

21/08/06 – 21/10/06:
**Stakeholder Consultation on the Implementation
of the GHS in Community Legislation**

Evaluation of the Stakeholder Replies

During the consultation, participants were invited to give comments and answers to the questions set out in an online-questionnaire or to send comments by email to a specified mailbox. The non-confidential replies and comments from the respondents are presented on the [GHS consultation website](#) of DG Enterprise & Industry. The results of the consultation can be summarised as follows:

- **General feedback:** Approximately 370 contributions were received, cf. Figure 1. 82% of these were sent by industry, i.e. by associations responding on behalf of their members and by companies. Out of the 254 company responses, 45% were received from enterprises with less than 250 employees, cf. Figure 2. The formulators of mixtures / preparations account for 85%, i.e. for 217 out of 254 industry responses, cf. Figure 3. 10 NGOs responded, and one response from a trade union was received. From the Member States, 18 governments and/or public authorities sent comments, including from three EU-10 Member States. Public authorities from non-Community countries (Romania, which is now an EU Member State, Iceland, Norway and Switzerland) gave their input as well. No international organisation sent comments. About 5 individuals, most of whom are or have been involved in the development of the GHS, provided specific input.
- **Implementation of the GHS as Regulation:** 97% of the responses support the implementation of the GHS in Community law, and out of these 96% by means of a Regulation. The draft proposal and the other related documents prepared by the Commission services were generally well appreciated by Member States authorities and industry.

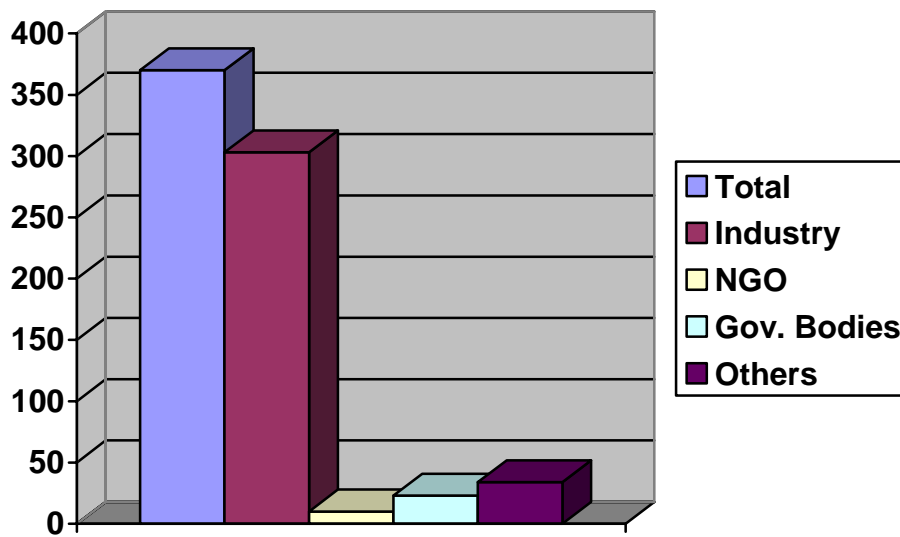


Figure 1 : Number of contributions received during the stakeholder consultations

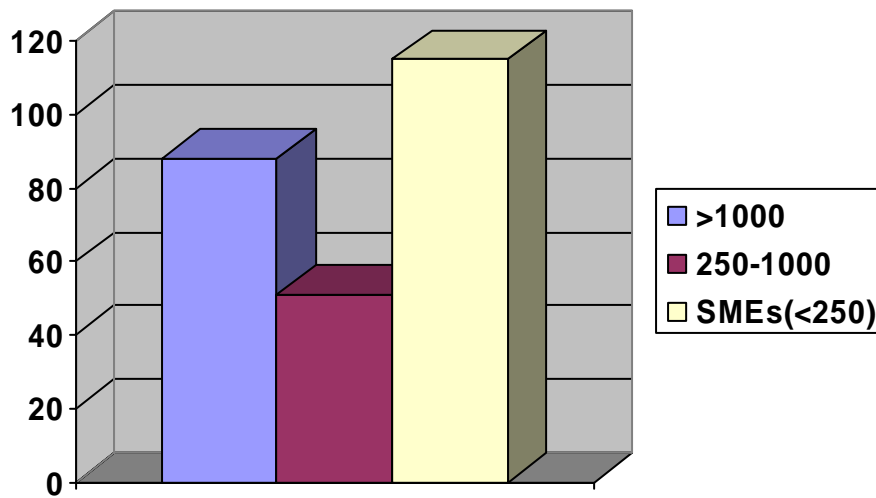


Figure 2 : Distribution of company size (number of employees) among industry respondents

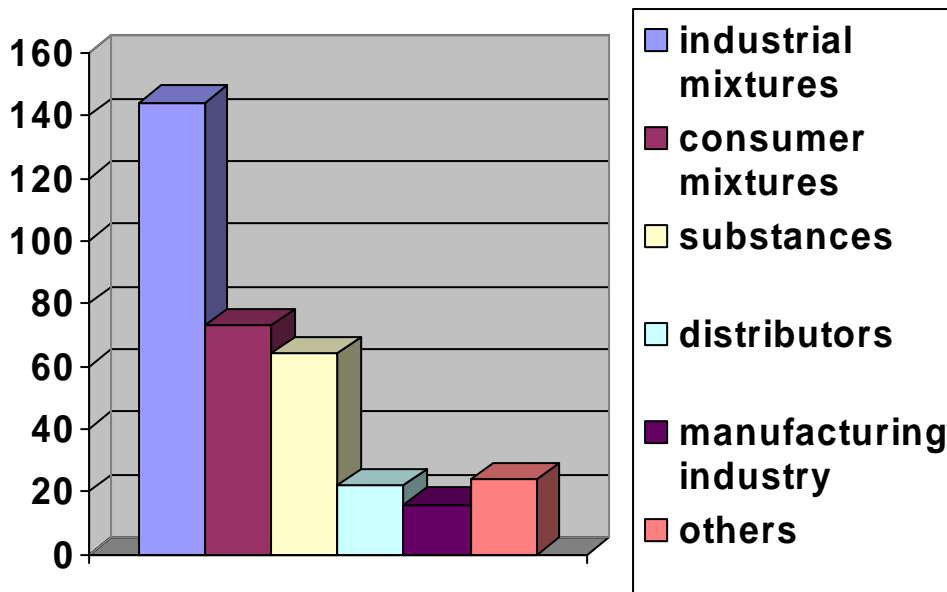


Figure 3: Distribution of manufacture type among industry respondents

- Scope of the system:** The GHS draft Regulation does not propose to extend or lower the level of protection in comparison with the existing EU system except where this is needed for reasons of consistency with the transport legislation or for consistency with the GHS. 59% supported this approach, 5% expressed no opinion including most of the 10 NGOs and 36% favoured a different approach. As requested by some Member States and industry, the GHS classification “Flammable Gases category 2” was included in the proposal afterwards as it is part of the current system.
- Transitional period:** No specific comments were received on the two stage structure (first substances, then mixtures) of the transitional period. A clear majority of respondents (around 60%) to the Public Internet Consultation support a transition period for substances of 3 years after the entry into force of REACH (now 3.5 years in the REACH Regulation), cf. Figure 4. For mixtures, the option of 5 years was the most popular choice, with about 50% of the responses given. Almost equal numbers, i.e. 25%, of the remaining responses expressed a preference for a longer or a shorter period. Industry responses were divided, with significant support for a 5 year period for mixtures, whereas most Member States were looking for a shorter transitional period, typically a 3 year period.

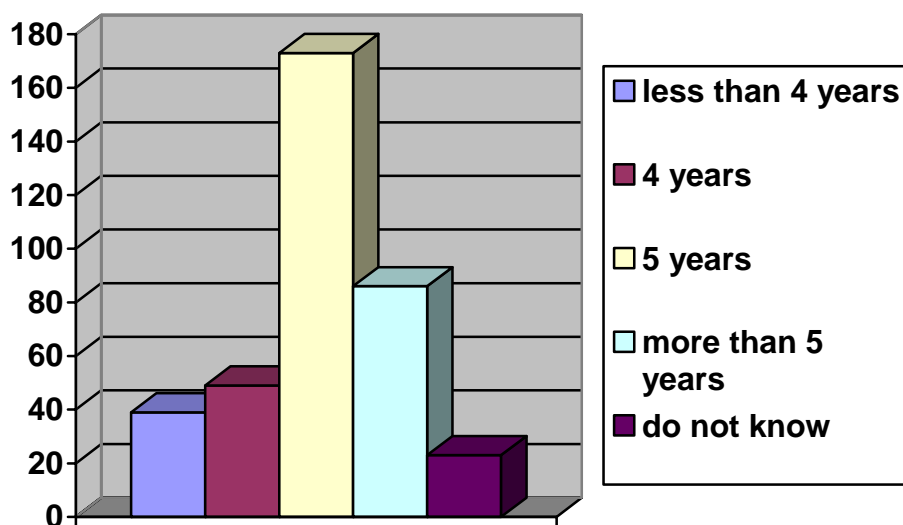


Figure 4: Support of the different timelines for mixture reclassification according to the GHS

- **Specific comments:** Around 15% of the respondents have provided more specific and detailed comments on the draft proposal, mainly by separate email. A large majority of these comments provided by industry and Member States were of technical nature seeking for further clarity and consistency. Issues that have repeatedly been raised were:
 - in Article 118 of the REACH Common Position text (now Article 119 of the REACH Regulation), to allow the use of an international chemical name in addition to the name in IUPAC nomenclature, to limit the names on a label for mixtures in line with the requirements of the current legislation, to include a provision to permit the use of shorter names;
 - to improve the wording of the provision that the content of the publicly accessible part of the classification and labelling inventory should be consistent with the Reach requirements under Article 118 of the REACH Regulation (Common Position text);
 - to include the specific rule of the current legislation pertaining to the advertisement of mixtures;
 - to specify more clearly the body or bodies responsible for receiving information relating to health in line with the current legislation;
 - to reconsider the provision for small packaging to counterbalance the bigger space demand of the label information due to the GHS implementing requirements;
 - to include the GHS pictograms.

Another issue raised by the majority of the Member States and downstream users was the request to transfer the current Annex I of Directive 67/548/EEC, i.e. the list of harmonised

classification and labelling of substances, to Annex VI to the GHS draft Regulation, in order to maintain the harmonisation achievements reflected in the current Annex I.

- **Impact assessment:**

- Many respondents indicated that they were not able to provide answers to the questions related to the impact assessment. Almost half of them expressed no opinion on the plausibility of the cost and benefit estimates from the RPA and London Economics studies are plausible. More than half of the respondents could not give a clear-cut answer to the question whether the trade-related cost savings would outweigh the costs (as quantified by RPA). These shares were higher for SMEs and firms with EU sales only.
- Nevertheless, a significant number of respondents expressed concern about the costs through their reaction on the plausibility of the estimates of the impact assessment studies: Almost 40% indicated that some cost items had been underestimated. In the corresponding individual comments, the costs of having a dual system were mentioned (in particular related to the ensuing confusion) as well as the costs of prematurely classifying mixtures (in particular the costs of changing labels and reaching agreement with suppliers of the same product). These two cost items were not quantified in the studies.
- Occasionally, respondents judged that some cost estimates presented in the studies were too low (specifically the IT and training outlays and the repackaging costs); however, most of these comments have not been specified; if they are, they often seem to be based on a misinterpretation of the requirements or to an over-attribution to GHS. An example of the latter is the alleged necessity to buy a colour printer to produce colour-printed labels.
- 16% judged that some benefit items had been overestimated; the concern was voiced that without “one product – one label – one safety data sheet” globally there would hardly be any benefit. Other responses pointed to the small share of classification and labelling costs compared to the total costs of trade and to the uncertainty of the estimates.
- Many comments related to the distribution of the costs over companies and over time. Most of them referred to the cost burden to for SMEs: the overhead costs would weigh relatively heavy on SMEs, also due to their lower earning back capacity. Some claim that SMEs would have no or less compensating benefits as they are allegedly less engaged in trade with countries from outside the EU.
- As to the cost distribution over time, respondents pointed to the peak load in the first three and a half years until the deadline of the classification and labelling inventory set up by REACH; and to the time needed to get a stable classification for a mixture.

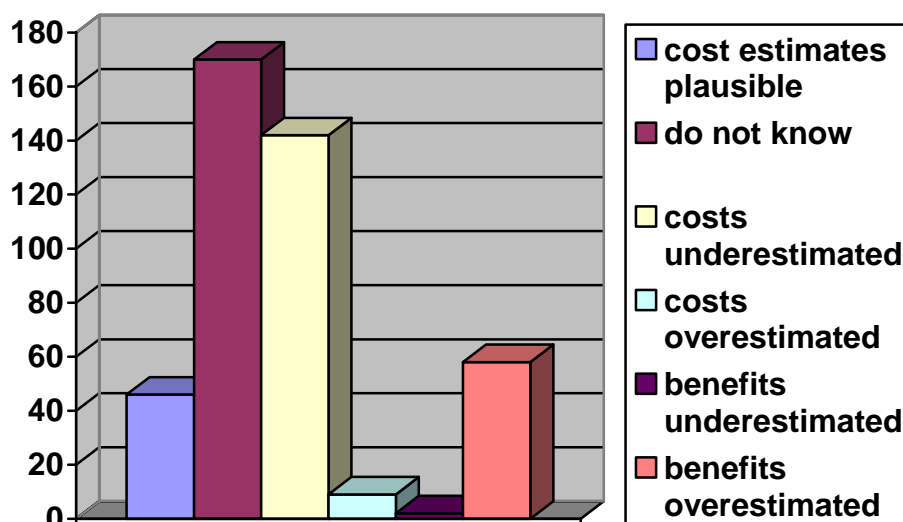


Figure 5: Assessment of plausibility of cost and benefit estimates from the RPA/LE impact assessment reports

- Coherence with other policies and potential effects on EU downstream legislation:**

The classification of substances and preparations according to the current Directives triggers many other obligations in Community legislation, referred to as EU “downstream legislation”. The Commission services have extensively assessed the potential effects of GHS implementation on the respective acts; a corresponding analysis concludes that effects are either minimal or can be minimised by appropriate consequential changes to a particular downstream act. The GHS draft Regulation proposed these changes to be made in Article 37 and Annex VIII of the GHS Regulation itself. The analysis as well as the proposed solutions to minimise effects were generally highly appreciated by industry and Member State competent authorities. During the consultation, various stakeholders from industry requested to adapt downstream legislation, e.g. the Seveso II Directive, in an appropriate way to the new GHS rules before the shift of references to the GHS criteria would become effective. This includes also introducing the necessary measures in separate amendments of particular acts.

During the stakeholder consultation, it was sometimes raised that the analysis of national legislation referring to the EU classification criteria was missing. However, the Commission considers the assessment of the effects on national legislation, including the legislation going beyond the implementation of minimum requirements, to be in the competence of the EU Member States. Corresponding analyses have therefore not been carried out. It may be worthwhile for Member States to analyse the national downstream acts along the lines taken in the study on Community legislation.