REACH TESTING

Overview of REACH

REACH is the Regulation (EC) NO 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals, which came into force on 1 June 2007 and applied on 1 June 2008. It becomes a harmonised regulation concerning preventative administration on all chemicals to be placed on the EU market superseding more than 40 directives and regulations for chemical management. The implementation of the regulation materially impacts the export to the European Union especially that of chemicals, electromechanical products, textiles, printing and dyeing, rubber, plastics, toys and furniture, etc.

Contents

- Registration: Substance manufactured/imported over 1 tonne per year needs to be registered with the European Chemical Agency (ECHA) by EU manufacturers and importers; non-EU companies have to rely on EU REACH Only Representative (OR) to submit registration on their behalf.
- Evaluation: Registration dossiers submitted will be examined by ECHA in terms of completeness and data requirements. ECHA will also assess a substance of concern for its environment/public health impact.
- Authorisation: Listed Substance of Very High Concern (SVHC) in Annex XIV will not be allowed to be used, placed on the market or imported into the EU after data to be set unless the company is granted an authorisation.
- Restriction: Annex XVII of the REACH Regulation contains the list of all restricted substances, specifying which uses are restricted or even banned.

Lists of Substances under REACH

1. Candidate List*——SVHC

SVHC , "Substance of Very High Concern" , refers to any substance that has adverse effects on human health and the environment. Strictly speaking, the list of SVHCs serves as a candidate list for List of Substances Subject to Authorisation.

The following substances may be included in Annex XIV according to Article 57 under REACH:

1) substances meeting the criteria for classification as carcinogenic, mutagenic, toxic for reproduction category 1 or 2 (**CMR 1/2**);
2) substances which are persistent, bioaccumulative and toxic (**PBT**);
3) substances which are very persistent and very bioaccumulative (**vPvB**);
4) substances - such as those having endocrine disrupting properties or those having PBT or vPvB properties, which do not fulfil the criteria of points (2) or (3) - for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (2) to (3).

The corresponding duties and obligations shall be fulfiled for products containing SVHC. ECHA publishes the updates for SVHC list successively along with the progression for implementation of REACH.

2. List of Substances Subject to Authorisation

The Authorisation List is the Annex XIV to REACH. It aims to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. ECHA will include SVHC into the Authorisation List if no safer alternative is available.
A manufacturer, importer or downstream user shall not place a substance on the market for a use or use it himself if that substance is included in Annex XIV, unless:
a) the use(s) of that substance on its own or in a preparation or the incorporation of the substance into an article for which the substance is placed on the market or for which he uses the substance himself has been authorised in accordance with Articles 60 to 64; or
b) the use(s) of that substance on its own or in a preparation or the incorporation of the substance into an article for which the substance is placed on the market or for which he uses the substance himself has been exempted from the authorisation requirement in Annex XIV itself in accordance with Article 58(2); or
c) the date referred to in Article 58(1)(c)(i) has not been reached; or
d) the date referred to in Article 58(1)(c)(i) has been reached and he made an application 18 months before that date but a decision on the application for authorisation has not yet been taken; or
e) in cases where the substance is placed on the market, authorisation for that use has been granted to his immediate downstream user.

3. List of Restricted Substances*

This list of restricted substances is Annex XVII to REACH known as Restrictions on the Manufacture, Placing on the Market and Use of Certain Dangerous Substances, Preparations and Articles. It creates important obligations for articles besides that for SVHCs. ECHA will include the substances in the Annex XIV into Annex XVII and give the maximum exemption to restrict its manufacture and import on a Community-wide basis when the risks resulting from their use can be properly controlled and suitable alternatives are available, which are economically and technically viable.
Previously, EU Directive 76/769/EEC placed restrictions on the marketing and use of certain dangerous substances and preparations. However, it was repealed on 1 June 2009 with all its provisions incorporated into REACH.

Pursuant to provisions of REACH, a substance on its own, in a preparation or in an article, for which Annex XVII contains a restriction shall not be manufactured, placed on the market or used unless it complies with the conditions of that restriction. All products shall comply with restrictions of Annex XVII on a Community-wide basis. Companies should evaluate and test products and abide by the conditions of restrictions so as to assure transactions are reached smoothly within the European Union.

***) You could inquire us for the latest Candidate List and List of Restricted Substances (Annex XVII) of REACH if it appears necessary for you.**

Duties and Obligations under REACH

Duties and Obligations for Substances and Preparations (Mixtures) under REACH

Requirement: Save where this Regulation provides otherwise, any manufacturer or importer of a substance, either on its own or in one or more preparation(s), in quantities of 1 tonne or more per year shall submit a registration to ECHA.

Obligation to register for non-phase-in substances and phase-in substances under REACH:

- **Phase-in substances:** There is a special transitional regime allows phase-in substances to go through registration after pre-registration. The pre-registration starts on 1 June 2008 and ends on 1 December 2008. Potential registrants who manufacture or import for the first time a phase-in substance in quantities of one tonne or more per year or use for the first time a phase-in substance in the context of production of articles or import for the first time an article containing a phase-in substance that would require registration, after 1 December 2008, shall be entitled to submit the information referred to the ECHA within six months of first manufacturing, importing or using the substance in quantities of one tonne or more per year and no later than 12 months before the relevant deadline in Article 23. After pre-registration, jointly submit relevant information for registration while sharing the data via Substance Information Exchange Forum (SIEF) and Consortium.
- **Non-phase-in substances:** No pre-registration is allowed. For non-phase-in substances manufactured or imported in quantities of one tonne or more per year, go through registration since 1 June 2008 as soon as possible to avoid risks arising from export. The first step for registration of such substances is inquiry. ECHA feedbacks previous and potential registrants, analyses data gaps according to results and shares data or obtains data via independent GLP test. Then ECHA will assign a submission number to each registration after completion of the dossier.

Duties and Obligations for Downstream Products (Articles) under REACH

- Any producer or importer of articles shall submit a registration to ECHA for any substance contained in those articles, if both the following conditions are met: (a) the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year; (b) the substance is intended to be released under normal or reasonably foreseeable conditions of use.
- If the substance is not intended to be released under normal or reasonably foreseeable conditions of use, refer to the following:

The articles contain SVHCs in a concentration of less than 0,1 % (w/w).	+	Even the articles contain 10 SVHCs in a concentration of 0,09 % (w/w).	=	PASS (REACH)
The articles contain SVHCs in a concentration of over 0,1 % (w/w).	+	SVHCs are present in those articles in quantities totalling less than one tonne per producer or importer per year.	=	Information Communication
The articles contain SVHCs in a concentration of over 0,1 % (w/w).	+	SVHCs are present in those articles in quantities totalling over one tonne per producer or importer per year.	=	Notification + Information Communication

1) Any supplier of an article contains SVHCs in a concentration of lower than 0,1% (w/w) needs not notify ECHA and shall communicate information with the recipient of the article, but he or she is obliged to provide relevant information at the request of importers or consumers;
2) Any supplier of an article contains SVHCs in a concentration of over 0,1% (w/w) and present in quantities less than one tonne per year shall notify downstream users and pass on the information with relevant certifications;
3) Any supplier of an article contains SVHCs in a concentration of over 0,1% (w/w) and present in quantities over one tonne per year shall notify the information to ECHA;

4) On request by a consumer, any supplier of such articles shall provide the consumer with sufficient information, available to the supplier, within 45 days of receipt of the request, to allow safe use of the article including, as a minimum, the name of that substance.

- **Restricted Substances**

Restricted substances are in the Annex XVII (also known as Restrictions on the Manufacture, Placing on the Market and Use of Certain Dangerous Substances, Preparations and Articles) to REACH. Any substance on their own, in a preparation or in an article should be restricted on a Community-wide basis when its use poses unacceptable risk to human health and the environment. You may refer to Annex XVII for specific thresholds and scope of restrictions.

Our REACH-Partner Programme

Only Representative——OR

A natural or legal person established outside the Community who manufactures a substance on its own, in mixtures or in articles, formulates a mixture or produces an article that is imported into the Community may by mutual agreement appoint a natural or legal person established in the Community to fulfil, as his only representative, other obligations on importers. Our headquarters—CIRS—has its own OR in Ireland so as to assure better and more convenient services for our customers.

REACH-Partner Programme——RPP

The program is initiated by CIRS, which is an authoritative agency for chemical consultancy and the largest Only Representative (OR) in the world. C&K Testing also joins the program with a view to render one-stop services for enterprises to eliminate trade barriers, specify duties and obligations in supply chains and cut down costs so as to accelerate trade progress. We strive to improve conformity awareness for all trading parties to facilitate healthy and sustainable development of trade.

RPP Content

REACH Solution

- ■Analysis of duties and obligations for product
- ■Product testing
- ■Plans to deal with supply chains

Conformity Assessment

- ■SVHC conformity assessment
- ■SVHC notification conformity assessment
- ■RSL (list of restricted substances) conformity assessment

Supply Chain Management

- ■Supplier training
- ■Testing for suppliers
- ■Supply chain information communication and data management

Regulation Seminar & Training

- ■Webinar
- ■On-site training

REACH Testing & SVHC Notification

- ■Testing for Candidate List (SVHC)
- ■Testing for Annex XVII (RSL)
- ■Solutions for SVHC & RSL testing
- ■On-behalf notification of SVHC
- ■SVHC notification conformity assessment

Regulation Consulting

- ■Interpretation of REACH and relevant guidance
- ■Duties and obligations for importers under REACH
- ■Product solutions to deal with REACH
- ■Management strategies for overseas suppliers

Solutions for Suppliers Conformity

- ■Hazardous substance analysis, control and management (HSF System) at the request of suppliers
- ■Regulation and risk evaluation at the request of suppliers
- ■Interpretation and formulation for special documents of suppliers (MSDSplus, AIS, Scorecard)
- ■Third-party statement for product conformity

REACH TESTING

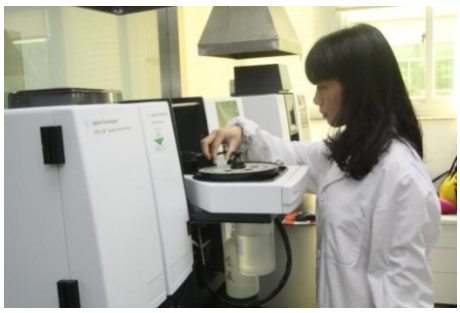
Company Profile

C&K Testing is a leading testing company to render you specialised solutions concerning green and sustainable development of products. Established in 2008, we've helped thousands of customers to minimise the risks of their products to human health and the environment through our testing services.

Our company is a member of CIRS which is a leading product safety management consulting firm. With our offices in Ireland and the United States as well as our laboratory in China, a global network of testing facilities enables you to meet all the relevant regulatory requirements across different markets more cost-efficiently.

Combining widely global recognition and extensive local experience, staffed by knowledgeable experts, C&K Testing will help you to gain a competitive advantage in the global marketplace by ensuring product safety and quality, removing trade barriers and optimising manufacturing procedures.

Our Testing Services: food and food-related products, cosmetics, environment, consumer products, industrial goods and chemicals, etc.



An Authoritative Platform for 3rd-Party Testing

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