Downstream Users of Chemicals Co-ordination group

# DUCC comments on the revision of REACH Annex II
# Public consultation Ares(2019)5713373

DUCC thanks the European Commission for the opportunity to comment, via public consultation under the Better Regulation agenda, on the proposed draft Commission Regulation amending Annex II to Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Safety data sheets (SDS) are a very important tool for communication in the supply chain, and DUCC welcomes the efforts of the Commission to update this Annex and to align it with the 6th and 7th revised editions of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), the provisions of Annex VIII to Regulation (EC) No 1272/2008 (CLP) and the new provisions for nanoforms of substances according to Commission Regulation (EU) 2018/1881. Nonetheless DUCC would like to provide the following comments and suggestions to improve/correct the draft texts.

## 1. Comments on the draft Regulation

- **Application date and transition period (Articles 2 and 3):** the draft Regulation includes an application date of 1 January 2020. Even if it would be feasible at this late stage for the Regulation to be published and enter into force before that date, this does not allow time for companies to comply. The draft includes a number of substantial amendments compared to the previous version (Commission Regulation (EU) 2015/830), and companies need sufficient time to implement the necessary adaptations to their IT systems and internal procedures before they are ready to produce new or updated safety data sheets (potentially numbering many thousands). From experience and the indications of compliance software providers, a period of twelve months is typically required.

  Furthermore the draft text includes the relevant obligations from Annex VIII to CLP regarding inclusion of the Unique Formula Identifier (UFI), the application date for which is now being postponed to 1 January 2021. Therefore for consistency between the two regulations, the date of applicability for Annex II to REACH should be in line with this change; this is in fact stated in recital 5 of the draft Regulation but not reflected in the legal text.

  DUCC therefore proposes that the application date in Article 3 of the draft Regulation be amended to **1 January 2021**, and Article 2 be amended to read as follows:

  "Safety data sheets provided to a recipient before 1 January ~~2020~~ 2021 may continue to be used and need not comply with the Annex to this Regulation until 31 December ~~2022~~ 2023."

## 2. Comments on the draft Annex

- **Subsection 3.1/3.2:** information on Acute Toxicity Estimate (ATE) and on M-factor is now required to be provided for substances listed in these sections. This represents a duplication with no added value, as this information is already required in sections 11 and 12 respectively; it is however likely to reduce the clarity and utility of sections 3.1/3.2, which are intended for composition information. DUCC therefore proposes to delete these elements from sections 3.1 and 3.2.3 (second indent).

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- **Subsection 3.2:** concerning the use of percentage ranges for substances in a mixture, the new text (below with addition underlined) is aligned a little more closely with the text of GHS Annex 4 A4.3.3.2.3:

  "When using a range of percentages, <u>if the effects of the mixture as a whole are not available,</u> the health and environmental hazards shall describe the effects of the highest concentration of each ingredient.

  If the effects of the mixture as a whole are available, this information shall be included under section 2."

  Although this removes an obvious inconsistency in the case of a tested mixture, this requirement still poses major problems for SDS compilers.

  For practical reasons concentration ranges are typically pre-defined in a company's IT system and reflect the classification boundaries for the relevant hazard classes. The true concentration of each substance will lie somewhere within the quoted range.

  In the case of an additive effect, the mixture classification will reflect summation of the actual concentrations and might not be the same as adding up the maxima of the ranges. The only way to make the latter reflect the former would be to manually adjust the ranges in each case, which is impractical in a production environment with thousands of mixture SDS. The maximum of a range would also need to be set at the true concentration, which would disclose confidential business information (i.e. proprietary recipe information).

  The primary purpose of a safety data sheet is to communicate information to the recipient on the safe use of the mixture, not to check the calculation of the hazard classification. If enforcing authorities need to check the classification of a mixture, industry is committed to providing more detailed composition information by means other than the SDS.

- **Point 3.2.1 (b):** this point still remains the only criterion for which no minimum concentration threshold is defined. This creates practical difficulties in implementation, since it implies that relevant substances need to be mentioned when present at <u>any</u> concentration greater than zero, however tiny.
  For the sake of proportionality a minimum concentration should be defined in 3.2.1 (b). DUCC proposes that this be set at 1 % by weight in non-gaseous mixtures and 0.2 % by volume in gaseous mixtures, for consistency with the parallel requirement in 3.2.2 (a) (ii).

- **Point 3.2.3:** the third indent refers to a substance (in a mixture) which "covers/includes a nanoform". Downstream users need positive confirmation that this will not be interpreted to cover the inherent particle size distribution of many raw materials. For example, pigments and extenders include particles in the micron (µm) size range but also in the nanometre range, as an inherent but incidental consequence of their production processes. The requirements for "nanoforms" must be limited to substances explicitly registered or characterized as such.

- **Subsection 8.2:** no changes are currently proposed for this section, but DUCC would like to request a revision in 8.2.2.2.(b)(i). The requirement for a clear specification of glove type, including material type and thickness and its breakthrough time, is largely impossible to meet for a mixture: there is no simple methodology to calculate the "correct" glove material, thickness or breakthrough time (which might in any case not exist on the market) for a mixture of substances with different hazards. This unrealistic expectation gives rise to a high level of reported non-compliances; for example the Dutch Human Environment and Transport Inspectorate reported that in 2016 almost 50% of inspected SDS contained this omission.

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DUCC considers that the requirement in 8.2.2.2.(b)(i) – which goes far beyond the corresponding text in GHS Annex 4 - is too prescriptive in the case of mixtures and should be adapted to enable more flexible recommendations to be given. A potential minimal revision to the text is proposed (additions underlined, deleted text in ~~strikethrough~~):

"Recommendations for t~~T~~he type of gloves to be worn when handling the substance or mixture shall be given ~~clearly specified~~ based on the hazard of the substance or mixture and potential for contact and with regard to the amount and duration of dermal exposure, including indications, where available, of:
— the type of material and its thickness,
— the typical or minimum breakthrough times of the glove material,

If necessary, any additional hand protection measures shall be indicated."

- **Section 9:** greater clarity is desired in the following text:

  "The properties listed in subsections 9.1 and 9.2 may be presented in a form of a list. The order of listing the properties may be different if deemed appropriate."

  Whilst this flexibility is welcome, it is not explicitly clear whether this allows properties from 9.1 and 9.2 to be combined/mixed within a single list, or whether the order may only be varied *within* each of subsections 9.1 and 9.2 (important to clarify since all section and subsection headings are mandatory).

  DUCC assumes that further clarification on the inclusion of information under subsection 9.2 (i.e. when and how) will be provided in an update to the ECHA *Guidance on the compilation of safety data sheets*. DUCC would like to know if any such update will also include guidance relating to Table A4.3.9.3 (Further safety characteristics) in GHS, which is not addressed in this revision of Annex II.

- **Point 11.2.1 and subsection 12.6:** both subsections include text reading as follows:

  "Information on adverse health effects caused by endocrine disrupting properties shall be provided, where available, for the substances identified as having endocrine disrupting properties in Subsection **2.3**. This information shall consist of brief summaries of the information derived from application of the assessment criteria laid down in the corresponding Regulations ((EC) No 1907/2006, (EU) 2017/2100, (EU) 2018/605), that is relevant to assess endocrine disrupting properties for [human health/the environment]."

  DUCC queries:
  (i) whether the reference to subsection 2.3 is a typographical error and should in fact read 3.2. Substances (having endocrine disrupting properties) are listed in subsection 3.2, whereas subsection 2.3 contains information on other hazards for the substance or mixture itself.
  (ii) what is meant by "information derived from application of the assessment criteria". For example in the case of REACH, is it data from the registration dossier, information from the Annex XV report (where the substance is a SVHC), etc.? Greater clarity is desirable to enable economic operators to comply with this provision (this could be provided through guidance if not in the legal text).

- **Section 12:** the second sentence in the first paragraph begins as follows:

  "Subsections 12.1. to 12.6. of the safety data sheet shall provide a short summary of the data."

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It is believed that this should read "Subsections 12.1 to **12.7**", since the insertion of the new subsection 12.6 on endocrine disrupting properties has incremented the number of the final subsection ('Other adverse effects') by one.

*DUCC, 10 October 2019*

**About DUCC**

DUCC is a joint platform of **11 European associations** whose member companies use chemicals to **formulate mixtures** (as finished or intermediary products) for professional and industrial users, as well as for consumers.
DUCC focuses on the downstream users' needs, rights, duties and specificities under **REACH** and **CLP**.
DUCC's membership represents several important industry sectors, ranging from cosmetics and detergents to aerosols, paints, inks, toners, pressroom chemicals, adhesives and sealants, construction chemicals, fragrances, lubricants and chemical distributors industries. Altogether, their membership comprises more than **9.000 companies** across the respective sectors in Europe, the vast majority being SMEs. The calculated turnover of these companies is more than **215 billion euros** in Europe.

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DUCC's public ID number in the **Transparency Register of the European Commission** is: **70941697936-72**