



Downstream Users of Chemicals Co-ordination group

## Revision of Annex II of REACH (Regulation (EC) N° 1 907/2006) on Safety Data Sheets

### Improving workability for small and large formulators, importers and manufacturers of chemicals

Safety data sheets (SDS) are a well established and effective means for suppliers of chemicals to provide health, environmental and safety information to users of their products in a standard format. SDS requirements have applied long before REACH to both substances and mixtures. The legal requirements governing SDS are now an integral part of the REACH Regulation, with Annex II of REACH describing the content of SDS.

In order to align Annex II of REACH with the new CLP Regulation (Regulation (EC) N° 1272/2008 on classification, labelling and packaging of substances and mixtures) and with the UN rules on SDS, the Commission drafted a new Regulation amending current Annex II of REACH.

Cefic and DUCC generally agree that alignment and harmonisation is needed. However, the draft text of the Commission requires all Safety Data Sheets to follow a new format and content by 1 December 2010, for both substances and mixtures. This deadline does not consider the practical problems and difficulties to modify the Safety Data Sheets from one day to another, being the 1st December 2010: changes do not only involve changing the lay-out of SDS and related IT-systems but also manual work to update the content of the new sub-headings (16 headings have become 63 headings + sub-headings that all need to be filled).

In practice, SDS of substances and mixtures will have to be updated on a regular basis after 1 December 2010, as new information generated under REACH and CLP for substances becomes available to formulators of mixtures: this is required under Article 31 of REACH. So SDS update will happen gradually after 1 December 2010, using the new format. However, there is no health or safety benefit in having to update and re-issue all safety data sheets of both substances and mixtures by 1 December 2010, including reworking the content based on “old” information, when the new relevant information will only become available after that date. Indeed, applying the new Annex II requirements does not only involve changing the SDS format and IT systems, but also to look into information to fill the new SDS sub-headings.

*DUCC represents a variety of European Industry Associations who member companies use chemicals to formulate mixtures. The DUCC platform is currently composed of 8 members and 1 permanent observer representing cosmetics (Colipa), detergents and maintenance products (A.I.S.E.), aerosols (FEA), paints, printing inks, artists' colours (CEPE), adhesives (FEICA), construction chemicals (EFCC), photographic materials (EPIA) and chemicals distribution (FECC). Altogether, they comprise more than 3,500 companies across the respective sectors in Europe.*

*Cefic, the European Chemical Industry Council is the Brussels-based organisation representing the European Chemical Industry. Cefic represents 29.000 companies that produce 30% of the world chemicals.*



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Regarding substances, new information generated under REACH will in most cases be communicated via SDS after 1 December 2010: this is because submission and acceptance of registration dossiers by ECHA is required prior to communicating to users. Similarly, the deadline for notifying classification of substances is 3 January 2011. Therefore, the new SDS requirements should apply only in 2011 to avoid creating double work.

For mixtures, the deadline of 1 December 2010 is inconsistent with the transition periods provided in the CLP Regulation for mixtures: CLP provides flexibility to reclassify mixtures until 1 June 2015. The SDS of mixtures should be modified and updated only after new information of substances has been received.

The date of application of the new SDS requirements poses a serious workability issue to all formulators of mixtures, importers of mixtures and substances, and manufacturers of substances throughout Europe. Many companies have tens or hundreds of thousand of SDS stored in their system. The update of these documents under the new format should be gradual and focus on integrating new health, safety and environmental information once this information has been received from substance suppliers.

### **Possible route to address the issue:**

The amendment below is proposed as a means to give the strictly needed time flexibility to allow the manufacturers, importers and formulators to adapt their safety data sheets.

The amendment could be read as follows:

#### *Article 1*

*Regulation (EC) No 1907/2006 is amended as follows:*

*(1) with effect from 1 December 2010:*

*(a) Annex II is replaced by Annex I to this Regulation;*

***(b) NEW For a period of one year [until 30 November 2011], suppliers of substances shall update safety data sheets in accordance with Annex I to this Regulation when:***

***(i) new information which may affect the classification, labelling of the substance and risk management measures becomes available; or***

***(ii) an authorisation has been granted or refused or***

***(iii) a restriction has been imposed***

**(c)** in Section 3.7 of Annex VI, in the title, the words “(see Safety Data Sheet heading 16)” are replaced by “(see Section 1 of the safety data sheet)”;

**(d) NEW – As of 1 December 2011, all safety data sheets of substances shall comply with Annex I to this Regulation;**

**(e) NEW - Until 30 November 2013, suppliers of mixtures shall update safety data sheets in accordance with Annex I to this Regulation when:**

**(i) new information which may affect the classification, labelling of the mixture and risk management measures becomes available; or**

**(ii) an authorisation has been granted or refused for a substance contained in the mixture; or**

**(iii) a restriction has been imposed for a substance contained in the mixture**

**(f) NEW – As of 1 December 2013, all safety data sheets of mixtures should comply with Annex I to this Regulation;**

**(2)** with effect from 1 June 2015, Annex II to Regulation (EC) No 1907/2006 is replaced by Annex II to this Regulation.

Explanation:

- This amendment builds on Article 31(9) of REACH and specifies in which cases the SDS update for substances and mixtures is required without delay after 1 Dec 2010 vs the cases where SDS can be updated later (e.g. no change in classification, no authorisation/restriction in place) to allow a workable transition for mixtures.

- A maximum of one year for manufacturers/importers for substances and an additional two years (after the deadline for substances) is provided to formulators to update their SDS if there is no change in mixture classification or substance authorisation/restriction: this is equivalent to the two-year additional transition period provided under Art. 61(4) of the CLP Regulation for substances and mixtures already in the supply chain in order to avoid unnecessary burden on enterprises.

This time span is also seen as the minimum required for the new substance information to be communicated to various downstream users in the supply chain, taking into consideration that massive amounts of new information on substances will have to be communicated after 1 December 2010, as a result of REACH and CLP requirements on substances.