

中国《新化学物质环境管理登记办法》的最新进展介绍

Update of China's MEE Order No.12 and Draft Guidance

LINGZHEN DONG, Ph.D.
PRODUCT STEWARDSHIP DIRECTOR
ASIA PACIFIC REGION
JOHNSON & JOHNSON CHINA LTD.
Sept. 17, 2020

Disclaimer: The information in the presentation is not official regulatory information. Please refer to MEE's website for official regulations.

Compliance with local regulatory requirements is the responsibility of companies and their local business areas.

AGENDA 大纲

- 《新化学物质环境管理登记办法》（12号令）及《新化学物质环境管理登记指南》（征求意见稿）简介
Brief Introduction of “Measures for Environmental Management Registration of New Chemical Substances” (MEE Order No.12) and the Guidance (draft for public consultation)
- 《中国现有化学物质名录》增补近况
《 Inventory of Existing Chemical Substances in China 》 (IECSC)
Supplementation Update
- 化学物质环境风险评估与管控条例 (WTO通报稿) – 相关条款
Environmental Risk Assessment and Control Regulation for Chemical Substances (WTO Notification Version)
- 总结和建议 (Summary and Recommendations)

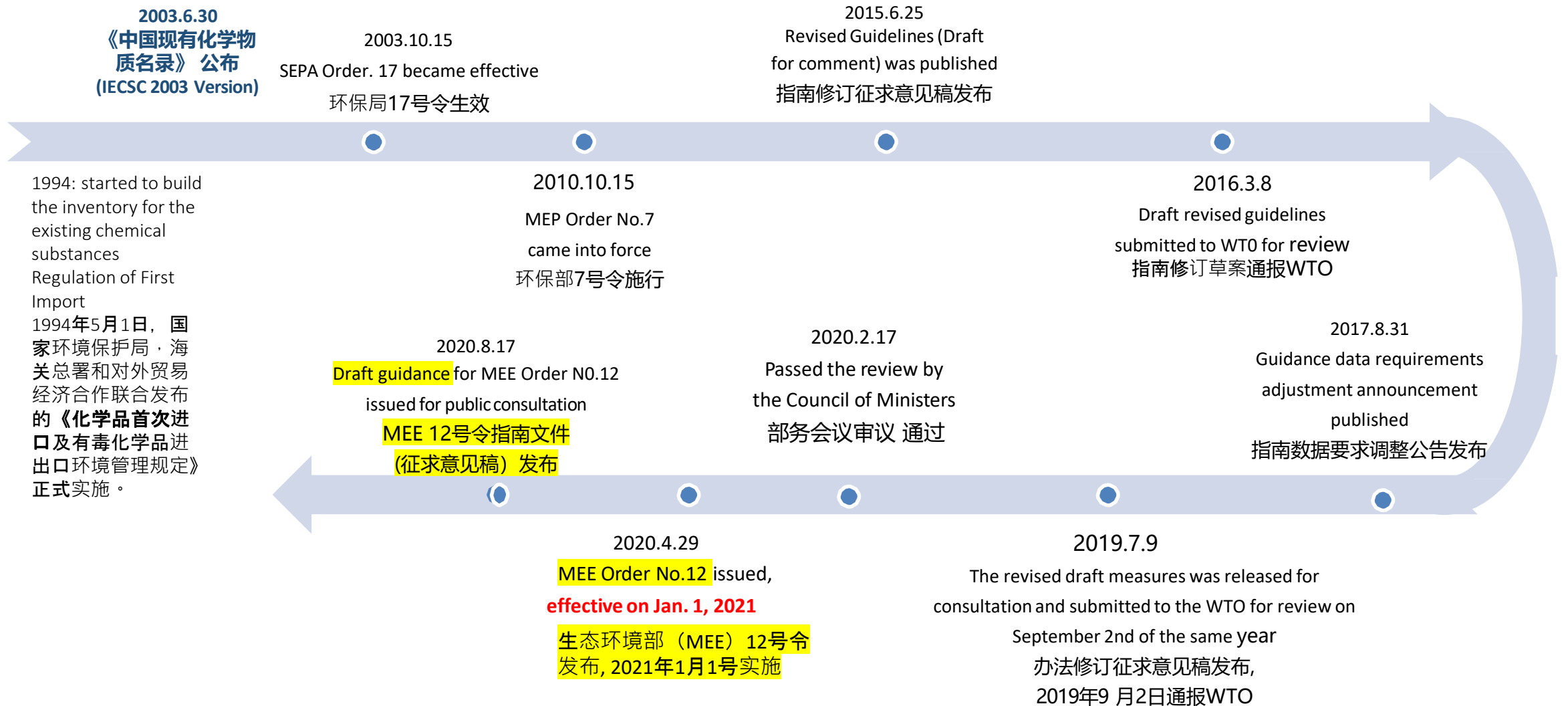
Bio 个人简介

- AP Product Stewardship Director, Johnson & Johnson China Ltd. 亚太区EHS&S产品监管总监, 强生（中国）有限公司
- Education 教育背景: BS, MS & PhD in Chemistry 化学博士
- Past experience 工作经历:
 - Working in J&J since 2013 于2013年加入强生
 - >20 years in Chemical Industry-Worked in Rohm and Haas Company (acquired by Dow Chemical) and Dow Chemical 在化工行业工作超过20年（罗门哈斯和 陶氏化学）
 - Different functions: R&D, Toxicology/Ecotoxicology, Regulatory Affairs and Product Stewardship, R&D Site Management, China Country Management (Rohm and Haas), and AP EHS & Sustainability (Rohm and Haas, Dow and J&J)
 - 从事过的工作包括研发、毒理/生态毒理、法规事务/产品监管、研发中心管理、中国区经理（罗门哈斯）及亚太区EHS和可持续发展总监（罗门哈斯、陶氏和强生）
 - >15 years in China/Asia Pacific region and 10 years in the U.S. 在美国工作了10年; 在中国/亚太区工作超过15年
- Contact information 联系方式: ldong20@its.jnj.com; +86-21-33379452



Lingzhen Dong
董玲珍

China New Chemical Substances Management Regulation (“China REACH”) Development Timeline 中国新化学物质法规进展一览



Scope Adjustment 范围调整

Good News for the Pharm Industry : APIs will be exempted!
However, Excipients have not been exempted (still being advocated).

Substance Scope 物质范围

- 1、 Chemical substances that have been listed in the “Inventory of Existing Chemical Substances in China (IECSC)” and are subject to environmental management for new uses, when they are used for industrial purposes other than permitted uses; should be registered. “已列入《中国现有化学物质名录》并实施新用途环境管理的化学物质，用于允许用途以外的其他工业用途”时，应当办理登记；
- 2、 MEE Order 12 does not apply to the following chemical substances or products: 下列化学物质或者产品不适用《办法》，不需要办理新化学物质环境管理登记：
 - (1) Pharmaceuticals (including active pharmaceutical ingredients (APIs), pesticides (including pesticide active ingredients), veterinary drugs, cosmetics, food, food additives, feed, feed additives, fertilizers and other products; 医药 (含原料药)、农药 (含农药原药)、兽药、化妆品、食品、食品添加剂、饲料、饲料添加剂、肥料等产品；
 - (2) Radioactive materials. 放射性物质。However, if it is changed to other industrial use and contains new chemical substance, it shall be registered. 但是, 但它们改变为其他工业用途且属于新化学物质的, 应当办理登记。
- 3、 "Products or formulations with specific functions, such as adhesion promoters, chelating agents, flocculants, surface treatment agents, etc., chemical substances produced by chemical reactions to achieve their specific functions", registration can be exempted. “具有特定功能的产品或配制品，如粘合促进剂、螯合剂、絮凝剂、表面处理剂等，为实现其特定功能而发生化学反应产生的化学物质”，豁免登记。
- 4、 One of the anhydrous form of chemical substance and its hydrate has been listed in the “IECSC”, another can be exempted registration. 无水形式的化学物质和其水合物，两者其一已列入《名录》的可豁免登记。

Refer to the Guidelines for details 参看《指南》了解其他豁免情况

Scope Adjustment 范围调整

Region Scope 地域范围

1. Engage in research, production, import, processing and use of new chemical substances **within the territory** of the People's Republic of China (**except HK, Macao, Taiwan**).

在中华人民共和国**境内**从事新化学物质研究、生产、进口和加工使用活动。（**港澳台除外**）

2. Except for imported new chemical substances that are stored in the **special customs supervision area** and have not undergone any processing (such as sub-packaging, selection, etc.) (**Including 6 types of special areas within the bonded zone and export processing zone**)

进口后在**海关特殊监管区**内存放且未经过任何加工（如分装、挑选等）即全部出口的新化学物质除外。（**含保税区和出口加工区之内的6种特殊区域**）

Registration certificate holder (for foreign export type)
登记证持有人（对于境外进口类型）

Only Representative (Chinese Agency)
唯一代表（中国代理）

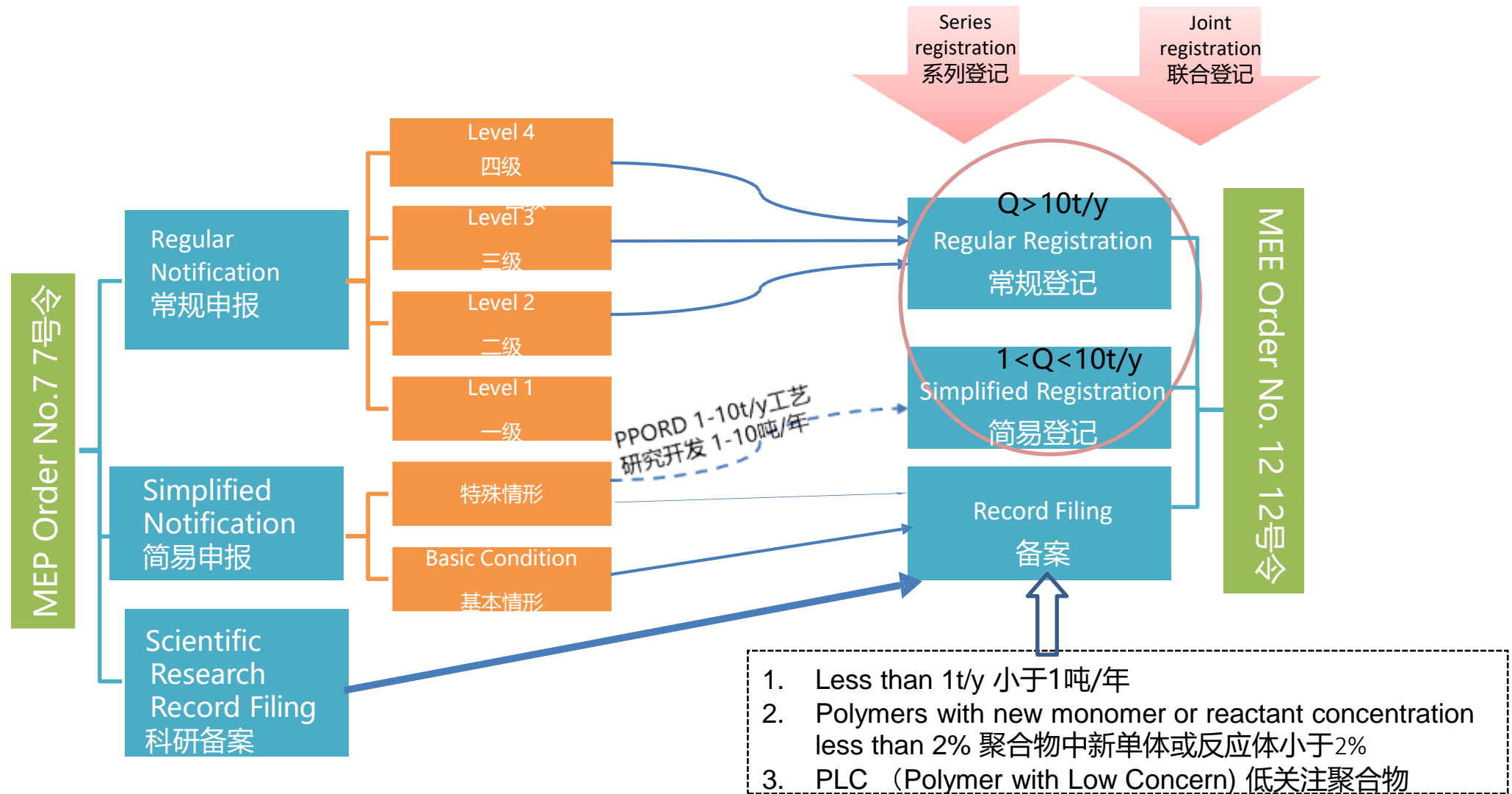
**MEP Order No.7
7号令**

Changes to
变更为

Foreign exporter can use an agent in China to do registration and be the registration certificate holder
登记证持有人（境外出口商通过代理人登记）

**MEE Order No.12
12号令**

Registration Types 申报类型调整为登记类型



Registration Type and Material Requirements of MEE Order No.12

12号令登记类型及材料要求

Registration Type 登记类型	Substance Scope 物质范围	Registration material requirements 登记材料要求
Regular Registration 常规登记	New chemical substances with an annual output or imported quantity of above 10 tons per year 新化学物质年生产量或者进口量10吨以上	Regular registration application form, application form attachments (including legal person certificate or business license, agency contract or agreement, authorization letter, test report or information, environmental risk assessment report, social-economic benefit analysis report (belonging to high-hazard new chemical substances) , etc.) 常规登记申请表、申请表附件（包括法人证书或营业执照，代理合同或协议、授权书、测试报告或者资料、环境风险评估报告、 社会经济效益分析报告（属于高危害新化学物质的） 等）
Simplified Registration 简易登记	New chemical substances with an annual output or an imported quantity between 1 to 10 ton per year 新化学物质年生产量或者进口量1吨以上不足10吨	Simplified registration application form, attachments to the application form (including legal person certificate or business license, agency contract or agreement, power of attorney, test report or information, determination conclusion and basis for persistence, bioaccumulation and toxicity of the applied substance, etc.) 简易登记申请表、申请表附件（包括法人证书或营业执照，代理合同或协议、授权书、测试报告或者资料、申请物质的持久性、生物累积性和毒性的判定结论及依据等）
Record Filing 备案	New chemical substances with an annual output or an imported quantity of less than 1 ton per year 新化学物质年生产量或者进口量不足1吨	Filing form, attachments to filing form (including legal person certificate or business license, agency contract or agreement, authorization letter, etc.) 备案表、备案表附件（包括法人证书或营业执照、代理合同或协议、授权书、等）
	Polymers with new monomer or reactant concentration less than 2% or PLC (no tonnage limit) 新化学物质单体或者反应体含量不超过2%的聚合物或者属于低关注聚合物（无吨位限制）	In addition to the above filing materials, also submit: List of monomers/reactants, molecular weight distribution diagram, polymerization reaction mechanism process, explanation materials for discriminating that the applied substance does not belong to the exclusion of polymer filing, etc. 除上述备案材料外，还应提交： 单体/反应体列表、分子量分布图、聚合反应机理过程、 申请物质不属于聚合物备案排除情形的判别说明材料等

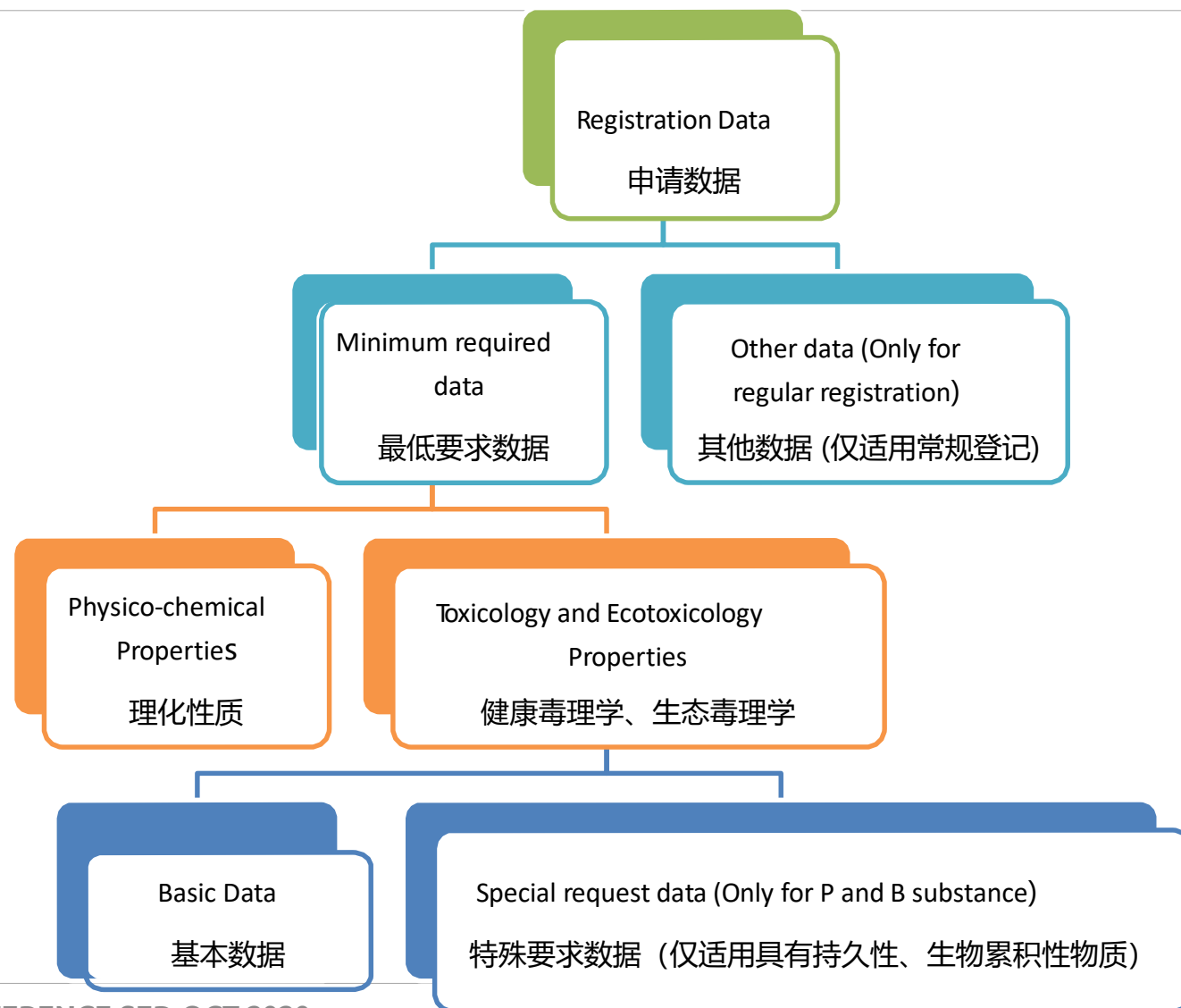
Registration Workflow 登记流程 (时间表)

Registration Type 登记类型	Regular Registration 常规登记 (WD=Working Day; M=Month)	Simplified Registration 简易登记	Record Filing 备案
SCC Review 形式评审	5WD 5个工作日	5WD 5个工作日	Random Check 随机抽查
Technical Review by expert committee 技术评审	60D 60日	30D 30日	/
Correction (If required) 补正(如有)	6M (one submission) 6个月 (一次性)	6M(one submission) 6个月 (一次性)	Not Specified 未规定
MEE Approval MEE 审批	20+10WD 20+10个工作日	20+10WD 20+10个工作日	/
Public Consultation 公示	at least 3WD 至少3个工作日	at least 3WD 至少3个工作日	/
Public Notice 公开	20WD 20个工作日	20WD 20个工作日	Make Public Notice Periodically 定期公开
Timeline 总周期	4-12M 4-12个月	3-10M 3-10个月	Can start the activity after submission (record filing) 提交即可开展活动

SCC= MEE's Solid Waste and Chemical Management Center
固体废物与化学品管理技术中心 (简称: 固管中心)

Data Requirement-MEE Order No.12

数据要求-12号令



Data Requirement-Physical and Chemical Properties

数据要求-理化特性



Data Requirement-Toxicity properties

数据要求-健康毒理特性

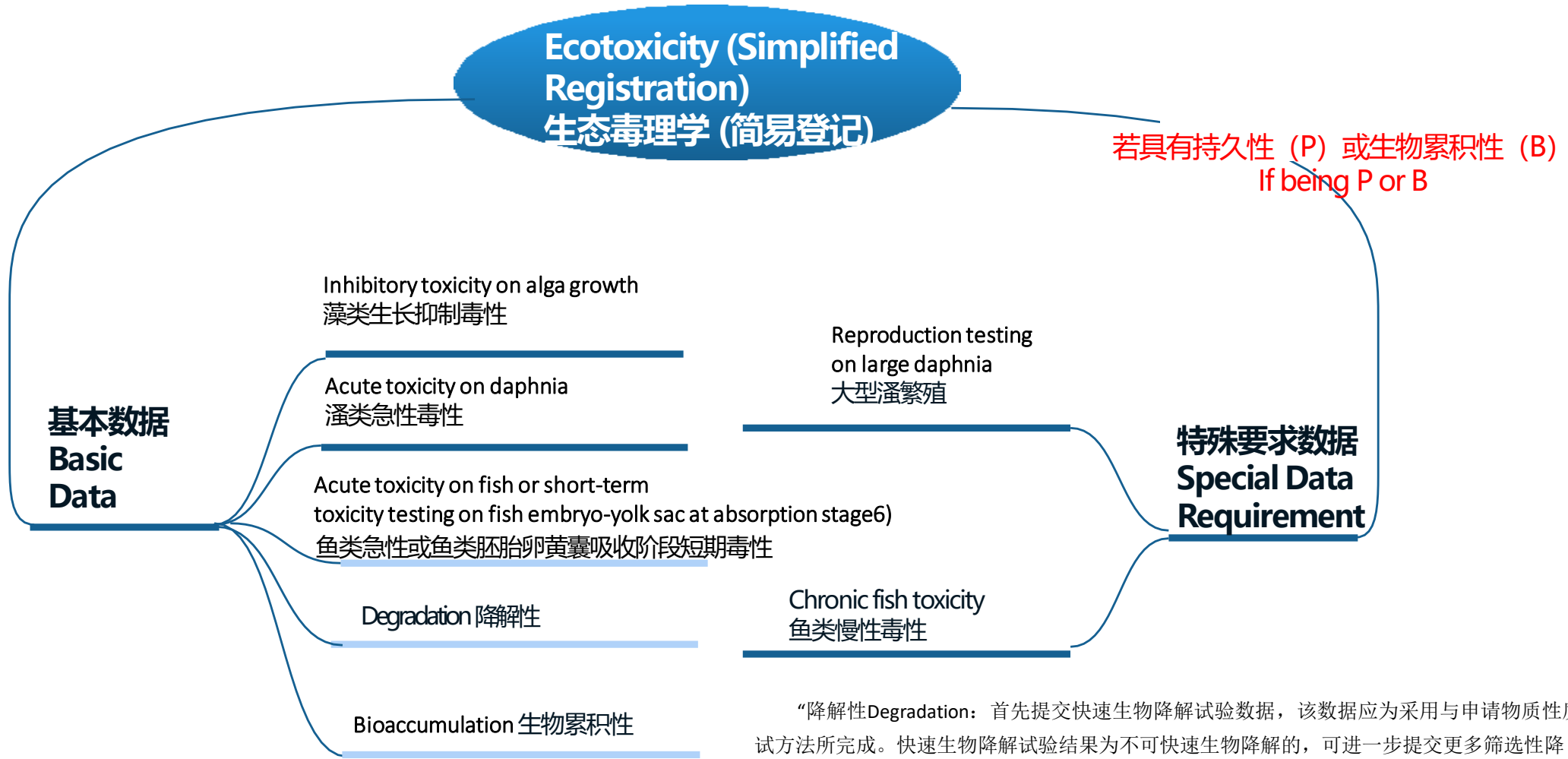
Toxicity (Regular Registration) 健康毒理学 (常规登记)

(Refer to Table 2 Minimum Required Data for Toxicology
指南中 表2 健康毒理学最低要求数据)

数据项目	基本数据 Basic data	特殊要求数据 Special requirement data
<u>急性毒性</u> Acute Toxicity ¹⁾	✓	✓
<u>皮肤刺激</u> Skin Irritation	✓	✓
<u>眼刺激</u> Eye Irritation	✓	✓
<u>皮肤致敏</u> Skin Sensitization	✓	✓
<u>致突变性</u> Mutagenicity ²⁾	✓	✓
<u>反复染毒毒性</u> Repeated dosing	✓ ³⁾	✓ ⁴⁾
<u>生殖/发育毒性</u> Reproductive /developmental Tox	✓ ⁵⁾	✓ ⁶⁾
<u>毒代动力学</u> Toxicokinetics ⁷⁾		✓
<u>慢性毒性</u> Chronic toxicity ⁸⁾		✓
<u>致癌性</u> Carcinogenicity ⁹⁾		✓
<u>其他</u> Others ¹⁰⁾	✓	✓

Data Requirement-Ecotoxicity properties

数据要求-生态毒理特性



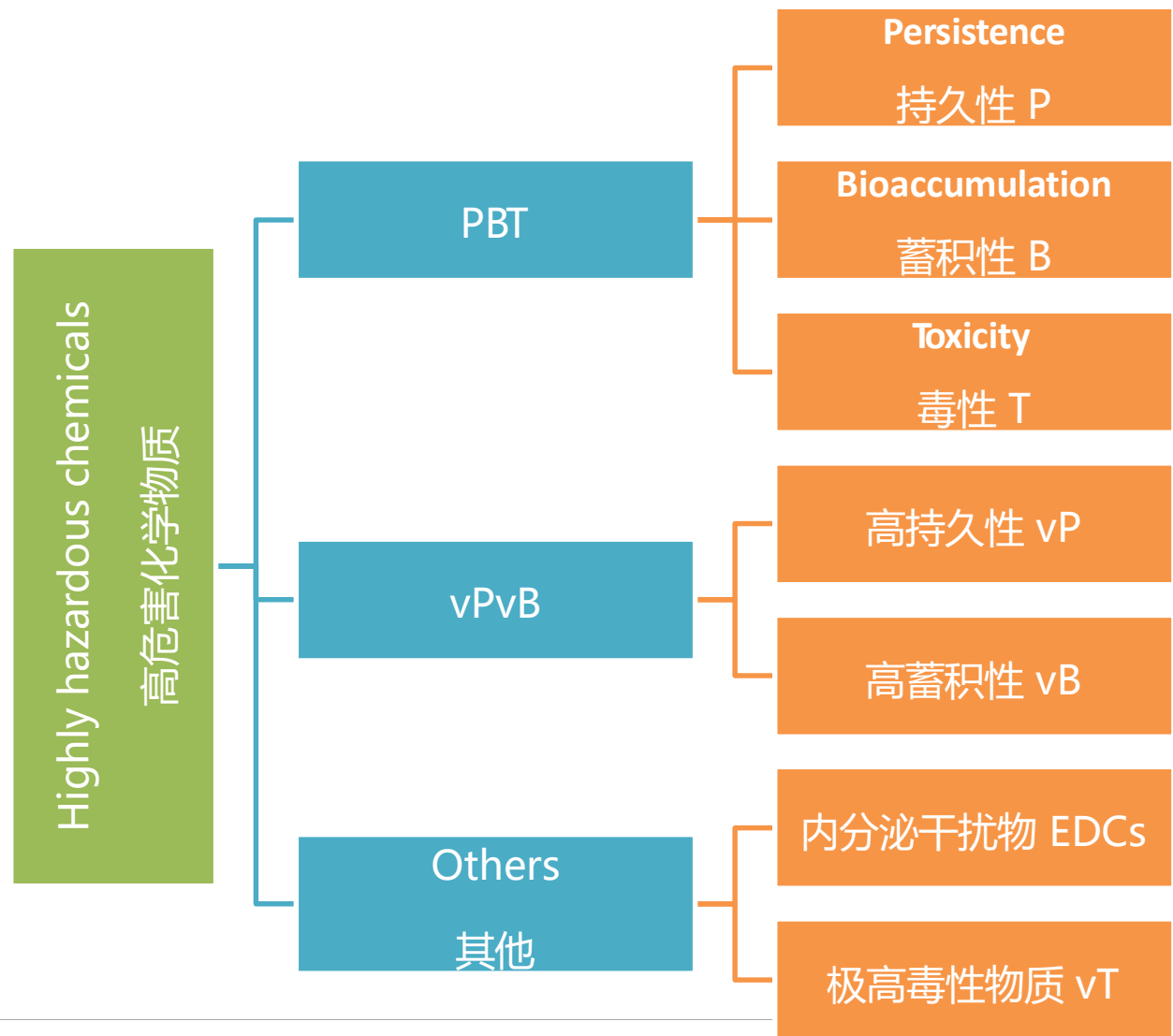
“降解性Degradation: 首先提交快速生物降解试验数据, 该数据应为采用与申请物质性质相适应的测试方法所完成。快速生物降解试验结果为不可快速生物降解的, 可进一步提交更多筛选性降解数据, 如强化快速生物降解试验、固有生物降解试验、水解、光解等降解数据, 以识别是否具有持久性特性。”

Data Requirement-Ecotoxicity properties

数据要求-生态毒理特性



Highly Hazardous Chemicals 高危害化学物质



PBT and vPvB chemical substance screening standards

PBT、vPvB化学物质筛选标准

<p>P</p>	<ul style="list-style-type: none"> If the chemical substance can be rapidly biodegraded, it can be screened and judged as not P and vP; If the degradation rate of 302B 7d is $\geq 70\%$ or the degradation rate of 302C 14d is $\geq 70\%$, it can be screened and judged as not p; If the chemical substance can be hydrolyzed or photolyzed, it can be screened and judged as non-P; 若化学物质能快速生物降解, 可筛选判定非P和vP; 若OECD 302B 7d降解率$\geq 70\%$或OECD 302C 14d降解率$\geq 70\%$, 可筛选判定非p; 若化学物质能水解或光解, 可筛选判定非P;
<p>B</p>	<ul style="list-style-type: none"> If the chemical substance's log Kow≤ 4.5, it can be screened and judged as not B and vB; If the chemical substance's log Kow> 4.5, it can be screened and judged as potential B; BCF> 2000, it can be judged as B; BCF= Bio-Concentration Factor BCF> 5000, it can be judged as vB; 若化学物质log Kow≤ 4.5, 可筛选判定非B和非vB; 若化学物质log Kow> 4.5, 可筛选判定潜在B; 生物富集因子> 2000, 可判定是B; 生物富集因子> 5000, 可判定是vB;
<p>T</p>	<ul style="list-style-type: none"> Acute aquatic toxicity EC50 or LC50 $< 0.1\text{mg/L}$, it can be screened and judged as potential T; (SR) Acute aquatic toxicity EC50 or LC50 $< 0.01\text{mg/L}$, it can be screened and judged as T; (SR) Chronic aquatic toxicity NOEC or EC10$< 0.01\text{mg/L}$, can be judged as T; (RR) Carcinogenic 1A or 1B, can be determined as T; (RR) Mutagenic 1A or 1B, can be judged to be T; (RR) Reproductive toxic substances with 1A 1B or category 2, can be judged to be T; (RR) Specific target organ toxicity (repeated exposure) category 1 or 2, can be judged as T. (RR) 急性水生毒性EC50或LC50$< 0.1\text{mg/L}$, 可筛选判定潜在T; (简易登记) 急性水生毒性EC50或LC50$< 0.01\text{mg/L}$, 可筛选判定是T; (简易登记) 慢性水生毒性NOEC或EC10$< 0.01\text{mg/L}$, 可判定是T; (常规登记) 致癌物1A或1B类, 可判定是T; (常规登记) 致突变物1A或1B类, 可判定是T; (常规登记) 生殖毒性物1A、1B或2类, 可判定是T; (常规登记) 特异性靶器官毒性(反复接触)类别1或类别2, 可判定是T。 (常规登记)

Data Exemption 数据豁免条件

- 1、 Delete the exemption clauses for Auto-ignition temperature, Flash point, Oxidation, Flammability, and Explosive endpoints; 删除自燃温度、闪点、氧化性、燃烧性、爆炸性数据豁免条款;
- 2、 新增: Newly added:

Endpoint 数据节点	Exemption Condition 豁免条件
Dissociation constant 解离常数	Unstable in water (hydrolysis half-life less than 12h) or easily oxidized in water 在水中不稳定 (水解半衰期小于12h) 或在水中易被氧化
Sediment-water chironomid toxicity test 底栖生物慢性毒性	With low adsorption (eg: logKoc<3) 吸附性很低 (如 logKoc<3)

- 3、 The chronic toxicity test can be exempted if it is only used for intermediate purposes (newly added) ; 慢性毒性数据豁免条件增加一项, 即若仅用作中间体用途的也可豁免该项测试;
- 4、 Deleted "Fish 14-day extended toxicity test"; 删除“鱼类14天延长毒性试验”要求 ;
- 5、 For the toxicity of terrestrial organisms, it is clear that the long-term toxicity test of earthworms is the "Enchytraeid reproduction test OECD 220 "or " Earthworm reproduction test OECD 222", and delete "Soil microbial influence test"; 对于陆生生物毒性, 明确蚯蚓长期毒性试验为线蚓繁殖试验或蚯蚓繁殖试验, 删除土壤微生物影响试验;
- 6、 Deleted the exemption condition of "Earthworm acute toxicity test", which is water solubility>1mg/L or log Koc<3.5. 删除依据水中溶解度大于1mg/L或logKoc小于3.5豁免蚯蚓急性毒性试验的条款。

Qualification Requirements of Testing Laboratory

测试机构资质要求

China Domestic Laboratory 境内测试机构

1. Qualification accreditation of inspection and testing should be obtained according to law for Physical and chemical testing institutions.
 2. Health toxicology testing institutions should also comply with good laboratory practice standards (notified by one of several different Chinese Authorities)
 3. Ecotoxicology testing institutions should also comply with good laboratory practice standards and Relevant requirements from MEE.
- 1、物理化学性质测试机构应当依法取得检验检测机构资质认定；
 - 2、健康毒理学测试机构通过国家食品药品监督管理局药物非临床研究质量管理规范（GLP）认证的机构、经中国疾病预防控制中心质量考核合格的化学品毒性鉴定机构、农业农村部公告的农药登记试验单位、通过中国国家认证认可监督管理委员会批准的良好实验室规范（GLP）评价的机构。
 - 3、生态毒理测试机构符合良好实验室管理规范(GLP)和生态环境部化学品测试机构管理相关要求

Non-Domestic Laboratory 境外测试机构

1. Physical and chemical testing institutions should comply with ISO17025 standard or good laboratory practice standards.
 2. Health toxicology and ecotoxicology testing institutions should meet internationally accepted requirements for good laboratory Practice. (GLP)
- 1、物理化学性质测试机构应当符合ISO17025标准认可或良好实验室管理规范要求。
 - 2、健康毒理学、生态毒理学测试机构应当符合国际通行的良好实验室管理要求

Environmental Risk Assessment Report

环境风险评估报告

New requirement under MEE Order No.12

For Regular Registration >10t/a only; 仅常规登记 >10吨/年需要

Can be exempted if new chemical <100 t/a without eco-toxicity and toxicity classification according to the hazard assessment, and it is non P or B ; 危害评估表明申请物质无生态环境和人体健康危害分类, 且不具有持久性、生物累积性, 同时申请量小于100 吨的, 可豁免。

The preparation technical unit shall bear relevant responsibilities for its own environmental risk assessment report, affix an official seal, and implement credit management. Critics notified, three-year ban. 编制技术单位对其编制的环境风险评估报告承担相应责任, 加盖公章, 实施信用管理。被通报批评者, 三年内禁止申报。

Both human health and ecological environment adopt (semi) quantitative assessment; Add special instructions for exposure scenarios of consumer use and waste disposal; PBT/vPvB special substances focus on the identification of discharge and exposure characteristics and all possible exposure pathways. 人体健康及生态环境均采用 (半) 定量评估; 增加消费者使用和废物处置等暴露场景的特别说明; PBT/vPvB类特殊物质重点开展排放和暴露特征识别及所有可能的暴露途径。

Adjustment of Confidentiality Time Period

调整保密期限

MEP Order No.7
环保部 7号令

Unspecified
未规定



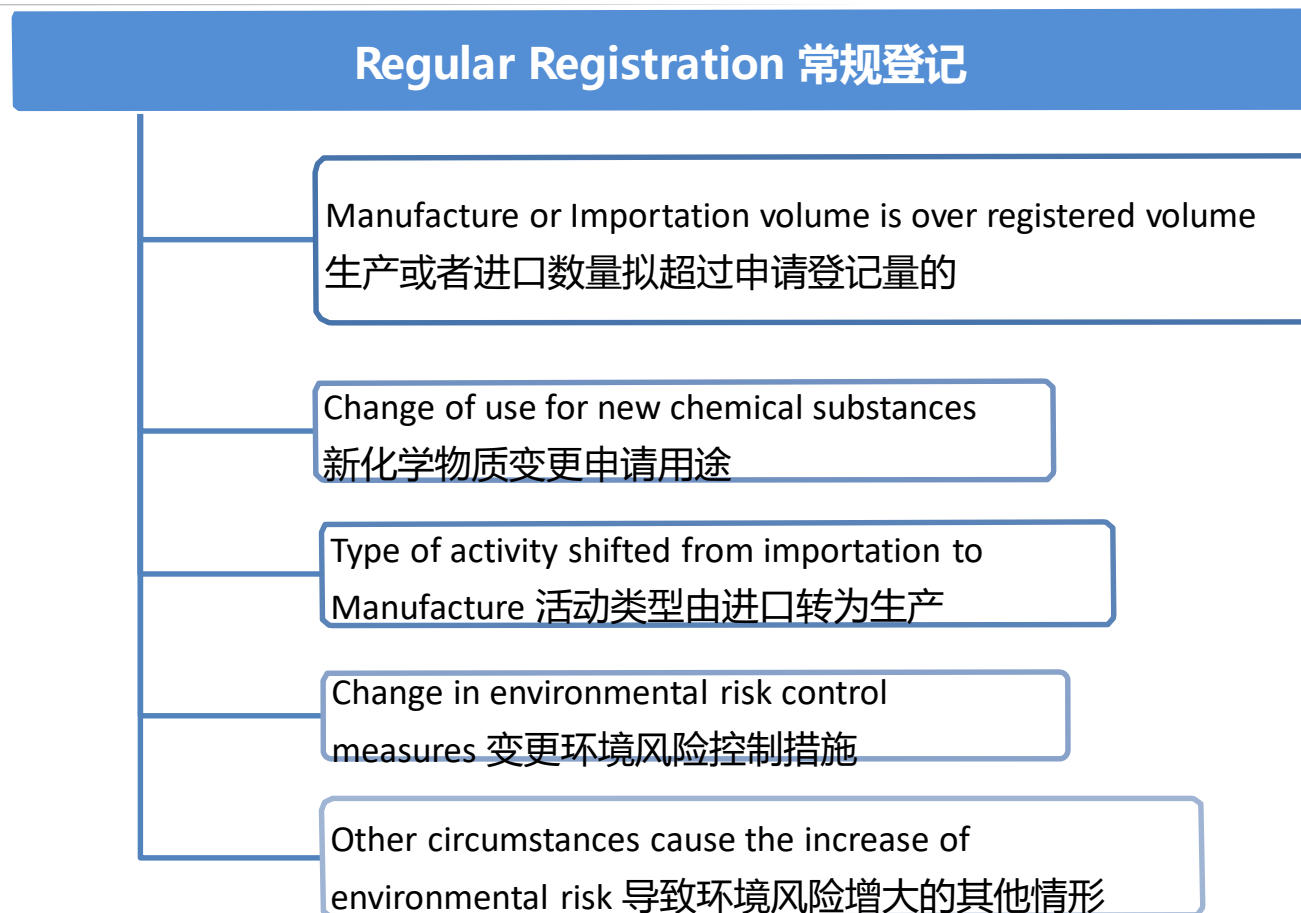
MEE Order No.12
生态环境部 12号令

≤5 years
≤5年

- The period of confidentiality of identification information such as the name of the substance shall not exceed **five years** from the date of registration or record filling. The extension application shall not exceed **another five years**. 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**。延期申请最多不超过**五年**。
- Substances that have been listed in the confidential section of "Inventory of Existing Chemical Substances in China" before the implementation of MEE Order No. 12, the confidential period of the identification information is up to **December 31, 2025**. 12号令施行前已列入《中国现有化学物质名录》并实施物质名称等标识信息保护的，标识信息的保护期限最长至**2025年12月31日**止。

Circumstances Requiring Re-registration

需重新办理登记的情形



The registration certificate is changed according to the simplified registration procedure, and there is no review by the expert committee (except for the change of substance identification info)

登记证变更按简易登记程序办理，无专家委员会评审环节（物质标识信息变更除外）

Simplified Procedures for Entering the Inventory

加入《名录》程序简化



For chemical substances that have been produced, sold, processed/used, or imported within the territory of the People's Republic of China before October 15, 2003, relevant enterprises may apply for additional inclusion in the IECSC.

2003年10月15日前已在中华人民共和国境内生产、销售、加工使用或者进口的化学物质，相关企业可申请增补列入《中国现有化学物质名录》。

Activity Reporting Requirements 活动报告要求

- Typical Notification
- Within 30 days from the date of first production or import and transfer to the process user
- 常规申报
- 首次生产或者进口并向加工使用者转移之日起三十日内

- Before Feb 1st ever year
- Simplified notification
- Typical notification (Hazardous category)
- 每年2月1日前
- 简易申报
- 常规申报 (危险类)

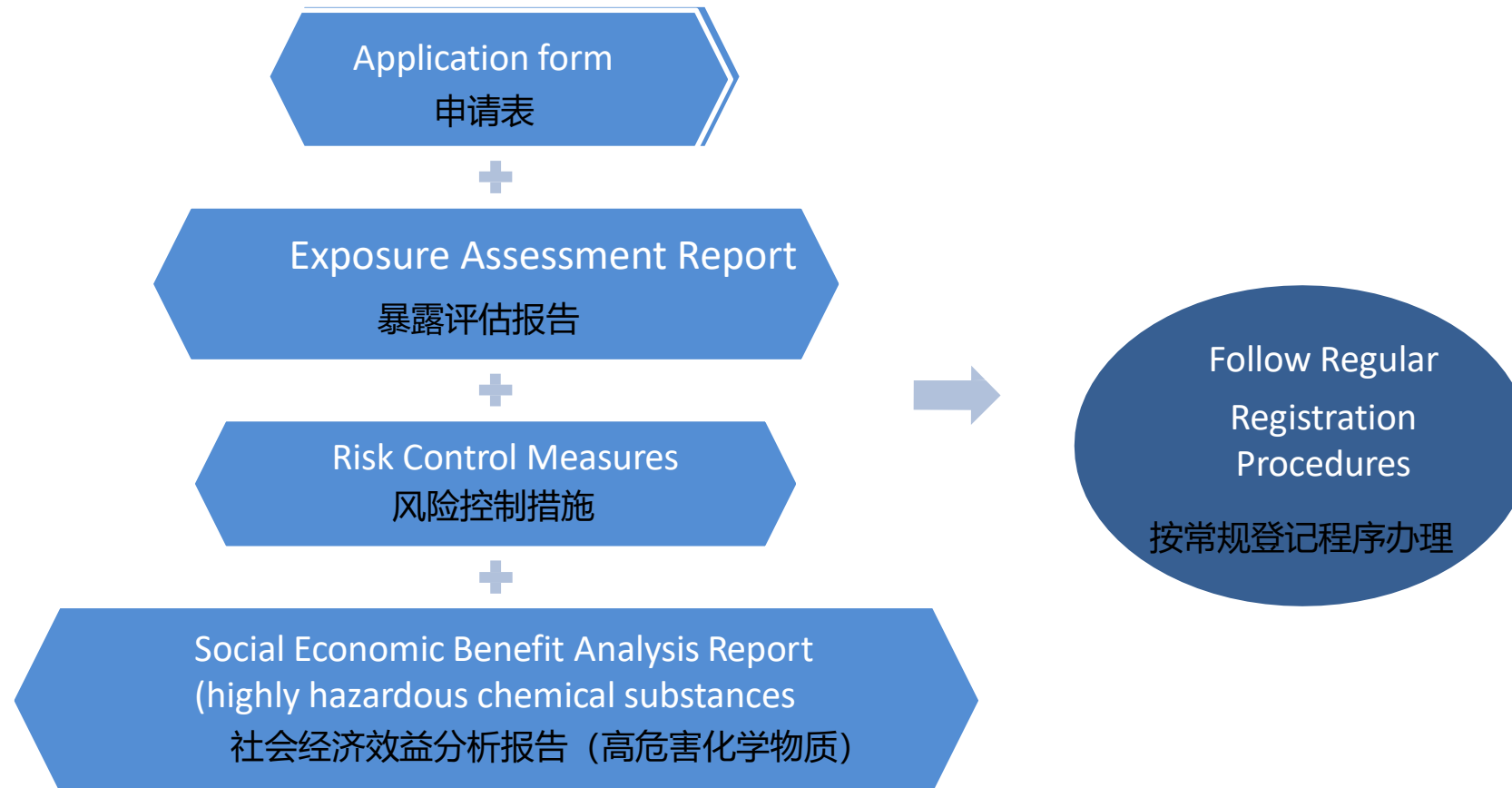
Order No. 7 7号令	Report Type 报告类型	Order No.12 12号令
√	First activity report 首次活动报告	√
√	Every activity report 每次活动报告	×
√	Annual activity report 年度活动报告	√
√	Five-year report on actual activities 五年实际活动情况报告	×

- Regular Registration
- Simplified Registration
- Within 60 days from the date of first production or import and transfer to the processing user
- 常规登记
- 简易登记
- 首次生产或者进口并向加工使用者转移之日起六十日内

- Before April 30th every year
- Regular Registration (whether it is required to submit is up to the information on registration certificate)
- 每年4月30日前
- 常规登记 (登记证上规定是否需提交)

New Use Management 新用途管理

- Application materials and registration procedures for new use registration
- 申请新用途登记所需材料及登记程序



Registration Certificate Contents

登记证内容

MEE Order No.12

生态环境部 12号令

- Registration Type 登记证类型
- Register and Agent info 申请人和代理人名称
- Identification info like CN/EN names or category name 新化学物质中英文名称或类名等标识信息
- Application purpose 申请用途
- Registration volume 申请登记量
- Activity Type 活动类型
- Environmental risk control measures 环境风险控制措施

Simplified or Regular
Registration Certificate
简易或常规登记证

- Limiting new chemical emissions or emission concentrations 限定新化学物质排放量或者排放浓度
- Requirements for implementing new-use environmental management when listed in IECSC 列入《名录》时实施新用途环境管理的要求
- Annual Report requirement 年度报告要求
- Other environmental management requirements 其他环境管理要求

Highly hazardous/PB/PT/BT substances
Regular registration certificate
Additional specification of one or more of
these
高危害/PB/PT/BT类物质 常规登记证 额
外载明其中一项或多项

《指南》：实施新化学物质环境管理制度前的化学物质增补列入《名录》

Guidance: IECSC Supplementation after Jan. 1, 2020

(八) 化学物质列入《名录》

1. 实施新化学物质环境管理制度前的化学物质增补列入《名录》

依据《办法》第三条规定，2003年10月15日前已在中华人民共和国境内生产、销售、加工使用或者进口的化学物质，相关化学物质生产、进口、加工使用企业可申请增补列入《名录》。

申请人应通过网上登记系统提交增补申请表和相关证明材料。相关证明材料包括化学物质的经销发票、进出口报关单、行业统计材料、化工年鉴、管理部门印发的文件、公开出版物以及其他能证明该化学物质在2003年10月15日前已在中华人民共和国境内生产、销售、加工使用或者进口的材料。

经审核认为申请材料不符合要求的，不予增补。符合增补要求的化学物质，在生态环境部政府网站进行公示。

VIII. Chemical Substances Listed in the Inventory

1. Chemical substances, before the implementation of the new environmental control system for chemical substances, supplemented and listed in the Inventory

According to Article 3 of *the Measures*, for chemical substances that have been produced, sold, processed, used or imported within the territory of the People's Republic of China before October 15, 2003, enterprises engaged in the production, import, processing and use of the relevant chemical substances may apply to be added to *the Inventory*.

The Applicant shall submit the supplementary application form and relevant supporting materials through the online registration system. Relevant supporting materials include sales invoice of chemical substances, import and export declaration forms, industry statistical materials, chemical yearbook, documents issued by administrative departments, public publications and other materials that can prove that the chemical substances have been produced, sold, processed and used or imported within the territory of the People's Republic of China before October 15, 2003.

《中国现有化学物质名录》增补情况 -2019至今

IECSC Supplementation Status since 2019

增补范围：2003年10月15日前已在中华人民共和国境内合法生产或者进口且未列入《名录》的化学物质 所需材料：申请表：企业信息，化学物质信息和用途，证明材料 证明材料：经销发票、进出口报关单、行业统计材料、化工年鉴、管理部门印发文件、公开出版物等
申请截止日期：2019年9月30日

China's Ministry of Ecology and Environment (MEE) has reopened the supplementation of IECSC (Inventory of Existing Chemical Substances in China).

Scope: Only substances manufactured in or imported into China before Oct. 15, 2003 would be eligible.

Documents required: Application form, Enterprise information, Chemical substance information and use/application

Supporting Documents: Distribution invoices, import and export declaration forms, industry statistics, chemical industrial yearbooks, government documents, publications and other legal documents.

Deadline: Sept. 30, 2019

增补材料提交情况：截止至2019年10月15日，MEE共收到317家公司（协会）申请将1562个物质增补列入《名录》。MEE会分多批次公示和批准符合要求的化学物质进入名录。目前MEE只于2020年5月6日发布了第一批156个化学物质进入名录。固管中心老师在2020年9月3日的培训中提到许多增补内容并不符合要求。

Based on MEE's update as of Oct. 15, 2019, there were 1562 chemical substances nominated from 317 enterprises(trade associations). MEE SCC will release approved chemical substances in different batches. So far MEE only announced 1 batch on May 6, 2020 with a total of 156 chemical substances approved and included into IECSC, including some Pharmaceutical APIs and intermediates.

Based on MEE SCC at the training workshop held on Sept. 3, 2020, many nominations do not meet the requirements/criteria(incorrect nomenclature, missing CAS number, etc.).

MEE Order No. 12 《新化学物质环境管理登记办法》

Punishment 违法处罚

Anyone violating the relevant provisions of MEE Order No.12 shall be punished by the MEE or the local MEE/EPB, according to the Chapter 5 of MEE Order No.12.

违反《办法》相关规定的，应按《办法》第五章法律责任相应情形，接受生态环境部或地方生态环境主管部门处罚。

- Order correction
- A fine between 10000 to 30000 RMB
- **Joint punishment for dishonesty**
- New applications will not be accepted within three years
- 责令改正
- 处一万元以上三万元以下的罚款
- **失信联合惩戒**
- **三年内不再受理新申请**

Sept. 2019 “Regulations on Environmental Risk Assessment and Control of Chemical Substances (WTO Notification version)”

The fines would be between 0.5 million to **2 million RMB**; if a crime is constituted, and criminal responsibility shall be investigated.

2019年9月《化学物质环境风险评估与管控条例》(WTO通报稿)
最高**200万元**罚款; 构成犯罪的, 追究刑事责任。

Attention!!!

化学物质环境风险评估与管控条例 (WTO通报稿) 第二条

Environmental Risk Assessment and Control Regulation for Chemical Substances (WTO Notification Version) – Article 2

化学物质环境风险评估与管控条例

(通报稿)

第一章 总 则

第一条 【立法目的】为评估和管控化学物质环境风险，保护生态环境，保障公众健康，促进经济高质量发展，依据《中华人民共和国环境保护法》，制定本条例。

第二条 【适用范围】对化学物质及其混合物开展环境风险评估、实施环境风险管控的活动，适用于本条例。

医药、农药、兽药、化妆品、食品、食品添加剂、饲料、饲料添加剂、肥料、放射性物质等的管理不适用本条例，但已改变用途为工业用途的，以及作为上述产品的原料和中间体的化学物质适用于本条例。

This is a higher level of regulation than MEE Order No. 12.

The WTO Notification (世贸组织通报稿) made in Sept. 2019.

Changes made from its initial version issued for public consultation (征求意见稿) in Jan. 2019, incorporating some industrial feedbacks

Article 2: The management of pharmaceuticals, pesticides, veterinary medicines, cosmetics, food, food additives, feed, feed additives, fertilizers, and radioactive materials, etc. shall be governed by other relevant laws and regulations. However, the environmental management of the above-mentioned substances that are to be used for other industrial purposes, as well as that of activities related to chemical substances as raw materials and intermediates of the above products is also governed by this regulation.

Attention!!! 化学物质环境风险评估与管控条例 (WTO通报稿) 第二十六条

Environmental Risk Assessment and Control Regulation for Chemical Substances (WTO Notification) – Article 26

第四章 新化学物质环境管理登记和环境风险管控

第二十五条 【新化学物质】新化学物质，是指未列入《中国现有化学物质名录》的化学物质。

《中国现有化学物质名录》包括在实施新化学物质环境管理登记前已在中华人民共和国境内生产、加工使用、销售或者进口的化学物质，以及根据新化学物质环境管理有关规定列入的化学物质。

国务院生态环境主管部门负责组织编制和公布《中国现有化学物质名录》，并动态更新。

第二十六条 【一般规定】国家实行新化学物质环境管理登记制度。

新化学物质环境管理登记分为简易登记、常规登记和备案。

生产或者进口新化学物质的单位，应当在生产或者进口前向国务院生态环境主管部门进行登记或者办理备案。未取得登记证或者未办理备案的新化学物质，禁止生产、进口和加工使用。

新化学物质环境管理登记的具体规定由国务院生态环境主管部门制定。办理新化学物质环境管理登记应当按照国家有关规定缴纳登记费。

第二十七条 【简易登记】新化学物质年生产量或者进口量 1

Article 26 [General Provisions] The state shall implement the environmental management and registration system for new chemical substances.

The environmental management registration of new chemical substances is divided into simplified registration, regular registration and record filing.

An entity producing or importing new chemical substances shall register or file with the ecology and environment administrative department (MEE) of the state council before producing or importing them. The production, import, processing and use of new chemical substances without registration certificate or record filing shall be prohibited.

The specific provisions on the environmental management registration of new chemical substances shall be formulated by the ecology and environment department (MEE) of the State Council. The registration fee shall be paid in accordance with the relevant national provisions when handling the environmental management registration of new chemical substances.

Attention!!! 化学物质环境风险评估与管控条例 (WTO通报稿) 第三十九条 (Environmental Risk Assessment and Control Regulation for Chemical Substances (WTO Notification version) – Article 39

第三十九条 单位法律责任

测试相关业务。

第三十九条 【单位法律责任（一）】生产、加工使用或者进口化学物质的单位存在以下违法行为的，应当由设区的市级以上地方人民政府生态环境主管部门责令限期改正，公告其违法行为，记载其不良记录，处以罚款；逾期未改正的，依法责令停产整治；情节严重的，报经有批准权的人民政府批准责令停业、关闭，并依法依规开展失信联合惩戒。

（一）违反第二十六条规定，未取得新化学物质环境管理登记证，违规生产、加工使用或者进口新化学物质的；

（二）违反第二十九条规定，未按要求办理新化学物质重新登记，违规生产、加工使用或者进口新化学物质的；

（三）违反第二十条和第三十三条规定，未经登记将化学物质用于新用途的。

有前款规定行为之一的，处五十万元以上一百万元以下的罚款；造成严重后果的，处一百万元以上二百万元以下的罚款。

第四十条 【单位法律责任（二）】存在下列违法行为的，由国

Article 39 Legal Liability (and Fines)

Article 39 If units that produce, process, use, and import new chemical substances commit the following illegal acts, the department of ecology and environment at or above the district level will order the units to make corrections within a time limit, and make public announcement of their violation, record their misconduct and impose fines; if it is not corrected within the time specified, it shall be ordered to suspend production for rectification; if the circumstances are serious, it shall be reported to the people's government for approval to stop their production and shut down the unit, and carry out joint punishment for their misconduct according to laws and regulations.

1. Violating the provisions of Article 26, failing to obtain a new chemical substance environmental management registration certificate, illegally producing, processing, or importing new chemical substances;
2. Violating Article 29, failing to re-register new chemical substances as required, illegally producing, processing or importing new chemical substances
3. In violation of Articles 20 and 33, chemical substances were used for new purposes without registration.

Any unit committing one of the acts mentioned above shall be fined from 500,000 yuan to 1 million yuan (CNY); if it has caused serious consequences, a fine from 1 million yuan to 2 million yuan shall be imposed.

总结 Summary

《办法》在**管控重点、登记类型和材料要求、登记后的跟踪管理**等方面进行了全面修订。

《指南》对《办法》**有关条款**进行了细化，明确了实施细则，包括**登记范围、登记类型、登记程序、登记申请材料要求、聚合物特别规定和新用途环境管理登记、重新登记、登记证变更、撤回与撤销以及登记后跟踪管理**等方面内容。

代理人选择：境外申报人和代理人共同承担责任和义务。

企业的主体责任：更加突出企业的主体责任，强化事中事后监管。

The Measures have been comprehensively revised in terms of key points of management and control, registration type and data/material requirements, and follow-up management after registration.

The Guidelines detail the relevant provisions of the Measures and clarify the implementing rules, including the scope of registration, type of registration, registration procedures, requirements for registration application materials, special provisions for polymers and registration of environmental management for new uses, re-registration, change of registration certificate, withdrawal and revocation, and follow-up management after registration.

Choice of agent: The overseas applicant and the agent shall bear joint responsibilities and obligations.

Responsibility of enterprises: more highlight on the responsibility of enterprises and the government will strengthen in-event and afterwards supervision.

建议 (Recommendations)

1. 如果企业在2003年10月15日前已在中国境内生产、销售、加工使用或者进口的化学物质还没有列入《名录》，请尽早按要求申请增补列入《名录》
 - Nominate any chemical substances manufactured or imported (not in IECSC yet) prior to Oct. 15, 2003 to MEE SCC with supporting documents so they can be supplemented to IECSC
2. 持续追踪法规条例和《指南》及《名录》的更新, 及时了解国家对化学物质的管理要求
 - Track regulatory changes, updated guidance and the inventory (IECSC) update, and understand regulatory requirements for chemical substances management
4. 建立企业内部化学物质数据库, 对已使用的化学物质 (原材料和产品) 进行合规排查
 - Establish an internal chemical inventory/database and review their regulatory compliance status
5. 重视化学品法规的合规, 针对企业实际情况和业务计划制定合规管理计划; 特别是在引入新化学物质之前, 先确认合规后, 再进行生产或贸易(及加工使用)
 - Focus on the compliance with the applicable chemical substance regulations and develop a compliance management plan based on the current status and future business plan; Confirm compliance before manufacturing or import activities (and processing and use), especially for any new chemical substances introduced
6. 完成申报后义务包括活动情况记录/报告、信息传递和信息公开、资料保存、在4月30号之前做年报等。
 - Fulfill required obligations after obtaining the registration certificate including activities record/report, information communicating to the downstream users, record retention, and annual report by April 30 if applicable.

Thank you for your attention!
谢谢!



CONTACT



pscinitiative.org



info@pscinitiative.org



Annabel Buchan:
+55 (11) 94486 6315



[PSCI](#)



[@PSCInitiative](#)

WeChat

[制药供应链组织PSCI](#)

For more information about the PSCI please contact:

PSCI Secretariat

Carnstone Partners Ltd
Durham House
Durham House Street
London
WC2N 6HG

info@pscinitiative.org

+55 (11) 94486 6315

About the Secretariat

Carnstone Partners Ltd is an independent management consultancy, specialising in corporate responsibility and sustainability, with a long track record in running industry groups.

