

## COMMITTEE OF EXPERTS ON THE TRANSPORT OF DANGEROUS GOODS AND ON THE GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS

Sub-Committee of Experts on the Globally  
Harmonized System of Classification  
and Labelling of Chemicals

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### PROGRAMME OF WORK FOR THE BIENNIUM 2009-2010

#### Development of criteria for the classification and labelling of substances hazardous to the terrestrial environment

Transmitted by CropLife International

#### **Summary**

1. CropLife International is extremely concerned by the high cost, to both Governments and Industry, of developing and implementing such a system, relative to the small, if any, benefits.
2. CropLife International believes that these costs are disproportionate to the small reasonably identifiable benefits of such a scheme
4. CropLife International also recalls the comments made by other experts about the difficulty of implementing the GHS when changes are continually being made to the system and their requests that the system should be frozen for a period of time so as to facilitate implementation
5. On these grounds, CropLife International believes that it is inappropriate include work on the development of criteria for the classification and labelling of terrestrial hazards in the programme of work for the next biennium

#### **Introduction**

6. Considerable resources have already been devoted to the subject of terrestrial hazards. If an extended mandate were to be given to the OECD to develop options for a harmonised scheme, additional considerable resources would be required by the OECD and members/observers. Additionally, we must not lose sight of the significant resources that would also be required in order to implement any scheme. Ultimately these costs will be borne by the purchasers of the affected products and their customers. To date, there has been limited debate on the costs and benefits of such a scheme. We note that the proposal for an extended mandate

(ST/SG/AC.10/C.4/2008/21) suggests that there could be a cost/benefit analysis of various detail options for a classification scheme. We do not agree that options for a scheme have to be developed before the costs and benefits can be estimated as many of the costs are independent of the complexity of any scheme. We believe that it is already possible to provide a broad estimate of costs and benefits of developing a classification scheme and to make decisions based on that estimate. We especially believe that there should be a reasonable likelihood that the benefits of implementing a scheme will exceed the costs of developing and implementing such a scheme before and that a cost/benefit analysis should not be deferred until after a scheme has been developed. This is simply a matter of standard good management.

### **Harmonisation of existing systems or creation of a new system?**

7. Table 1.1 of the OECD document (UN/SCEGHS/15/INF.28) submitted to the July 2008 meeting, identifies existing systems. CropLife International questions the inclusion of the European Union as an existing system: if a system has not been applied nor contains criteria after more than 30 years, how can this be considered to be existing? We also note that only 5 countries have been identified as having existing and implemented schemes. These schemes are also only applied to one sector: pesticides. We note that the New Zealand Hazardous Substances and New Organisms Act 1996, frequently referred to as a model for a GHS terrestrial classification scheme, applies terrestrial hazards only to pesticides and excludes application of terrestrial classification to industrial chemicals under their Group Standard approval approach (see for example the “Additives, Process Chemicals and Raw Materials (Flammable) Group Standard 2006” (page 7 Section 11)); there are no data for most of these chemicals.

8. The GHS is intended to apply to all countries and, with a few small exceptions, to all chemicals. When the narrow scope and small number of existing schemes is taken into consideration, we believe that in reality there are no existing and implemented schemes that are consistent with the scope of GHS to harmonise and therefore that if the current work continues, any extension to the GHS by including terrestrial hazards would be a new scheme and not a harmonisation of existing schemes. The costs and benefits should be considered in this respect.

### **Benefits**

9. The benefits that are usually assumed to be derived from harmonising existing classification are not relevant as the vast majority of chemicals currently do not have any labelling for terrestrial hazards.

10. For pesticides, it is difficult to see how a benefit will occur from a globally harmonised labelling scheme. The way a pesticide is used is always prescribed on the label taking into account the risks to public health and the environment as determined by a competent authority in each country. The risk is related to the use rate and application method which is invariably different for different countries. Hence it is not possible to have a globally harmonised label. Pesticides are already evaluated for terrestrial hazard, so overlaying a GHS scheme will duplicate what is already being done by a competent authority using already available data. This duplication will only put one more approach to labelling and cause further dis-harmonisation. In effect, it will lead to double regulation. Additional hazard statements on already complex labels could detract from key safety messages and could cause confusion with existing risk based

labelling. It is widely accepted that risk management measures are more effective at changing behaviour than hazard communication. Furthermore, some of the data generated for risk assessments are not suitable for use in a simple hazard based classification system.

11. Considering the vast majority of chemicals are not intended to be released into the terrestrial environment, we need to take account of data availability. Without applicable data, a classification and labelling scheme would have little practical value. In our document (UN/SCEGHS/15/INF.38 ) submitted to the July 2008 meeting of this Sub-Committee, we quoted from a number of analysis that showed that there is very little data on terrestrial hazards for chemicals except pesticides and biocides. The expert from the United Kingdom confirmed the actual conclusion of the United Kingdom' analysis; that there is very little data on terrestrial effects for non-pesticides. The implementation of the Regulation for Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) in the European Union is expected, by some, to dramatically increase the availability of data on terrestrial organisms. We believe that this expectation is over optimistic. Substances manufactured below 100 tonnes per year do not trigger any data generation requirements for terrestrial organisms under REACH. For substances manufactured at greater than 100 tonnes per year, testing for the terrestrial environment is only required if safe use cannot be demonstrated. We expect that for a large proportion of affected substances, safe use including safe disposal of wastes and residues, will be demonstrated and hence that data generation will not be required. At the July 2008 meeting of this subcommittee, a representative from the European Commission stated that as a matter of fact, the implementation of REACH in the EU will not lead to significant amounts of new data relating to terrestrial hazards.

### **Costs**

12. Although the detailed criteria have not yet been developed, it is possible to produce a first estimate of the costs to industry of implementing a new classification scheme. These costs are divided into variable costs, such as the time required to analyse data and decide on the classification, and fixed costs such as changing the plates used to print labels. The balance between fixed and variable costs will vary between industries. For the pesticide industry, the costs of implementing a new classification scheme are dominated by the fixed costs and therefore it is possible to produce a first estimate of the costs at an early stage. We estimate that for the pesticide industry, the costs of globally implementing a scheme for classification and labelling of terrestrial hazards would be in excess of one hundred million dollars. As the pesticide industry makes up only a small proportion of the global chemical industry, the costs for the global chemical industry can be expected to be significantly higher. Governments would also need to invest significant resources to develop and implement a new classification scheme.

The costs of extending the scheme to mixtures (Products) must also be considered.

Costs which need to be taken into account include:

- (a) Cost of developing the system;
- (b) Cost of introducing the system into national laws;
- (c) Cost of training industry and government staff who will be responsible for making the classifications;

- (d) Cost of changing, for example pesticide labels (to both industry and the registration authorities); this is in addition to the changes that will have to be made in the near future to accommodate the adoption of GHS in its current form;
- (e) Cost of training product users, particularly millions of consumers and farmers, on how to interpret and use the new labels; and
- (f) Cost of development and implementation of the changes in GHS to accommodate terrestrial classification in developing countries.

### **Double regulation**

13. Development of a scheme for terrestrial hazards could also lead to a very inefficient and potentially confusing double regulation of pesticides. For example, in the EU the terrestrial labelling of Crop Protection Products is already covered by the existing Pesticide Directive and its Annexes, based on the conditions of use. Adding an extra, hazard based, label would not increase protection of the environment. In other countries, the risk to terrestrial organisms is already considered during the authorisation of a pesticide and the outcomes incorporated into the labelling of the pesticide.

### **Implementing a moving target**

14. During previous meetings of the Sub-Committee, experts have informed the Sub-Committee of the difficulty of implementing the GHS while the contents are being amended or extended. The Sub-Committee has taken account of these difficulties by focussing on activities that aid implementation and restraining from adding additional criteria where there are not widespread existing systems.

### **Conclusion**

15. Taking into account:
- (a) the limited data available;
  - (b) the low likelihood of significant increase in data availability in the foreseeable future;
  - (c) the limited scope of the few existing schemes;
  - (d) the limited opportunities for harmonisation for pesticide labels;
  - (e) the dangers of double regulation with resulting further complication of already complicated labels;

CropLife International does not believe that there is a reasonable chance of the significant costs of developing a scheme exceeding the limited benefits.

16. Considering also the desire of this Sub-Committee for a stabilisation period to allow the GHS to be implemented, we believe that the existing OECD mandate should not be extended and that development of a scheme for classification of terrestrial hazards should not be included in the programme of work for the following biennium.

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