



LET US **REACH** A SAFER FUTURE

GLOBAL TESTING, CONSULTING & MANAGEMENT OF CONSORTIA

SGS

PROTECTING **FUTURE** GENERATIONS

Phthalates in toys, solvents in glues, formaldehyde in wooden furniture, synthetic musks in shampoo... Hazardous substances are present in most of **consumer goods used today** at home, school or work. More vulnerable than adults, children have a potential for long-term cumulative exposures to environmental hazards. Children often put things in their mouths and can accidentally ingest harmful substances. Chemicals cause irreversible damage to health. With only 3% of chemicals fully tested today, the control of chemicals should be one of the major stakes for future generations.



A NEW APPROACH TO **CHEMICALS** REGULATION

Adopted in December 2006 after more than three years of discussion, REACH, the new EU regulation concerning the **Registration, Evaluation, Authorisation and Restriction of Chemicals** (EC N°1907/2006) has entered into force since 1st June 2007. REACH applies to the 27 Member States of the European Union immediately, without any adoption of national law.

Replacing 40 existing chemicals regulations and directives, REACH aims at improving the protection of human health and the environment through the better and earlier identification of the properties of chemicals.

The objective is to harmonise hazard /risk assessment approaches and test guidelines. From now on there is a procedure for the risk assessment reporting. REACH requires Good Laboratory Practise (GLP) compliance for Toxicology and Ecotoxicology testing.

REACH creates a single system of chemicals regulation.

Under REACH, some **30,000 chemical substances** used today will be registered over a period of 11 years in a central public database administered by the new EU Chemicals Agency (ECHA) in Helsinki (Finland).

The Agency will manage the technical, scientific and administrative aspects of the REACH system at Community level, aiming to ensure that REACH functions well and has credibility with all.

REACH reinforces communication obligations up and down the supply chain.

Under REACH the most hazardous substances will be known as **Substances of Very High Concern** (SVHC).

It covers mainly substances that cause cancer, damage the genetic makeup or are toxic to reproduction (CMR), substances that are persistent, accumulate in the food chain and toxic (PBT and vPvB) and endocrine disrupters.

The regulation will encourage the progressive **substitution** of the most dangerous chemicals when suitable safer alternatives have been identified. REACH will also enable more rapid total or partial bans where unacceptable risks are detected.

To answer the demand of its clients, SGS has anticipated for several years the implementation of the REACH regulation. Thanks to its expertise in physico-chemistry, toxicology and ecotoxicology and expertise in various products, SGS has already conducted tests, managed risk assessment and Safety Data Sheets for its clients.

ARE YOU UNDER **REACH** SCOPE?

You are concerned if you manufacture or use chemicals within the EU or import chemicals into the EU in volumes of 1 tonne or more per year:

- Either as a single chemical **substance**, products made from mixtures of chemicals – **preparations**,
- Or as chemicals that may be released from **articles**

REACH transfers the burden of proof from the authorities to the industry. Before placing chemical-based products on the European market, **manufacturers, retailers, importers and downstream users** are required under REACH to prove that substances are safe to use and that they control the risks. Substances should not affect either human health and/or the environment.

REACH affects a **variety of products from different sectors**:

- Chemicals
- Softlines: Textiles, footwear, fabrics, leather...
- Hardlines: Toys, Furniture, Paints, Cosmetics, Detergents...
- Electrical & Electronic: Household appliances, components, luminaires, audio video, automotive...



KEY ELEMENTS OF **REACH**

• **REGISTRATION**

The registrant can use existing scientific data or share data with another registrant if the chemical concerned is identical. The registrant completes a Technical Dossier by inputting the required information into a database created by the ECHA. For registration of chemical over 10 tonnes/year a **Chemical Safety Report (CSR)** is required as an additional criterion.

• **EVALUATION**

There are 2 levels of evaluation, **dossier and substance evaluation**. Substances which required animal testing shall submit a test proposal as part of the Technical Dossier. Only after the competent body has approved the test proposal, the registrant can proceed with the testing with the suggested methods. The ECHA may select certain high risks chemicals for evaluation and request further information from the industry.

• **AUTHORISATION**

Use-specific authorisations are required for **SVHC**. Authorisations will be granted only if the applicant demonstrates the risk from the use of the substance is adequately controlled or if socioeconomic benefits outweigh the risks in the absence of suitable alternatives.

• **RESTRICTION**

It concerns substances on their own, in preparations or in articles whose uses represent **unacceptable risks** to human health or the environment (list in Annex XVII REACH).

In the absence of REGISTRATION, further use or marketing is not possible. It is the principle of 'no data = no market'.

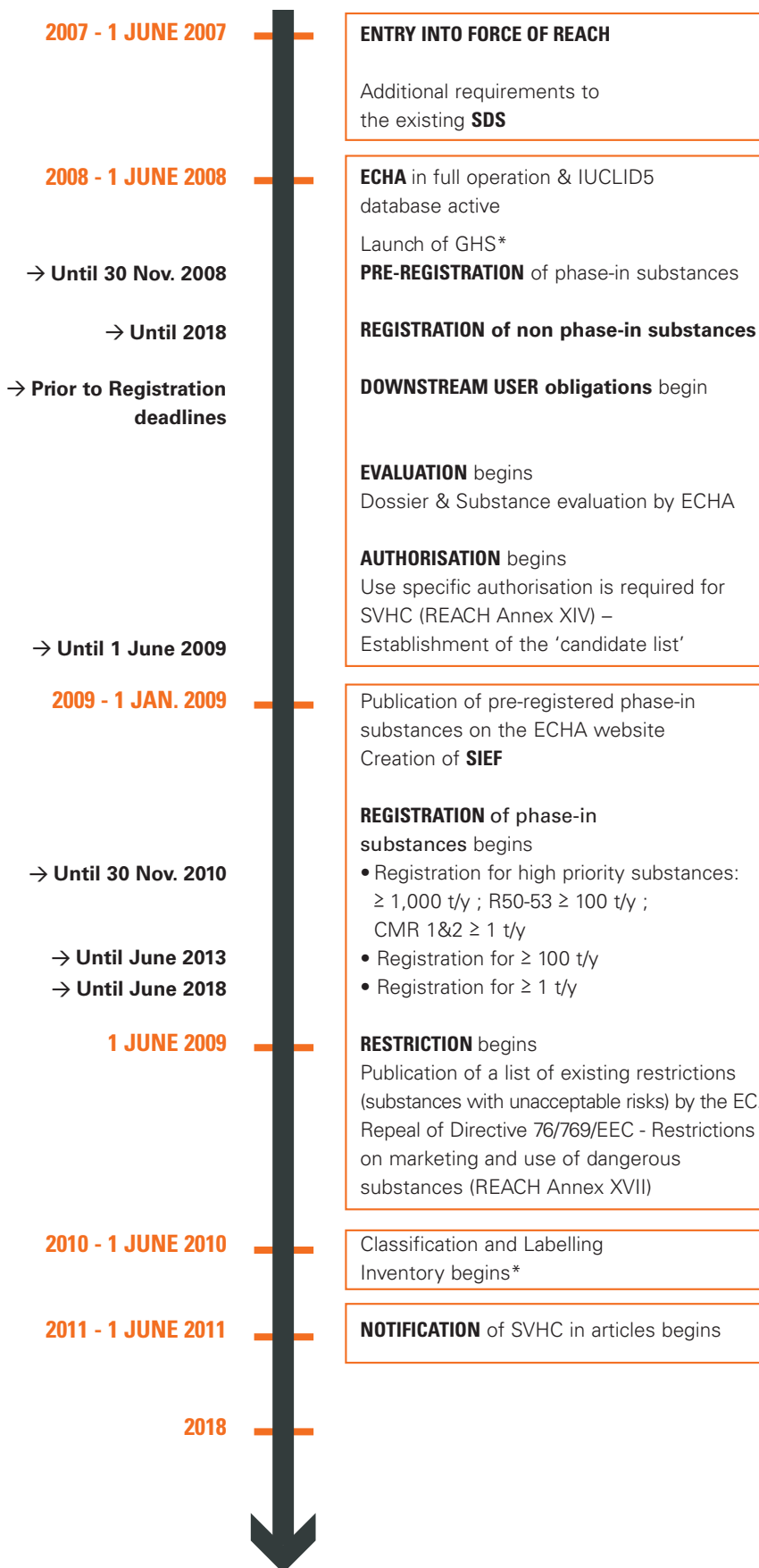
The REGISTRATION of substances in articles is not required if the substance has already been registered for that use.

AUTHORISATION is a procedure which does not depend on the Registration. It does not require any quantity threshold, is granted case by case for a specific duration.

Under REACH, a substance can be withdrawn from the market because its risks have been proven or because a manufacturer decided not to assess its risks.

KEY IMPLEMENTATION STAGES

Quantity is considered per producer or importer – legal entity



→: deadlines

*In parallel to REACH, the EC approved the necessary harmonisation of classification across the EU.

YOUR OBLIGATIONS

MANUFACTURERS & IMPORTERS

ENTRY INTO FORCE OF REACH

Be aware! **1 - 2**

Ensure traceability of data
Is my substance under REACH scope?
(Start product inventory, calculate volumes) **2 - 3**

Evaluate and update existing SDS: inversion of chapters 2&3, information on exposure scenarios...
Prepare GHS compliance: by 2010 for substances and by 2015 for preparations. **6**

PRE-REGISTRATION OF PHASE-IN SUBSTANCES

Collect available data and list use of your substances.
Pre-register to continue to make, use or sell the substance until the full registration process is completed. **3 - 4 - 5**

AUTHORISATION

Submit a substitution plan if safer alternatives available or a substitution study if no alternative available. **3 - 4 - 5**

SIEF

Share data: Identify other companies manufacturing or importing the same substance in order to negotiate the sharing of costs for the compilation of existing data, avoid the duplication of animal testing, generate new data to complete Registration. **3 - 8**

REGISTRATION OF PHASE-IN SUBSTANCES

Know the use of your substance (risk assessment).
Submit your completed registration as part of a joint registration consortium to minimise costs and avoid animal testing.
Register data with IUCLID 5 database and prepare documents required for Registration (CSA, CSR if needed). **4 - 6 - 7 - 8**

NOTIFICATION

Prepare Notification documentation. **3**

DOWNSTREAM USERS

Communicate relevant exposure and use information upstream for the purpose of Registration of phase-in substances.
Check if your substance has been registered for this use. If not, get the substance registered by your supplier or register it yourself.
Follow the risk management measures. **3 - 4 - 5**

- **KNOW YOUR PRODUCTS AND THEIR RISKS**
- **REDUCE THE USE OF SVHC**
- **COMMUNICATE THROUGH THE SUPPLY CHAIN**

SGS OFFERS **ONE-STOP** REACH COMPLIANCE SOLUTION

GET YOUR REACH COMPLIANCE WITH A TAILORED ACTION PLAN!

SGS experts can assist you at each stage of the REACH implementation.

1. SEMINARS AND WORKSHOPS

SGS offers seminars providing companies and their suppliers with practical guidance on different topics:

- REACH, has entered into force: are you ready?
- Context and obligations
- SDS/GHS Classification & Labelling
- Toxicology and Ecotoxicology requirements under REACH
- etc.

2. SGS REACH SOFTWARE

SGS provides a comprehensive REACH software to help you understand the technical and regulatory aspects of REACH, as well as your obligations for REACH compliance.

An interactive training for your staff!

3. CONSULTING

SGS offers consultancy services, especially for pre-registration, for:

- Inventory of product portfolio (data-gap analysis)
- Proposal of testing strategy
- Assessment of chemical risk management in Industry
- Suppliers evaluation and scoring, all over the world
- Definition of a REACH action plan, including alternative chemicals suggestion

4. STANDARD LABORATORY TESTING

SGS is your Testing partner and conducts all additional testing needed according to REACH requirements:

- Physico-chemical Testing
- Toxicological Testing
- Ecotoxicological Testing

Testing services are available through our labs in Europe, Asia and Americas.

Our labs are Good Laboratory Practises (GLP) compliant as required by REACH. To minimise costs, SGS experts can help you set up testing strategy.

5. SCREENING OF SUBSTANCES OF VERY HIGH CONCERN (SVHC)

To identify substances subject to restriction.

Thanks to its product expertise SGS offers intelligent testing with screening in homogeneous matrixes:

- Categories 1&2 CMR Screening
- Preparation/Updating Risk Assessments

It enables a cost-effective and time-saving assessment of dangerous substances.

6. SAFETY DATA SHEETS (SDS)

Thanks to its expertise, SGS ensures SDS compliance with extended SDS requirements and GHS classifications.

- SDS generation and data management
- SDS benchmark
- SDS internet hosting

7. REGISTRATION DOSSIER

SGS offers assistance for:

- Collection of all data via the SIEF and identification of data gap
- Writing of the Technical Dossier: collection of exposure scenarios (ES) and pertinent Risk Management Measures (RMM)
- Chemical Safety Assessment (CSA) and Chemical Safety Report (CSR) (if needed)
- Risk Assessment
- Submission of Registration Dossier via IUCLID 5 database

8. MANAGEMENT OF CONSORTIA

SGS is the partner of a worldwide law firm to assist you in the creation and management of consortia. SGS helps you in the writing of Dossier. Lawyers negotiate and draft consortium agreements, manage relationships with authorities and handle litigations if any.

WHY CHOOSE SGS?

WE SHARE OUR KNOWLEDGE AND EXPERIENCE WITH OUR CLIENTS.

Thanks to its expertise and extensive global network of laboratories, SGS has full capability for REACH compliance. SGS offers a cost effective and customised solution to help you meet REACH requirements.

- SGS is the world's leading inspection, verification, testing and certification company. SGS is recognized as the global benchmark for quality and integrity.
- SGS has one of the largest networks of technical experts, with **specific expertise in chemicals and on various products** that are mainly affected by REACH (wood, textile, plastic, pigments, paint...).
- Technical experts located in Finland can follow guidelines and updates from the Agency (ECHA) closely. SGS experts are present across Europe, mainly in France, Germany, UK, Belgium, Spain and Italy. It enables us to remain close to the Member States and competent authorities during the progressive REACH implementation.
- SGS performs all the tests mentioned in the REACH annexes: physico-chemical, toxicological, ecotoxicological tests are already performed in its **worldwide GLP laboratories** according to OECD guidelines. SGS is the only company to be able to perform **in-house physico-chemical, toxicological and ecotoxicological tests**.
- Our worldwide network of offices and laboratories enables us to **coordinate REACH services throughout Europe, Asia and Americas**. This makes it easier to handle with your worldwide suppliers.
- SGS has first-hand knowledge of worldwide standards and regulations as well as local conditions. SGS keeps you informed of evolution of chemical regulations.

For further information about SGS services go to www.sgs.com/reach. Detailed REACH requirements can be found in our informative pocket flyer '**REACH OVERVIEW AND TIMELINE**'. This is freely available on request.



REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals; **EC:** European Commission; **GLP:** Good Laboratory Practise; **ECHA:** European Chemicals Agency; **SDS:** Safety Data Sheet; **SIEF:** Substance Information Exchange Forum; **t/y:** tonne per year; **C&L:** Classification & Labelling; **CSR:** Chemical Safety Report; **CSA:** Chemical Safety Assessment; **GHS:** Globally Harmonised System for Classification and Labelling of Chemicals; **IUCLID:** International Uniform Chemical Information Database; **SVHC:** Substances of very high concern - category 1 and 2 Carcinogens, Mutagens and Reproductive toxicants (CMR), Persistent Bioaccumulative Toxic substances (PBT), very Persistent and very Bioaccumulative substances (vPvB); **DOWNSTREAM USER (DU):** formulator of preparations or user of preparations /substances; **PHASE-IN SUBSTANCES:** a substance which was placed on the market before September 1, 1981 and has been used since then with several exemptions; **NON PHASE-IN SUBSTANCES:** new Chemical Substances (without an EINECS or ELINCS registration number)

GET IN TOUCH WITH THE **BEST** NETWORK IN THE WORLD

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WHEN YOU NEED TO BE SURE

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