

## LET US REACH A SAFER FUTURE

**GLOBAL LEADERSHIP IN REACH TESTING AND CONSULTING** 



### 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 N°. 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	EXAMPLES
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
- THIRD PARTY REPRESENTATION



## 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

#### WWW.SGS.COM/REACH

SGS is the world's leading inspection, verification, testing and certification company. SGS helps clients ensure safety compliance and meet quality and performance requirements for their chemicals and consumer products.

## **KEY OBLIGATIONS**

OBLIGATION Highlights	REACH SCOPE	CONDITIONS	RESPONSIBLE BODY	
REGISTRATION	Substance / Substance in mixture	If Substance ≥ 1 tonne/year	<ul> <li>EU manufacturer</li> <li>EU importer</li> <li>Only Representative of non-EU manufacturer</li> </ul>	
	Substance	If Substance of Very High Concern (SVHC)*: 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:  EU producer  EU importer  EU distributor	
COMMUNICATION	Substance in mixture	If Substance of Very High Concern (SVHC)* >0.1% in the mixture: 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  EU producer  EU importer  EU distributor	
	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  • To their customer from the date of inclusion of a new substance on the candidate list,  • and to EU or EEA consumer upon request within 45 days	<ul> <li>EU or EEA article supplier, including</li> <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 - > 0.1% w/w, and - > 1 tonne/year in all articles per EU or EEA producer or importer of articles.	<ul><li>EU producer</li><li>EU importer</li></ul>	
AUTHORISATION	Substance / Substance in mixture	If SVHC included in REACH Annex XIV: From the sunset date, suppliers must have REACH market authorisation.	<ul><li>EU producer</li><li>EU importer</li></ul>	
RESTRICTION	Substance / Substance in mixture / Substance in article	If substance included in REACH Annex XVII: From the sunset date, suppliers can no longer use the substance for the banned use.	<ul><li>EU producer</li><li>EU importer</li></ul>	

<sup>\*</sup> Refer to substance on the SVHC candidate list

EU:

European Union

## **COMMONLY USED ACRONYMS**

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

## GFNFRAI

# SGS ONE-STOP REACH COMPLIANCE SOLUTIONS

#### 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

#### **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** SIEF PARTICIPATION AND THIRD PARTY REPRESENTATIVE

Thanks to its large team of experts, including toxicologists, eco-toxicologist and in-house legal counsel, SGS is able to provide you with valuable advice to negotiate data and cost sharing in the Substance Information Exchange Forum (SIEF). If you feel it is necessary due to business sensitivity, SGS can act as your third party representative to participate in SIEF activities.

#### **6** 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

#### 7 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.

#### 8 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:

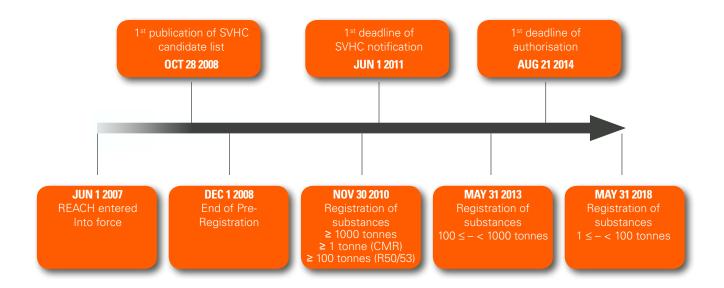
- Clarify your role and responsibilities in the supply chain
- · Risk assessment to identify high risk products
- Suggest compliance strategy (e.g. document collection from suppliers and smart testing)
- Assist you with IT solution for data collection and consolidation
- Prepare SVHC notification dossier

#### 9 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.



## REACH IMPORTANT DATES



### **SVHC TIPS**

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

- 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.
- WHERE DO YOU FIND THE SVHC CANDIDATE LIST?
- A On the European Chemical Agency (ECHA) official website: http://echa.europa.eu/chem\_data/authorisation\_process/candidate\_list\_table\_en.asp
- 0 HOW MANY SVHC ARE ON THE CANDIDATE LIST?
- On average, the list is updated twice per year. It is expected to grow from 15 substances in 2008 to over 400 substances by 2020.
- WHEN DO YOU COMMUNICATE SVHC IN AN ARTICLE?
- When the article supplier delivers the article to the recipient. The date of supply is the relevant date.
- 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.



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