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Observations on the Proposal for Harmonised Classification and Labelling based on Regulation (EC) No 1272/2008 ("CLP") regarding the substance 1,3,5-triazine-2,4,6-triamine (Melamine; EC: 203-615-4, CAS: 108-78-1) submitted by the Federal Institute for Occupational Safety and Health (BAuA), Germany, Version: 1.0, November 2019 (hereinafter referred to as "Proposal")

Submitted by
Fritz EGGER GmbH & Co. KG
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The Egger Group, with its head office in St. Johann in Tirol (Austria), is an international wood-based materials manufacturer. Founded in 1961, the family-based company now has 20 production plants with approx.. 10.000 employees worldwide.

I. Scientific and regulatory assessment of the Proposal submitted by EMPA

(1) We support the observations and comments on the Proposal submitted by the European Melamine Producers Association (EMPA). For the avoidance of reiteration, we refer to the details set out in the submission of EMPA during the public consultation and emphasize that we share the views and interpretations prepared by EMPA regarding the scientific assessment of the studies and justifications provided by BAuA in the Proposal.

(2) We are of the opinion that available scientific data as referred to in the Proposal does neither demonstrate sufficient evidence that Melamin fulfils the criteria set out in Annex I to CLP for carcinogenicity, category 2 (Annex I, section 3.6, to CLP) nor the criteria for specific target organ toxicity – repeated exposure (Annex I, section 3.9, to CLP).

II. Additional Observations and Comments

(3) In addition to the observations and comments submitted by EMPA we would like to submit the following details:

1. No need for action at Community level

(4) The Proposal correctly states that Melamine (1,3,5-triazine-2,4,6-triamine) is neither listed in the Annex VI to CLP nor has a proposal for a harmonised classification and labelling previously been submitted for this substance. It is also correct that none of the notifiers and/or registrants has self-classified the substance as STOT RE 1. The Proposal further states that

> *"data assessed and discussed in the current CLH dossier, however, support classification in category STOT RE 1 (section 10.11). Thus, a justification that action is needed at community level is given due to disagreement of the dossier submitter with the current self-classification by the notifiers and/or registrants".*

(5) We submit that this does not constitute a enough justification for a harmonised classification and labelling. The mere fact that available data supports a classification other than the classification notified in accordance with Articles 39 et seqq. CLP does not trigger a need for action at Community level but rather the obligation for notifiers to re-assess their notifications and submit corresponding updates if and to the extent necessary. Otherwise, any new scientific evidence or updated conclusions drawn from available data deviating from previous notifications would constitute a need for action on Community level. Nothing in CLP supports such approach. Moreover, the justification outlined in the Proposal would lead to an inflationary use of harmonized classifications as any opinion of a competent authority deviating from notifications reported in the classification and labelling inventory would be a sufficient basis for a proposal for harmonised classification.

(6) Bearing in mind that Annex VI, Section 2, to CLP states

> *"For other effects than carcinogenity, mutagenicity, reprotoxicity and respiratory sensitisation a justification shall be provided that there is a need for action demonstrated at Community level"*

it goes without saying that a specific need for action needs to be demonstrated. If the EU legislator had considered that a mere deviation between the opinion of a

competent authority and notifications reported in the classification and labelling inventory shall constitute a sufficient justification it would have been more than likely that this aspect would already have been included in the regulation.

(7) Furthermore, it needs to be noted that Member States are obliged to introduce penalties for non-compliance with the provisions of CLP and take all measures necessary to ensure that this Regulation is applied (cf. Article 47 CLP). Therefore, Member States established national legislation which entitles competent authorities to issue administrative orders (e.g. correction orders) or impose sanctions (e.g. administrative fines) in case information according to Article 40(1) CLP is not submitted correctly. Therefore, CLP stipulates that incorrect notifications, i.e. notifications which a competent authority can proof wrong due to its own assessment of available data, as well as omitted notifications despite availability of data supporting a notification requirement are subject to administrative control mechanism and potential sanctions rather than the basis for a harmonised classification.

(8) In addition, we submit that the Proposal does not sufficiently reflect the provision set out in Article 36(1) CLP. According thereto, a

> *"substance that fulfils the criteria set out in Annex I for the following shall normally be subject to harmonised classification and labelling in accordance with Article 37"*.

(9) While Annex VI, Section 2, to CLP states that a specific justification needs to be submitted only for other effects than carcinogenity, mutagenicity, reprotoxicity and respiratory sensitisation, it needs to be noted that even a potential classification of a substance as carcinogenic does not automatically constitute a basis for a proposal for harmonised classification. CLP only states that such classification "shall normally be subject to harmonised classification". Thus, any proposal for harmonised classification regarding the aforementioned hazard criteria needs to assess whether there is relevant information available indicating that there is no need for a harmonized classification due to the fact that exceptional circumstances allow for a deviation from the normal process as enshrined in Article 36(1) CLP.

(10) The Proposal does not contain any assessment or even statement as to whether such deviation could be considered in the case at hand and, thus, is lacking an essential requirement.

(11) Moreover, the observations already submitted by EMPA (cf. Section I. above) outline that the life cycle of Melamine does not include a wide-spread use in a way that the proposed classification would have a relevant effect. Given that in 95 % of the volume

of Melamine available on the EU market, Melamine is chemically converted into a new substance, any harmonized classification would have only limited effects. This, in particular, holds true as the vast majority of end-uses relate to the production of articles which on the one hand, do not contain any Melamine as such but Melamine resins not subject to classification requirements due to a Melamine content of less than 1 % (cf. Table 3.6.2 of Annex I to CLP) and, on the other, are not subject to classification requirements as such (cf. Article 4(8), (10) CLP).

(12) Given that the vast majority of Melamine uses would not be affected by the proposed harmonized classification due to the chemical conversion of the substance and further given that the articles produced with Melamine resins would not be subject to classification requirements, there is no relevant argument to demonstrate that there is a need for action on EU level regarding the harmonized classification of Melamine.

(13) This also holds true with respect to a potential wide-spread use of Melamine resins also in consumer products as no relevant exposure to Melamine as such is to be expected in relation to such products. In this regard it needs to be noted that the scientific data referred to by the submitter of the Proposal primarily relate to adverse health effects on basis of an oral intake of Melamine. Such oral intake could generally be excluded with respect to articles produced from or on basis of Melamine resins.

(14) Further given that scientific justification has been put forward by the Proposal only with respect to oral intake and due to the fact that there seems to be no relevant evidence for carcinogenic properties in connection with other exposure routes, we submit that a restriction of a harmonized classification to that specific route of exposure would be adequate.

2. Market effects

(15) We submit that Melamine cannot be substituted by other substances that can be used for similar purposes and in the same way as Melamine. Although other options are, in general, technically possible, available substitutes involve higher risk potentials and, therefore, should not be used. We further submit, that Melamine is produced industrially in large quantities and potential market effects of a potential harmonized classification would require a change of production procedures worldwide.

(16) This, inter alia, due to the fact that a classification as STOT RE would require a change of operational practices and permits with respect to storage requirements. Currently, Melamine does not trigger specific storage requirements, e.g. according to the TRGS

510 in Germany or similar provisions. With a mandatory change to STOT RE Melamine would qualify as a hazardous substance with chronic health effect so that other storage categories would apply. This would tremendously affect all operating sites throughout the EU as amendments to existing permits for businesses (operating, building or storage permits, depending on the applicable national regime) would be necessary. To this end, we respectfully submit that the Commission should grant sufficient lead time and transitional periods prior to the entry into force of a harmonized classification, if and to the extent the Proposal is upheld.

(17) We are of the opinion, however, that the Proposal should be withdrawn on the basis of the scientific arguments submitted by EMPA as well as the aforementioned details.

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Yours sincerely

Klaus Schlusen
Leitung CC Produkte