
**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
Transport of Dangerous Goods
Tenth session
Geneva, 7-9 December 2005
Item 2 (b) of the provisional agenda

UPDATING OF THE GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND
LABELLING OF CHEMICALS (GHS)

Carcinogenicity Potency Estimation Methods

Transmitted by the Organization for Economic Co-operation and Development (OECD)

1. The mandate initially given by the UN Sub-Committee of Experts on the GHS for the biennium 2003-2004 was to start examining methods for potency estimation. In December 2004, the Sub-Committee agreed that the work should be completed in 2006, and a scientific issue paper should be submitted in 2005.
2. The OECD Expert Group on Carcinogenicity started working on this issue in the beginning of 2004. A draft description of existing carcinogenicity potency estimation methods used in different countries/region was proposed by Norway experts, and comments were requested at an early stage.
3. There was no agreement, at the February 2005 Task Force Meeting, on providing the UN SCEGHS with the draft description of methods, and it was stressed that more work is needed to describe the strengths and weaknesses, domain of applicability, and the type of expertise required to use the methods. However, no country supplemented or proposed to supplement the draft description proposed by Norway. Taking note that not all countries are willing to pursue the work on this issue, the Task Force agreed, in February 2005, on only providing the UN SCEGHS with a very short status report.
4. At the UN SCEGHS that was held on 11-13 July 2005, the OECD Secretariat presented a short status report on carcinogenicity potency estimation methods (see Annex 1) and requested the advice of the Sub-Committee on whether or not the work should be continued.
5. Several delegations considered that, due to difficulty in agreeing on the use of potency estimation methods, the work should be discontinued for the time being. The Sub-Committee finally decided to ask the OECD to come to a conclusion on this issue and to present a report at the December session.

Conclusion of the OECD Task Force on Harmonization of Classification and Labelling*

Considering that for the time being,

- (i) there is no agreement on whether potency estimation method should be used for deriving specific concentration limits for certain carcinogenic mixtures, or only for risk assessment,
- (ii) providing a description of carcinogenicity potency estimation methods with strengths and weaknesses, domain of applicability and type of expertise potency would require a substantial amount of work from carcinogenicity experts, which would only be justified if an agreement on using potency estimation methods for deriving specific concentration limits for certain carcinogenic mixtures seems possible,

the work on carcinogenicity potency estimation methods should be discontinued for the time being and a decision on whether or not to restart it should be taken later.

* *The UN SCEGHS request to report at the next December meeting does not allow the consultation of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology.*

Annex 1

(Status report on carcinogenicity potency estimation methods submitted by the OECD at the 9th session of the UN SCEGHS).

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

Ninth session, 11-13 July 2005

Item 2 (b) (iii) of the provisional agenda

**UPDATING OF THE GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING
OF CHEMICALS (GHS)**

Health hazards

Status report on carcinogenicity potency estimation methods

Transmitted by the Organization for Economic Co-operation and Development (OECD)

1. Many substances have been identified as carcinogens from rodent bioassays and classified according to the strength and weight of this evidence. In general, no specific considerations are given to the carcinogenic potency of the substance. Also, the GHS criteria for classification of mixtures containing carcinogens do not reflect the potency of a carcinogen in a mixture or the preparation as such. This general classification system for carcinogenic mixtures does not take into account the wide range of carcinogenic potency that can be observed both in human epidemiological studies and in animal experiments (Allen et al., 1988; Gold et al., 1989). Several methods have been developed to estimate carcinogenic potency for use for varied purposes. The listing provided below may be representative of these methods, which will be further investigated for strengths and weaknesses. The use of these methods requires expert judgement and experience in the use and interpretation of the potency estimate. It may be possible, based on some methods for potency estimation, to derive specific concentration limits for certain carcinogenic mixtures (GHS Section 1.3.3.2).

2. Accurate and reliable potency estimates based upon human data have preference above those based on animal data. However, as reported by Allen and colleagues (Allen et al., 1988), there are several difficulties in evaluating human data, such as e.g. establishing reliable quantitative estimates of human exposure doses and differentiation of problems associated with mixed exposures. Therefore, in most cases, human data are unlikely to be helpful in spite of the obvious species relevance. There are several approaches available for determining potency of carcinogens or dose descriptors from animal data. Ideally, mechanistic data would be available to support the application of a chemical-specific biologically-based model. In the absence of such data, several potency estimation methods have been developed: ‘TD50’, ‘TI’, ‘TDx’, ‘T25’, ‘LED10/ED10’, Slope factor/unit risk’.

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