FEICA The European voice of the adhesive and sealant industry

FEICA practical Guidance on Use Reporting

Introduction

The REACH Regulation (EC N° 1907/2006) introduces new concepts and requirements with regard to exposure assessment and safe use confirmation in the context of chemical safety assessment. Alignment between Manufacturers/Importers (M/I, i.e. registrants) and Downstream Users on identification of uses is the first step of the key tasks to be implemented along the supply chain to conduct Chemical Safety Assessment (CSA) and prepare Chemical Safety Report (CSR). While the CSA/CSR development is primarily the duty of registrants, Downstream Users (DUs) have important rights and duties in this process. In particular, DUs have the right to make a use known to M/I (Article 37(2) of REACH). This should be done 12 months before the registration deadline (Article 37(3)).

On 12 October 2009, ECHA issued an alert entitled "less than two months left to deadline for users of chemicals to inform suppliers", recommending that downstream users inform their suppliers about their use of a substance before 1 December 2009 for substances to be registered by 1 December 2010.

In June 2009, FEICA issued a first version of this practical Guidance.

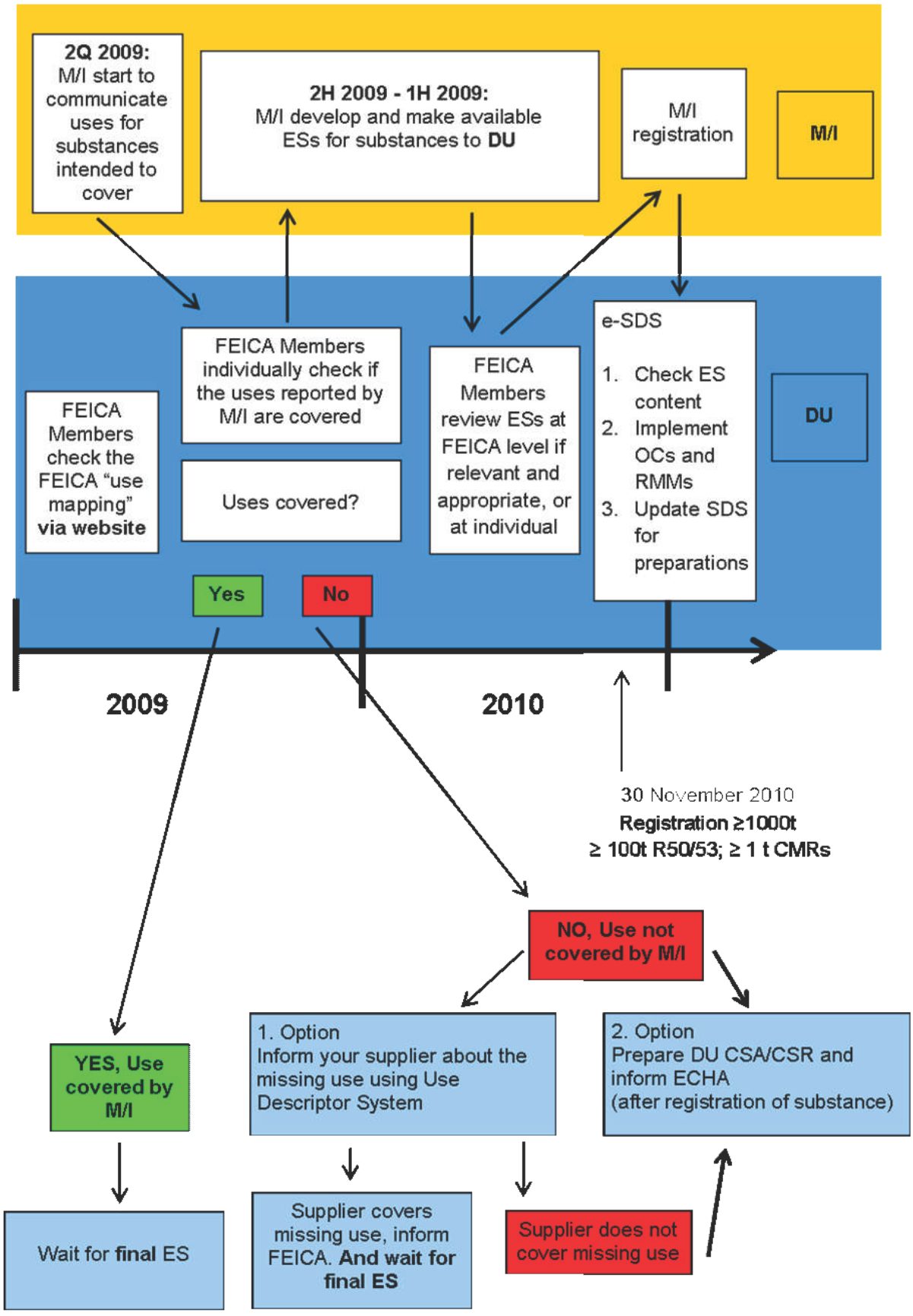
The present version takes into account recent developments at ECHA and industry level and provides additional recommendation to assist FEICA Members in communicating information in the supply chain during the use reporting phase (until 1 December 2009 for the first wave of registrations).

Industry approach for communicating information in the supply chain

The proposed industry approach (initiated by Cefic) for communicating information in the supply chain for the purpose of Chemical Safety Assessment consists of two consecutive steps:

1. Align on uses between M/I and DU by means of the Use mapping exercise (to be done by 30 November 2009)
2. Align on Exposure Scenarios (ES) content development (from mid 2009 until mid 2010). The preferred approach for the latter involves Generic Exposure Scenarios (GES), where applicable.

Indicative timeline and key tasks:



Use mapping

The use mapping exercise carried out at FEICA level resulted in an inventory of Use Descriptors that describe FEICA uses in a standard REACH-compatible manner. Such standardization is needed to structure the communication between M/I and DUs.
FEICA mapped the uses following the Use Descriptor System described in the ECHA TGD on Information Requirements and Chemical Safety Assessment (Chapter R12 of the Guidance on http://guidance.echa.europa.eu/guidance_en.htm) and in cooperation with other downstream user within the DUCC platform.
FEICA updated the use mapping tables to reflect latest developments (*e.g.* addressing questions received, taking into account the draft revised Chapter R12 of the ECHA Guidance).

Use Descriptor System (UDS)

The use description is based on five separate categories of codes: Sector of Use (SU), chemical Product Category (PC), Process Category (PROC), Article Category (AC) and Environment Release Category (ERC).
The **Sector of Use (SU)** identifies the main user group (manufacture, formulation, consumer, industrial, professional use) and the industry sector, for example "SU22: public domain" or "SU21: private household".
A broad description of the product type is given by the **Product Category (PC1)** relevant for the adhesives and sealants. The sealants have 4 subcategories (B01 – B04). PC is particularly relevant for consumer uses.
The **Process Category (PROC)** characterises occupational activities and needs to be reported when applicable (example PROC11: spray application). Within FEICA PROCs are an essential element of industrial and professional uses description.
The **Article Category (AC)** needs to be reported if applicable, when a dangerous substance is processed into an article, if relevant for exposure. In general, ACs do not apply to FEICA uses.
Strictly speaking the **Environmental Release Category (ERC)** is not part of the Use Descriptor System as reported in the current ECHA Guidance because it was originally developed to assess environment exposure. However, it has evolved into a code that allows to describe environmental release and fate characteristics. Therefore in practice, it is considered as an element to report to suppliers. Due to the specific process of curing of adhesives, FEICA will develop specific ERCs for FEICA uses. These will be implemented in the FEICA UseR table as soon as they are available. [1]

[1] The ECHA Guidance on the Use Descriptor System is currently being revised. The UDS will be further clarified taking into account experience recently gained. The ERC is expected to become part of the UDS in the revised guidance.

To know more about the UDS, please see here attached Chapter R. 12 of the ECHA Guidance: Use descriptor system of the Guidance on information requirements and chemical safety assessment. This piece of Guidance is currently being updated. The draft revised text has been made available by ECHA. However, the formal endorsement process will take another two months so that the revised Guidance will become fully official only in January 2010. FEICA already reflected some of the changes being made in Chapter R12 in the updated use tables.

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf?vers=20_08_08

FEICA product categories

FEICA members typically sell products:

- Directly to consumers (often via retailers);
- To professionals directly or via dealers;
- To Industrial customers

REACH requires different assessments for different types of uses. The exposure models that are to be used depend on the assessment type.

- For **consumer products**, a "Consumer" type of exposure assessment should be run for human health (using fairly conservative defaults). For environment, a consumer use is almost always qualified as "wide dispersive" (cannot be controlled via Risk Management Measures (RMMs).

- For **professional uses**, a "Worker" or occupational type of assessment is required for human health (assumes product use all along working time). For environment, the use is always qualified as "wide dispersive".

- For **industrial adhesives and sealants**, and **manufacturing adhesives and sealants** a "Worker" or occupational type of assessment is required for human health. For environment, a "point source" type of assessment is expected to apply (point source meaning emissions from a particular site, that can be controlled via Risk Management Measures);

For more information on exposure assessment, see: FEICA website http://www.feica.eu/

Therefore FEICA collected the use descriptors distinctly for Consumer adhesives and sealants, Professional & Industrial adhesives and sealants and Manufacturing of adhesives and sealants.

Note:

Some niche product categories manufactured by a minority of FEICA members may not be covered by the FEICA use mapping. Such product categories may be added to the list in the future if a National Association sees a need and collects the corresponding information (general rule: a minimum of three companies should provide input for a use to be considered as "representative of the sector" and included in the FEICA tables).

Please consider that this document is based on the best available information and knowledge at this point in time.
It is essential to get the use reporting as complete and as accurate as possible because this establishes the basis for subsequent exposure assessment. In the future, the use descriptors will also be used as key input information for documenting life-cycle and uses of substances in the Chemical Safety Assessment IT Tool being developed by ECHA.

Purpose of the use mapping tables

The objective of the use mapping table is to allow suppliers (M/I = registrants) to cover FEICA uses in their registration dossiers. Cefic advocates for a "Top-Down" approach on use communication and developed IT Requirements that can be implemented by chemical suppliers, on a voluntary basis and on their own systems, to facilitate alignment on uses in the supply chain. We believe that giving access to the FEICA Use Mapping Tables to all actors via the FEICA website will increase the likelihood that FEICA uses are covered by M/I in the top-down approach and therefore minimise the need for one-to-one communication up and down the supply chain.
These tables have also been provided to Cefic for posting on their website.

In addition to serving the M/I-DU communication process, the Use Mapping Tables allow FEICA members to use a common terminology for use description for each product group. The Tables will also be useful in the future for FEICA members to check compliance and make sure their uses are covered in the Exposure Scenarios communicated via annexes of Safety Data Sheets.

FEICA approach on use reporting

The REACH Implementation Working Group of FEICA recently assessed the situation and decided on the following approach:
FEICA members should ask their suppliers to confirm, in a generic manner and in written, that they will assess the uses as reported in the FEICA use mapping tables, with the intent to make them identified uses covered in the registration dossier (if safe use can be demonstrated in the exposure assessment phase). Written confirmation will be sought by 15 September 2009. If confirmation from suppliers is not received by that date, FEICA will recommend its members to proactively report their uses to their individual suppliers, in line with Article 37(2), using the same template as the FEICA tables. The latter should be done before 1 December 2009.

The aim of the above approach is on one hand to ensure that DUs obtain feedback and reassurance from suppliers that they are aware of the FEICA uses and on the other hand to minimize workload for both M/I and DU by avoiding unnecessary one-to-one communication).

In other words, FEICA acts as a surrogate for dialogue at individual company level, but not on behalf of individual companies since REACH is an individual company responsibility. This means that some complementary work has to be done at company level.

Next steps

FEICA will monitor the situation on use alignment and update documents accordingly (website, letters, etc.). We will also continue to work with Cefic and other supplier associations on exposure scenario development.

Further Guidance on Exposure Scenarios will be distributed in the future.

What FEICA members should do and when:

• Acquire knowledge on the Use Descriptor System	NOW
• For internal purposes, companies should extract from the FEICA Tables the uses that are relevant to their business and map these uses against their raw materials. This will be needed for future compliance checking (for each substance, the DU has to check that his uses are covered in the substance exposure scenario)	Start second half 2009
• Report proactively your uses if you have not received confirmation from your supplier	By 30 November 2009
• Be aware that if your use is confidential, you will have the option to develop your own DU CSA in the future	2010 or later (after registration of the corresponding substances)