NEW FORMAT FOR SAFETY DATA SHEETS

From 1st June 2015, Safety Data Sheets (SDS) must be prepared or updated according to Regulation (EU) 2015/830.

Regulatory requirements: Annex II of REACH

The format and content of SDS provided according to Article 31 of the REACH Regulation are defined in Annex II of said Regulation: "requirements concerning the preparation of safety data sheets".

Until 31 May 2015, such Annex II was established according to Regulation (EU) No 453/2010 that prescribed two versions of it:

- Annex I to Regulation (EU) No 453/2010, applicable to:
  - substances until 1st June 2015
  - mixtures labelled according to the old system of classification and labelling (DPD)
- Annex II to Regulation (EU) No 453/2010, applicable to:
  - substances after 1st June 2015
  - mixtures labelled according to CLP (with additions relating to the former classification system until 1st June 2015)


Amendments introduced by Regulation (EU) 2015/830

A brief description of the amendments to Annex II of REACH by the new regulation is given below.

To avoid making the text more cumbersome, we have not included essentially editorial amendments.

The changes are listed below by taking the references to Annex II of REACH. They are for the most part minor, and induced by the 5th revised edition of the GHS adopted internationally (UN).

- 0.5. "Other information requirements" - Mention of further information at the request of the International Maritime Organisation (IMO).
- 2.3. "Other hazards" – Addition of a note to be included in case of dust explosion hazards.
- 5.1. "Extinguishing media" – Addition aiming at the means to prevent dust explosions.
- 7.1. "Precautions for safe handling" - Addition of a new point (c) in Section 7.1.1.
- 11.1. "Information on toxicological effects" - Obligation to mention all the effects listed in the SDS.
- 12. "Ecological Information" - new wording of the introduction to the section. Clarification was requested on the particular reasons for not providing information.
The new format set forth by Regulation (EU) 2015/830 has been applicable since 1st June 2015.

However, SDS which have been sent to at least one recipient before 1st June 2015, prepared in accordance with the previous version of Annex II of REACH (set forth by Regulation 453/2010), can be used until 31 May 2017 without having to comply with the new regulation.

Accordingly, provided that such SDS have been supplied at least once before 1st June 2015, until 31 May 2017:

- substances may continue to have a SDS format “Annex I 453/2010” [or possibly "Annex II 453/2010”];
- mixtures may continue to have a SDS format “Annex II 453/2010" (it is important to remember here that the format "453/2010 Annex I" is not compatible with mixtures labelled according to CLP). [1]

Also, any update of an SDS induces the need for compliance with Regulation (EU) 2015/830.

It may be useful to note that:

- There is absolutely no requirement, on an SDS, to indicate the reference to the Regulation setting the version of Annex II of REACH used;
- Annex II of REACH sets out the requirements for SDS but does not prohibit the presence of additional information such as, for example, elements related to the old classification system. An update is not required for the sole removal of these elements.

This suggests that, insofar as they are not affected by the changes described above, SDS conforming to "453/2010" may also be "2015/830" compliant.

Furthermore, Article 31(9) of REACH specifies the occasions when an SDS must be updated without delay and the new version provided to all recipients to whom the substance or mixture has been supplied within the preceding 12 months. This refers, for example, to situations where “new information which may affect the risk management measures or new information on hazards becomes available.” Strictly speaking, the mere passage to the CLP classification and labelling or the adoption of a new regulatory format for SDS are not included in these cases.

So if, as indicated above, for reasons of consistency with labelling, the transition to CLP required an adaptation of the SDS, REACH does not impose a duty to systematically send the new SDS to all recipients who received the product during the previous year. However, it is important to point out the usefulness for downstream users, receiving products labelled according to CLP, to have updated SDS containing information relating to the CLP classification and labelling.

Anyway, if a mixture was not classified dangerous according to DPD but has become hazardous according to CLP, an SDS should be provided to the recipients of the previous 12 months as their risk management measures may be affected.

The ECHA Guidance on the Compilation of SDS is being updated to take into account both the deadline of 1st June 2015 for the application of CLP to mixtures and all changes to the Annex II of REACH. The new version should be published before the end of 2015.

[1] The mixtures labelled according to DPD, on the market as of 31 May 2015 and thereby benefiting from derogation on labelling until 31 May 2017, retain a SDS format “Annex I 453/2010”.
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