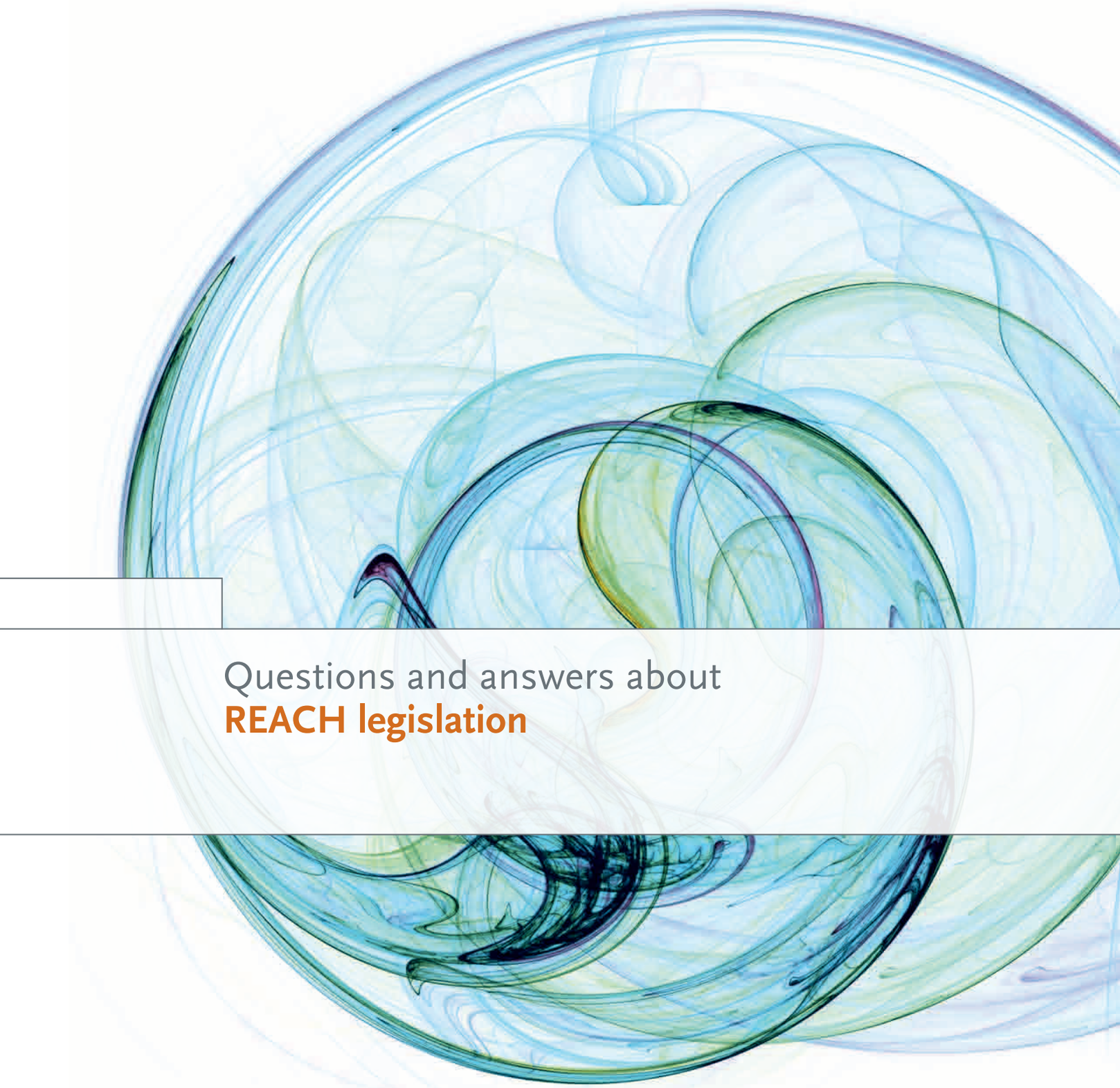

Questions and answers about **REACH legislation**

cefic

Questions and answers about REACH legislation

1

What is REACH?

REACH is a piece of European legislation that came into force on June 1, 2007.

REACH stands for Registration, Evaluation, Authorisation and Restriction of CHemicals.
This legislation requires industry to register substances with the European Chemicals Agency (ECHA), established in Helsinki (Finland).

One of the fundamental changes brought by REACH is the shift of responsibility from public authorities to industry in demonstrating the safe manufacture and use of chemicals.

2

What are its aims?

The REACH legislation was implemented in order to:

- Gain information on and control the risks of chemicals on the EU market:
  → "no data, no market"
- Give responsibility to industry to assess its products, and to communicate to customers about hazards and risks associated with the use and disposal of products
- Identify substances of very high concern (SVHC) and ensure that these substances are adequately controlled, and progressively substituted by suitable alternative substances or technologies or only used where there is an overall benefit for society
- Prevent unnecessary testing of chemical products on vertebrate animals and
- Provide a coherent and complete European regulation on chemicals, consolidating approximately 40 individual pieces of legislation that existed at the time.

3

What are the duties for Industry?

In the REACH legislation, it is the responsibility of those who manufacture or import substances into the EU to demonstrate that the substances they manufacture or import can be used safely.
The main challenges for the industry will be to:

- Assess the hazards of their substances and generate the required data
- Document the use of these substances through a "Chemical Safety Report"
- Share data and information with all companies manufacturing/ importing the same substance within what is called a SIEF (Substance Information Exchange Forum)
- Register jointly this substance with the European Chemicals Agency (together with other manufacturers/importers).
- Communicate appropriate information (via "Safety Data Sheet" including "Exposure Scenarios") to the entire supply chain
- Substitute or apply for an authorisation for substances of very high concern requiring an authorisation
- Ensure no breach of competition law

Some of these tasks will be ongoing until 2018 for existing substances. Many will continue after 2018.
New substances can only come onto the market when registration has been successfully achieved.

4

Who are the actors?

- All companies within EU Member States (as well as Iceland, Norway, Liechtenstein) are involved
  - Manufacturers and importers
  - Distributors and downstream users of substances
  - Only Representatives representing manufacturers outside the EU who export chemicals to the EU
- ECHA, The European Chemicals Agency, based in Helsinki
- The EU Commission
- National authorities
- The Public, who are able to request information on chemicals

5

Are there substances exempted from the REACH legislation?

Yes, mainly substances already covered by other legislations: radioactive substances, substances under customs supervision, non-isolated intermediates, waste, ...

6

What are the main steps of REACH?

- Pre-registration[1]
- Data sharing in a SIEF (Substance Information Exchange Forum)
- Communication up and down the Supply Chain to identify and characterise uses
- Registration
- Evaluation
- Authorisation and Restriction
- Enforcement
- Communication through the supply chain

[1] ended in December 2008

7

What is pre-registration?

Manufacturers and importers had to pre-register substances between 1 June 2008 and 1 December 2008 that were already on the EU market before REACH came into force (so-called phase-in substances).
Pre-registration enables registrants to benefit from an extended registration deadline and to know who the other registrants of the same substance are: all will have to share data for the submission of the joint part of the registration dossier. In some cases, a late pre-registration remains possible.

The registration deadlines for preregistered phase-in substances depend on the yearly tonnage and classification. There are three deadlines: November 2010, June 2013 and June 2018.

8

How does data sharing work? What are SIEFs?

SIEF stands for Substance Information Exchange Forum. Data sharing in order to make joint submission for registration is done through a SIEF. Sharing of data is mandatory under the REACH legislation, thereby avoiding duplication of studies, in particular vertebrate animal testing. The characteristics of a SIEF are as follows:

- Is formed by and with companies
- Is not 'owned' by ECHA or any other authority
- Leads to a joint submission
- Allows submission of testing proposals for more advanced tests
- Allows agreement on mandatory classification and labelling
- Leads to working together towards registration

ECHA expects 9,000 substances to be registered by the first registration deadline (30 November 2010).

9

What is Registration and what is a Chemical Safety Report (CSR)?

To register a substance, one must submit a technical dossier to the European Chemicals Agency via the REACH IT portal on the web. During the registration process a Chemical Safety Report (for substances > 10 t/year) assessing the risks associated with the uses of the substance has to be produced, containing risk management measures.

10

What is Evaluation?

There are two types of evaluation:

Dossier evaluation: Following the submission of the registration dossier ECHA will evaluate the registration data, and decide in some cases on further testing.

Substance evaluation: When the Agency or a Member State Competent Authority has an indication that a substance may pose a risk to human health or the environment, the Agency will include that substance on a list for "substance evaluation". For each substance on this list, one Member State shall evaluate in more detail whether further information is needed and in that case, the registrant(s) will be requested to provide such information.

1ST REGISTRATION DEADLINE

30 NOVEMBER 2010

≥ 1 000 tonnes a year
≥ 100 tonnes/year very toxic to aquatic environment
≥ 1 tonne/year CMRs

11

What are Authorisation and Restrictions?

Authorisation: on the basis of their intrinsic properties, substances are first put on the candidate list. Priority substances of this candidate list will be included in Annex XIV of REACH.
The use of a substance listed in Annex XIV of REACH is allowed only if an authorisation has been granted for a particular use.

Member State Competent Authorities and the Commission are responsible for setting up the candidate list for authorisation and their inclusion in Annex XIV.
If an authorisation is not granted, the use of that substance is not allowed anymore.

Restrictions: If a risk is identified as unacceptable to human health or the environment, a proposal to restrict the marketing and use of a substance can be made by the Commission in consultation with the Member States, taking into account the socio-economic impact of the restriction including the availability of alternatives. The list of existing restrictions can be found on the ECHA website.

12

How is Enforcement of the REACH legislation implemented?

Enforcement is the critical step for implementation. It is the responsibility of individual Member States to set up the appropriate framework of penalties.

Therefore, penalties for non-compliance are decided by individual Member States.

To harmonise enforcement among Member States, ECHA has set up a FORUM where all Member States meet to harmonise their enforcement actions.

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Communication through the supply chain

The information that has been gathered on hazard and risk needs to pass through the supply chain. This communication is done through the Safety Data Sheet (SDS).
REACH specifies the requirements for SDS. An exposure scenario describing the exposure and risk management measures for the identified use may be added for substances where a Chemical Safety Report has been part of the registration dossier.

Consumers can ask for information on articles containing any SVHC (Substances of Very High Concern) included in a candidate list when it is present in a concentration above 0,1%. The new requirement obliges companies supplying these articles to inform the consumer about the safe use of these articles.

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What is Industry doing to make REACH a success?

Cefic and national chemical associations are making every effort to help businesses in their preparation for REACH, supporting effective compliance to the benefit of European business and society.

Cefic has dedicated a part of its website to help in the implementation of REACH: documents, tools and guidance can be found. This information is open to all businesses – and not restricted to Cefic members.
This contributes to the sustainability of the European industry:
www.cefic.org/Reach

REACH Registration deadlines

2ND REGISTRATION DEADLINE	3RD REGISTRATION DEADLINE
31 MAY 2013	**31 MAY 2018**
100 tonnes/year	1 tonne/year

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Cefic - The European Chemical Industry Council

Chemistry making a world of difference

Cefic is the Brussels-based organisation representing national chemical associations and chemical companies in Europe. Cefic represents, directly or indirectly, around 29,000 large, medium and small companies in Europe, which employ directly about 1.2 million people and account for nearly 30% of world chemicals production.

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