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

Eighteenth session
Geneva, 9 – 11 December 2009
Item 7 of the provisional agenda

OTHER BUSINESS

Proposal to consider the harmonisation of the criteria for classification and labelling of persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) substances

Transmitted by the representatives of the European Commission
(DG ENTERPRISE and DG ENVIRONMENT)

Background

1. Different jurisdictions like Canada, the United States, Japan and the European Union and international and/or intergovernmental organisations like the United Nations or the OSPAR Commission (Convention for the Protection of the Marine Environment of the North-East Atlantic) have set up schemes to screen for substances with persistent, bioaccumulative and/or toxic properties, although the criteria of the schemes are slightly different (see Annex). The main aim of all these schemes is to identify substances which potentially might have these effects, in order to manage any risk. In case they pose a risk, the aim is to control and reduce exposure as far as possible.

2. Part 4 (environmental hazards) of the GHS provides the criteria for classification and labelling of substances and mixtures for acute and long-term hazards to the aquatic environment using criteria, for acute aquatic toxicity, bioaccumulation, rapid degradability and chronic aquatic toxicity.

3. The GHS allows the inclusion of additional information on the label about hazards not yet incorporated into the GHS (Chapter 1.4, section 1.4.6.3), but does not allow the inclusion of new labelling elements without having developed harmonised criteria for classification as well.

Situation in the EU under regulation (EC) No 1272/2008

4. During the co-decision process leading to the adoption of Regulation (EC) 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation) based on the GHS, the idea of labelling for persistent, bioaccumulative and toxic (PBT) and for very persistent and very bioaccumulative (vPvB) substances was raised by some Members States, but did not find sufficiently broad support there for taking it up in the Regulation. However during these co-decision negotiations, some political groups of the EU Parliament pleaded as well for labelling in the form of a pictogram for PBT/vPvB substances.

5. The legislator in the end decided to insert an Article into the text of the CLP Regulation (EC) No 1272/2008 pointing towards future action as follows:

> Article 53(2) Regulation (EC) No 1272/2008:
>
> *"Member States and the Commission shall, in the manner appropriate to their role in the relevant UN fora, promote the harmonisation of the criteria for classification and labelling of persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) substances at the level of the UN."*

Criteria for classification and labelling in part 4 of the GHS

6. If one applies the GHS criteria (Rev. 2) for environmental classification, substances that meet PBT or vPvB screening criteria would in most cases get classified and labelled for environmental hazards and in certain cases also for human toxicity. Accordingly, in most cases they will bear the pictogram for "environment" and in certain cases the one for "health hazards".

7. It is expected that the few PBT substances (those showing no/low acute toxicity to the aquatic organisms) that would not be classified under the GHS Rev.2, or that would be classified in a category not requiring a symbol/pictogram for the environment on the label, will be caught under the GHS via the introduction of the criteria based on chronic toxicity for the aquatic organisms, as laid down in Revision 3 of the GHS, adopted in December 2008. The revision 3 of the GHS is intended to be incorporated in the CLP Regulation via the normal procedure of ATP (adaptation to technical progress). Most substances identified as vPvB meet the criteria for classification for environmental effects under the UN GHS Rev 2 and will be labelled accordingly, but not necessarily with a symbol or pictogram. Only the vPvB substances having no observed effect concentrations (NOECs) above water solubility limit (or > 1 mg/l) might not be classified (cf. decision logic 4.1.3 (a) and 4.1.3 (b) of the GHS Rev.3).

Issue

8. The CLP Regulation requires EU Member States and the European Commission to promote, in the manner appropriate to their role in the relevant United Nations fora, the harmonisation of the criteria for classification and labelling of persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) substances at the level of the United Nations.

9. Accordingly, the European Commission and EU Member States want to bring this issue to the attention of the GHS Sub-Committee and seek its views on it.

10. Based on the above considerations, the Commission proposes to monitor closely the effects which the introduction of revision 3 of the GHS will have on the labelling of substances identified in different jurisdictions as PBTs or vPvBs and return, based on experience, to the issue of whether further labelling requirements would provide an added value once experience has been gained.

Additional considerations

11. The existing schemes in different jurisdictions to identify substances with properties such as persistent, bioaccumulative and toxic (PBT), persistent and toxic (PT), bioaccumulative and toxic (BT), or very persistent and very bioaccumulative (vPvB) are not classification schemes in the meaning of the GHS.

12. The term "hazard classification" is used to identify the intrinsic hazardous properties of a substance or mixture. It means to identify the nature of the physical, health or environmental hazard and to determine the appropriate hazard class, e.g. flammable solids, carcinogens, environmental hazards. It does not as such foresee the combination of properties as in "PBT" or vPvB. Such combinations of properties are used to trigger specific actions in terms of risk assessment and risk management.

13. With regard to international harmonisation of PBT criteria, the OECD has set up a project to develop OECD guidance documents for harmonising environmental risk assessment practices of pesticides with persistent, bioaccumulative and toxic (PBT) characteristics. The goal of that project is to develop guidance that will promote the harmonisation of environmental risk assessment practices involving pesticides with PBT characteristics. Phase 1 of that project will consist of developing guidance that facilitates a common understanding of critical environmental risk assessment issues facing the regulation of pesticides with varying PBT profiles. The guidance will also include developing a consistent set of definitions of key concepts related to environmental persistence, bioaccumulation and toxicity, keeping in mind ongoing scientific and regulatory activities in scientific disciplines. It is the intention of the OECD that these definitions will pertain to the underlying concepts and not the actual numeric criteria used by regulatory institutions to classify chemicals according to their persistent , bioaccumulative and toxic attributes. Phase 2 of this project involves developing risk assessment guidance for promoting consistency among OECD member countries in the understanding and application of available methods (empirical and model-based) for assessing ecological risks of pesticides with varying PBT profiles.

Annex

Overview of main POPs/PBT criteria

	Persistence	**Bioaccumulation**	**Long-range transport potential**	**Toxicity**
UNECE POPs protocol[1]	Half life in water > 60 d, sediment > 180 d, soil > 180 d **or** evidence chemical is otherwise sufficiently persistent	BCF > 5000 **or** BAF > 5000 **or** Log K_{ow} > 5	Half-life air > 2 day **and** Vapour Pressure < 1000 Pa, **or** detected in remote areas	Potential to adversely affect HH and/or ENV
UNEP POPs Convention	Half life in water > 60 d, sediment > 180 d, soil > 180 d **or** evidence chemical is otherwise sufficiently persistent	BCF > 5000 **or** BAF > 5000 **or** Log K_{ow} > 5 **or** evidence of other reasons for concern, **or** monitoring data indicating the bio-acc. potential	Half-life air > 2 days **or** detected in remote areas	Potential to adversely affect HH and /or ENV **or** toxicity or ecotoxicity data indicating potential for damage to HH and ENV
OSPAR[2] PBT criteria	Half life in water ≥ 50 d	BCF ≥ 500 **or** Log K_{ow} > 4	NA	Acute aquatic toxicity L(E)C50 ≤ 1 mg/L **or** long term NOEC ≤ 0.1 mg/L **or** mammalian toxicity: CMR or chronic toxicity
EU PBT criteria REACH	Half life in marine water > 60 d, fresh water > 40 d, marine sediment > 180 d, freshwater sediment > 120 d, soil > 120 d	BCF > 2000	NA	long term aquatic NOEC ≤ 0.01 mg/L **or** CMR: carc and mut cat 1A , cat 1B [3]**or** reprotoxic cat 1A, cat 1B or cat 2 [2] **or** other evidence of chronic toxicity STOT-RE cat 1, cat 2
EU vPvB criteria REACH	Half life in marine or fresh water > 60 d, marine or fresh water sediment > 180 d, Soil > 180 d	BCF > 5000	NA	NA

[1] *1998 Aarhus Protocol on Persistent Organic Pollutants*
[2] *Convention for the Protection of the Marine Environment of the North-East Atlantic*
[3] *Based on CLP Regulation (EC) No 1272/2008*

	Persistence	**Bioaccumulation**	**Long-range transport potential**	**Toxicity**
CEPA[4]	Half life in water ≥ 180 d, sediment ≥ 365 d, soil ≥ 180 d	BAF [5][6] ≥ 5000 **or** BCF[7] ≥ 5000 **or** Log K_{ow} ≥ 5	Half-life air ≥ 2 days[8]	Inherently toxic (proposed acute aquatic ≤ 1 mg/L **or** chronic aquatic toxicity of NOEC ≤ 0.1 mg/L, 2007, HH under development)
US EPA Control Action	Half life aquatic environment > 60 d	BCF > 1000	NA	Toxicity data based on level of concern
US EPA Ban Pending	Half life aquatic environment > 180 d	BCF > 5000	NA	Toxicity data based on level of concern
US EPA PBT profiler	Half life moderate concern water > 60 d, sediment > 60 d, soil > 60 d Half life high concern water > 180 d, sediment > 180 d, soil > 180 d	Moderate BCF > 1000 High BCF > 5000	NA	Moderate chronic aquatic toxicity of NOEC 0.1-10 mg/L High chronic aquatic toxicity of NOEC < 0.1 mg/L

[4] *Canadian Environmental Protection Act*

[5] *BAF = Ratio of the concentration of a substance in an organism to the concentration in water, based on uptake directly from the surrounding medium and food*

[6] *BAF are preferred over BCF, in absence of BAF or BCF, Log K_{ow} may be used*

[7] *BCF = Ratio of the concentration of a substance in an organism to the concentration in water, based only on uptake directly from the surrounding medium*

[8] *A substance may be considered as persistent in air if it is shown to be subject to atmospheric transport to remote regions such as the arctic*

Classification criteria in accordance with GHS Rev.2 and GHS Rev.3

Effects on the aquatic environment

Acute hazard categories toxicity

GHS Rev 2/and Rev 3	Category : Acute 1 [9) 10)]	Category : Acute 2*	Category : Acute 3*
96 hr LC_{50} (fish) 48 hr EC_{50} (crustacea/daphnia) 72 hr or 96 hr ErC_{50} (algae/aquatic plants)	≤ 1 mg/L	> 1 - ≤ 10 mg/L	>10 - ≤ 100 mg/L

Chronic hazard categories toxicity

GHS Rev 2 and Rev 3[11]	Category : Chronic 1 [9)10)]	Category : Chronic 2	Category : Chronic 3
96 hr LC_{50} (fish) 48 hr EC_{50} (**crustacea**) 72 hr or 96 hr ErC_{50} (algae/**aquatic plants**)	≤ 1 mg/L	> 1 - ≤ 10 mg/L	> 10 - ≤ 100 mg/L
- **Rapidly** degradability, and/or	No	No	No
- Potential to bioaccumulate:			
- log **Kow,** unless	≥ 4	≥ 4	≥ 4
- BCF	≤ 500	≤ 500	≤ 500
- Unless chronic toxicity NOECs		> 1 mg/L	> 1 mg/L

[9] GHS: Category Acute 1 may be subdivided for some regulatory systems to include a lower band at L(E)C50≤0.1 mg/l
[10] CLP: When classifying substances as Acute Category 1 and/or Chronic Category 1 it is necessary at the same time to indicate an appropriate M-factor.
* Not included in CLP(Regulation (EC) No 1272/2008
[11] Substances for which adequate chronic toxicity data is not available

GHS Rev 3	Category : Chronic 1	Category : Chronic 2
Non-rapidly degradable substances for which there are adequate chronic toxicity data avaialble Chronic NOEC or EC_x (fish) and/or Chronic NOEC or EC_x (**crustacea**) and/or Chronic NOEC or EC_x (algae**/aquatic plants**)	$\leq$ 0.1 mg/L	$\leq$ 1 mg/L

'Safety net'

The GHS system introduces as "safety net" classification for use when the data available do not allow classification under the formal criteria but there are nevertheless some grounds for concern (Chronic 4).

GHS Rev 2 and Rev 3	Category : Chronic 4

- Water solubility (Sw)
- **Rapidly** degradability, and/or
- Potential to bioaccumulate:
  - log **Kow**, unless
  - BCF
- Unless chronic toxicity NOECs
	The precise criteria are not defined with one exception:
	
	< 1mg/l
	No
	
	$\geq$ 4
	$\leq$ 500
	> 1 mg/l