



什么是欧盟REACH法规注册?

欧盟于2008年6月1日开始实施全称为“Registration, Evaluation, Authorisation and Restriction of Chemicals”的化学品注册、评估、许可和限制法规(以下简称REACH法规),注册是该法规下最主要的义务。企业向欧洲化学品管理署(ECHA)成功递交化学物质的注册卷宗之后,可获得一个由18位数字组成的注册号码。未能在相应的截止日期前完成注册的企业,则不能将对应产品继续投放欧盟市场。

注册主体及注册完成时间:

- 注册主体: 欧盟境内的物质、配制品、物品生产/进口商; 非欧盟物质、配制品、物品生产商必须通过欧盟境内的唯一代表(OR)来履行注册义务;
- 注册对象: 投放欧盟市场超过1吨/年的化学物质, 及配制品和物品中涉及有意释放的超过1吨/年的化学物质。涉及化工、医药、矿产、农药等众多行业;
- 注册时间:
 - ▶ 大于等于1000吨/年的常规物质, 大于等于100吨/年的R50/53类物质(水生动植物毒性), 大于等于1吨/年的CMR类物质(致癌致畸变), 需在2010年11月30日前完成正式注册;
 - ▶ 100-1000吨/年的常规物质, 2013年5月31日前完成正式注册;
 - ▶ 1-100吨/年的常规物质, 2018年5月31日前完成正式注册;

注: 以上物质均指分阶段物质。非分阶段物质(即新物质)需立即完成注册, 然后方可进入欧盟市场。

注册费用分析及减免途径:

注册工作极其繁复, 需要数月甚至长达一年的时间。费用视情况而不同, 普遍较为高昂。在下列情况中, 物质的注册费用可以得到部分减免:

费用组成/物质	备注
行政费	0-33,699欧元, 由欧洲化学品管理署(ECHA)收取
数据费	领头注册人或数据持有人收取
代理费	注册代理机构收取

- 物质为严格可控的中间体, 可降低数据费与行政费;
- 物质注册吨位为 1-10 吨/年时, 如注册卷宗中提交了REACH法规附件VII包含的所有数据, 行政费可豁免;
- 企业若符合SME(即为中小型企业)标准, 可大幅降低行政费;
- 通过瑞旭技术独有的智能测试策略的有效应用, 可豁免部分数据测试费用。





EU REACH Registration

What is EU REACH?

The REACH regulation was implemented on June 1st 2008. The full name of REACH is "Registration, Evaluation, Authorization and Restriction of Chemicals". When companies are importing or manufacturing chemicals in the EU, they are responsible for registering their chemicals according to the REACH regulation. After the registration is completed, an 18-digit registration code will be issued to the registrant. If companies are unable to complete the registration before the deadline, they are not allowed to continue importing or manufacturing their products in the EU market until a full registration has been completed and evaluated.

Registration Body and Registration Deadline

Registration Body:

Importer/manufacturer of substances, preparations and articles within the EU. For suppliers located outside of the EU, they need to appoint an Only Representative (OR) in the EU to fulfill their Regulation obligations.

Registration Scope:

Substances that are imported or manufactured in the EU above 1 ton per year. The substances contained in the preparations and articles that are intended to be released ≥ 1 ton per year. The registration scope includes chemical, pharmaceutical, mineral, agrochemical and many other industries.

Registration Deadline:

- Normal substance ≥ 1000 tons per year needs, R50/53 substance (aquatic toxicity) ≥ 100 tons per year, CMR substance ≥ 1 ton per year needs to complete full registration before November 30th 2010;
- Normal substance with 100-1000 tons per year needs to have completed full registration before May 31st 2013;
- Normal substance with 1 - 100 tons per year needs to have full registration completed before May 31st 2018.

*All the above mentioned substances are phase-in substances. Non Phase-in substances (new substances) can be imported/manufactured in EU market only after completing full registration.

Registration Fee

The registration work is very complicated, it may take from several months to one year to complete the registration. The total registration fee will vary due to different circumstances.

Fee Structure	Notes
EU Administration Fee	0~33,699 EURO, for ECHA
Data Fee	Cost varies, for LR or Data owner
Service Fee	Cost varies, dependent upon the registration agent

Only under the following situations can the registration fee be reduced:

- If substance is a intermediate under Strictly Controlled Conditions, the Data fee and EU Administration Fee can be reduced;
- If the REACH Regulation exempts the payment of the fee (fee waiver) only for registrations in the range of 1 to 10 tonnes per year for those substances that are not considered priority substances (substances that fulfil the Annex III criteria);
- If the company meets the SME Criteria, the EU Administration Fee can be reduced;
- Certain Study requirements may be waived based on good registration strategies.



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