

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**

26 November 2018

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Geneva, 5-7 December 2018

Item 8 of the provisional agenda

Programme of work for the biennium 2019-2020

Preparation of the work programme for the biennium 2019- 2020 – Continuation of work on non-animal testing

**Transmitted by the experts from the Netherlands and the United
Kingdom on behalf of the informal working group on the use of non-
animal test methods for classification of health and environmental
hazards**

Background

1. The terms of reference the Sub-Committee gave to the informal working group on non-animal test methods (INF.27/Rev.2, thirty-first session) set out four main activities:
 - (a) To identify and evaluate the available *in vitro* and *in chemico* test methods, validated at the international level, and the existing guidance on *in silico* methods, including grouping approaches, quantitative structure activity relationship (QSARs) and read-across, that could be useful for GHS hazard classification for health hazard and environmental hazard classes, using a step-wise approach, starting with a hazard class to be determined by the Group;
 - (b) To assess for each hazard class whether an integrated or tiered evaluation approach should be developed, taking into account all relevant scientific information and combination of methods for hazard classification, and where substances and mixtures may be classified using non-animal methods, whether new or amended GHS classification criteria are needed;
 - (c) To prepare draft amendments and additions to the GHS to facilitate hazard classification using non-animal methods where appropriate, taking into account relevant limitations and uncertainties. The amendments and additions should include as appropriate classification criteria, notes, decision logics, tiered evaluation and guidance, and should take into account the needs of all sectors;
 - (d) To report progress to the GHS Sub-Committee as appropriate.
2. The informal working group has around 50 members, reflecting the interest in its work. The latest status updates are informal documents INF.28 (thirty-sixth session) and INF.25 (thirty-fifth session).

3. The informal working group identified at an early stage that skin corrosion/irritation would be a good starting point for this work, as internationally accepted and validated *in vitro/ex vivo* test methods are well established. In the current biennium the group has worked almost exclusively on revising Chapter 3.2 of the GHS. The outcome of this work, in the form of a proposal for a revision of this chapter to fully incorporate non-animal test methods, is presented to the Sub-Committee for consideration at its December meeting in Document ST/SG/AC.10/C.4/2018/29 and informal document INF.6 (Rev 1).

Proposal

4. If the Sub-Committee is generally content with its approach, the informal working group proposes to continue working in a stepwise manner, and build on the work undertaken so far.

5. Taking into account the general state of developments in non-animal testing methods and approaches, the working group proposes to address the following specific workstreams in 2019/20 within its existing terms of reference (paragraph 1 above):

Workstream 1 To review and revise Chapter 3.3, Serious Eye Damage, Eye Irritation, following as appropriate the work already done on Chapter 3.2.

Workstream 2 To review and revise Chapter 3.4 in regard to skin sensitisation.

6. As part of Workstream 1, the working group will consider again the specific issue of classification using pH to resolve, in particular, the current ambiguity on whether the appropriate classification is corrosive or inconclusive where a substance or mixture has extreme pH and low acid/alkaline reserve. In considering paragraphs 3.3.2.2.4 and 3.3.3.1.2 in Chapter 3.3, the working group will also consider whether the outcome of its discussions should be applied to the corresponding parts of Chapter 3.2, and if appropriate revise section 3.2.2.5 and paragraph 3.2.3.1.3 as presently set out in Annex 2 of INF.6 (rev 1). This will address a specific issue for classification as skin corrosive using pH that could not be resolved in the current biennium, and where the existing position in GHS rev 7 has been retained pending further work.

7. The Sub-Committee is invited to agree the work programme for 2019/20 proposed in paragraphs 5 and 6 above for the informal working group on non-animal testing.
