

REACH Update

ASPA Winter Meeting

Sean McNear

December 10, 2008

Honeywell

REACH Update AGENDA

- ✓ **Overview**
- ✓ **Pre-registration**
- ✓ **Timelines**
- ✓ **Only Representative (OR)**
- ✓ **Articles**
- ✓ **Substances Information Exchange Forum (SIEF)**

- **REACH – Registration Evaluation Authorization and Restriction of Chemical substances**
- **The European law entered into force on June 1, 2007**
- **The primary purpose of REACH – “To improve the protection of human health and the environment through better and earlier identification of the intrinsic properties of chemical substances”.**
- **Responsibility shift from government to manufacturers and importers to demonstrate the safety of chemicals used in all commodities**

- **Pre-registration (phase-in) with the European Chemicals Agency (ECHA) began on June 1, 2008 and closed on November 30, 2008**
- **If the substance was not pre-registered during this timeframe, the substance will require full registration before importing or manufacturing it in the EU market.**
- **ECHA is not extending pre-registration**

First Time Manufacture/Import

If a substance is manufactured/imported for the first time (above 1 metric ton annually) after Dec. 1, 2008, then a pre-registration is still possible under the following conditions:

- Pre-registration within 6 months after first manufacture/import**
- Pre-registration not later than 12 months before the registration deadline**

- **Registration Deadlines and Tonnage**

November 30, 2010

≥ 1 ton/year CMRs (carcinogens, mutagens or reproductive toxins)

≥ 100 tones/year very toxic to aquatic environment

≥ 1000 tones/year

May 31, 2013

≥ 100 tones/year

May 31, 2018

≥ 1 ton/year

- **REACH provisions will be phased in over the next 10 years**

Only Representative (OR) Clarifications

- **OR for “non-Community manufacturer”**
 - **Registration is required for substances imported into the EU on their own, in preparations or in articles**
 - **If the manufacturing of these substances, preparations or articles are outside of the EU they cannot register the substances themselves**
 - **If you do not have a legal entity within the EU, you can nominate an OR that is located within the EU**
 - **The OR would be required to pre-register and register the substances**
 - **The EU importers are considered downstream users and they are relieved from their registration obligations**

Only Representative (OR) Clarifications

- **OR for “non-Community manufacturer”**
 - **Distributors can not appoint an OR**
 - **The OR must document who they are representing and attach that information in IUCLID as an OR of a “non-Community manufacturer”**
 - **An OR is not the same as a “third party representative”**
 - **The role of a “third party representative” is used to remain anonymous during the data sharing process**

Only Representative (OR) Clarifications

- **OR for “non-Community manufacturer”**
 - **The “non-Community manufacturer” must provide the list of EU importers and quantities that are covered by the registration of the OR**
 - **The “non-Community manufacturer” must inform all the EU importers in the same supply chain that an OR has been appointed and that they are relieved of their registration obligations and become a downstream user**
 - **The “non-Community manufacturer” can only appoint one OR per substance**

Only Representative (OR) Clarifications

- **EU Importers**

- **The EU importer is only covered for the quantities identified through the OR. Additional imports would require a separate registration**
- **The importer should obtain written confirmation that the imported tonnage and use are covered by the OR**
- **This would confirm that the information is correct as well as provide clear documentation for enforcement (when needed)**

- **OR Requirements**

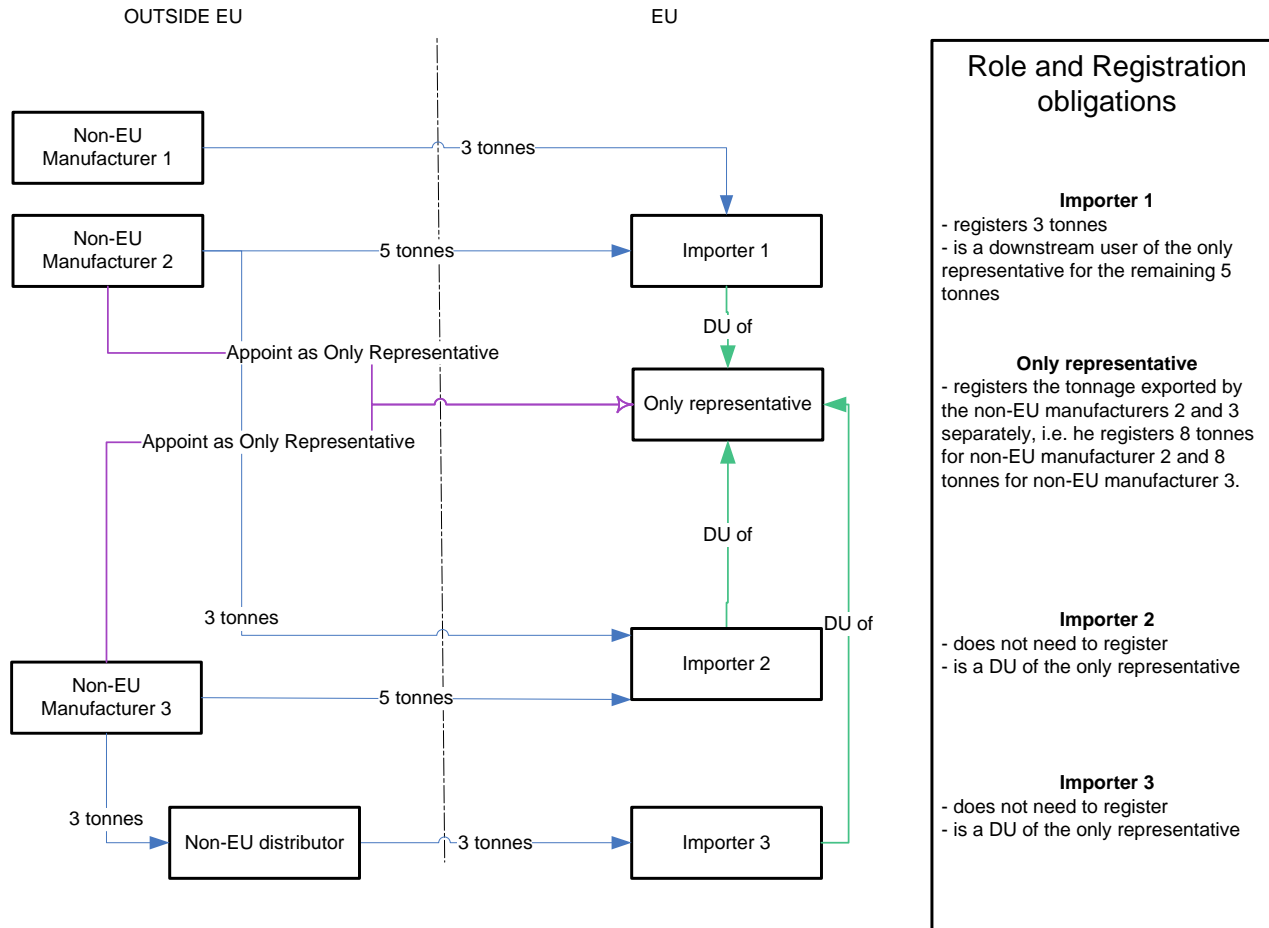
- **The OR is fully liable for completing the pre-registration, registration, communication in the supply chain, notification of substances of very high concern (SVHC), classification and labeling and any obligations as a result of potential authorizations or restrictions**
- **The OR registers the imported quantities based on the contractual agreements with the “non-Community manufacturer”**
- **REACH does not differentiate between direct and indirect importers**

Only Representative (OR) Clarifications

- **Changing from one OR to another**
 - **In order for the “non-Community manufacturer” to change the OR for a substance the new OR can submit an update as long as the original OR is in agreement**
 - **The agreement with the new OR should be documented in the update**
 - **To avoid conflicts in changing an OR in the future consider adding a clause in the contract that addresses this issue**
 - **If an agreement does not exist with the original OR the new Or will have to submit a full registration dossier**
 - **If all parties agree the new OR could reuse the previous registration dossier**

ECHA Guidance for OR of “Non-Community Manufacturer”

Example: Role and registration obligations of different actors when an only representative is appointed



- **Definition of an Article**
 - “Article means 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”
- **Types of Articles**
 - Articles with intended release
 - Articles without intended release
- **Registration verses Notification of Substances in Articles**
- **Substances of Very High Concern (SVHC)**

- **Registration of substances in articles is only required if these two conditions are relevant:**
 - 1. The substances are intended to be released from the article during normal and reasonable foreseeable use**
 - 2. If the annual amount of the substance in the article that is intended to be released exceeds 1 ton per year per producer or importer**
- **If more than one type of article with intended release is imported/produced, the total quantity of that substance is measured to determine the 1 ton annual threshold**
- **Pre-registration of these substances should have been considered for phase-in status**

- **Notification of substances in articles without intended release is required when all these conditions are met:**
 - **The substance is present on the candidate list for authorization**
 - **The total amount of the substance present in the articles produced or imported are greater than 1 ton per year per producer or importer**
 - **The substance is present in the articles at a concentration greater than 0.1% (w/w)**
- **Exemptions to notification exist if you can demonstrate no exposure to the substance and if the substance has already been registered for that use**

- **Producers and importers of articles that contain substances of very high concern (SVHC) included on the candidate list for authorization at a concentration greater than 0.1% (w/w) must provide the name of the substance to the recipients**
- **Consumer requests for this information must be provided within 45 days, free of charge**
- **Packaging materials are considered articles**
- **The notification of substances in articles shall be made at the latest 6 months after it has been included on the candidate list for authorization starting from June 1, 2011**

Substances of Very High Concern (SVHC)

- **The following properties can be identified for SVHC:**
 - Carcinogens, mutagens or toxic to reproduction (Cat. 1&2)
 - Persistent, bioaccumulative and Toxic (PBT)
 - Very persistent and very bioaccumulative (vPvB)
 - Substances of equivalent concern (Annex XIV)
- **The Candidate list was published by ECHA on October 28, 2008.**
- **This is not the total list of SVHC**
- **Additional substances will be identified in the future by the EU member state competent authorities**

Substances of Very High Concern (SVHC)

- Anthracene
- 4,4'- Diaminodiphenylmethane (MDA)
- Dibutyl phthalate (DBP)
- Cobalt dichloride
- Diarsenic pentaoxide
- Diarsenic trioxide
- Sodium dichromate
- Alpha-hexabromocyclodecane
- Beta-hexabromocyclodecane
- Gamma-hexabromocyclodecane
- 5-tert-butyl-2,4,6-trinitro-m-xylene(musk xylene)
- Bis (2-ethyl (hexyl)phthalate) (DEHP)
- Hexabromocyclododecane (HBCDD)
- Alkanes, C10-13 Chloro (short chain chlorinated paraffins)
- Bis (tributyltin) oxide (TBTO)
- Lead hydrogen arsenate
- Triethyl arsenate
- Benzyl butyl phthalate (BBP)

What do you do with the list of SVHC?

- **If you produce or import articles you will need to verify that none of these substances are used in the articles and exceed the designated limits**
- **In order to confirm that your articles (including all packaging components) do not contain any SVHC you will need to communicate with all of your suppliers**
- **Utilizing templates and forms in your communication will assist in receiving consistent data that you can retain for future use**
- **Non EU suppliers will require more education on REACH and why you are asking for the information**

One SIEF per pre-registration substance

SIEF members:

- **Pre-registrants (Manufactures/Importers)**
- **Early registrants who already submitted registration**
- **Data holders (Manufactures/Importers; Downstream Users; Universities, Associations)**
- **Third party representatives on behalf of (anonymous) SIEF members**

- **Exchange/sharing of studies, in order to avoid duplication of animal studies**
- **In the case of data gaps, only one study shall be conducted by the SIEF on behalf of the others**
- **Agreement with testing proposals**
- **Agreement on classification and labeling**
- **Optional: Agreement on Chemical Safety Report (CSR)**

- **Web-based page: all SIEF members have access and see the identity of the other members**
- **Pre-SIEF (until Dec. 1, 2008): substances identity check amongst members; re-adjustment of SIEFs possible**
- **Agency will publish list of pre-registered substances by Jan. 1, 2009: substance name, EINECS and CAS numbers, first expected registration deadline (but not identity of pre-registrant)**
- **Data holder may apply to become SIEF member (shall share data, but must not request data)**
- **Downstream user who does not find their substance on the published list may notify agency. Agency will publish substance name in order to find a potential registrant for a late pre-registration**

SIEF Example

	Chemical Company A	Chemical Company B
Tonnage band	100...1,000 t/a	1...10 t/a
Registration deadline	2013	2018

SIEF:

Tests \geq 1 t/a	~ 20 tests	~ 20 tests
Tests \geq 10 t/a	~ 10 tests	-----
Tests \geq 100 t/a	~ 10 tests/proposals	-----
Cost-participation	~ 40 tests	~ 20 tests

Registration:

Dossier submission	Lead registrant 2013 <ul style="list-style-type: none"> ▪ registrant-specific data ▪ 40 tests ▪ Classification & Labeling 	2018 <ul style="list-style-type: none"> ▪ registrant-specific data ▪ references to 20 tests of lead registrant
---------------------------	--	---

SIEF – How could it work?

- **The SIEF members determine how to organize themselves and how they will exchange data**
- **The designation of a SIEF facilitator is encouraged by ECHA**
- **The collective approach is encouraged by ECHA (collect all of the data and incorporate it into the dossier)**
- **There are still a lot of unanswered questions**

Collective Route

- 1. Individual gathering of available information**
- 2. Agreement on the form of cost sharing mechanism**
- 3. Collection and inventory of all available data**
- 4. Evaluation of all available information**
- 5. Consideration/identification of data gaps**
- 6. Generation of new information/testing proposal**
- 7. Data and cost sharing**
- 8. Joint submission of data**

Registrant may leave the SIEF and submit data separately in any of the following situations:

- 1. If the joint submission is disproportionately costly**
- 2. If the joint submission implies disclosure of confidential business information**
- 3. If there is disagreement of how the lead registrant selects information**

- **If this is the first time that you are learning about REACH you have a steep learning curve and limited options**
- **You should have already pre-registered your substances that you import into the EU**
- **You should be in the process of finalizing your communication with your articles suppliers and tracking the use of SVHC in those articles**
- **If you intend to utilize the only representative (OR) option you should be in negotiations at this point and working through the contractual agreements**
- **You may also be discussing the options of sourcing materials and/or manufacturing within the EU so that you are considered a downstream user and alleviate your registration obligations**

Additional Resources on REACH

- **Guidance documents**
 - http://reach.jrc.it/guidance_en.htm
- **European Chemical Agency**
 - http://echa.europa.eu/reach_en.asp