

中国REACH法规—新化学物质环境管理办法

什么是中国版REACH法规？

国家环保部于2010年1月发布环境保护部第7号令，即修订版的《新化学物质环境管理办法》（以下简称新办法），此法规将于2010年10月正式施行。新化学物质生产或进口前必须办理新化学物质申报，领取新化学物质环境管理登记证。

哪些人必须履行申报义务？

- 拟从事新化学物质生产的国内注册机构；
- 拟从事新化学物质进口的国内注册机构；
- 拟向中国出口新化学物质的境外厂商；

注：申报人是境内申报人时，应是国内注册机构，可以直接办理新化学物质申报或者委托他人办理新化学物质申报。申报人是境外申报人时，应委托国内注册机构作为代理人办理新化学物质申报。

哪些物质在申报范围之列？

- 未列入《中国现有化学物质名录》的新化学物质；
- 含有上述新化学物质的配制品；
- 在物品中属于有意释放的新化学物质

医药、农药、兽药、化妆品、食品、食品添加剂、饲料添加剂等制成品，属于其他法规管理范畴，可不用申报，但生产这些产品的原料或者中间体，属于新化学物质的，必须按照规定进行申报。

企业为何要对新化学物质进行申报？

- 未能申报登记的新化学物质，在中国境内禁止生产或进口；
- 未按《办法》进行申报的企业，将被环保部门通报、罚款，直至取缔，且在三年之内不能进行新化学物质申报；
- 新化学物质是否申报是环保部门环评立项的重要因素之一；
- 许多国家不会进口未完成申报的新化学物质

企业该如何进行新化学物质申报？

首先应该明确自身在新化学物质申报法规下的责任和义务，然后根据申报要求确定合理的申报类型，并向新化学物质登记中心递交完整的申报材料。新化学物质登记对申报报告进行形式审查以后，交至评审委员会进行技术评审，环境保护部收到评审委员会提交的新化学物质登记技术评审意见后，对给予登记的，颁发登记证。

在新办法下有哪几种申报类型？

在新办法下，申报类型分为科学研究备案、简易申报和常规申报三类：

□科学研究备案：以科学研究为目的，年生产或进口量不满0.1吨的，或为了在中国境内采用中国供试生物进行生态毒理学测试而进口新化学物质样品的；

□简易申报：新化学物质年生产量或进口量不足1吨，或满足以下条件之一的，可申请简易申报：

- 用作中间体或仅供出口，年生产量或进口量不足1吨的；
- 以科学研究为目的，年生产量或进口量在0.1吨以上但不足1吨的；
- 新化学物质单体含量低于2%的聚合物或属于“低关注聚合物”的；
- 以工艺和产品研究开发为目的，年生产或进口量不超过10吨的且不超过2年的

□常规申报：企业新化学物质年生产量或进口量在1吨以上的，应进行常规申报，常规申报根据物质吨位分为四个等级（1-10吨/年、10-100吨/年、100-1000吨/年及1000吨/年），不同申报等级有不同数据要求。

新化学物质申报的费用大概是多少？企业该如何控制申报费用？

新化学物质申报主要包括三部分费用：测试费、咨询费和行政费用。总体费用通常在几千元至几十万元不等。基于物质属性和用途，申报费用会有较大区别。

□测试费：检测费通常在总体费用中所占比例较高。对于科学备案和特殊情况下的简易申报，一般无需开展实验测试，不涉及到实验费用；对于一般情况下的简易申报，需在有中国境内有资质的实验室开展生态毒理学实验，测试费用较低；对于常规申报，测试费用则基于物质申报吨位和数据缺口；

□咨询费：如委托代理机构进行申报代理，需支付一定的咨询费用。咨询费是根据申报类型和物质吨位来确定的，通常占总体费用比例不高，为20%-30%左右；

□行政费：由新化学物质登记中心收取（如查新费等），一般较低。

控制新化学物质申报费用的关键在于如何降低测试费用，通过合理的途径（Read Across、QSAR等）获得申报数据节点，减少测试项目则是降低测试费用的关键。瑞旭技术运用智能测试策略通过非实验手段获得相关数据，同时能对数据节点进行合理分析，豁免相关测试项目，能大大降低新化学物质申报费用。

我司能提供哪些新化学物质申报服务？

（1）法规咨询和物质查新服务

提供专业的法规咨询服务，判断客户经营活动范围是否需要履行申报义务，进行物质查新，确定物质是否属于新化学物质范畴，并确定申报类型；

（2）申报代理服务

• 数据评估和缺口分析（根据客户的申报类型，通过智能测试策略获取已有的可用数据，并进行数据缺口分析）；

• 开展实验测试，获得所需数据（将样品送至具有合格资质的实验室进行测试；制定实验项目；协调实验进程；根据实验结果，进行实验项目逐级豁免；得出实验报告，分析实验结果，获取申报所需数据）；

• 完成和递交申报卷宗（收集和整理申报所需的文件/资料/数据，填写申报卷宗，递交至新化学物质登记中心）

（3）申报代理维护服务

• 化学物质量级或重点管理类新化学物质变更登记用途的，办理重新申报登记；

• 证人完成并递交化学物质流向信息表、年度报告和年度计划表，新化学物质的中国MSDS制作等；

• 管机构保持沟通，确保持证人履行其它申报后义务

China New Substance Notification – China REACH Consulting

On 19 Jan 2010, the Ministry of Environment Protection formally released the revised version (the Order No. 7) of the Measures on Environmental Administration of New Chemical Substances. The new regulation has replaced the current version issued by the State Environment Protection Agency (SEPA) in 2003 and come into force on 15 Oct 2010. The Order No. 7 is similar to EU REACH and thus is called China REACH.

China REACH would apply to new chemical substances irrespective of tonnage, ie chemicals other than the approximately 45,000 substances currently listed on the Inventory of Existing Chemical Substances Produced or Imported in China (IECSC). New chemical substances, preparation that contains new chemical substance and manufactured articles “designed to be intentionally released” new chemical substances are all within the scope.

If you would like to search if your substance is listed on IECSC or not, please go to:<http://www.crc-mep.org.cn/iecscweb/IECSC.aspx?La=1>

Who shall submit China new chemical notification?

Chinese manufacturers or importers of new chemicals shall submit new chemical notification to the Chemical Registration Centre (CRC) of the Ministry of Environmental Protection Agency (MEP) of China, apply for and receive a registration certificate from CRC prior to manufacturing or importing the new substances. Foreign companies have to reply a local Chinese agent to submit new chemical notifications and the local agent shall be knowledgeable enough to carry out the registration.

How many types of notification are in China REACH (new provision)?

There are three types of notification in China REACH: typical notification, simplified notification and scientific research record. Once you find that your substance is not listed IECSC after inquiry, you shall determine which type of notification applies to your substance.

Type of Notification	Applicable Scope
Typical notification	New chemical substances to be manufactured or imported at or above the annual volume of 1 ton;
Simplified notification	<ul style="list-style-type: none"> • Use as an intermediate and for export only: New chemical substances to be produced or imported into China solely for use as an intermediate or solely for export (if the volume produced or exported is less than one tonne per year); • Scientific research: New chemical substances to be produced or imported for the purpose of scientific research with an annual quantity greater than 0.1 tonne but less than one tonne; • Technological R&D: New chemical substances to be produced or imported for the purpose of technological research and development with an annual quantity of less than 10 tonnes and less than 2 years; • Monomer in polymer: New chemical substances that form less than 2 percent of a polymer or polymer of low concern.
Scientific research record	New chemical substance used for scientific research has an annual quantity lower than 0.1 ton or if the sample is to be tested in laboratories in China.

Which data is required for typical notification in China REACH?

The volume and complexity of data that must be supplied to the authorities for notification is greatly increased based on a principle that "the higher the volume, the more information required".

- notification application form;
- a test report detailing the substance's physiochemical properties and its toxicity and eco-toxicity;
- an environmental risk assessment report (new);
- recommended classification and labeling(new); and
- Chinese Safety Data Sheets (new).

Note: Eco-toxicological tests must be carried out on Chinese specific creatures in certified Chinese laboratories. Other data generated in GLP labs outside of China is acceptable.

How much does China REACH cost?

The total cost consists of three major parts: administration fee, testing fee and consulting fee.

- The administration fee is fixed and it is charged by CRC. It is a small proportion of the total costs (typically around 200 RMB).

- The testing fee accounts for a large proportion of the total costs and it is charged by laboratories. The testing fee is tonnage based. It typically costs several hundred thousand

RMB to carry out testing to obtain a full set of data. Some high level testing items could be waived by analyzing the results of the basic testing items and thus the corresponding testing fee would be lower. If your company owns available data, the total costs could be reduced significantly.

- The consulting fee charged by CIRS is fixed depending on the type of notification. It normally does not exceed 30% of the total costs.

How we can help you comply with China REACH?

Initially set up by China Inspection and Quarantine Bureau, CIRS has strong presence in China and close links with Chinese Government Agencies including **Chemical Registration Center** and state testing laboratories such as **Shanghai Environmental Academy of Sciences and Shenyang Research Institute of Chemical Industry Testing Center**.

We provide all services in one package to help you complete notification at the most competitive prices in the market. Those services include:

IECSC Search and Inquiry

We conduct IECSC search, provide technical advice on whether your identity and/or activities are within the applicable scope of this provision and help you determine the right type of notification.

Analysis and evaluation of the data gap

We refer to the scientific data source, collect all the available data and analyze the data gaps in accordance with your specific volume band

Coordinate the laboratory testing

We can act as your legal importer and send your sample to the accredited labs to carry out the necessary testing. We can arrange and set out testing terms and schedules, coordinate the testing progress of labs, adjust high-level testing items according to the basic-level testing results (if possible), analyze and report test results to your company.

Prepare and submit notification dossier

We gather all the documents/information/data needed, prepare the notification dossier and submit it to the CRC.

Fulfill post-notification obligations

We update the notification dossier if your tonnage band has changed, report the trade/manufacture activities of the new substance to local enforcement authorities, fulfill other post-notification obligations after the Registration Certificate has been issued and prepare Chinese MSDS's should they be required.

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