European Commission

Ready for REACH

Bratislava - 19 April 2007
European Commission, DG ENTR, REACH Unit

This presentation only represents the views of its author and does not necessarily reflect the official opinion of the Commission

1

Outline

- Introduction
- Overview of industry's main obligations under REACH:
  - Producers and Importers:
    - Registration
    - Pre-registration (to benefit from extended registration deadlines)
    - Data Sharing
    - Information in the Supply Chain
    - Preparation of ES for "identified uses"
    - Seeking an Authorisation (for substances in Annex XIV)
    - Compliance with Restrictions
    - Reporting on C&L

2

Why REACH?

- To improve the protection of human health and the environment through:
  - Increased knowledge about chemicals.
  - Shifting burden of ensuring safety of chemicals from authorities to chemical operators.
- To increase the competitiveness of the EU chemical industry by:
  - Setting up a single and coherent system for new and existing chemicals.
  - Creating a more favourable environment for R&D activities:
    - R&D up to 1 tonne (instead of 100 kg).
    - PPORD for minimum of 5 years (instead of 1 year).

3

Entry into Force

- REACH enters into force on 1 June 2007
- However, most provisions will apply at a later stage:
  - 1 June 2008: -Pre-registration of phase-in substances.
    -Registration of non phase-in substances.
    -Evaluation and authorisation.
    -DUs obligations.
  - 1 June 2009: -New restrictions procedure.
  - 1 Dec 2010: -C&L obligations.

4

Main Obligations of Producers and Importers under REACH

1. Registration
2. Pre-registration (to benefit from extended registration deadlines)
3. Data Sharing
4. Information in the Supply Chain
5. Preparation of ES for “identified uses”
6. Seeking an Authorisation (for substances in Annex XIV)
7. Compliance with Restrictions
8. Reporting on C&L

5

Obligations for Industry

- A registration dossier must be submitted for every substance manufactured or imported in the EU in quantities over 1 tonne/year.
- Registration mandatory as from 1 June 2008 unless substance has been pre-registered.
- Amount of information required depends on volume.
  - No CSR below 10 tonnes.
  - However, duty to submit all relevant and available information.

6

Exempted from Registration

- Non-isolated intermediates
- R&D
  - PPORD subject to notification.
- Certain substances :
  - Annex IV (well-known substances *e.g.* water, oils, fatty acids, cellulose).
  - Annex V (substance for which registration would be inappropriate, *e.g.* by-products, naturally occurring substances).
- Certain uses : Medicines, food, and feedingstuffs covered by relevant EC legislation.
- Recovered and re-imported substances under certain conditions.
- Polymers
  - However, their components may require registration.
- Specific rules apply to isolated intermediates, articles, and substances regarded as being registered.

7

Getting Ready

- Identify all substances you manufacture or import above 1 tonne.
- Check whether any of the exemptions apply.
- Identify which substances qualify as “phase-in substances”.
- Make a dossier for every substance you need to register:
  - Gather all information you have available.
  - Identify your information needs and registration deadline.

8

Some Remarks

- Volumes as the average of three years.
- Scope of exemptions must be carefully considered:
  - PPORD must meet the conditions of Article 9.
  - Exclusion for use in medicines, food and feedingstuffs only to the extend that covered by the relevant EC legislation.
  - "Natural substances" only exempted if they have not been chemically modified.
    - *e.g.* oil obtained by cold pressing may be exempted from registration, but that might not be the case for oil obtained by steam distillation as the distillation process can modify the composition of the final product.
- Distinction between article and preparation is sometimes difficult.
    - Products whose main purpose is to release a substance likely to be considered as containers, their content being a preparation (*e.g.* ink cartridge).

9

Main Obligations of Producers and Importers under REACH

1. Registration
2. Pre-registration (to benefit from extended registration deadlines)
3. Data Sharing
4. Information in the Supply Chain
5. Preparation of ES for "identified uses"
6. Seeking an Authorisation (for substances in Annex XIV)
7. Compliance with Restrictions
8. Reporting on C&L

10

Why to pre-register?

- Pre-registration is not mandatory, but it is **required to benefit from extended registration deadline**:
  - **1 December 2010**
    - CMR 1 and 2.
    - very toxic and may cause long-term effects (R50-53) if >100tons/year.
    - phase-in substances >1000 tonnes
  - **1 June 2013**
    - phase-in substances >100 tonnes
  - **1 June 2018**
    - phase-in substances > 1 tonne
- Only **phase-in substances** may be pre-registered.

11

Obligations for Industry

- From **1 June 2008 to 1 December 2008**, the following must be submitted to the Agency:
  - identify of the potential registrant;
  - identity of the substance;
  - the envisaged registration deadline and tonnage band; and
  - identify of other substances relevant for (Q)SARs and read-across.
- Companies that pre-register must join a **SIEF**.

12

Getting Ready

- Make now a list of your phase-in substances (in quantities above 1 tonne).
- Decide whether you want to pre-register.
  - Duty to share data also applies in cases of substances that are not pre-registered.
- Make a list of substance that are relevant for (Q) SARs and read-across.

13

Some Remarks

- If you miss the pre-registration deadline, the obligation to register applies immediately.
- Substance identification is critical, particularly for multi-constituent substances.
  - The extended registration deadline only applies to the substance that has been pre-registered.
  - Guidance is RIP 3.10 is relevant to establish the identity of your substances.
    - Impurities over 10% are to be registered as a substance if the one tonne threshold / year is exceeded.

14

Main Obligations of Producers and Importers under REACH

1. Registration
2. Pre-registration (to benefit from extended registration deadlines)
3. Data Sharing
4. Information in the Supply Chain
5. Preparation of ES for "identified uses"
6. Seeking an authorisation (for substances in Annex XIV)
7. Compliance with restrictions
8. Reporting on C&L

15

OSOR

- Obligation to submit jointly certain parts of the registration dossier, including studies and proposals for testing.
  - CSR may be done jointly but not mandatory.
- Right to opt out if:
  - Disproportionately costly.
  - Disclosure of commercial sensitive information.
  - Disagreement with lead registrant.

16

Obligation to Share Data

- For pre-registered and not pre-registered substances:
  - Duty to share information involving testing with vertebrates.
  - Other information must also be shared on demand.
- Compensation:
  - Costs of tests shared.
  - However, information that has been submitted at least 12 years ago is free of charge.

17

Getting Ready for Data-Sharing

- Identify your information needs (on the basis of your estimated volume).
- Identify all the information you have available.
  - Keep track of all expenses linked to generation of information required under REACH.
- Identify substances in the list of pre-registration substances that are relevant for your registration needs (after 1 January 2009).
  - IT system will facilitate relevant contact details.

18

Some Remarks

- Consider appointing a third party representative if you think that divulgation of your contact details may be detrimental to your business.
- Opting out from joint registration is possible but discouraged through:
  - Higher registration fees.
  - Prioritisation of "opting out" dossiers for compliance check.
- Agency will not solve disputes on cost-sharing.

19

Main Obligations of Producers and Importers under REACH

1. Registration
2. Pre-registration (to benefit from extended registration deadlines)
3. Data Sharing
4. Information in the Supply Chain
5. Preparation of ES for "identified uses"
6. Seeking an Authorisation (for substances in Annex XIV)
7. Compliance with Restrictions
8. Reporting on C&L

20

Obligations for Industry

- SDS remain the main tool to communicate information.
  - Main changes to current system:
    - SDS also required for PBTs, vPvBs and substances in the candidate list.
    - Relevant ES mandatory if duty to make CSR.
- Minimum information to be provided when no SDS.
  - Duty to communicate at least the name of substances in the candidate list contained in an article in a concentration >0.1% weight.
    - This information to be provided to consumers also on demand.
- Information up/down the supply chain on hazardous properties or concerning adequacy of RMMs.

21

Getting Ready

- Identify which substances will require SDS because of the extended scope of REACH.
- If you are a producer of articles, start working on communication schemes with your customers to identify substances in the candidate list that present in your articles in concentration above 0.1%.

22

Main Obligations of Producers and Importers under REACH

1. Registration
2. Pre-registration (to benefit from extended registration deadlines)
3. Data Sharing
4. Information in the Supply Chain
5. Preparation of ES for “identified uses”
6. Seeking an authorisation (for substances in Annex XIV)
7. Compliance with restrictions
8. Reporting on C&L

23

Obligations for Industry

- The supplier of a substance to a DUs is required to develop ES for the DU’s identified uses.
  - Duty to carry out ES applies as from 1 month from request (for non pre-registered substances) and 12 months before the pre-registration deadline in the case of pre-registered substances.
- The supplier can refuse to make an ES on grounds related to the protection of public health or the environment.

24

Getting Ready

- Start discussing early with your customers.
  - Identify the “identified uses” asap.
  - Collaboration in the development of ES between suppliers and customers can drive overall costs down.

25

Main Obligations of Producers and Importers under REACH

1. Registration
2. Pre-registration (to benefit from extended registration deadlines)
3. Data Sharing
4. Information in the Supply Chain
5. Preparation of ES for “identified uses”
6. Seeking an Authorisation (for substances in Annex XIV)
7. Compliance with Restrictions
8. Reporting on C&L

26

General Principles

- **Substances in Annex XIV** must be authorised before they are manufactured or placed on the EU market.
- Authorisation is **granted by the Commission** on the basis of an opinion from the Agency.
- Authorisation is indefinite but is subject to a **time-limited review**.

27

Annex XIV

- **Which substances?**
  - Substances that are CMR 1 or 2, or PBT/vPvB, or equivalent concern, regardless of volume.
- **Which procedure?**
  - Substance is included in "**candidate list**".
    - First substances could be put in the candidate list by Autumn 2008.
  - Substance is **prioritised by the Agency**.
  - **Commission decision** to include substance in in Annex XIV.
- Annex XIV to be updated at least every two years.

28

Some Remarks

- No action required until a substance is placed in Annex XIV.
  - The inclusion of a substance in Annex XIV allows industry to provide input.
- Application for an authorisation can be done jointly (and also for a group of substances).

29

Main Obligations of Producers and Importers under REACH

1. Registration
2. Pre-registration (to benefit from extended registration deadlines)
3. Data Sharing
4. Information in the Supply Chain
5. Preparation of ES for “identified uses”
6. Seeking an Authorisation (for substances in Annex XIV)
7. Compliance with Restrictions
8. Reporting on C&L

30

Main Changes introduced by REACH

- **Faster procedure** to adopt restrictions to enter into force on June 2009.
  - Restrictions will no longer require co-decision.
  - Restrictions adopted by the Commission under the comitology procedure.
- Restrictions adopted until June 2009 will **automatically** be included **in Annex XVII**.

31

Industry's Main Obligations

1. Registration
2. Pre-registration (to benefit from extended registration deadlines)
3. Data Sharing
4. Information in the Supply Chain
5. Preparation of ES for "identified uses"
6. Seeking an Authorisation (for substances in Annex XIV)
7. Compliance with Restrictions
8. Reporting on C&L

32

C&L

- **Main changes**:
  - Discrepancies in C&L will become more obvious thanks to the database of the Agency.
  - Harmonised C&L for new endpoints possible if:
    - Substance is CMR, 1,2, or 3; or
    - Substance is a respiratory sensitiser.
- **Timing**:
  - Duty to notify C&L information to the Agency applies as from 1 December 2010.
  - Commission currently working on GHS implementation.

33

Further Information

Further information is available on the internet pages of the Commission:

http://ec.europa.eu/enterprise/reach/index_en.htm

http://ec.europa.eu/comm/environment/chemicals/reach.htm

http://ecb.jrc.it/REACH/

34