



Let us REACH  
a safer future

GLOBAL LEADERSHIP IN REACH TESTING AND CONSULTING

**SGS**

# Sound chemical management

Most of the household commodities that we use in our daily life - from detergents and shampoo to stationery, synthetic garments, plastic toys and even electronic products - are made of chemicals.

However, despite their important role in making our lives more convenient, some groups of chemicals can be harmful to human health and the environment.

Although the situation has improved, there are still parts of the world where chemical safety management is not implemented.

In 2006, the International Conference on Chemicals Management in Dubai gathered over 600 participants, including 140 governments and various intergovernmental and NGOs, to agree on the adoption of a Strategic Approach to International Chemicals Management (SAICM). The aim of SAICM, as an international policy framework, is to promote a sound management of chemicals, ensuring that by 2020, chemicals will be produced and used in a manner that minimizes significant adverse impacts on the environment and human health.

## REACH in a few words

In the European Union, the contribution to SAICM was made through the implementation of REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) which entered into force on June 1, 2007 (EC No. 1907/2006). Prior to its implementation, the majority of chemicals (96%) did not require safety risk assessment before being placed on the market.

REACH governs chemicals which are being manufactured or placed as substances, in mixtures and in finished products, on the EU market by EU manufacturers or importers. As explicitly laid down in the recital (clause 6) of the REACH Regulation, the EU is committed to ensuring sound chemical management along with other parts of the world.

REACH requires risk assessment of chemicals, monitoring occupational safety during manufacturing processes and professional use of chemicals, elimination of the use of persistent bioaccumulative and toxic substances (PBT), sharing of chemical hazard information, promotion of industry participation and responsibility and implementation of the Globally Harmonized System of classification and labelling.

REACH as an EU "Regulation" is directly applicable in the 27 EU Member States as well as Iceland, Norway and Liechtenstein.

### DEFINITIONS

| REACH SCOPE | DEFINITION IN BRIEF   |
|-------------|---|
| Substance   | A chemical element and its compounds (natural or synthetic)   |
| Mixture     | A mixture or solution composed of two or more substances  |
| Article     | An object which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition |

## A complete range of services

SGS offers cost-effective and tailor-made solutions to help you meet REACH requirements, including:



TRAINING AND SEMINARS



TESTING AND ANALYSIS



CONSULTING AND AUDITING

## Why SGS?

### THE LARGEST GLOBAL NETWORK OF EXPERTS ON RESTRICTED SUBSTANCES

- Specific expertise in chemicals and on various products affected by REACH: Wood, Textile, Plastic, Pigments, Paint
- Experts with a broad knowledge in Global Chemicals Restriction

### WORLDWIDE GLP LABORATORIES

- Laboratories located in Europe, Asia and the Americas
- GLP laboratories for toxicology and eco-toxicology testing as required by REACH
- In-house physico-chemistry, toxicology and eco-toxicology testing services

### A NETWORK OF STRATEGICALLY LOCATED OFFICES

- Offices located in key manufacturing and importing zones throughout Europe, Asia and the Americas
- Strategic locations to work closely with your suppliers worldwide
- A strong presence in Helsinki, Finland next to the European Chemicals Agency (ECHA), and in all European countries to remain close to the Member States and competent Authorities

For further information about SGS services for REACH visit:

[sgs.com](http://sgs.com)



## KEY OBLIGATIONS

| OBLIGATION HIGHLIGHTS | REACH SCOPE   | CONDITIONS   | RESPONSIBLE BODY   |
|-----------------------|---|--|--|
| Registration          | Substance / Substance in mixture                        | If substance ≥ 1 tonne/year  | <ul style="list-style-type: none"> <li>EU manufacturer</li> <li>EU importer</li> <li>Only Representative of non-EU manufacturer</li> </ul>   |
| Communication         | Substance   | If Substance of Very High Concern (SVHC)*:<br><br>From the date of inclusion of a new substance on the candidate list, EU or EEA suppliers have to provide their customers a Safety Data Sheet on request.   | EU or EEA substance supplier, including:<br><ul style="list-style-type: none"> <li>EU producer</li> <li>EU importer</li> <li>EU distributor</li> </ul>   |
|                       | Substance in mixture                                    | If Substance of Very High Concern (SVHC)* >0.1% in the mixture:<br><br>From the date of inclusion of a new substance on the candidate list, EU or EEA suppliers have to provide their customers a Safety Data Sheet on request.  | EU or EEA mixture supplier, including:<br><ul style="list-style-type: none"> <li>EU producer</li> <li>EU importer</li> <li>EU distributor</li> </ul>   |
|                       | Substance in article                                    | If Substance of Very High Concern (SVHC)* in article > 0.1% w/w: EU or EEA suppliers of articles have to provide at least name of substance and all requirements for a safe use<br><br><ul style="list-style-type: none"> <li>To their customer from the date of inclusion of a new substance on the candidate list,</li> <li>and to EU or EEA consumer upon request within 45 days</li> </ul> | EU or EEA article supplier, including:<br><ul style="list-style-type: none"> <li>EU producer</li> <li>EU importer</li> <li>EU distributor</li> <li>Other actor in the supply chain placing an article on the market</li> </ul> |
| Notification          | Substance in article                                    | If SVHC* in article<br><br><ul style="list-style-type: none"> <li>&gt; 0.1% w/w, and</li> <li>&gt; 1 tonne/year in all articles per EU or EEA producer or importer of articles.</li> </ul>   | <ul style="list-style-type: none"> <li>EU producer</li> <li>EU importer</li> </ul>   |
| Authorisation         | Substance / Substance in mixture                        | If SVHC included in REACH Annex XIV:<br><br>From the sunset date, suppliers must have REACH market authorisation.  | <ul style="list-style-type: none"> <li>EU producer</li> <li>EU importer</li> </ul>   |
| Restriction           | Substance / Substance in mixture / Substance in article | If substance included in REACH Annex XVII:<br><br>From the sunset date, suppliers can no longer use the substance for the banned use.  | <ul style="list-style-type: none"> <li>EU producer</li> <li>EU importer</li> </ul>   |

\* Refer to substance on the SVHC candidate list

## COMMONLY USED ACRONYMS

|       |  |         |  |        |   |
|-------|--|---------|--|--------|---|
| C&L:  | Classification & Labelling                       | GHS:    | Globally Harmonised System for Classification and Labelling of Chemicals | RS:    | Restricted Substances                               |
| CLP:  | Classification Labelling & Packaging             | GLP:    | Good Laboratory Practice   | SAICM: | Strategic Approach to Chemicals Management          |
| CMR:  | Carcinogens, Mutagens and Reproductive toxicants | IUCLID: | International Uniform Chemical Information Database                      | SDS:   | Safety Data Sheet                                   |
| CSA:  | Chemical Safety Assessment                       | PBT:    | Persistent Bioaccumulative Toxic substances                              | SIEF:  | Substance Information Exchange Forum                |
| CSR:  | Chemical Safety Report                           | REACH:  | Registration, Evaluation, Authorisation and Restriction of Chemicals     | SVHC:  | Substances of Very High Concern                     |
| EC:   | European Commission                              |         |  | vPvB:  | Very Persistent and very Bioaccumulative substances |
| ECHA: | European Chemicals Agency                        |         |  |        |   |
| EEA:  | European Economic Area                           |         |  |        |   |
| EU:   | European Union                                   |         |  |        |   |

# SGS one-stop REACH compliance solutions

## GENERAL

### 1. SEMINARS AND CUSTOMIZED TRAINING

SGS dedicated REACH experts in the EU as well as our key trading partners can offer seminars and tailor-made training to manufacturers, importers, retailers and their suppliers at various levels (from elementary to advanced) to suit the unique situation of the audiences.

Topics covered by previous seminars/training:

- REACH key requirements and updates
- Substances Identification
- Compliance strategy for SVHC notification
- REACH audit
- CLP regulation and Safety Data Sheet
- Toxicology and Eco-toxicology requirements for substance registration
- Registration dossier preparation

and many more...

### 2. CONSULTANCY / IMPACT ANALYSIS

Assess your role and current compliance status to define a specific REACH strategy adapted to your business.

Frequently addressed areas of concern:

- Product classification and their corresponding compliance requirements
- High Risk SVHC in articles and how to manage SVHC notification
- Is my quality approach compliant with REACH?
- What to do if the pre-registration deadline was missed
- How to respond to the requests of the lead registrant/SIEF?
- What company specific data is needed for registration?

### 3. ANALYSIS

#### LABORATORY TESTING:

SGS can develop an intelligent testing strategy and generate required testing data according to the REACH requirements. The test strategy suggested by SGS may help you to minimize costs and avoid unnecessary new testing.

Testing scope:

- Substance identification
- Physico-chemical
- Toxicology
- Eco-toxicology

Testing services are available through our laboratory networks in Europe, Asia and the Americas. Our labs can perform testing according to and in compliance with Good Laboratory Practices (GLP) as required by the regulation for toxicological and eco-toxicological studies.

#### ANALYSIS OF RESTRICTED SUBSTANCES (RS) AND SVHC:

SGS is a pioneer for consumer products testing, we can deliver almost any kind of product chemical analysis required by regulations. Here are some examples:

- REACH Annex XVII for RS
- SVHC under Authorization (Annex XIV)
- SVHC candidate list
- Potential SVHC according the regulatory definition

#### SUBSTANCE / MIXTURE

### 4. DATA COLLECTION AND VOLUME TRACKING

SGS has an extensive network in EU and non-EU countries assisting EU importers and retailers to collect substance data for registration as well as SVHC notification. In cases where the importers and retailers do not have their own internal IT system, SGS is able to provide alternative solutions which enable effective consolidation of data that can be kept for 10 years.

### 5. REGISTRATION DOSSIER

SGS can assist you in preparing and submitting to the ECHA a comprehensive and reliable registration dossier.

Our work includes:

- Substance Identification
- Collection of data via the SIEF and identification of data gap
- Preparation of a technical dossier, collection of exposure scenarios and pertinent risk management measures
- Preparation of Chemical Safety Assessments and Chemical Safety Reports
- Risk assessment and exposure assessment
- Submission of Registration dossier using IUCLID 5 software and REACH IT platform

### 6. CHEMICAL SAFETY DATA SHEET (SDS)

SGS has many years of experience in helping our clients to prepare SDS and our services are continuously evolving with regulatory development. We can draft SDS under the Globally Harmonized System (GHS) format and according to the location of import; we can prepare SDS in all European languages and Simplified Chinese.

## ARTICLE

### 7. RISK ASSESSMENT AND STRATEGY CONSULTATION FOR SVHC NOTIFICATION

For medium to large size multi-product retailers and importers, it could be a difficult task to identify products containing SVHCs and consolidate their concentration and volume in a systematic manner. SGS offers various solutions to identify and support your SVHC notification obligation:

- Clarify your role and responsibilities in the supply chain
- Risk assessment to identify high risk products

- Suggest compliance strategy (e.g. document collection from suppliers and smart testing)
- Assist you with IT solution for data collection and consolidation
- Prepare SVHC notification dossier

### 8. REACH AUDIT

Around the globe, we have specially trained inspection teams who excel in system audit and have in-depth knowledge in the regulation. We conduct REACH audits for manufacturers in EU as well as non-EU countries. Our audit check list can be adjusted to the unique needs of our clients.



## SVHC tips

Substance of Very High Concern (SVHC) is a collective term which includes substances with the following hazard classifications:

- Category 1 & 2 Toxic to reproduction (1A & 1B Toxic for reproduction under CLP)
- Category 1 & 2 Carcinogen (1A & 1B Carcinogen under CLP)
- Category 1 & 2 Mutagen (1A & 1B Mutagen under CLP)

- Category 1 & 2 Toxic to reproduction (1A & 1B Toxic for reproduction under CLP)
- Persistent bioaccumulative & Toxic (PBT) and very Persistent very Bioaccumulative substance (vPvB)
- Substances of equivalent level of concern.

## Submitting I6Z file to SCIP

If Substance of Very High Concern (SVHC) in an Article with a concentration higher than 0.1% (w/w), a I6z file generated by IUCLID 6 has to be submitted by duty holder to Substances of Concern in Product (SCIP) database according to Article 9.1 of EU waste framework directive. The duty holder can be the following, but not include the EU retailer who direct sells product to consumers.

- EU importer
- EU manufacturer
- EU assembler

### Q: WHERE DO YOU FIND THE SVHC CANDIDATE LIST?

A: On the [European Chemical Agency \(ECHA\) official website](#).

### Q: WHEN DO YOU COMMUNICATE SVHC IN AN ARTICLE?

A: When the article supplier delivers the article to the recipient. The date of supply is the relevant date.

### Q: WHEN TO SUBMIT SVHC NOTIFICATION TO ECHA?

- Within six months after a SVHC is included in the candidate list, once the notification requirements are fulfilled.
- Immediately, if SVHC has already been on the candidate list for 6 months, once the notification requirements are fulfilled.

**When you need to be sure**

SGS SA  
Zugerstrasse 57  
6340 Baar  
Switzerland

**sgs.com**

**in**    

