FABI Formaldehyde Biocide Interest Group

Brussels, 23 January 2015

Legal & Regulatory
Statement from FABI members in response to the 45 day public consultation[1] on the proposed harmonised classification of Reaction product of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2) (MBO)

The following represents a common statement of all EU formaldehyde-releaser producers participating in the Biocidal Products Regulation (BPR) Review Programme, as represented by the Formaldehyde Biocide Interest Group (FABI) which is a CEFIC registration group.

Summary

1. FABI members are seriously concerned that the CLH Report for MBO submitted the Austrian Competent Authority (the CLH Proposal) is vitiated by fundamental errors of law arising from:

   a. conclusions not substantiated by the available scientific information;
   b. a failure to apply properly the general binding principles of EU law; and
   c. a failure to apply properly the specific requirements of Regulation (EC) No. 1272/2008 (the CLP Regulation) and its Guidance.

   The combined effect of these flaws is that any Adaptation to Technical Progress (ATP) adopted on this basis would be potentially susceptible to challenge. It is in no one's interest to have this process result in a pipeline of weak decisions awaiting review. FABI members hope that such a course of events can be avoided in the mutual interest of all stakeholders concerned to ensure sound decision making. We respectfully submit that this should be treated as a matter of serious concern by both the RAC (which has an obligation to achieve "regulatory and scientific consistency"[2] of its opinions) and the European Commission (which would be unable to submit a draft decision to a vote[3] which it considers is not "appropriate" for such reasons).

2. This statement focuses on the aforementioned failures to follow the mandatory regulatory regime established by the CLP Regulation. The RAC may only assess the available information within the context of the procedural and substantive limits and rules established by the CLP Regulation. FABI's submissions are the result of it commissioning a legal review[4] of the approach taken in the CLH Proposal which clearly confirms the basis of its concerns. In addition to these errors of law, the complementary submissions made by Schülke, which should be read in conjunction with this Statement, demonstrate how the CLH Proposal is not substantiated by the available scientific information.

3. The issues raised in this statement are of key importance not only for MBO but potentially for the whole category of biocidal active substance known as formaldehyde-

[1] http://echa.europa.eu/registry-of-submitted-harmonised-classification-and-labelling-intentions/-/substance-rev/1295/term
[2] RAC Rules of Procedure , Doc: MB/40/2012 (1) final, Article 8 (e).
[3] Under the Regulatory Procedure with Scrutiny (see Article 37(5) of Regulation (EC) No. 1272/2008).
[4] Conducted by Steptoe & Johnson LLP

releasers (or formaldehyde-donors), which control microbial growth in a water-containing product or equipment by the slow release of formaldehyde directly into the matrix. There are at least ten other formaldehyde-releasers being considered for approval under the BPR for several different product types, including MBM[5] for which a parallel public consultation is underway.

Lawful Limits on action under the CLH regime

The EU's powers are limited by the principle of allocation of powers or 'conferral'.[6] That principle is applicable to the bodies which administer the CLH procedure. They have no choice but to apply the legal framework which the EU legislator has adopted (the CLP Regulation, in this case) and entirely governs the exercise of powers.[7] The CLP Regulation clearly defines and necessarily limits the powers which may be exercised on the basis of a RAC opinion. Similarly, neither the submitting authority (Austria) nor the RAC can confer upon themselves new powers which they do not have, in this particular case as regards the approach to be taken to the identification and examination of available information on substances.

Moreover, in the CLP context it should be recalled that the Regulatory Procedure with Scrutiny remains applicable for the adoption of an ATP. This entitles the European Parliament to oppose (and thereby veto) the adoption of proposed measures. It can do this where the draft measures: (i) exceed the implementing powers provided for in the basic instrument (as in the CLP Regulation); (ii) are not compatible with the aim or content of the basic instrument; or (iii) do not respect the principles of subsidiarity or proportionality. For the reasons set out below, the CLH Proposal would seem to breach both of the first two grounds for a Parliamentary veto. Moreover, where a proposed measure is vetoed the Commission does not have the option to resubmit it without amendment.

Legal obligations on how the CLH process must be administered

Even within the lawful limits of the rules prescribed by the CLP Regulation, ECHA and its committees (including the RAC) are limited in the exercise of any discretion by general principles of EU law:

a) They must take into account of all the relevant factors and circumstances of the situation the act was intended to regulate.[8]
b) They have a duty to examine carefully and impartially all the relevant elements of the individual case.[9]
c) They must be able to establish before the EU Courts that the evidence they relied on is factually accurate, reliable and consistent but also that the evidence contains all the information which must be taken into account in order to assess a complex situation and that it is capable of substantiating the conclusions drawn from it.[10]

The CLH Proposal fails to satisfy these three requirements by ignoring the form in which the substance is actually marketed and the available data relating to it. A RAC opinion which is based upon a flawed proposal by a member state Competent Authority would lead to a CLH Proposal by the Commission which would breach these fundamental EU principles of law.

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5 N,N'-methylenebismorpholine (MBM) http://echa.europa.eu/registry-of-submitted-harmonised-classification-and-labelling-intentions/-/substance-rev/1512/term, on which FABI members also submitted statement in response to the 45 day public consultation on its proposed harmonised classification.

6 Article 5(1) of the Treaty on European Union.

7 By analogy, see the Decision of the Board of Appeal in Case A-001-2012, *Dow Benelux B.V.*, paragraphs 54 to 59 where the obligation to adhere to the REACH Regulation prohibited ECHA from doing anything other than following the legislative procedures (which were claimed to be illegal).

8 See Case T-96/10 Rütgers Germany GmbH and Others v ECHA, para. 100

9 See Case C-269/90 *Technische Universität Munchen* [1991] ECR I-5469, paragraph 14.

10 See Case C-12/03 P *Tetra Laval* [2005] ECR I-987, paragraph 39.

The CLH Proposal also suffers from specific breaches of the CLP Regulation, which are now summarized below.

Breach of requirement to address the form/physical state

The proposed classification of MBO is not in accordance with the applicable legal requirements because it cannot be supported when the substance which is actually placed on the market is examined. There is an express requirement, set out in Article 5(1), last sub-paragraph, of the CLP Regulation, which requires this to be the starting point for any examination:

> "*The information [relevant available information for the purposes of determining whether the substance entails a physical, health or environmental hazard as set out in Annex I] shall relate to the forms or physical states in which the substance is placed on the market and in which it can be reasonably expected to be used*."[11]

This is emphasised in recital (30) to the CLP Regulation:

> "*Testing that is carried out for the sole purpose of this Regulation should be carried out on the substance or mixture in the form(s) or physical state(s) in which the substance or mixture is placed on the market and in which it can reasonably be expected to be used*" (emphasis added).[12]

However, the proposed classification is based on a fictitious presumption: that the total amount of formaldehyde present in MBO is "releasable", as a result of which MBO should be classified on the basis of the current classification of formaldehyde because, allegedly, the effects of MBO on human health are the same as the effects upon exposure to the entire quantity of formaldehyde present in MBO. Such a fictitious presumption would render any CLH measure based upon it *ultra vires*, because it ignores the legal requirement that a conclusion as to whether the relevant classification criteria are met must be taken in view of the form of the substance as it is placed on the market and as it can be reasonably expected to be used.

Indeed, Article 12(a) and (b) of the CLP Regulation indicate the importance of this approach by obliging manufacturers, importers and downstream users to take into account:

- "*adequate and reliable information [that] demonstrates that in practice the physical hazards of a substance or a mixture differ from those shown by the tests*" and

- "*conclusive scientific experimental data [that] show that the substance or mixture is not biologically available and those data have been ascertained to be adequate and reliable*."

The proposal to classify MBO as a carcinogen and as a mutagen is essentially based on the presumption that a "sufficient" level of formaldehyde is released and reaches the relevant biological tissues to produce an adverse toxicological effect. However, such a presumption is directly refuted by the available data showing that there is no discernible hydrolysis of MBO in the form in which it is placed on the market and used, as a result of which there is negligible release of "bound" formaldehyde in the form in which MBO is placed on the market.

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[11] All underlining of text in quotations is added in this statement.

[12] Recitals are an important tool for interpretation and are not of themselves legally operative (see case C-162/97, *Nilsson and Others*, *paragraph 54*). The articles are the only legally binding provisions.

Moreover, in the context of biocidal active substances, the expected and reasonably foreseeable conditions that must be taken into account for classification are clearly quantifiable and controlled by the pre-marketing authorization requirements mandated by the BPR. The authorities know therefore, with certainty, the permissible uses and the related form/physical state and must only consider the hazards of MBO in this context.

Breach of requirement to consider occupational data as part of a weight of evidence approach

Article 5(1)(b) of the CLP Regulation provides that:

> *"epidemiological data and experience on the effects on humans, such as occupational data and data from accident databases"* is considered to be *"relevant available information for the purposes of determining whether the substance entails a physical, health or environmental hazard as set out in Annex I [to the CLP Regulation]."*

This need for regard to occupational data is emphasised in recitals (20) and (28) to the CLP Regulation:

> "*[t]he manufacturer, importer or downstream user should also take into account historical human data, such as epidemiological studies on exposed population, accidental or occupational exposure and effect data, and clinical studies. That information should be compared with the criteria for the different hazard classes*."
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> "*[t]he results of animal studies should be weighed against the results of data from humans and expert judgment should be used to ensure the best protection of human health when evaluating both the animal and human data*."

A weight of evidence approach is required in such circumstances. This is reflected in Article 9(3) of the CLP Regulation, which states:

> "*Where the criteria cannot be applied directly to available identified information, manufacturers, importers and downstream users shall carry out an evaluation by applying a weight-of-evidence determination using expert judgment in accordance with Section 1.1.1 of Annex I, weighing all available information having a bearing on the determination of the hazards of the substance…*"

Recital (33) emphasises this:

> "*[r]ecognising that the application of the criteria for the different hazard classes to information is not always straightforward and simple, manufacturers, importers and downstream users should apply weight of evidence determinations involving expert judgment to arrive at adequate results.*"

Fundamentally, taking this approach, the available evidence decisively refutes the proposed classification:

- As regards the proposal to classify for mutagenicity, the in-vitro assays assessing the genotoxicity of MBO demonstrate that MBO is weakly mutagenic and does not meet the relevant criteria. These results, showing positively that the relevant criteria are not met, cannot be overridden by relying, instead, on an un-substantiated assumption that the genotoxic effects would be the same as those of formaldehyde when all the formaldehyde present in MBO is released.

- As regards the proposal to classify for carcinogenicity, the proposed classification is not supported by the applicability of the "weight of evidence" approach taking into consideration the available occupational data, as required.

Unlawful application of the precautionary principle

The proposed classification wrongly invokes the precautionary principle:

> "*The formaldehyde releasing substance should be classified like formaldehyde -based on the considerations of total releasable formaldehyde, intended use, category of users and exposure taking into account the precautionary principles in this case of difficulties with the risk assessment of substances that are instable, showing equilibrium behaviour and having half lives depending on dilution, temperature and/or UVCB characteristics."*[13]

This is entirely unlawful in the context of hazard (rather than risk) assessment under the CLP Regulation). This important difference between hazard and risk assessment was acknowledged by the General Court in case T-13/99, *Pfizer Animal Health SA v Council* in which it held that

> "*[t]he precautionary principle can therefore apply only in situations in which there is a risk, notably to human health, which, although it is not founded on mere hypotheses that have not been scientifically confirmed, has not yet been fully demonstrated*."[14], and that
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> "*'risk' thus constitutes a function of the probability that use of a product or a procedure will adversely affect the interests safeguarded by the legal order. 'Hazard' ('danger') is, in this context, commonly used in a broader sense and describes any product or procedure capable of having an adverse effect on human health…*"[15]
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> "*a situation in which the precautionary principle is applied […] by definition coincides with a situation in which there is scientific uncertainty" in the context of a risk assessment*."[16]

Even in the risk assessment context (which is not the applicable procedure in the instant case), fictitious presumptions cannot justify action:

> "*a preventive measure cannot properly be based on a purely hypothetical approach to the risk, founded on mere conjecture which has not been scientifically verified"*[17]

Based on this clear precedent of the EU Courts, the precautionary principle cannot be invoked in the context of the classification of substances.[18] The classification of substances is intrinsically linked to the assessment of hazards (having regard to the form in which they are actually marketed), while the precautionary principle could, if all conditions are met, be assessed in the context of considering measures to address the actual risks posed by the substances for which the hazard has been identified. Discussions related to the precautionary principle therefore have no place in the context of decisions on the classification of substances.

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[13] CLH Report, section 4.9.4 "Summary and discussions of carcinogenicity".
[14] Paragraph 146 of Case T 13/99.
[15] Paragraph 147 of Case T-13/99.
[16] Paragraph 142 of Case T-13/99.
[17] Paragraph 143 of Case T 13/99.
[18] Indeed, in case C-15/10, *Etimine SA v Secretary of State for Work and Pensions*, the Court of Justice decided not to follow Advocates General Bot's Opinion suggesting that the principle might be applicable.