

BDI-Comments to the Stakeholder Consultation "On the Implementation of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) in Community Legislation"

October 20, 2006

1. General Remarks

The "Globally Harmonised System for Classification and Labelling" and its implementation within the European Community is appreciated as an instrument towards further global harmonisation and against the further diversification of systems for classification and hazard communication. In this respect, the approach which is subject to the internet consultation appears as rather constructive. However, we still suggest some further aspects to be improved. Moreover, in general terms, further harmonisation should be strived for at UN-level.

2. Detailed Remarks

➤ Downstream Consequences

Undoubtedly more substances and preparations will be subject to classification as hazardous and to labelling provisions under the GHS. In addition to that, within the EU there are many pieces of legislation on community and on national level referring to the classification of a chemical. A major concern of industry is that the scope of the existing legislation will be extended due to that presetting. The Commission in depth analysed the hazard based provisions on community level in its study "Analysis of the potential effects of the proposed GHS Regulation on EU Downstream Consequences". The solutions to that challenge are already integrated as far as possible in Art. 37 and Annex VIII of this draft Regulation. In consequence, the Commission services are responsible for the implementation. Industry will follow up whether or not the proposed solutions are put into practice. We understand that the SEVESO II Directive has to undergo some more extended rework. We understand as well and appreciate that industry will be involved in that rework.

Moreover, we want to draw the attention to the fact that legislations under Art. 137 EEC treaty an extensive number of national legislation has to be adapted to the GHS. The time needed to achieve this has to be taken into account when defining the transition periods.

➤ Industry agreements on entries (Article 25 - based on Article 112 REACH)

We disapprove the obligation of the "notifiers and registrants to make every effort to come to an agreed entry to be included in the inventory". According to the general rule "that no new testing has to be generated for the purpose of classification only" each registrant has to perform the registration of a substance on the basis of the data he has. The consequence will be that of course some registrants will come to different results in the classification of a substance. It is not acceptable, that a registrant has to justify a not agreed result of a substance classification.

➤ Protection of Confidential Business Information

Also with regard to the Lisbon Strategy, this is a vital issue for industry. Under the GHS, the labelling provision takes this well into account. We urgently ask the Commission to make precautions for the

protection of CBI in the provisions for the publicly accessible inventory. The identification of a connection between a substance and a manufacturer like e.g. via the registration number or the exactly defined impurities or a trade name is not necessary for the purpose of the inventory. We ask for a provision that on request, the Agency is not going to publish any information that may allow such a tracing back for the general public.

➤ **SDS Provisions**

The Building Block "Safety Data Sheet" is not taken from the GHS and thus not included in this Regulation. The Safety Data Sheet is regulated under the proposed REACH Regulation. However, hazard classification and hazard communication are two interlocked halves of one part: hazard description. It might be beneficial to consider having both topics entirely covered in one Regulation.

➤ **Scope**

The DSD and the DPD refer to substances and mixtures placed on the market. For reasons of consistency and simplification and in order to be concurrent with the objective of well preserving the current level of protection, we suggest to define the scope of this Regulation accordingly. This is as well consistent with the fact that most of the provisions of this Regulation as e.g. outlined in Art. 4 refer to substances and mixtures placed on the market only.

➤ **De minimis value for the inventory under Art. 26**

Industry understands and appreciates that R&D substances including Process orientated Research and Development is excluded from the scope of this Regulation, when the products are not placed on the market. Notifying the agency of all substances placed on the market and classified as hazardous under this Regulation is a laborious process. For substances only placed on the market in small quantities, the costs may be higher than the earnings from the market. In accordance with the proposed REACH Regulation, we therefore propose a De minimis value for the obligation to notify the agency of 1t/a. This De minimis value does not exempt the supplier from any other legal obligation concerning the supply and use of such chemicals.

➤ **Normal Handling and Use**

In order not to fall back behind the current level of protection we propose to preserve the "normal handling and use principle" as an important provision to adequately address risks.

➤ **Annex VI**

Art. 21 defines the base for a harmonised classification on community level. Not substances but end-points will be subject to a harmonised classification on community level. Mainly these will be cmr and respiratory sensitizers. Others only will be included on a case by case basis. Referring to Article 26 (3) (f) it will be marked in the inventory whether or not there is a harmonised classification. To our understanding and on a factual basis this will make a separate Annex of harmonised end points superfluous, because it will not provide any additional information not already contained in the inventory.

➤ **Labelling Requirements**

The labelling requirements should be strictly as described in the UN-GHS to avoid deviant labels in different parts of the world. Especially the requirements based on the transport regulation (proper shipping name and pictograms taken from the UN Model Regulations) should not be used on the labelling for use, as this provides also misleading information regarding the transport (for the transport, a pictogram is not always required (limited quantities)).

➤ **Advertisement**

The provisions made in this article for advertisement go over and above the current provisions: For mixtures, Art. 13 of DPD is the relevant provision and it only regulates direct marketing. The provisions are to be applied only for the general public and without prior knowledge of the label. This Regulation however, is intended to maintain the level of protection and should not go beyond existing provisions; therefore, we suggest amending the necessary changes.