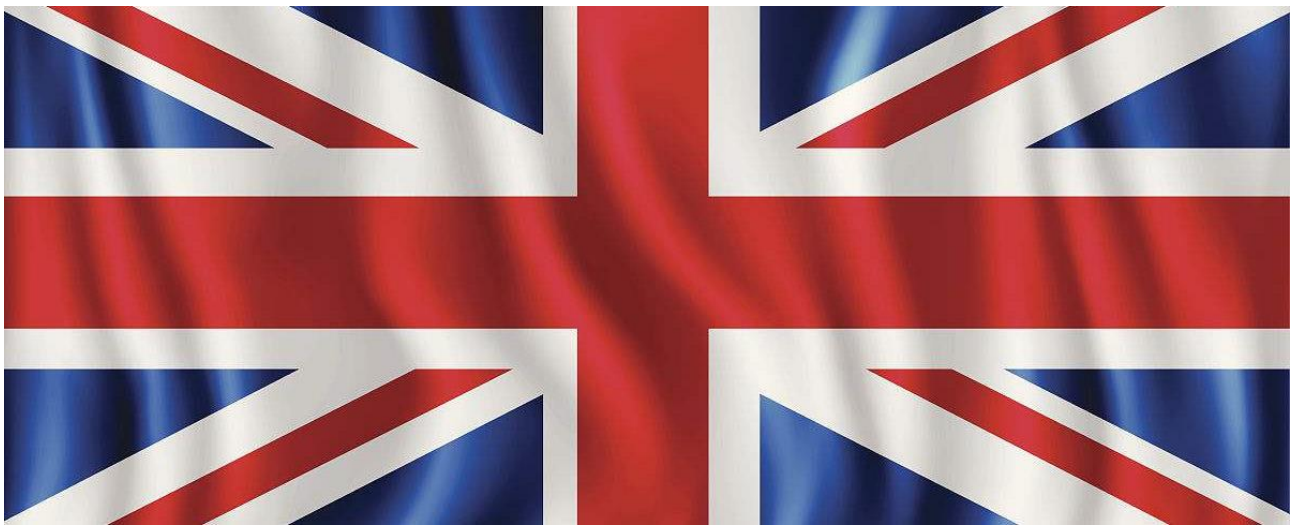
Existing substances under K-REACH Regulation are registered in the form of joint registration. To join the joint submission, enterprises shall join the corresponding Chemical substance Information Communicative Organization (CICO) first. Then the CICO members who intend to do registration can vote for a Lead Registrant (LR) who is responsible for the consortium or the joint submission.

目前大多数完成预注册的企业，都加入了 CICO。特别是注册吨位是 1000+的企业，因为截止期 2021 年 12 月 31 日临近的原因，大多数已经开始了正式注册的流程。很多物质 LR 已经产生，并在组建注册联合体中。

At present, most enterprises that have completed pre-registration have joined CICO, especially those whose tonnage exceeding 1000 t/y. Due to the deadline of December 31, 2021, most of them have started the registration process. Many LRs of the substances already have been selected and the consortium are undergoing the process of establishing.

为了减轻企业负担，韩国化学物质管理协会（KCMA, Korea Chemicals Management Association）计划选定一些现有化学物质作为政府支持项目。由 KCMA 指定咨询机构管理支持物质的注册联合体，控制联合体管理费，从而降低企业的注册成本。2019 年底 KCMA 公布了 81 个物质作为支持项目，后期也会有更多物质被指定支持。

In order to relieve the burden of enterprises, the Korean Chemicals Management Association (KCMA) plans to select some existing chemical substances as government support projects. KCMA will appoint the consulting agency to manage the registered consortium of the supported substances and control the management fee of the consortium, so as to reduce the registration cost of enterprises. At the end of 2019, KCMA announced 81 substances as support projects, and it is expected that more substances will be designated in the future.



3. UK-REACH （Brexit）

当地时间 1 月 31 日晚，英国宣布正式脱欧，由于本次脱欧英国和欧盟还没有就贸易，安全等达成协定，双方将进入 11 个月的谈判过渡期。

On 31 January 2020, UK formally left EU. The two sides have yet to reach any substantive agreements on the key issues (trade, safety), and will seek a new UK-EU trade agreement in the remaining 11 months of this year.

虽然目前英国不算是欧盟成员国，但目前这个阶段算是过渡期，过渡期依旧以欧盟法规为主，所有的法规要求照旧，相关的法规要求整理如下：

1) 所有在英国脱欧前的注册，授权，分类继续保持有效；
2) 欧盟 REACH 法规继续适用英国；
3) 所有注册新的化学品流程不变，英国公司需要继续向 ECHA 提交注册；
4) 英国认可所有欧盟批准的新的注册，授权和分类；

Although UK is not a member state of EU any more, the UK-EU trade, should continue on the same terms before the end of the transition period, which means the EU regulations still apply during the transition period. Relevant requirements are as follows:

1. The registration, authorization, and classification completed before UK left the EU will still be valid;

2. The EU REACH regulation will still apply to UK;

3. The process for substances registration remains the same, UK enterprises are still required to submit applications for registration to ECHA;

4. UK will recognize all new registrations, authorizations, as well as classifications granted by EU.

自 2021 年 1 月 1 日起，英国预计将采纳自己的化学品管理法规，即 UK REACH，由于细则尚没有发布。目前企业暂时不用担心英国脱欧对出口造成任何影响，在 2020 年 12 月 31 日前，按照现有的欧盟 REACH 法规来应对英国的法规即可。由于过渡期到 2020 年 12 月 31 日为止，英国和欧盟还将继续谈判达成新的协议，届时，相关的指南文件将继续更新，企业及时关注相关信息即可。

UK is expected to adopt its own chemicals regulation (UK REACH) from January 1, 2021. As the detailed regulations have not yet been released, enterprises have no need to worry about the impact of brexit on exports. Before December 31, 2020, enterprises can still comply with the existing EU regulations. As the transition period ends on December 31, 2020, the UK and the EU will continue to negotiate and reach a new agreement, and relevant guidance documents are also expected to be updated continuously. Enterprises only need to pay close attention to the follow-up progress in that time.

4. 土耳其 KKDIK 法规

Turkish KKDIK Regulation

土耳其 KKDIK 法规，已于 2017 年 12 月 23 日正式实施，KKDIK 即土耳其语的 REACH 法规首字母，和 REACH 法规一样，土耳其要求所有在土耳其进口或者生产的吨位超过 1 吨/年的化学品进行注册。

The KKDIK regulation came into force on December 23, 2017. "KKDIK" are the first letters of REACH written in Turkish. Like EU REACH regulation, the KKDIK regulation requires companies to register all substances manufactured in Turkey or imported into Turkey with volume above 1t/y before a given deadline.

除此之外，KKDIK 法规也是全球范围内比较少的要求开展预注册的法规，所有吨位超过 1 吨/年的生产商/进口商要求在 2020 年 12 月 31 日前完成预注册，非土耳其的制造商可以委托唯一代表（OR）来完成相关预注册工作。

In addition, KKDIK regulation is also a less global regulation requiring pre-registration. All manufacturers or importers with tonnage exceeding 1 ton/year are required to complete

pre-registration by December 31, 2020. Non-Turkish manufacturers can entrust the only representative (OR) to complete the pre-registration.

在完成预注册后，企业有 3 年缓冲期用于完成 KKDIK 正式注册，注册分成 1-10 吨/年，10-100 吨/年，100-1000 吨/年以及 1000+吨/年四个吨位，数据要求以及风险评估与 REACH 相似，但不同的是所有的吨位的注册截止日期都是 2023 年 12 月 31 日。

After completing the pre-registration, enterprises will have a three-year grace period to complete the formal KKDIK registration. The registered tonnage is divided into four tonnages: 1-10 tonnage/year, 10-100 tonnage/year, 100-1000 tonnage/year and 1000+tonnage/year. Data requirements and risk assessment are similar to EU REACH, but the difference is that the registration deadline for all tonnages is December 31, 2023.

KKDIK 豁免物质：

1） 放射性物质和混合物；

2）以自身，在混合物或者物品中受海关监管的物质，未经任何处理，只是为了再出口或者转口目的临时存放再保税区或保税仓库中；

3）非分离中间体；

4） 以铁路，公路，内河，海运，空运模式运输下的危险物质和混合物；

5） 废物；

6）国防需要生产或者进口的物质和混合物。

KKDIK exempted substances:

1. Radioactive substances and mixtures;

2. Goods, mixtures or articles in transit and goods in free-zone for re-export;

3. Non-isolated intermediates;

4. Transport of dangerous substances and mixtures by various modes;

5. Wastes;

6. Substances or mixtures manufactured or imported for defense purpose;

以下物质可豁免注册：

1）人用或者兽用医药产品；

2）食品和饲料；

3）附件 4 和 5（KKDIK）；

4）再次进口的已完成 KKDIK 注册的物质或混合物

5）回收的已完成过 KKDIK 注册的物质

6）聚合物

7）PPP 法规中的活性物质和配合剂以及 BPR 法规中的活性物质。

The following substances are exempt from registration:

1. Medicinal and veterinary products;

2. Food and feeds;

3. Annexes 4 and 5 (KKDIK)

4. Re-imported substances or mixtures which have been registered under KKDIK.

5. Recovered substances which have been registered under KKDIK.

6. Polymers.

7. Active substances and complexes in PPP regulation and active substances in BPR regulation.

工业界的其他义务：

1. 提供符合 GHS 标准的含 16 项的 SDS，语言必须是土耳其语；

2. 如果物质列入附件 14 授权清单，生产/进口必须完成授权；

3. 如果物质列入附件 17 限制清单，必须满足相关限制要求。

Other industry's Obligations:

1. Provide SDS with 16 items in accordance with GHS standard. The language must be Turkish.

2. Substances on Annex XIV Authorization List must be authorized before production/import.

3. Substances on Annex XVII Restricted Substance List must comply with restriction conditions.

授权清单和限制清单和欧盟授权清单和限制清单类似。

Authorization List and Restricted Substance List are REACH-LIKE.

5. 俄罗斯名录收录

Inventory Nomination in Russia

俄罗斯现有物质名录于 2019 年 11 月开放提交，旨在为欧亚经济联盟（EAEU）《化学品安全技术条例》(TR EAEU 041/2017)的生效做准备，该目录将成为建立欧亚经济联盟化学物质和混合物的注册基础。

Russian Inventory of Existing Chemical Substance was opened for submission in November 2019 to prepare for the entry into force of the "*Technical Regulation of Eurasian Economic Union on Safety of chemical products* (TR EAEU 041/2017)", which will serve as the basis for the registration of chemical substances and mixtures in the Eurasian Economic Union.

凡在 EAEU 境内流通的浓度超过 0.1% (w/w)的化学物质，都应在 2020 年 5 月 1 日前向官方提交相关信息以列入现有物质名录中。在 TR EAEU 041/2017 生效后，所有未列入名录的化学物质在欧亚关税地区都将被视为“新”物质，在释放任何含有该等新物质的化学品前，必须办理有关新物质的通报程序。

Any chemical substance with a concentration of more than 0.1% (w/w) circulating in EAEU shall submit relevant information to the official before May 1, 2020 to be listed into the existing substance inventory. After TR EAEU 041/2017 comes into effect, all chemical substances not listed in the inventory will be regarded as "new" substances in Eurasia tariff area. Notification procedures for the new substances must be carried out before releasing any chemicals containing such new substances.

目前只有俄罗斯境内的法律实体（进口商、制造商等）允许提交收录。对于俄罗斯境外的生产企业，可以通过其俄罗斯子公司或委托俄罗斯提名代表（NR）提交相关收录资料。

At present, only legal entities (importers, manufacturers, etc.) in Russia are allowed to submit for nomination. Production enterprises outside Russia can submit relevant information through their Russian subsidiaries or by entrusting Russian nominated representatives (NR).

俄罗斯名录豁免物质：

- 科研目的
- 未经化学改性的矿物资源
- 医药及兽医产品
- 香水及化妆品
- 构成电离辐射源的化学产品
- 食品、生物活性添加剂和营养添加剂及动物饲料
- 制成品中包含的产品（在某些条件下，例如，不会释放有害物质）
- 化工产品生产和消费产生的可弃置的废物
- 属于经俄罗斯联邦领土的海关过境程序范围内的化学品

Substances exempted from the Russian Inventory:

- for scientific research
- mineral resources without chemical modification
- medical and veterinary products
- perfumes and cosmetics
- chemical products that constitute the source of ionizing radiation
- food additives, bioactive additives, nutritional additives and animal feed
- products included in finished products (under certain conditions, for example, no hazardous substances will be released)
- Disposable wastes generated in the production and consumption of chemical products
- chemicals within the scope of customs transit procedures through the territory of the Russian Federation

名录收录应提交的信息：

1. 物质的识别参数：
    - CAS 号
    - EC 号
    - RTECS 号
    - TN VED EEU 编码（海关编码）
2. 化学物质名称：
    - IUPAC 名称（俄语）
    - IUPAC 名称（英语）
    - 英文名称
    - 其他化学名称
    - 缩写（如果有）
3. 分子式（如果有）
4. 结构式（如果有）

5. 用途（使用说明）
6. 年生产量/进口量（吨）- 以最近 3 个日历年的平均值计算
7. 分类 - 依据 GOST 32419 和 GOST 32424

Information required for Inventory Nomination:

1. Identification parameters of the substance:

- CAS number
- EC number
- RTECS number
- TN VED EEU code (customs code)

2. Name of the substance

- IUPAC name (in Russian)
- IUPAC name (in English)
- English name
- Other chemical names
- abbreviations (if any)

3. Molecular formula
4. Structural formula
5. Uses (instruction for use)
6. Annual production / import (tons) - calculated as the average of the last three years
7. Classification - according to GOST 32419 and GOST 32424

新物质通报需提交的信息：

1. 物质识别信息（IUPAC 名称，CAS 号，杂质信息等）
2. 预期用途
3. 处理和运输方法以及风险预防及消除的措施
4. 分析报告

5. 理化特性
6. 毒理学和生态毒理学数据
7. 化学品安全报告

Information required for the notification of new chemical substance:

1. Identification information of the substance (including IUPAC name, CAS number, information about the impurities, etc.)
2. Intended use
3. Handling and transportation methods and risk prevention and elimination measures
4. Analysis report
5. Physical and chemical properties
6. Toxicology and ecotoxicology data
7. Chemical safety report

6. 中国新化学物质环境管理办法

2019 年 7 月 9 日，生态环境部发布《新化学物质环境管理办法（修订征求意见稿）》（简称《修订稿》），面向社会公开征求意见。2019 年 9 月 2 日，世界贸易组织（WTO）根据 TBT 协定正式分发《新化学物质环境管理办法（通报稿）》（简称《通报稿》），公开向各成员征求意见，截止期为通报发出后 60 天。《通报稿》与《修订稿》内容一致。2020 年 2 月 17 日，生态环境部部长李干杰主持召开生态环境部部务会议，审议并原则通过修订的《新化学物质环境管理登记办法》。

On July 9, 2019, MEE released the "Provisions on Environmental Administration of New Chemical Substances (Revised Draft)" (hereinafter referred to as the "Revised Draft") for public consultation. On September 2, 2019, the World Trade Organization (WTO) officially issued the "Provisions on Environmental Administration of New Chemical Substances (Circular)" (hereinafter referred to as the "Circular") in accordance with the TBT agreement, and solicited opinions from the members, with a deadline of 60 days after the issuance of the circular. The contents of the "Revised Draft" and "Circular" are the same. On February 17, 2020, Li Ganjie, Minister of MEE, reviewed and

approved the revised "Provisions on Environmental Administration of New Chemical Substances" (hereinafter referred to as the "Provisions") in principle at the ministerial meeting.

修订的《办法》（指公开的《修订稿》和《通报稿》）核心变化内容：

The revised "Provisions" (refer to the "Revised Draft" and "Circular") has been significantly changed in the following aspects:

1、地域范围及豁免类别有变化。适用地域新增“自由贸易区”和“及其他海关特殊监管区”；豁免类别中已有其他法律法规管理的制成品，新增“肥料”；明确已有其他法律法规管理的制成品拟改变用途为其他工业用途的也适用修订的《办法》。

1. The geographical scope and exemption categories have been changed. " Free trade zone" and "other special customs supervision zone" are added in the applicable area. "Fertilizer" will be added to the finished products under other laws and regulations in the exemption category. The revised "Provisions" is also applicable to the finished products that have been regulated by other laws and regulations and are intended to be used for other industrial purposes.

2、 申请类型设置和数据提交要求更加优化。（1）以研究为目的，且年生产量或者进口量小于 100 千克的新化物质，不再适用修订的《办法》。（2）原简易申报调整为备案，提交完整的备案材料后即可开展活动，无需开展测试和等待受理。（3）原常规一级申报，调整为简易登记，减少登记数据要求，只提交与环境危害性相关的少数几项测试数据或者资料，同时简化登记流程，取消专家委员会评审环节。（4）原常规二级及以上申报，调整为常规登记，数据要求不再简单地按量级设置，而是聚焦环境风险评估和管控需求，综合考虑危害和暴露情况提出数据要求。

现行《办法》		修订的《办法》	
申报类型	登记范围	申报类型	登记范围
科学研究备案	研究目的，小于 0.1 吨/年	不适用本办法	
简易申报特殊情形	1、中间体，小于 1 吨/年； 2、仅供出口，小于 1 吨/年； 3、科学研究，0.1-1 吨/年； 4、新物质单体或反应体含量不超过 2%的聚合物或低关注聚合物；	备案	1、小于 1 吨/年； 2、新物质单体或反应体含量不超过 2%的聚合物或低关注聚合物；

	5、工艺和产品研究开发，且年生产量或者进口量不满 10 吨，不超过二年。		
简易申报基本情形	小于 1 吨/年		
常规申报一级	1-10 吨/年	简易登记	1-10 吨/年
常规申报二级	10-100 吨/年	常规登记	10 吨/年以上
常规申报三级	100-1000 吨/年		
常规申报四级	1000 吨/年以上		

2. The application type settings and data submission requirements are more optimized. (1). Substances currently subject to scientific research record in volumes less than 100 kg/y are exempted from the requirements under the revised "Provisions"; (2). Substances currently subject to simplified notification will be subject to record under the revised "Provisions"; Enterprises can carry out business activities once they submit the completed record materials; (3). Substances currently subject to first level of typical notification (in volumes between 1-10t/y) will be subject to simplified registration under the revised "Provisions"; the data requirements as well as the registration process for simplified registration will be reduced under the revised "Provisions"; the review process of Expert Committee will be cancelled; (4). Under the revised "Provisions", substances currently subject to second, third or fourth level of typical notification (in volumes more than 10t/a) will be subject to regular registration; data requirements for substances subject to regular registration substance will be variable depending on the environmental risk and exposure.

Current "*Provisions*"		Revised "*Provisions*"	
Notification Type	Notification Scope	Notification Type	Notification Scope
Scientific Research Record	For scientific research; less than 0.1t/y	Exempted	
Simplified Notification Specific	1. Intermediates, less than 1t/y; 2. For export only, less than	Record	1. Less than 1t/y; 2. Polymers containing less than 2%w/w new

Condition	1t/y; 3. Scientific research, 0.1-1t/y 4. Polymers containing less than 2%w/w new substances of monomers or reactants; or polymers of low concern; 5. For research and development of processes and products, and the annual production or import volume is less than 10 tons; no more than two years.		substances of monomers or reactants; or polymers of low concern;
Simplified Notification Basic Condition	Less than 1t/y		
Typical Notification First Level	1-10t/y	Simplified Registration	1-10t/y
Typical Notification Second Level	10-100t/y	Regular Registration	More than 10t/y
Typical Notification Third Level	100-1000 t/y		
Typical Notification Fourth Level	Over 1000t/y		

3、 列入《中国现有化学物质名录》（以下简称《名录》）的程序更加优化。修订后，将调整为取消回顾性评估，自首次登记之日起满五年，由主管部门发布公告，将其列入《名录》。

3. Procedures for supplementation of Inventory of Existing Chemical Substances in China (known as IECSC) are optimized. Under the revised "Provisions", new substances will be added into IECSC and be regulated as existing substances five years after the date they are first registered.

4、 标识信息的保密时限有调整。修订的《办法》规定申请人可以在登记或者备案材料中提出信息保密申请，并提交申请商业秘密或者技术秘密保护的必要性说明材料，但物质名称等

标识信息保护期限自登记或者备案之日起不超过五年。而现行《办法》对保密时限无明确规定。

4. Confidentiality has been adjusted. Under the revised "Provisions", if enterprises need to apply for protection of CBI, they must submit documents demonstrating the necessity. The period for the CBI protection is limited to 5 years at most from the date of registration or record. Currently, there is no expiration date for CBI protection.

5、 列入《名录》的 PB、PT 或 BT 类以及高危害化学物质需实施新用途管理。已列入《名录》的 PB、PT 或 BT 类化学物质，拟用于允许用途外其他工业用途的，所有申请人应当向主管部门申请新用途登记；已列入《名录》的高危害化学物质，新申请人用于任何用途，均需办理新用途登记。

5. Substances that are persistent and bio-accumulative (PB), persistent and toxic (PT), bio-accumulative and toxic (BT) or highly hazardous (listed in the IECSC) will be managed as new use rule （NUR）. In terms of substances (listed in the IECSC) that are considered PB, PT or BT, the applicant shall apply for the new registration to the authority for the uses other than the approved uses. In terms of highly toxic substances, all uses of these substances are under management. That is to say, enterprises need to apply for new use registrations for any use of these substances.

6、 需重新办理常规登记的情形有所增加。修订的《办法》施行后，完成常规登记的新化学物质，增加生产或者进口数量需重新办理常规登记；而现行《办法》下，只有当增加生产或进口量超过登记量级的，才需重新办理申报。此外，新增的需重新办理常规登记的情形还包括，活动类型由进口转为生产、中英文名称或者 CAS 等标识信息变更等。

6. The scope in need of re-registration has been expanded. After the implementation of the revised "Provisions", the new chemical substances that have completed the regular registration shall carry out regular registration again for the tonnage increase. Under the current "Provisions", only new chemical substances whose increase of production or import quantity exceeds the registration level shall carry out re-registration. In addition, situations such as the change of

activity type from import to production, the change of identification information (including Chinese and English names or CAS, etc.) are also required for re-registration.

7、 活动报告制度简化。修订的《办法》取消了每次活动报告和五年活动报告的要求，仅保留首次活动报告和年度报告制度，并且常规登记证将注明是否要求提交年度报告。此外，年度报告提交的时间由每年的 2 月 1 日前调整为每年 4 月 30 日前。

7. The report system has been simplified. The revised "Provisions" cancels the requirements of each activity report and five-year activity report, only keeps the first activity report and annual report system, and the need of annual report will be indicated in the regular registration certificate. In addition, the annual submission time is adjusted from February 1st to April 30th per year.

8、 企业主体责任强化。办理新化学物质登记或者备案时，申请人需要同时提供落实风险控制措施和环境管理要求的承诺书。承诺书应当由法定代表人签字或者盖章。

a、2020 年 2 月 17 日召开的生态环境部部务会议，虽审议并原则通过了修订的《新化学物质环境管理登记办法》，但新闻稿中并未披露修订的《办法》文本信息，也未透露何时施行。新化学物质环境管理工作仍按照现行《办法》进行。

b、修订的《办法》删除了原简易申报特殊情形中 PPORD 情形，原 PPORD 情形可以做备案（Q<1）或简易登记（1=<Q<10）。

c、修订的《办法》中数据要求不再简单地按量级设置，而是根据危害和暴露情况提出数据要求。其中，对具有持久性或者生物累积性且有暴露的新化学物质，才要求提交长期慢性毒性等测试报告或者资料。

d、预计规范和指导申请人进行新化学物质申报登记的《办法》配套文件《新化学物质申报登记指南》也将迎来修订，《新化学物质申报登记指南》将规定修订的《办法》实施的具体细节。

8. The main responsibility of enterprises are strengthened. When carrying out registration or record of new chemical substances, the applicant shall provide a letter of commitment to implement risk control measures and environmental management requirements. The letter of

commitment shall be signed or sealed by the legal representative.

Note：

a. Although the revised "Provisions on Environmental Administration of New Chemical Substances" was reviewed and approved in principle at the ministerial meeting, relevant news release didn't disclose the contents of the revised "Provisions" or mention the implementation time. The registration of new substances are carried out according to present measures.

b. The revised "Provisions" deletes the PPORD situation in the original simplified notification of special circumstances. Under the revised "Provisions", the PPORD situation can carry out record (Q<1) or simplified registration (1=<Q<10).

c. Under the revised "Provisions", data requirements for substances subject to regular registration substance will be variable depending on the environmental risk and exposure of these substances. If the new substances are considered persistent or bio-accumulative with exposure risk, then enterprises shall also submit long-term chronic toxicity test reports etc.

d. It is expected that the "Guidance for New Chemical Substance Notification", the supporting document of the revised "Provisions" for standardizing and guiding applicants to notify and register new chemical substances, will also be revised in the near future, in which will stipulate the specific details of the implementation of the revised "Provisions".

7. 台湾地区 TCSCA 法规

Taiwan TCSCA Regulation

台湾毒性化学物质管理法（Toxic Chem. Subs. Control Act, TCSCA）要求生产或进口每年达一定数量的既有化学物质，按规定期限向中央主管机关申请登录；生产或进口新化学物质者应于制造或输入 90 日前向中央主管机关申请登录化学物质资料，该法规已于 2014 年 12 月 11 日施行。

The "*Toxic Chemical Substances Control Act*" (TCSCA), implemented on December 11, 2014, existing chemicals produced or imported up to a certain amount each year shall be registered with the central competent authority within the prescribed time limit; those who produce or import new chemicals should examine and verify the registered chemical materials with the central competent authority within 90 days after manufacture or import.

2019 年 3 月 11 日，台湾地区环保署正式发布了《新化学物质及既有化学物质资料登录办法》修正案（以下简称《办法》）。台湾地区的法规与修改前的韩国法规类似，筛选出风险高的物质优先进行注册。因此，在该《办法》附表六中列明了 106 种化学物质即为第一批指定标准登录的既有化学物质，该 106 种既有化学物质与 2018 年 3 月，《新化学物质及既有化

学物质资料登录办法》修正案草案内容一致。《办法》于发布之日起执行，但第一批既有化学物质标准登录有适当的缓冲期，既有物质标准登录正式开启登录的时间为 2020 年 1 月 1 日。

On March 11, 2019, Taiwan Environmental Protection Administration released the "*Amended Regulation of New and Existing Chemical Substances Registration*" (hereinafter referred to as "*Regulation*"). The "*Regulation*" will screen out substances with high risks for priority registration. Appendix 6 of the "*Regulation*" lists 106 substances as the first batch of existing substances subject to standard registration, which is the same as the contents in the draft issued in March 2018. The "*Regulation*" takes effect as of the date of issue, yet it will grant an appropriate grace period to first batch of existing substances subject to registration – the standard registration for existing substances formally starts from January 1, 2020.

《办法》的核心内容：

1、既有化学物质年生产量、进口量在 100 kg 以下的，企业也可进行第一阶段登录（之前不能）。

2、危害及暴露评估的信息提交量有所调整。化学物质年生产量或进口量为 10 公吨以上需提交危害评估报告（之前为 1000 公吨以上），若所登录的物质有理化特性造成人体健康危害、人体健康危害分类、以及环境危害分类，登录人还需要提交暴露评估报告，即完整的风险评估报告。

3、对 2%聚合物规则进行了修订：原有法规规定如果原聚合物为既有物质，对原聚合物中的单体/反应体改变不超过 2%得到的新聚合物，则该新聚合物也可视为既有物质；如果原聚合物是新物质，并且进行了新物质的登录（或豁免确认），单体/反应体发生了 2%以内改变得到的新聚合物也可以认为是已经登录的新物质从而完全豁免登录义务。

新的《办法》规定“已列于既有化学物质清册适用百分之二规则之聚合物”，即如果原聚合物是既有物质，在原聚合物基础上进行 2%以内单体/反应体改变后得到的新聚合物依旧可视为既有物质进行豁免。

如果原聚合物是新物质，并且已经进行了新物质的登录（或豁免确认），则在原聚合物基础上进行 2%以内单体/反应体改变后的聚合物可以有两种选择：1) 与已登录的原聚合物合并

计算量级（若总共的年生产量/进口量使得登录量级上升，则需更新登录）；2) 或者将其视为一种新物质重新开展登录（或豁免确认）。

4、完善了保密申请相关内容:既有物质第一阶段登录可申请保密，保密期为 5 年，最长为 10 年；低关注聚合物少量登录保密期限为 5 年，与登录码有效期保持一致。

5、增加了对年报的要求。2020 年起登录人需在每年的 4 月 1 日至 9 月 30 日对核准登录的物质上一年度的生产量和进口量向主管机构进行报告。

6、既有物质标准登录的具体期限：

在 2019 年 12 月 31 日前首次取得第一阶段登录码的企业：

年总量	标准登录期限
1~100t	2022 年 12 月 31 日前
＞100t	2021 年 12 月 31 日前

在 2020 年 1 月 1 日后首次取得第一阶段登录码的企业：

年总量	标准登录期限
1~100t	次年 1 月 1 日起，3 年内完成
＞100t	次年 1 月 1 日起，2 年内完成

首次取得第一阶段登录码时，所登录制造或输入数量未满 1 吨的企业：

年总量	标准登录期限
在 2019 年 12 月 31 日前达到 1t 以上的	2022 年 12 月 31 日前
在 2020 年 1 月 1 日后达到 1t 以上的	次年 1 月 1 日起，3 年内完成

Major Amendments:

1. Enterprises may carry out Phase I registration for chemical substances in tonnages less than 100kg/y (not available before amendments);

2. Information required for hazard and exposure assessment is adjusted: (a.) Chemical substances in tonnage of 10t or over shall submit hazard assessment report (the tonnage was 1000t or over before amendments); (b.) If the registered substances are harmful to human health and the environment, registrants also need to submit the exposure assessment as well (the full risk

assessment report).

3. Requirements for polymer registration is amended. The old regulation stipulates that if the original polymer is an existing substance, then the new polymer for which 2% rule is also applicable can be considered as an existing substance; if the original polymer is a new substance, and has completed new chemical substance registration (or exemption confirmation), then the new polymer for which 2% rule is applicable can be considered as a new chemical substance and can be exempted from registration.

In accordance with the requirements of the amended "*Regulation*", polymers, for which 2% rule is applicable and are listed on the existing substances lists, can be considered as existing substances as well and are exempted from registration.

However, if the original polymer is a new chemical substance, and this substance has completed new chemical substance registration (or exemption confirmation), polymers for which 2% rule is applicable: (a.) calculated the tonnage together with the original polymer (if the tonnage band changes, registration shall be updated); (b.) considered as a new polymer and shall complete registration (or exemption confirmation).

4. Information concerning the application of confidentiality is improved: enterprises may apply for confidentiality for existing substances Phase I registration and the confidentiality period is 5 years (10 years at most); the confidentiality period for PLC small quantity registration is 5 years (consistent with the validity period of the registration code)

5. Annual report is required. From 2020, registrants need to report the annual manufacturing/importing tonnage of the last year to the competent authority between 1 Apr. and 30 Sep. each year.

6. Existing substance standard registration deadline:

Enterprises obtaining Phase I registration code for the first time before 31 Dec. 2019:

Tonnage per year	Standard registration deadline

1~100t	Before 31 Dec. 2022
＞100t	Before 31 Dec. 2021

Enterprises obtaining the Phase I registration code for the first time after 1 Jan. 2020:

Tonnage per year	Standard registration deadline
1~100t	Within 3 years from 1 Jan. of the following year (the second year of registration)
＞100t	Within 2 years from 1 Jan. of the following year (the second year of registration)

Enterprises whose manufacturing/ importing tonnage is less than 1t when obtaining the Phase I registration code for the first time:

Tonnage per year	Standard registration deadline
The tonnage reaches 1t before 31 Dec. 2019	Before 31 Dec. 2022
The tonnage reaches 1t after 1 Jan. 2020	Within 3 years from 1 Jan. of the following year (the second year of registration)

PS.

a. 《办法》公布了的 106 个既有物质为第一批需要进行标准登录的既有物质，后续相关部门可能还会公布第二批需要标准登录的既有物质名单，已在台湾进行既有物质登录的相关企业值得关注。

The "*Regulation*" published a list of 106 substances as the first batch of existing chemicals subject to standard registration. Related authority may release the second batch of existing substances subject to standard registration in the future.

b. 目前在台湾地区，若需要进行进出口的企业，物质的进出口量超过了 100kg 就需要进行第一阶段登录，标准登录的实施并不意味着进出口该 106 个物质不需要进行第一阶段登录，

登录人依旧需要取得第一阶段登录码。

Currently in Taiwan, related enterprises must complete Phase I registration if the import/export volume exceeds 100kg; besides, the implantation of standard registration does not mean enterprises do not need to complete Phase I registration for the 106 substances. Actually, related enterprises still have to obtain the Phase I registration code.

c. 为协助登录人履行遵守《办法》中化学物质登录的责任义务，2019 年 9 月，发布了《分期指定应完成既有化学物质标准登录指引（草案）》（一下简称《指引》）。预计台湾主管机关近期将发布正式版《指引》，为企业开展既有物质标准登录提供详细的指导条文。

c. To assist the registrant to comply with the obligations of chemicals registration specified in the "Regulation", EPA released the "Guidance for Standard Registration of Designated Chemical Substances by stages (draft)" (hereinafter referred to as the "Guidance") in September 2019. It is expected that Taiwan's competent authority will issue the formal version in the near future to provide detailed guidance for enterprises to carry out the standard registration of designated chemicals.

台湾境内的生产商或是进口商可作为登录人直接登录；也可委任第三方机构 TPR 进行，此时需出具委任书。台境外贸易商不能作为登录人委托 TPR 进行登录，但可协助台境内的进口商进行登录，可将保密资料直接传送给 TPR。如果有多个台湾进口商，建议委托同一个 TPR，进行共同登录。

Manufacturers or importers in Taiwan can register directly as registrants or appoint a third party TPR to complete the registration, at which time a letter of appointment is required. Foreign traders cannot register as registrants or appoint TPR either. However, they can assist importers in Taiwan to register by transmitting confidential information directly to TPR.

8. 化学物质环境风险评估与管控条例 （征求意见稿）

Regulations on Environmental Risk Assessment and Control of Chemical Substances (Draft)

2019 年 1 月 8 日，生态环境部网站发布了《化学物质环境风险评估与管控条例（征求意见稿）》，向社会公开征求意见建议。2019 年 9 月 2 日，世界贸易组织（WTO）根据 TBT 协定正式分发《条例》（通报稿），公开向各成员征求意见，截止期为通报发出后 60 天。

On January 8, 2019, Ministry of Ecology and Environment issued the "*Regulations on Environmental Risk Assessment and Control of Chemical Substances*" (Draft) and referred to the general public for comments. On September 2, 2019, the World Trade Organization (WTO) officially released the "Regulations" (Circular) in accordance with the TBT agreement, and solicited opinions from the members, with a deadline of 60 days after the issuance of the circular.

该管控条例对新物质和现有物质均提出了管控要求。新物质部分简化了之前的简易申报要求，改成备案形式。年生产量或进口量 1 吨（含）以上不满 10 吨的，调整为简易登记；年生产量或进口量 10 吨（含）以上的，需要在生产或进口前办理常规登记；用于实验室研究或用作参照标准，且生产量或进口量<100kg/年的新化学物质将豁免新化学物质登记或备案。现有物质部分，引入了目前国际主流的优先物质评估方案，通过筛查，制定和发布优先化学物质风险评估计划，由具备专业能力的技术支持单位对这些化学品进行优先评估，如果数据缺

失，可要求企业提供相关数据。在进行评估后，这些物质有可能被列入《优先控制化学物质名录》，《严格限制化学物质名录》，《禁止化学物质名录》等名录，依据不同的名录，分别进行相关管理。企业的产品如果具有 CMR, PBT 等特性就非常容易被列入优先控制化学物质名录，需要考虑列入后对企业的影响。

The draft puts forward management and control requirements for both new and existing substances. In terms of new substances, the previous abbreviated notification requirements are simplified to filing forms. Substances in volumes between 1-10t/y will be subject to simplified registration according to the draft, and substances in volumes more than 10t/y shall carry out regular registration before production or import. New chemical substances in volumes less than 100 kg/y for scientific research or as reference standard will be exempted from registration or record. For existing substances, the current international mainstream priority substance assessment scheme is introduced. Priority substances risk assessment plan will be conducted by screening, formulating and issuing. These substance will be evaluated by technical support units with professional competence. If the data is incomplete, enterprises can be asked to provide relevant data. After assessment, these substances may be listed in the "*Category of Priority Environmental Management Chemical Substances*", "*Category of strictly restricted Chemical Substances*", "*Category of Prohibited or Restricted Chemical Substances*", etc. Then they will be managed separately according to different categories. If the enterprise's product has the characteristics of CMR, PBT, etc., it will be easily listed in the "*Category of Priority Environmental Management Chemical Substances*". In case of that, enterprises shall consider the effect of listing in the category.

9. 《危险货物道路运输安全管理办法》正式实施

"Measures for the Administration of Road Transportation Safety of Dangerous Goods" comes into force

《危险货物道路运输安全管理办法》（交通运输部令 2019 年第 29 号）（以下简称《办法》）由交通运输部、工业和信息化部、公安部、生态环境部、应急管理部、市场监督管理总局联合发布，并将于 2020 年 1 月 1 日起正式施行。

The "Measures for the Administration of Road Transportation Safety of Dangerous Goods (Exposure Draft)" (hereinafter referred to as the "Exposure Draft") was issued on February 15, 2019. Nine months later, on November 25, 2019, the Ministry of Transport, in conjunction with the Ministry of Industry and Information Technology, Ministry of Public Security, Ministry of Ecology and Environment, Ministry of Emergency Management and State Administration for Market Regulation, released the formal edition "Measures for the Administration of Road Transportation Safety of Dangerous Goods" (Order No.29 [2019] of the Ministry of Transport) (hereinafter referred to as "Measures"), which will come into force on January 1, 2020.

该《办法》作为 2018 年 9 月交通运输部发布的《JT/T 617 危险货物道路运输规则》的上位法，为 JT/T 617 中危险货物道路运输面临的运输、包装、装卸等多方面问题提供了法律依据，该《办法》的正式实施也同时意味着 JT/T 617 在道路运输上将被强制执行。

The "Measures", as ministerial rules with higher legal effect of the "Regulations Concerning Road Transportation of Dangerous Goods" (JT/T617) issued by the Ministry of Transport in September 2018, provided detailed legal basis to the transportation, packaging, handling and other problems faced by road transport of dangerous goods. The formal implementation of the "Measures" will mean the better enforcement of the "JT/T617 Standard" in road transport.

该《办法》相较于《征求意见稿》在实质内容上并没有太大变动，改动涉及：规范了表述，细化了罚则等。在《办法》正式实施后，托运人将承担更多的责任，诸如在 JT/T 617 中提及的分类、危货标志、托运清单等信息的传递。例外数量、有限数量危险货物的包装、标记、包件测试、最大数量等也需要符合相关要求。另外，满足有限数量和例外数量条件运输的危货也有望免除诸如危货运输车辆资质等要求，可视作一类特殊普货进行运输。规定了如果按照有限数量或例外数量方式运输，包装需要满足一定要求，有限货物的总质量（含包装）不超过 8000Kg， 例外数量货物包件数量不得超过 1000 个。这种低成本运输的合规方式，对试剂企业，小包装化工品，消费品相关企业来说可谓收益良多。

Compared with the "Exposure Draft", the "Measures" haven't changed much in the essential contents. However, it gives out more standard expression and more detailed penalty provisions. After the formal implementation of the "Measures", consignors will bear much more responsibilities in the road transportation. Consignors shall inform carriers of the classification, labeling, consignment list of dangerous goods mentioned in the "JT/T617 Standard". The packaging, labeling, package testing, maximum quantity and other related contents of dangerous goods which can apply exceptional quantity / limited quantity, shall also meet relevant requirements. In addition, dangerous goods that meet the transport conditions of exceptional quantity or limited quantity are expected to be exempted (i.e. allowed to be transported as a kind of special ordinary good) from the requirements related to road transport of dangerous goods, such as the qualification of dangerous goods transport vehicles. In addition, requirements related to road transport of dangerous goods can be exempted only when meet one of the following conditions: (a). when consigning dangerous goods in exceptional quantities and the exceptional quantity of

dangerous goods packages transported by each transport vehicle no more than 1000; (b). when consigning dangerous goods in limited quantities and the total quality of dangerous goods (including packaging) transported by each transport vehicle no more than 8 tons. This kind of low-cost transportation compliance mode has a lot of benefits for reagent enterprises, and enterprises related to small packaging chemicals and consumer goods.

另外，对哪些危险化学品需要用专用车辆运输做了规定，未列入《危险货物道路运输规则》（JT/T 617）的危险化学品不适用该管理办法，也澄清了之前法规的一些模糊地带。

Furthermore, the "Present Measures" clarifies some ambiguous conceptions in the previous regulations, and also specifies what kinds of hazardous chemicals shall be transported by corresponding special vehicles. The "Present Measures" is not applicable to the hazardous chemicals not listed in the "Regulations Concerning Road Transportation of Dangerous Goods (JT/T 617)".

此外，交通部还将发布关于有限数量和例外数量的相关指南，届时，企业需关注相关指南，可以对符合有限数量和例外数量的货物进行操作，更好满足合规要求。

In addition, the Ministry of transport will also issue relevant guidelines on limited quantities and excepted quantities in the future. Enterprises shall pay attention to that and carry out compliance transport of goods in limited and excepted quantities in accordance with relevant requirements.

10. 易制爆危险化学品治安管理办法（征求意见稿）

"Measures for the Public Security Management of Hazardous Chemicals Liable to Produce Explosives" (Draft)

2019 年 1 月 20 日，公安部 《易制爆危险化学品治安管理办法（征求意见稿）》，征求意见截止时间为 2019 年 2 月 20 日。

On January 20, 2019, Ministry of Public Security issued the "*Measures for the Public Security Management of Hazardous Chemicals Liable to Produce Explosives*" (Draft) and referred to the general public for comments. The deadline for soliciting comments was February 20, 2019.

在之前的法规管理框架下，易制爆危险化学品主要是通过 591 号令即《危险化学品安全管理条例》实行，对生产/储存易制爆危险化学品的数量和流向，设置治安保卫机构，专用仓库的要求，经营企业的申请，购买许可，文件保存，运输等作了相关规定。

Under the previous regulations, the administration of hazardous chemicals liable to produce explosives were mainly referred to the "*Regulation on the Safety Management of Dangerous Goods*" (Order No.591 of the State Council), in which stipulated requirements of the quantity and whereabouts of hazardous chemicals liable to produce explosives produced/stored, establishment of security organs, special warehouses, application of business enterprises, license purchasing, document preservation, transportation, etc.

此次发布的管理办法征求意见稿，可以认为是对 591 号令中相关规定的细化，更加明确了如何操作。如以储存场所为例，之前的 591 号令仅仅规定专用仓库，并设置技术防范措施，在新的管理办法中对专用储存场所有了细致的要求，对教学，科研，医疗，测试等需求规定了可以储存的上限。

This draft can be regarded as a refinement of the relevant provisions in Order No.591. Take storage sites as an example. Order No.591 only provides for technical precautions of special warehouses, while the new draft sets a maximum storage limit for special storage sites for teaching, scientific

research, medical treatment, testing and other purposes.

针对电商，也特别规定了易制爆危险化学品从业单位不得在本单位网站以外的互联网应用服务中发布易制爆危险化学品信息及建立相关链接，禁止个人在互联网上发布易制爆危险化学品生产、经营、储存、使用信息，禁止任何单位和个人在互联网上发布利用易制爆危险化学品制造爆炸物品方法的信息，也禁止任何单位和个人利用互联网走私、贩卖易制爆危险化学品。

In terms of e-commerce, the draft stipulates that enterprises producing hazardous chemicals liable to produce explosives shall not publish relevant information and establish relevant links in Internet application services other than their own websites. It is forbidden for individuals to publish information on the production, operation, storage and use of hazardous chemicals liable to produce explosives; it is forbidden for any unit or individual to publish information on the methods of manufacturing explosives by using hazardous chemicals liable to produce explosives on the Internet; it is also forbidden for any unit or individual to use the Internet to smuggle or sell hazardous chemicals liable to produce explosives.

针对含有易制爆危险化学品的食品添加剂，药品和兽药等生活用品，成品的生产，销售，购买，储存，使用，运输和处置不受本办法管辖，执行这些成品的其他法规管辖。

The production, sale, purchase, storage, use, transport and disposal of food additives, pharmaceuticals and veterinary drugs containing hazardous chemicals liable to produce explosives are not governed by the draft, and shall comply with corresponding regulations.

总而言之，该管理办法将会加强对易制爆危险化学品的管理，企业需要在 591 号令基础上，更加关注信息化手段的应用。

In a word, the draft will strengthen the administration of hazardous chemicals liable to produce explosives. Enterprises shall pay more attention to the application of information technology means on the basis of Order No. 591.

11. CLP article 45 的实施

The implementation of CLP article 45

欧盟毒理中心通报（The Poison Centres Notification，简称 PCN）是基于《欧盟物质和混合物的分类、标签和包装法规》（欧盟 CLP 法规）第 45 条令和附件 VIII 的一项义务。在特定截止期后，企业必须将统一格式的通报卷宗提交并通报成功后，才可将产品投放于欧盟市场。

The Poison Centres Notification (PCN) is an obligation based on Article 45 and Annex VIII of the "EU Regulation on Classification, Labeling and Packaging of Substances and Mixtures" (CLP Regulation). After a specific deadline, enterprises must submit unified format notification files. Only after successful notification can products be put into the EU market.

通报主体

Who shall do notification

将危险混合物投放欧盟市场的欧盟境内的进口商和下游用户（纯物质的制造商及分销商不需要通报），非欧盟供应商不能取代欧盟境内责任持有人。

Importers and downstream users placing hazardous mixtures on the EU market have direct responsibility to submit Poison centre notifications (PCN). Distributors who distribute hazardous mixtures only in the same MS as the supplier do not need to submit notifications. Non-EU suppliers cannot replace responsible holders in EU.

通报受理机构

Appointed bodies

欧盟毒理中心通报门户及各成员国委任机构（或毒理中心）

The PCN portal and the appointed bodies of relevant EU countries (or the Poison Centres)

通报对象

Which substances shall be notified

同时满足三个条件的化学产品必须通报：

1. 混合物

2. GHS 分类具有物理危害或健康危害

3. 投放于欧盟市场。

Chemical products meeting all three conditions must be notified:

1. Mixtures;

2. Classified as hazardous on the basis of their health or physical effects;

3. Placing on the EU market.

注：

1.生物杀灭剂产品和植物保护产品属于此义务范围。

Attention: Biocide products and plant protection products fall into this category.

2.物品：

物品和物质/混合物的结合：物品(作为容器或载体材料)和物质/混合物的组合，例如喷墨打印

机墨盒、蜡烛、湿纸巾、干燥剂袋，这些物品上承载的混合物符合上述条件的需要通报；单一物品如塑料勺子，不需要通报；带有物质/混合物的物品(即该物质/混合物构成物品的整体的某部分)，不需要通报（例如电池中的电解质，温度计中的液体，固定地毯的胶带中的粘合剂）。

2. Article:

Combination of articles and substances/mixtures: As a combination of articles (as containers or carrier materials) and substances/mixtures, such as ink-jet printer cartridges, candles, wet tissue, desiccant bags, the mixture contained shall be subject to notification. Single articles such as plastic spoons are exempted from notification. Articles with integral substance/mixtures (i.e. the substance/mixture forms an integral part of the articles) are exempted from notification (e.g. electrolyte in the battery, liquid in the thermometer, adhesive in the tape for fixing carpet).

豁免通报的产品：

- 仅分类为环境危害的混合物；
- 放射性混合物；
- 受海关监管的混合物；
- 用于科学研究和开发的混合物；
- 药用和兽用产品；
- 化妆品；
- 医疗器械；
- 食品和饲料;
- 仅分类为加压气体的混合物；
- 爆炸物。

Mixtures exempt from PCN:

- Mixtures with environmental hazards only;
- Radio-active substances and mixtures;
- Mixtures subject to customs supervision;

- Mixtures for R&D use;
- Medicinal and veterinary products;
- Cosmetics;
- Medical devices;
- Food and feed;
- Mixtures only classified with gases under pressure;
- Explosives.

自愿通报

Notification on a voluntary basis

对于仅具有环境危害分类的混合物或者无危害分类的混合物，企业可进行自愿通报。

For hazardous mixtures which are not subject to submission obligations (i.e. mixtures with environmental hazards only), submission may be done on a voluntary basis.

若企业的产品被下游配置商用作为 MIM（Mixture in mixture）以配置成其他的混合物，且该混合物具有健康危害或物理危害，则自愿通报可帮助企业保护其产品的机密商业信息，例如产品的组分信息。企业仅需向客户提供产品的 UFI（唯一配方标识符，一串 16 字符的特定编码）。

If an enterprise's product is used as a MIM (Mixture in mixture) by downstream users to configure it into other mixtures with health or physical hazards, voluntary notification can help the enterprise protect confidential business information of its products, such as component information. Enterprises only need to provide UFI (Unique Formula Identifier, a unique 16-character code) to customers.

统一格式通报强制执行日期

Date of unified format notification of enforcement

消费者用途：2021 年 1 月 1 日

Mixture for consumer use: January 1, 2021

专业用途：2021 年 1 月 1 日

Mixture for professional use: January 1, 2021

工业用途：2024 年 1 月 1 日

Mixture for industrial use: January 1, 2024

在这些日期之前，混合物通报继续受成员国国家现有法规要求的约束。

Prior to these dates, mixture notifications still are subject to the existing regulatory requirements of member States.

对于已经通报过并在市场上销售的产品可享有过渡期，此类通报在 2025 年 1 月 1 日之前仍保持有效，若产品发生变化（例如混合物成分，毒理学特性或产品标识符的变化）则需要以新的统一格式进行通报。

A grace period is available for products that have been notified and placed on the market, and those notifications will remain valid until January 1, 2025. If the product changes (e.g., changes in the composition of the mixture, toxicological properties or product identifiers), a new unified format is required for notification.

通报步骤

1. 确定产品投放的市场；

2. 明确所需通报产品的使用类型以确定截止日期及相关信息要求；

用途包括直接用途以及下游用户最终用途，可以是一种也可以是多种，用以确认最早的通报开始日期。

3. 依据 CLP 附件 VIII，收集统一格式通报所要求的产品相关信息，如提交者信息，混合物成分、分类、标签要素、毒理学信息，产品包装、类别、颜色等；

4. 生成产品的唯一配方标识符（UFI）用以信息提交及标签、包装标识；

5. 制作通报卷宗；

6. 通报卷宗提交，根据各成员国规定通过欧盟成员国国家提交系统或者 ECHA 毒理中心通报门户（PCN portal）进行提交；

7. 产品信息发生变化时，企业有义务及时更新通报。

Notification steps:

1. Inquire whether the product has been notified and determine the market for the product;

2. Define the type of product to be notified to determine the deadline and related information requirements. The uses include the direct use and the uses of downstream users. They're used to determine the starting date of notification.

3. According to Annex VIII of CLP, collect the relevant information of products required by unified format notification, such as the identification of submitter; the composition, hazard classification, label elements, available toxicological information of mixtures; packaging, category, color of products; etc.

4. Generate Unique Formula Identifier (UFI) for information submission, labeling and packaging identification;

5. Make notification files;

6. Submit notification files through the submission system of EU member countries or the PCN portal of ECHA in accordance with the regulations of each member country;

7. When the product information changes, the enterprise has the obligation to update the notification in time.

12. 澳大利亚法规 AICIS 更新

Updating of Australia AICIS

澳大利亚计划将用 AICIS 法规框架来替代之前的 NICNAS，新的法规框架预计于 2020 年生效。在新的法规框架下，主要针对引入的化学物质以及企业进行管理。制造商或者进口商在引入化学物质前应先对企业进行注册，同时，这些引入的化学物质根据分类不同采取不同的管理措施。此外，AICIS 框架下还将建立澳大利亚工业化学品名录（AIIC），规定了特定的记录和报告义务。

Australia plans to replace the previous NICNAS with "Australian Industrial Chemicals Introduction Scheme" (AICIS), which is a new scheme expected to come into effect in 2020 for regulating the introduction (manufacture or import) of industrial chemicals in Australia. AICIS defines an industrial chemical and requires manufacturers or importers of industrial chemicals to register their businesses before introduction. Introductions must also comply with the requirements of a category of introduction, which are based on the level of risk to human health and the environment from the introduction. In addition, AICIS establishes Australian Inventory of Industrial

Chemicals (AIIC) and specifies certain record keeping and reporting obligations.

以下用途不受 AICIS 法规管辖：

a) 用于农业或者兽医用途；

b) 用于医疗；

c) 用于食品；

d) 用于饲料。

The following uses are not governed by AICIS regulations:

(a.) use as an agricultural chemical product or veterinary chemical product;

(b.) use as a therapeutic good;

(c.) use as food;

(d.) use as feed.

以下物质可以豁免授权和评估；

a) 天然发生物质；

b) 非分离中间体；

c) 偶尔产生物质；

d) 物品中非有意释放物质。

The following chemical substances are excluded from authorization and assessment.

(a.) a naturally-occurring chemical;

(b.) a non-isolated intermediate;

(c.) an incidentally-introduced chemical;

(d.) an industrial chemical that was released from an article that was not designed to release it;

根据化学物质对人类健康和环境的风险从低到高把物质分类以下几类：列入名录引入；豁免引入；报告引入；评估引入；商业评估引入以及非常情况下引入。

AICIS sets out the categories of the introduction of industrial chemicals based on the level of

risk to human health and the environment from the introduction: listed introductions, exempted introductions, reported introductions, assessed introductions, commercial evaluation introductions and exceptional circumstances introductions.

列入名录引入：风险很低，物质列入 AIIC，只需要满足名录中的条款即可。

豁免引入：物质风险很低，需要保存豁免判断的文件；

报告引入：物质风险低，需要提交预引入报告；

评估引入：物质风险中到高，不属于上述分类，一般需要评估引入，需要申请评估证书；

商业评估引入：物质风险中等，物质不销售给普通公众，并且暴露可控，需要申请商业评估授权；

非常情况引入：特定情况下引入，需要申请非常情况下引入授权。

Listed introductions: at very low risk level; listed in Chemical substances already listed in the Inventory (AIIC); need to comply with the terms in Inventory listings.

Exempted introductions: at very low risk level; record keeping needed to justify exemptions.

Reported introductions: at low risk level; need to submit pre-introduction reports.

Assessed introductions: at medium to high risk level; if an introduction of an industrial chemical does not fall within the definition of a listed introduction or an exempted or reported introduction, it is generally an assessed introduction; need to apply for assessment certificate.

Commercial evaluation introductions: at medium risk level; the chemical is not sold to the general public and its release and exposure is controlled; need to apply for commercial evaluation authorization.

Exceptional circumstances introductions: for exceptional circumstances; need to apply for exceptional circumstances authorization.

此外，新的工业物质名录 AIIC 将替代之前的 AICS 名录，列入上面的物质可以由任意注册

过的生厂商或进口商引入。

A new inventory called Australian Inventory of Industrial Chemicals (AIIC) will be established. It will replace current AICS. Industrial chemicals that are listed on the AIIC can be introduced by any registered introducers.

澳大利亚计划 2020 年 7 月 1 日起完全禁止用于化妆品组分的化学物质的新的动物测试，意味着终端用途为化妆品，在 2020 年 7 月 1 日之后，将不能采用动物测试来满足评估，引入要求的信息。

AICIS plans to implement a national ban on the use of new animal test data to support the introduction of chemicals used exclusively as cosmetic ingredients. This will mean that animal test data produced after 1 July 2020 cannot be used to meet the information requirements for categorization or assessment of unlisted chemical introductions, where the only end use is cosmetics.

13. 印度化学品安全管理法规 20xx (草案)

Chemicals （Management & Safety）Rules, 20xx

印度发布的关于化学品安全管理法规草案，根据这个版本的草案，和韩国之前的 K-REACH 有几分接近。

The "Draft Chemicals (Management & Safety) Rules" (hereinafter referred to as "Draft") in India is similar to the K-REACH Regulation of South Korea.

法规引入了通报(notification)概念，通报类似于 EU REACH 下的预注册，在指定的时间前所有印度人境内的制造商，进口商或者授权代表(Authorised Representative)需要对所有的现有物质和新物质进行通报，通报内容包括通报人的信息，物质识别信息，用途，以及吨位信息等。通报完成后，相关的通报人还将提交年度报告，主要是关于在印度境内的吨位信息。

The "Draft" introduces notification, which is similar to pre-registration under EU REACH. A manufacturer or importer (or authorised representative acting on behalf of a foreign manufacturer) shall notify the Chemical Regulatory Division of all existing substances and new substances that they have placed in Indian territory within the initial notification period. The notification shall include information relating to the notifier, identity of the substance, its uses, the quantity of the

substance that will be placed in Indian territory, etc. After the completion of the notification, the notifier shall also submit an annual report, mainly focusing on the tonnage information in Indian territory.

如果物质被分类为 CMR 1,2 类或者 STOT SE 1,2 类 或者 STOT RE 1,2 类或者满足 PBT, vPvB 条件，或者属于其他主观机构指定的物质，这些物质就是法规下的优先物质。除了通报外，制造商，进口商或者授权代表应对所有超过 1 吨/年的优先物质进行注册，注册根据吨位可分为 1000+吨/年，100-1000 吨/年，1-100 吨/年，可享受不同的注册缓冲期。同时，所有的新物质如果属于优先物质，这些优先新物质必须在引入印度境内 30 天前完成注册。所有完成注册的物质，制造商，进口商或者授权代表同样需要提交年报信息，一般不迟于日历年结束的 30 天内。

“Priority substance” under the "Draft" refers to any substance which belongs to carcinogenicity and/or germ-cell mutagenicity and/or reproductive toxicity and categorised as Category 1 or 2, or specific target organ toxicity (repeated exposure or single exposure) Category 1 or 2; or any substance which fulfill the criteria of persistent, bio-accumulative and toxic or very persistent or very bio-accumulative; or any other substances as may be notified by the Chemical Regulatory Division from time to time. In addition to the notification, a manufacturer or importer (or authorised representative in case of a foreign manufacturer) shall also be required to register any priority substance that they have placed or are intending to place in Indian territory in a quantity greater than 1 t/y. The registration can be carried out on the basis of the quantity placed in Indian territory which will correspond to different grace periods: 1000+ t/y, 100-1000 t/y and 1-100 t/y. In addition, a manufacturer or importer (or authorised representative in case of a foreign manufacturer) shall register all new substances which are also priority substances at least 30 days prior to the date on which such priority substance will be placed in Indian territory. All manufacturers, importers or authorised representatives who have registered a priority substance shall update the information in the registration annually, not later than 30 days after the end of such calendar year.

目前，没有发布具体的数据要求，从化学品安全报告 Chemical Safety Report 格式来看，与欧盟 REACH 法规要求很接近，预测将会接近目前 REACH 注册的数据要求，需要等相关的指南文件发布后才会明确。

Currently, no specific data requirements have been issued. According to the format of chemical safety report, it is very similar to the requirements of EU REACH Regulation, which may be close to the data requirements of the current REACH registration. However, specific requirements will only be clear after the release of relevant guidance documents.

整体来看，印度的化学品法规和之前的韩国法规很像，由于这个版本只是草案版本，预计后续将面临修改，具体的实施时间也无法确定，但通报和注册的要求很大可能会被要求，企业近期需要关注这个法规的后续进展即可。

To sum up, the "Draft Chemicals (Management & Safety) Rules" in India is similar to the K-REACH Regulation of South Korea. Although the "Draft" is expected to be revised in the future, and the specific implementation time cannot be determined, the requirements for notification and registration are likely to be retained. Enterprises need to pay attention to the follow-up progress of this "Draft" in the near future.