

中国

新化学物质登记

2003年,原国家环境保护总局发布了《新化学物质环境管理办法》(简称17号令),2010年,原环境保护部发布了修订后的《新化学物质环境管理办法》(简称7号令),之后,生态环境部对其进行了修订,于2020年4月29日发布了《新化学物质环境管理登记办法》(生态环境部令第12号,简称12号令),12号令自2021年1月1日起施行。根据12号令的规定,在中国境内从事研究、生产、进口和加工使用新化学物质活动之前,需进行登记并取得新化学物质环境管理登记证。

在12号令下,凡未列入《中国现有化学物质名录》的化学物质被认为是新化学物质。医药、农药、兽药、化妆品、食品、食品添加剂、饲料、饲料添加剂、肥料等产品拟改变为其他工业用途的,以及作为上述产品的原料和中间体的新化学物质,以及设计为常规使用时有意释放出所含新化学物质的物品,也属于12号令管控的范围。此外,已列入《中国现有化学物质名录》并规定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的,也应按照新化学物质进行环境管理。根据新化学物质的登记量,12号令包括了3种不同登记类型:备案、简易登记和常规登记。



申请人的种类:

- 拟从事新化学物质生产的境内生产商(企业事业单位);
 - 拟从事新化学物质进口的境内进口商(企业事业单位);
 - 拟向中国境内出口新化学物质的境外生产商;
 - 拟向中国境内出口新化学物质的境外贸易商;
- * 境外申请人应委托具有代理人资格的企业事业单位办理新化学物质登记。

我们的服务:

Intertek针对新化学物质登记提供一站式的解决方案及合规服务:

- 登记方案和流程制定
- 唯一代理服务
- 新化学物质查新
- 数据评估及数据缺口分析
- 测试方案设计及实施
- 测试项目跟踪及审核
- 专家声明制定
- 制作风险评估报告
- 登记相关材料制作、递交及跟踪
- 登记前后与法规监管机构的有效沟通
- 登记后义务服务(如年报、首次活动报告等)及列入《名录》申请
- 法规培训
- 法规咨询

联系我们

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登记类型

登记类型	适用范围
备案	新化学物质登记量 < 1吨/年; 新化学物质单体含量低于2%的聚合物或者属于低关注聚合物的
简易登记	1吨/年 ≤ 新化学物质登记量 < 10吨/年
常规登记	新化学物质登记量 ≥ 10吨/年

China New Chemical Substances Registration

The "Measures for the Environmental Management of New Chemical Substances" (i.e., Order No. 17) was issued by State Environmental Protection Administration of China (SEPA) in 2003. The updated "Measures for the Environmental Management of New Chemical Substances" (i.e., MEP Order No. 7) was revised and issued by Ministry of Environmental Protection (MEP) of the People's Republic of China in 2010. Afterwards, MEP Order No. 7 was revised by Ministry of Ecology and Environment (MEE) of the People's Republic of China in 2020, and the revised regulations - "Measures for the Environmental Management Registration of New Chemical Substances" (i.e., MEE Order No. 12)" was issued on April 29th 2020 and would take into force on January 1st 2021. As per provisions of MEE Order No. 12, new chemical substances which are to be researched, manufactured, imported, processed and utilized within the customs territory of the People's Republic of China, are subject to registration and approval of new chemical substance certificate for environmental management.

Under MEE Order No. 12, all chemical substances not listed in Inventory of Existing Chemical Substances in China (IECSC) are new chemical substances. MEE Order No. 12 applies to medicines, pesticides, veterinary drugs, cosmetics, food, food additives, feed, feed additives, fertilizers and other products that are intended to be changed to other industrial uses, and the new chemical substances used as raw materials or intermediates of the above-mentioned products, as well as articles intentionally releasing new chemical substances used under normal conditions. In addition, chemical substances listed in IECSC and subject to environmental management of new uses as stipulated in IECSC, used for industrial purpose other than the permissible use are also subject to MEE Order No. 12. Based on registered volume of new chemical substance, MEE Order No. 12 includes filing, simplified registration and regular registration.



Varieties of Applicants


- Domestic manufacturer of new chemical substances (the enterprises or public institutions);
- Domestic importer of new chemical substances (the enterprises or public institutions);
- Foreign manufacturer of new chemical substances exporting new chemical substances into China;
- Foreign trader of new chemical substances exporting new chemical substances into China;
- **Foreign applicants shall commission qualified agents (the enterprises or public institutions) for new chemical substance registration.**

Our Services

Intertek provides one-stop solutions and compliance services for new chemical substance registration:

- Development of registration strategies and procedures
- Only Representative services
- Inventory check
- Data evaluation and data gap analysis
- Design and placement of testing programs
- Stewardship of testing programs
- Set-up of expert statement
- Preparation of chemical safety report
- Preparation of registration dossiers, submission and follow-up
- Pre- and post-registration communications with the regulatory authorities
- Post-registration obligation services (annual report, first activity report, etc.) and IECSC inventory listing application
- Training
- Technical consultation

Contact us

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Type of Registration

Registration Type	Scope of Application
Filing	Registered volume < 1 ton/a; Polymer with new monomer content less than 2% or polymer of low concern
Simplified registration	1 ton/a ≤ registered volume < 10 ton/a
Regular registration	Registered volume ≥ 10 ton/a