

# Post-Pre-Registration Score Card

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# Pre-Registration Statistics

- 6-month pre-registration phase ended 1 December 2008
- 2,752,646 pre-registrations submitted vs. 132,000 expected
- 146,171 pre-SIEFs w/ 1 to >5000 members
- 138 pre-SIEFs have between 1,000-5,000 members
- List of pre-registered substances can be accessed at <http://apps.echa.europa.eu/preregistered/pre-registered-sub.aspx>
- ECHA still reviewing the validity of some of the pre-registrations made by some companies and the identity of some of the substances.
- The ECHA website advises: “14,000 of the entries on the list could contain mistakes as far as we can see.”

# WHAT ARE YOUR OPTIONS?

- **If**
  - You Didn't Appoint an OR to Timely Pre-register?
  - You Signed up in REACH-IT as a U.S. Entity?
  - Your OR Didn't Submit Separate Pre-registrations for Each Non-EU Legal Entity in Your Company?
  - Your Pre-registration was Declared Invalid?
  - You Pre-registered the Wrong Substance?
  - You Mistakenly Believed that Your Supplier was Covering Your Volumes?

# Changes to Pre-Registrations

- Substance pre-registered under a wrong EINECS entry
- During the SIEF Formation Stage, possible to change SIEFs if verification of substance identity with pre-registrants of similar EINECs No. leads to the conclusion that the substance fits more closely into this other SIEF.
- REACH-IT has no functionality for changing SIEFs
- ✓ Indicate Correct EINECS No. in Resd-Across Box
- ✓ Contact Pre-SIEF Facilitator of the correct SIEF
- ✓ Document what you are doing
- Not possible to make modifications beyond refinement of substance identity (e.g. can't join a SIEF of an unrelated substance to the one that has been pre-registered).

# Late Pre-registration

- Pre-registration after 1 December 2008 is possible in the following situation only:
  - 1) potential registrants, who after 1 December 2008 manufacture or import **for the first time** since EIF a phase-in substance in quantities of 1 t/yr or more, can submit a late pre-registration provided they do so:
    - at the latest 6 months after first manufacturing or importing a substance above the 1 tonne threshold per year; and
    - at least 12 months before the relevant transitional deadline for registration
- **Late pre-registrations can only be submitted via the REACH-IT portal.**
- **You will need to indicate the date that 1 t/yr was first exceeded.**

# Double Pre-registration Problem

- In October 2008, the ECHA and the Commission took position on the need to pre-register certain classes of substances even though the pre-registrant will be exempt at the registration stage:
  - re-imported substances, Article 2 (7)(c)
  - recovered substances, Article 2(7)(d)
  - monomers in polymers, Article 6(3)
  - substances intended to be released from articles, Article 7(6)
- This largely took industry by surprise which argued unsuccessfully that pre-registration can not be decoupled from registration within the meaning of the above exemptions
- A number of Member States have announced that they do not intend to enforce the failure to pre-register in these cases.

# Pre-Registration Deactivation vs Deletion

- ECHA position is that one can only deactivate the pre-registration so as not to participate in the pre-SIEF discussions on sameness.
- A pre-registrant still remains responsible for sharing data that she owns even if there is no intention to register.
- The same is true for a data holder that signs on to REACH-IT
- Cancellation of the pre-registration was only available until 1 December 2008 although invalid pre-registrations are being deleted from the system.

# The Only Representative Mechanism

- Is it true that Only Representative (OR) can not pre-register late if the non-EU manufacturer already exceeded the 1 tonne/ yr threshold?
- An OR can be changed during the phase-in period by sending a letter to the ECHA.
- After registration, one needs to amend the registration to indicate the appointment of a new OR and pay the update fee of 1500 Euro per substance
- Still possible to ask your supplier to agree to cover your exports into the EU

# Indirect Supply Chain Coverage

- Your Supplier can agree to have their OR cover your exports of their substance as such or as part of a preparation
- Your EU importers need the Notice of Appointment of the OR per Article 8(3) from the Supplier.
- You need to provide your supplier with:
  - ✓ List of EU importers
  - ✓ Volumes Imported
  - ✓ Agree to transmit Supplier SDS

# Will Monomers in Imported Polymers Be Subject to Registration?

- Article 6.3 already provides an exemption if the monomer has already been registered by an actor up the supply chain.
- What about monomers in polymers with no supplier registration?
- ECB case challenging interpretation and validity of Article 6.3.

# Advocate General Opinion

- Advocate General to the ECJ recommends rejection of Industry position.
- Two Interesting Side-Lines in her Opinion:
  - 1) Lifecycle of Monomer Ends at Polymer Formation: Has Implications for CSR.
  - 1) Polymer importer can rely on the registration of the monomer by the OR of the non-EU monomer producer because the OR is indeed an actor up the supply chain within the meaning of Article 6(3).

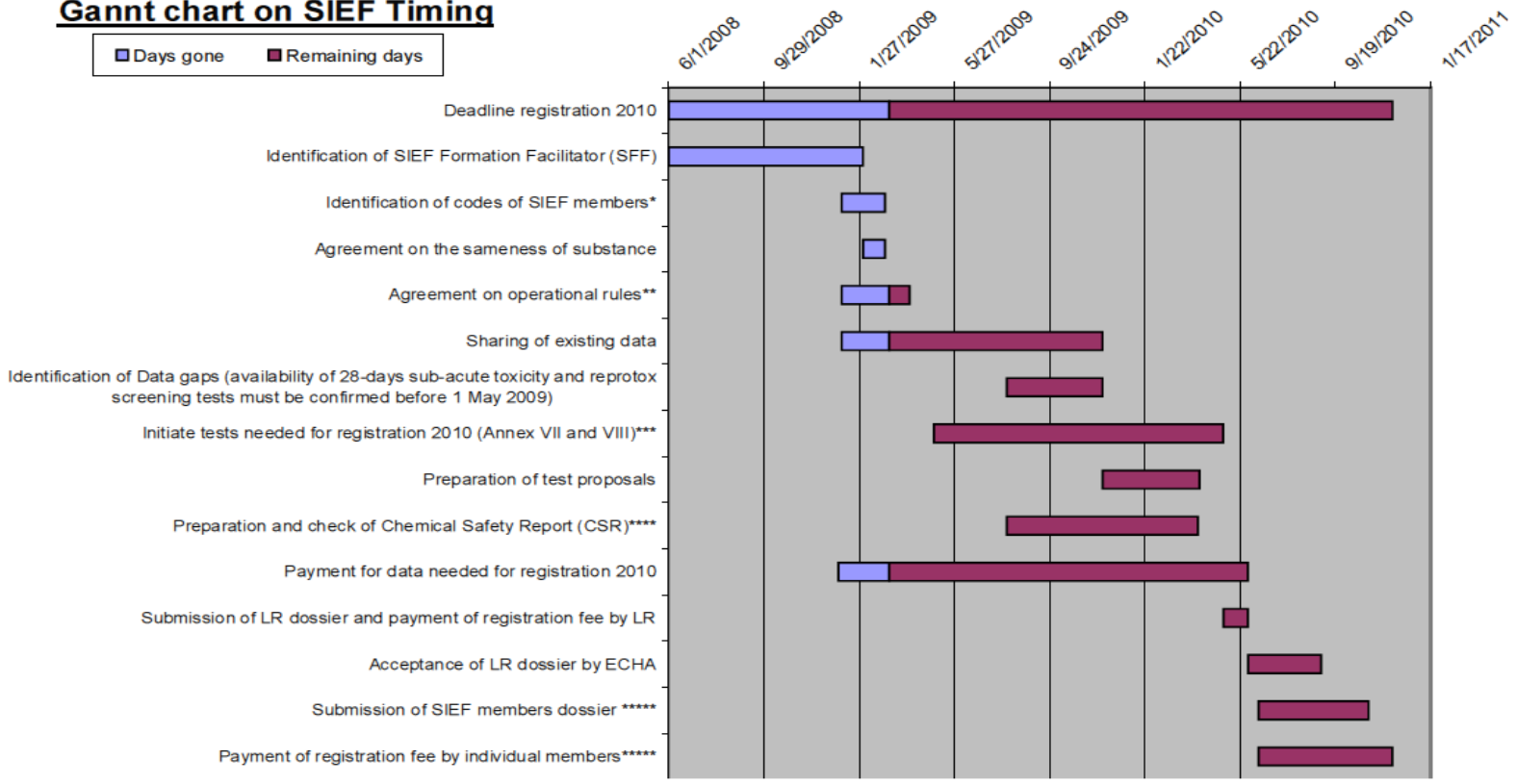
# Pre-Registration is a Predicate for Registration

- 30 November 2010 – 1<sup>st</sup> Tier
- 31 March 2013 – 2<sup>nd</sup> Tier
- 31 March 2018 – 3<sup>rd</sup> Tier

# SIEF Timing

**Gantt chart on SIEF Timing**

■ Days gone ■ Remaining days



# Pre-SIEF Organization

- REACH does not address organization of the SIEFs.
- Guidance on Data Sharing (RIP 3.4) provides some general guidance and establishes the role of the SIEF formation facilitator (SFF).
- Cefic and FECC have developed a questionnaire to help organize the SIEFs

# SIEF Formation Facilitator (SFF)

- The SFF role is not formally recognized under REACH
- Any pre-registrant can volunteer via REACH-IT to be the SFF. Some 50% of SFFs are 5 consulting firms.
- SFFs have no management role beyond facilitating discussions and they have no legal basis to force other pre-SIEF participants to co-operate with them.
- SFFs cannot demand information or fees for their services unless mutually agreed.
- Pre-registrants have no obligation to use a SFF to form a SIEF.
- A SFF can withdraw at any time.
- ECHA advises all companies to decide what role they wish to take in the SIEF.

# SIEF Organization Categories

- Four types of status were defined which describe the intention of the SIEF participant in relation to their pre-registered substance:
  - **Involved:** Those who want to be involved in the dossier creation process and to register but cannot participate in all SIEF activities due to resource constraints. These firms will receive a SIEF progress report, an invoice and an invitation to comment on proceedings.
  - **Leading:** Firms that regard the pre-registered substance as being of strategic value, have the resources and are willing to lead the registration process
  - **Passive:** Companies that may plan to register but have limited resources or interest in actively taking part in discussions. They only need to be involved in the final part of joint registration and will receive a SIEF progress report and an invoice.
  - **Dormant:** Companies that pre-registered to be on the safe side and to secure future business but have no concrete intention at present to register chemicals. These firms will not be communicated nor invoiced but will be required to comply with mandatory data-sharing rules;

# What Has ECHA Been Doing While Industry is Tied Up

## With SIEF Formation?

- **Testing proposals**
  - No complete registration dossiers containing a testing proposal were received during 2008 and thus ECHA did not examine any dossiers for this purpose.
- **Compliance check**
  - A relatively small number (94) of registration dossiers were submitted in 2008, of which
    - ✓ only 10 passed the completeness check.
    - ✓ ECHA started a compliance check for three dossiers and completed one of them.
    - ✓ These three dossiers concerned the lowest tonnage band, 1 – 10 tonnes/year.
- **Substance evaluation**
  - No examination of new data for transitional substances were performed, because industry still had time to submit the new information in accordance with deadlines from the previous legislation.

# Candidate List

- Only 15 substances added. Odd list of substances.
- Registry of Intentions at:  
[http://echa.europa.eu/chem\\_data/reg\\_intentions\\_en.asp](http://echa.europa.eu/chem_data/reg_intentions_en.asp)
- Only 8 substances being moved forward for Annex XV at this time
- 5 Member States : Austria, Belgium, Denmark, France, Germany, and Sweden disagree on the 0.1% issue.

# More Action on the Candidate List is Expected in Y2009/ 2010

- The Candidate list will be updated twice a year.
- The next updates of the Candidate List are scheduled for December 09, June and December 2010
- Fixed dates are set for the submission of annex XV dossiers to ECHA: Aug 3, 2009/ Feb. 8, 2010/ Aug. 2, 2010
- The Netherlands, France, Austria and Germany have set up an informal expert group to:
  - identify SVHCs that could be prioritized for the Candidate List within the next 2- 3 years,
  - group them in a way that makes it easier for member states to choose which ones to notify to the registry of Intent.
- ECHA to increase publicity and promotion of public consultations.
- ECHA promises that future public consultations are not organized during the holiday period.

# Other REACH Developments

- Competent Authorities Close Non-EU Produced Cosmetics Discussion as No Longer Productive
- Industry and ECHA debate the requirement to include the last four digits of the registration number, which identify the substance manufacturer/ importer, on the SDS.
- Member states did not endorse the Commission paper on the “Identification of Substances at Nanoscale in REACH.” Reasons cited include unclear criteria on how to identify nanosubstances, disagreement with the Commission’s position that it is up to the SIEF to decide whether a substance is nano or not, and a general lack of clarity.
- The Commission is investigating whether the bulk form of carbon (not the nanoform) can be placed in Annex IV/V. No timeline for decision was given. The Consultation on Annex V guidance will take place at the end of April 09.

# REACH Enforcement

- Per Article 76(1)(f), the ECHA must establish a *Forum for Exchange of Information on Enforcement* to coordinate the enforcement activities of Member States authorities.
- Article 2(1)1 of the Forum Rules of Procedures (ROP):
  - a) spreading good practice and highlighting problems at Community level;
  - b) proposing, coordinating and evaluating harmonized enforcement projects and joint inspections;
  - c) coordinating exchange of inspectors;
  - d) identifying enforcement strategies, as well as best practice;
  - e) developing working methods and tools for use by local inspectors;
  - f) developing an electronic information exchange procedure;
  - g) liaising with industry, taking particular account of the specific needs of SMEs;
  - h) examining proposals for restrictions with a view to advising on enforceability.
- Per Article 117(1) each Member State must report to the Commission on enforcement activities on a 5-year cycle.

# Enforcement Regulations

- The Commission will start infringement proceedings against the 8 Member States who did not notify the Commission of their enforcement measures by 1 December 2008 as required by REACH (Austria, Belgium, Greece, Spain, Italy, Latvia, Lithuania and Portugal).
- The Commission will launch a study to compare penalties in the different member states. Interim results of the study will be presented at the Competent Authorities meeting in June 09. The study should be completed by the end of 2009.

# Some Examples – The Netherlands

- Distinction between ‘misdemeanors’ and ‘felonies’ and between ‘intentional’ and ‘non intentional’.
- Maximum jail sentence and fines:
- Misdemeanors/non intentional: 6 months & € 18500.
- Misdemeanors/intentional: 2 years & € 18.500.
- Felony/non intentional: 1 year & € 18.500.
- Felony/intentional: 6 years & € 74.000.

# Some Examples – Spain

- Sanctions: different categories, minor, major and serious offense depending of the infringement of the REACH obligations listed in the draft), and the seriousness of the infringement, intentionally, repeated...
- Minor offense -- fines up to 6000 Euros
- Major offense -- fines from 6001 until 300,000 Euros
- Serious offense from 300,001 until 1,200,000. In this case, in addition depending on the intention, repeat offenses, etc., they can close partial or permanently your installation.

# Some Examples – Germany

- **Acting contrary to regulations:** Prison sentence up to 2 years or fine. When acting negligently: prison sentence up to 1 year or fine. The attempt is accusable.
- **Knowingly making wrong indications in the CSR acc. to Art. 37 (4):** Prison sentence up to 2 years or fine. When acting negligently: prison sentence up to 1 year or fine. The attempt is accusable.
- **Making a CSR in contradiction to Art. 37 (4) not, not in the right way, not complete or not in time:** Prison sentence up to 5 years or fine. When acting negligently: prison sentence up to 2 years or fine. The attempt is accusable.
- **Knowingly making wrong indications in the registration dossier acc. to Art. 6 (1 or 3), Art. 7 (1, sent. 1, or 5, sent. 1) or in an application for authorisation acc. to Art. 62 (1 or 4):** Prison sentence up to 2 years or fine. When acting negligently: prison sentence up to 1 year or fine. The attempt is accusable.
- **Acting against Art. 56 (1) by marketing or using a substance mentioned there:** Prison sentence up to 2 years or fine. When acting negligently: prison sentence up to 1 year or fine. The attempt is accusable.
- **Endangering life or health of somebody else or properties of considerable value by actions mentioned above:** Prison sentence up to 5 years or fine. When acting negligently: prison sentence up to 2 years or fine. The attempt is accusable.
- **Relation to other legal acts:** The provisions mentioned above are not valid if the German Criminal Code foresees same or higher sanctions.

# Enforcement in Practice

- Report of a shipment blocked from entering Belgium as officials demanded evidence that the substances had been pre-registered under REACH.
- Reported that the Dutch Environment Ministry (VROM) has advised that enforcement authorities in the Netherlands are seeking evidence of pre-registration for imports and asking to see Safety Data Sheets that are REACH-compliant.
- REACH Regulation requires that companies must pre-register phase-in substances, it does not actually stipulate that companies must provide evidence of pre-registration.

# Article 36 – Obligation to Keep Information

- “Each manufacturer, importer, downstream user and distributor shall assemble and keep available all the information he requires to carry out his duties under this Regulation for a period of at least 10 years after he last manufactured, imported, supplied or used the substance or preparation.”
- “That manufacturer, importer, downstream user or distributor shall submit this information or make it available without delay upon request to any competent authority of the Member State in which he is established or to the Agency.”
- “In the event of a registrant, downstream user or distributor ceasing activity, or transferring part or all of his operations to a third party, the party responsible for liquidating the registrant, downstream user or distributor's undertaking or assuming responsibility for the placing on the market of the substance or preparation concerned shall be bound by the above obligations in place of the registrant, downstream user or distributor.”

# REACH Scorecard

- **Guidance Development**
  - ✓ Comprehensiveness: A
  - ✓ Usefulness: B
  - ✓ Timeliness: B-
- **Pre-Registration** C
- **Pre-SIEF** D
- **Candidate List Development** D
- **Enforcement**
  - ✓ Toughness A
  - ✓ Proportionality C
  - ✓ Execution ??
- **Protection of Health and Environment** C-

**Thank you!**

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