



FACTSHEET: REACH Regulation



REACH is composed primarily of three elements: Registration, Evaluation, and Authorization. There is also the possibility of a restriction - use permitted for certain applications only.

Registration requires substance manufacturers and importers to gather information on the substances they manufacture or import and use it for responsible and well-informed risk management. It is estimated that data on around 30,000 substances (all existing and new substances exceeding a production volume of 1 metric ton) will be submitted into a central database.

Evaluation of an estimated 5,000 substances will be carried out by Competent Authorities (CAs) of Member States. CAs will receive technical support and advice from the newly-created EU Chemical Agency, including the development of substance-tailored testing programs focusing on the effects of long-term exposure.

Authorization of substances with certain hazardous properties that give rise to very high concern, such as CMR substances, will be compulsory. Authorization requires EU Commission authorities (not Member States) to give specific permission before a substance can be used for demonstrably safe, particular purposes. The number of substances subject to authorization is estimated to be around 1,000.

A priority substance list will be released in 2009. Some of the categories on the list include:

- 850 substances currently classified as CMR substances
- PBTS and vPvBs
- Possibly up to 500 additional CMR substances (cancer-causing substances, termed categories 1 and 2) which may be identified through future testing

Data Generation: Substance importers and manufacturers must provide the authorities with information. Downstream users are required to provide information if the use of a given substance differs from that intended, or if there is a conflict with the manufacturer's recommended risk management measures.

The European Union (EU) has taken an active role in establishing a central repository of data (IUCLID 5 and REACH-IT) and has encouraged sharing by creating a market for test data, sending out contact names of producers who have previously registered a chemical. Pre-registration data will be used to encourage the formation of consortia to share information where possible (e.g., SIEF - Substance Information Exchange Fora).

Articles: One of the most complex challenges of REACH is how to comply with the requirements as they apply to substances in articles. The actual responsibility for registration for manufacturers and importers is limited to the following scope:

Registration is required if the substance is:

- manufactured / imported in quantities > 1 metric ton per year
- intended to be released from the article

Notification (a simplified registration) is required if the substance:

- appears on the candidate list for authorization
- is manufactured / imported in quantities > 1 metric ton per year
- is in the article at > 0.1 % concentration

Tetra Tech is the industry leader in providing Product Compliance services in Europe and North America. We are staffed with experienced consultants, materials scientists, and toxicologists who are able to assist you in understanding, planning, and implementing your REACH program.

Reference
REACH Regulation (EC 1907/2006)

Definitions
CMR Chemicals: Chemicals classified as carcinogenic, mutagenic, or toxic to reproduction under Council Directive 67/548/EEC relating to the classification, packaging, and labeling of dangerous substances (as amended).

PBT: Persistent, Bioaccumulative, and Toxic

vPvB: Very Persistent, very Bioaccumulative

For manufacturers, importers, and downstream users, REACH's impact will be much greater than that implied by the limited scope of registration requirements. This is because the registration requirements will cause higher costs for many substances used in articles and will cause some substances to be removed from the market due to the increased demands and restrictions on their use. Even if there is an exemption to apply (i.e., medical devices) all manufacturers, importers, and downstream users of articles would be advised to contact their suppliers to find out what substances are being used in their articles.

With the advent of REACH, it is imperative that all producers of articles determine and document which substances are in their articles and assess the impact of REACH with their suppliers. This is the best way to discover what the risk of increased costs and/or supply chain disruptions would be without investing resources in much more costly efforts (i.e., testing) which may be unnecessary.

Tetra Tech provides the following services to some of the largest manufacturers in North America:

Turnkey Product Registration: Tetra Tech can arrange for an "Only-Representative" scenario where you and your customer do not need to incur the legal obligations applying to an importer. This is a way of differentiating yourself from competitors as essentially full REACH compliance is outsourced and your customers need not worry about risks of noncompliance.

Another advantage of a turnkey, third-party approach is your confidential business information will not be revealed to competitors. Your name is not publicly disclosed and proprietary information remains secret.

SVHC Inventories: Tetra Tech has conducted EU regulation substance inventories for hundreds of manufacturers. With REACH, our approach is to leverage any of your existing MSDS, RoHS/ELV, and other environmental data; then compare your existing data with the data needed for REACH compliance. A substance inventory is rapidly conducted with your supply chain, information is compiled into a database, and the gaps needed for REACH compliance are filled. By using existing data, REACH compliance costs are substantially lower.

REACH Compliance Database Implementations: The mountain of substance data generated in the course of REACH compliance requires an intelligent solution for data management. Tetra Tech has implemented IT solutions for substance tracking and management for EU environmental regulations for some of the largest companies in the world.

We work with the software to manage your data through a combination of automation and expert analysis. Datasheets are reviewed by knowledgeable technical staff, but flow smoothly through the reporting process. We have fine-tuned our processes to achieve the right blend of expert analysis and automation - a rational solution for minimizing the time and effort for compliance determination and report generation, without sacrificing data integrity.

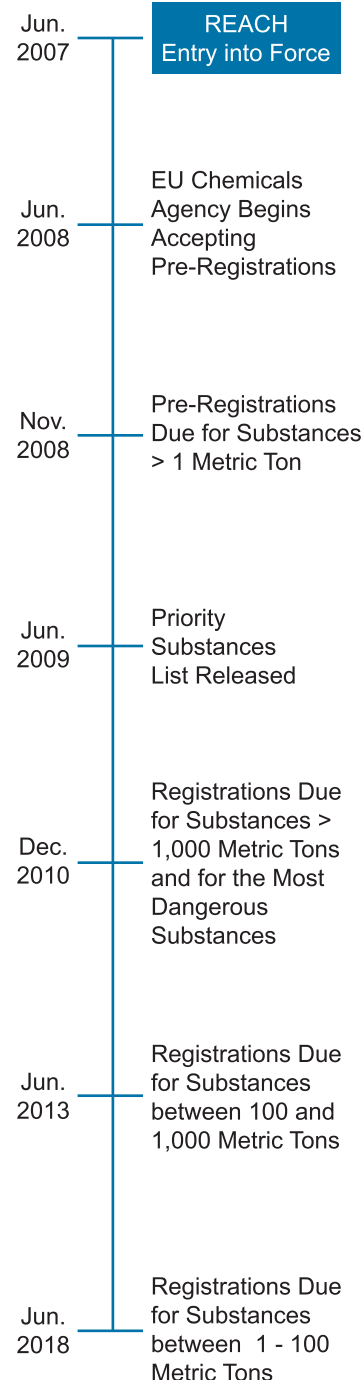
Substance Information Exchange Forum (SIEF) and Consortium Facilitation: Tetra Tech is lead facilitator for several REACH national industry consortia. We serve as the REACH intellectual resource for the entire industry and keep all companies in the sector informed of the latest developments in REACH legislation, interpretation, and enforcement.

We write industry guidance, provide REACH trainings for consortium members, and represent these industries in interactions with EU enforcement authorities. We will assist specific companies and joint registrants to complete their pre-registrations in June 2008.

Toxicology Expertise: Tetra Tech has over 100 toxicologists who represent a knowledge base with world-class expertise on carcinogenicity, reproductive toxicology, endocrine disruptors, and on persistent and bio-accumulative toxins.

We have a national practice center where REACH knowledge is shared and experts from each of these fields collaborate to provide the full spectrum of viewpoints required to complete a REACH registration and chemical risk assessment. Our toxicologists are leaders in the field and regularly speak and publish on REACH-related topics.

For more information on REACH services, please call [734.213.4095](tel:734.213.4095).



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