



National Aeronautics and
Space Administration

Principal Center for Regulatory Risk Assessment and Communication

REGULATORY SUMMARY

Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) Regulation: Europe's comprehensive reform of manufacturing, marketing, import, and use of chemical substances

This information is provided as a service of NASA's Principal Center for Regulatory Risk Assessment and Communication (RRAC PC) to inform you of regulatory developments. If you have further questions and/or need assistance with this matter, please contact Sharon Scroggins/MSFC (256-544-7932, sharon.scroggins@nasa.gov).

Introduction

The European Union's Council of Environment Ministers adopted the [Registration, Evaluation, Authorisation and Restriction of Chemicals \(REACH\) Regulation](#) on 18 December 2006. REACH requires the registration, over a period of 11 years, of approximately 30,000 chemical substances in use today. This process is intended to:

- Require more complete hazard information regarding regulated substances and identify appropriate risk management measures to ensure their safe use.
- Require the further evaluation of such substances with perceived risks and establish an authorization system for the use of substances with properties of very high concern.
- Require more rapid total or partial bans where unacceptable risks are detected.
- Require the progressive substitution of the most dangerous chemicals when suitable alternatives have been identified.
- Minimize animal testing and encourage the use of alternative testing methods.
- Ensure a comprehensive flow of information about the risks of substances throughout industry and to consumers.

Although the REACH regulation primarily is effective for manufacturers and importers of substances in Europe, it may cause indirect effects on NASA by adversely affecting material availability or causing materials to be reformulated.

Background

The existing European Union (EU) legislative framework for chemical substances comprises numerous Directives and Regulations that were developed over time. Under the existing framework:

- Sufficient information is not produced about the effects of the majority of existing chemicals on human health and the environment.
- The allocation of responsibilities is considered inappropriate: public authorities are responsible for undertaking risk assessments of substances rather than the enterprises that manufacture, import, or use the substances.
- Risk assessments are required to be comprehensive rather than targeted and use-specific.
- Downstream users are not always required to provide substance information, thus making it difficult to obtain information regarding uses of substances and exposure arising from downstream uses.

In the “Strategy for a Future Chemicals Policy” published in 2001 ([COM\(2001\) 88](#)), the European Commission outlined the results of the existing system and its new strategy for ensuring a high level of chemical safety and a competitive chemicals industry through a system for the “Registration, Evaluation and Authorisation of Chemicals” – the REACH system. REACH was adopted by the EU’s Council of Environment Ministers on 18 December 2006.

Summary of the REACH Regulation

REACH is based on the idea that industry is best placed to ensure that the chemicals it manufactures and puts on the market in the EU do not adversely affect human health and the environment. Under REACH, authorities will focus their resources on ensuring that the chemicals industry is meeting its obligations and taking action on substances of very high concern and where there is a need for European Community action.

The day-to-day management of the new requirements will be carried out by the new European Chemicals Agency (ECHA), which will be established in Helsinki, Finland.

Goals

The two most important goals of REACH are to improve the protection of human health and the environment from the risks of chemicals while enhancing the competitiveness of the EU chemicals industry. The other objectives of REACH are as follows:

- Prevention of fragmentation on the internal market
- Increased transparency
- Integration with international efforts

- Promotion of non-animal testing
- Conformity with EU's international obligations under the World Trade Organization

Requirements of REACH – Registration, Evaluation, Authorisation, and Restriction of Chemicals

REACH covers most chemical substances, whether manufactured, imported, used as intermediates, or placed on the market, on their own, in preparations, or in articles, with several specific exceptions and exemptions. The general applicability is outlined in Article 2 of the REACH regulation. Specific lists of substances that will be subject to restrictions, classifications, and other materials information may be found in the various Annexes and Appendices at the end of the regulation.

Registration

Manufacturers or importers of substances covered under REACH must provide a registration dossier to the ECHA for most substances manufactured or imported in quantities of 1 metric ton or more per year. Manufacturers and importers must determine how their substances are being used, assess the risks arising from these uses, and ensure that the risks are properly managed. Downstream users must make their uses of a substance known so their suppliers can assess and communicate the risks from their uses.

To facilitate data sharing, consequently reducing the amount of duplicative testing on vertebrate animals, manufacturers and importers intending to register existing substances are required to pre-register them between 1 June 2008 and 30 November 2008.

Information relating to health, safety and environmental properties, risks, and risk management measures must be passed both down and up the supply chain to ensure that all parties have the information needed to use chemicals safely.

To further facilitate hazard communication and ensure safety, REACH requires implementation of the Globally Harmonized System (GHS) for Classification and Labeling of Chemicals (see http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html). Additional information regarding the United States' (U.S.) perspective on GHS can be found on the [U.S. Environmental Protection Agency's, Occupational Safety and Health Administration's](#), and [U.S. Department of Transportation's](#) websites.

Evaluation and Authorization

Once the ECHA is established, it will perform quality checks on the registration dossiers, check testing proposals, and evaluate substances to clarify suspicions of risks to human health or the environment. For substances of high concern, the ECHA must authorize their use and being placed on the market. The ECHA may amend or withdraw any authorization if a suitable alternative becomes available.

Restriction

Dangerous substances may be subject to a Restrictions procedure that regulates and/or prohibits the manufacture, placing on the market, or use of these substances. REACH also calls for the progressive substitution of the most dangerous substances when suitable alternatives have been identified, thus potentially causing these substances to become obsolete.

Implementation

REACH will enter into force on 1 June 2007. REACH aims to ensure a smooth changeover from the current framework. Deadlines have been set for the repeal of various aspects of the current legislation and by setting corresponding deadlines for the phasing in of various provisions of REACH. The ECHA is required to be operational in December 2007.

Potential Operational Impacts

Because REACH requires registration and risk assessments for a wide range of substances, it is possible that this EU regulation could pose supportability risks to NASA programs through materials obsolescence and supply-chain viability.

The initial lists of carcinogenic, mutagenic and other restricted substances provided in the regulation's Annexes and Appendices include numerous materials relevant to space vehicle operations, including chromium and cadmium compounds, hydrazines, asbestos, and solvents. More detailed or updated risk assessments could identify previously unrealized hazards related to programmatically relevant substances. Where additional hazards are identified, there may be requirements for additional protective equipment or usage restrictions. For particularly dangerous substances, ECHA will have the authority to ban their manufacture, sale, or use within the EU.

Although ECHA's authority does not extend to the manufacture of materials outside the EU, limitations or bans on sale and use of certain substances in EU countries could constrict the market for those materials significantly. Such a reduction in demand could cause suppliers to stop production or to reformulate materials with ingredients considered less hazardous under REACH. Either of these supplier responses could result in a materials obsolescence risk for NASA programs, especially if only one flight-qualified material exists.

Product reformulation may pose an additional risk, in that these changes may not be effectively communicated to the end-user. Even small changes in a formulation have the potential to adversely affect materials compatibility or technical performance in space vehicle applications. Although purchasing contracts may be written to stipulate that vendors must provide notification of any materials changes, distributors may not be aware of changes made by sub-tier vendors. Receipt and inadvertent use of reformulated materials without testing and qualification could result in unacceptable performance in space vehicle operational environments.