

UN/SCEGHS/3/INF.12

**Sub-Committee of Experts on the Globally
Harmonized System of Classification
and Labelling of Chemicals**
**(Third session, 10-12 July 2002,
agenda item 3)**

Norwegian Pollution Control
Authority
P.O.Box 8100 Dep, N-0032
Oslo, Norway
Visiting address:
Strømsveien 96

Telephone: +47 22 57 34 00
Telefax: +47 22 67 67 06
E-mail: postmottak@sft.no
Internet: www.sft.no

Possible areas of future work

Transmitted by the expert from Norway

Introduction

Proposal for changes in chapter 3. Carcinogenicity of the document ST/SG/AC.10/C.4/2002/2.

Proposal and justifications for 3.1 Estimating Potency for Labelling Limits

The following text is proposed to be added as a last paragraph in section 3.1. The item is linked to the objective of this section as well as to 3.2:

“In paragraph 9, chapter 3.6 of the criteria, a number of factors are mentioned which may increase or decrease the level of concern that an agent may pose a carcinogenic hazard in humans. These considerations (weight of evidence) are important in the assessment of carcinogenic hazards for classification purposes as well as for potency estimations for labelling limits. Guidance on the importance of these factors has to be elaborated in order to indicate their effects or level of concern “.

Proposal and justification for 3.2 Factors to be taken into consideration when assessing carcinogenic hazards

The two different issues in paragraph 3.2. should be distinguished and the following wording is proposed:

“Objective: To develop guidance on the importance of the different factors mentioned in paragraph 9, chapter 3.6 and on the principles necessary to resolve a number of scientific questions arising for classification of chemicals

In paragraph 9, chapter 3.6, a number of factors are mentioned which may increase or decrease the level of concern that an agent may pose a carcinogenic hazard in humans. These considerations (weight of evidence) are important in the assessment of carcinogenic hazards for classification purposes as well as for potency estimations for labelling limits. Guidance on the importance of these factors has to be elaborated in order to indicate their effects or level of concern. “

The proceedings of a WHO/IPCS working group on harmonized risk assessment for carcinogenicity points to a number of scientific questions arising for classification of chemicals e.g. mouse liver tumours, peroxisome proliferation, receptor-mediated reactions, chemicals which are carcinogenic only at toxic doses and which do not demonstrate mutagenicity. Accordingly, there is a need to articulate the principles necessary to resolve these scientific issues, which have led to diverging classifications in the past. Once these issues are resolved, there would be a firm foundation for classification of a number of chemical carcinogens. (Excerpt from Chapter 3.6, paragraph 16.)