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**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

REPORT OF THE SUB-COMMITTEE OF EXPERTS
ON ITS NINTH SESSION
11-12 (a.m.) July 2005

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REPORT

ATTENDANCE

1. The Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals held its ninth session in Geneva from 11 to 12 July 2005 with Ms. Kim Headrick (Canada) as Chairperson, Mr. Roque Puiatti (Brazil) and Mr. Gregory Moore (Sweden) as Vice-chairpersons.
2. Experts from the following countries took part in the session: Argentina, Australia, Austria, Belgium, Brazil, Canada, China, Denmark, Finland, France, Germany, Ireland, Italy, Japan, Mexico, Netherlands, New Zealand, Norway, Qatar, Senegal, South Africa, Spain, Sweden, United Kingdom and the United States of America.
3. Under rule 72 of the rules of procedure of the Economic and Social Council, observers from the following countries took part: Gambia, Indonesia, Nigeria, Philippines, Russian Federation, Slovenia, Switzerland and Thailand.
4. Representatives of the United Nations Environment Programme (Secretariat of the Basel Convention) (UNEP/SCB) and of the United Nations Institute for Training and Research (UNITAR) were present.
5. The following intergovernmental organizations were represented: European Commission (EC), Organization for Economic Co-operation and Development (OECD).
6. Representatives of the following non-governmental organizations took part in the discussion of items of concern to their organizations: Croplife International, European Chemical Industry Council (CEFIC), Compressed Gas Association (GCA), Dangerous Goods Advisory Council (DGAC), Detergent and Maintenance Products Industry (AISE), European Industrial Gases Association (EIGA), International Council of Chemical Associations (ICCA), Industrial Federation of Paints and Coats of Mercosul (IFPCM), International Petroleum Industry Environmental Conservation Association (IPIECA), International Organization for Standardization (ISO), International Paint and Printing Ink Council (IPPIC) and Soap and Detergent Association (SDA).

ADOPTION OF THE AGENDA

Document: ST/SG/AC.10/C.4/17

Informal document: UN/SCEGHS/9/INF.1

7. The Sub-Committee adopted the provisional agenda prepared by the secretariat, after amending it to include late submissions of informal documents (INF.1 to INF.22).
8. The expert from France withdrew document UN/SCEGHS/9/INF.12.

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

Physical hazards

Informal document: UN/SCEGHS/9/INF.6 (Germany)

9. After the presentation of the document made by the expert from Germany, the Chairman of the

Sub-Committee of Experts on the Transport of Dangerous Goods (TDG Sub-Committee), informed the GHS Sub-Committee that the TDG Sub-Committee had agreed to work on the issues raised in INF.6, as the focal point on physical hazards, if it were requested to do so by the GHS Sub-Committee, on the understanding that experts from the supply and storage sector would be involved in the work.

10. There was no objection to the principle to work on the issues raised in INF.6, but the decision would have to be taken at the December session since these issues had been raised informally. The Chairperson invited those who were willing to participate in the preparatory work for the December meeting to inform the expert from Germany before the end of July.

Informal document: UN/SCEGHS/9/INF.20 (Secretariat)

11. The Sub-Committee endorsed, with some modifications, the draft amendments to the GHS text proposed by the secretariat on the basis of the decisions taken by the TDG Sub-Committee at its 27th session (see annex).

Health hazards

Carcinogenicity

Document: ST/SG/AC.10/C.4/2005/2 (OECD)

12. The proposal contained in this document was adopted without modifications (see annex).

Informal document: UN/SCEGHS/9/INF.4 (OECD)

13. The representative of the OECD updated the Sub-Committee on the status of the carcinogenicity potency estimation methods and requested the advice of the Sub-Committee on whether or not the work should be continued.

14. Several delegations considered that, due to the difficulty in agreeing on the use of potency estimation, the work should be discontinued for the time being.

15. The Sub-Committee finally decided to ask the OECD Technical Focal Point on health hazards to come to a conclusion on this issue and to present a report at the December session.

Toxic to reproduction substances

Document: ST/SG/AC.10/C.4/2005/3 (OECD)

16. Following the presentation of the scientific issue paper on reproductive toxicity potency, the Sub-Committee took note of the fact that the available scientific knowledge on this issue does not allow a general revision of the existing classification criteria and that none of the identified possible sources of additional information could provide any additional input on reproductive toxicity potency.

Guidance on carcinogenicity and reproductive toxicity potency

17. Some delegations were of the opinion that the guidance developed by the OECD was rather general and that there could still be situations where the same chemical would be classified differently depending on the country. More concrete examples would be particularly helpful to those countries which do not have experience in the sound management of chemicals.

18. Others suggested that posting examples and approaches on the UNECE or UNITAR website

might be useful. Delegations were encouraged to submit written proposals for consideration at the next Sub-Committee meeting.

Miscellaneous proposals

Document: ST/SG/AC.10/C.4/2005/4 (Germany)

19. Several comments were made on the proposal presented by the expert from Germany, particularly with reference to the rationale for the inclusion of the vapour pressure cut-off value in a precautionary statement in Annex 3 rather than in the corresponding chapter of the GHS, as well as to the rationale for the cut-off value itself.

20. The expert from Germany explained that the document was presented as a basis for discussion and that he intended to submit a revised proposal in the future, taking into account the comments received. Delegations which so wished were invited to send him any additional comments in writing.

Environmental hazards

Informal document: UN/SCEGHS/9/INF.13 (Spain)

21. The expert from Spain informed the Sub-Committee of its intention to set up a working group which will address terrestrial environmental hazards and prepare a proposal for their classification. Experts interested in participating in the work were invited to contact the Spanish expert by email, at the address indicated in the document, before 10 September 2005.

Informal document: UN/SCEGHS/9/INF.19 (Secretariat)

22. The representative from OECD informed that this document, containing a draft detailed comparison of classification and labelling systems for Ozone Depleting Chemicals, had not yet been submitted to the OECD Task Force on Harmonization of Classification and Labelling nor to the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology.

23. Experts were encouraged to send comments to the representative of the OECD by the end of August.

HAZARD COMMUNICATION ISSUES

Guidance on the interpretation of the building block approach

Informal document: UN/SCEGHS/9/INF.2 (Canada)

24. The Sub-Committee had an informal discussion on the interpretation of the building block approach. After some exchange of views, there appeared to be a common interpretation that both hazard classes and hazard categories could be considered as building blocks within the GHS. Each sector would have the choice to select the hazard classes, and within them, the hazard categories which are applicable to it. In the case of the transport sector, for example, within the hazard class of acute toxicity only categories 1, 2 and 3 are regulated, and some GHS hazard classes are not subject to transport regulations (for example, toxic to reproduction hazard or carcinogenicity).

25. Once the hazard class and category have been chosen, the cut-off values for those hazard classes and/or categories should be applied in accordance with the GHS. The same applies for the hazard communication elements assigned to those hazard classes and/or categories.

26. The observers from pilot countries noted that the development of guidance on which building blocks should be chosen for each sector would be very useful in the case of those countries which do not have any chemical management system in place. They also expressed their willingness to apply the GHS to all sectors.

27. A member of the secretariat recalled that, for the transport sector, they should follow the UN Model Regulations on the Transport of Dangerous Goods.

28. Most of the delegations were of the opinion that the Safety Data Sheets (SDS) should be considered as being an independent building block.

29. Concerning harmonization among sectors, the Sub-Committee considered that making an assessment at this stage of implementation would be premature. However, it was also considered that this issue will become more and more important in forthcoming sessions.

30. Finally, delegations were invited to submit documents on the implementation of the building block approach to the next meeting for further discussion.

Miscellaneous proposals

Document: ST/SG/AC.10/C.4/2005/1 (Chairperson)

Informal document: UN/SCEGHS/9/INF.8 (Australia)

31. There was general support for the standardization of the numbering of hazard statements for ease of reference and practical implementation of the GHS.

32. Most of the delegations were in favour of the Australian approach, since it allows the grouping of hazard statements depending on the type of hazards they are related to (physical, health or environmental hazards) as well as more flexibility for further developments, particularly for the allocation of new codes, if needed.

33. A joint revised proposal will be submitted to the December session for formal decision.

Informal document: UN/SCEGHS/9/INF.7 (Australia)

34. The Sub-Committee welcomed the proposal for the codification of precautionary statements. Some delegations expressed the wish that such a codification system be as simple as possible and avoid duplication of precautionary statements with similar meanings.

35. The expert from Australia said that he would submit a revised proposal for the December session.

Informal document: UN/SCEGHS/9/INF.16 (CEFIC)

36. For the Detailed Review Document on current provisions in existing systems for the labelling of very small packagings, the Sub-Committee was informed that a questionnaire had been sent to its members with a request for it to be completed and returned to CEFIC by the end of August 2005.

37. The results will be compiled in a new document which will be submitted by CEFIC to the next session.

IMPLEMENTATION OF THE GHS

Reports from Governments or organizations

Informal documents: UN/SCEGHS/9/INF.5 (Brazil)
UN/SCEGHS/9/INF.14 (European Commission)
UN/SCEGHS/9/INF.17 (Canada)
UN/SCEGHS/9/INF.18 (IPPIC)
UN/SCEGHS/9/INF.22 (Secretariat)

38. A number of countries and organizations updated the Sub-Committee on their progress in implementing the GHS. In particular, the representatives of the pilot countries (Senegal, Thailand, Nigeria, Gambia, Indonesia Philippines and Slovenia) thanked UNITAR and their sponsoring countries and organizations for their support and informed the Sub-Committee about the different activities in progress in their countries (analysis and identification of institutes, comprehensibility tests, development and evaluation of their respective National Profile on chemicals, establishment of work plans in cooperation with stakeholders, etc).

39. The Chairperson encouraged countries (especially developing countries) and organizations to inform the Sub-Committee about their action plans for implementation of the GHS and to submit reports on its degree of implementation. She requested that this information be provided to the Sub-Committee preferably in the form of informal documents, which will then be made publicly available on the UNECE website.

Cooperation with other international organizations

Conference of the Parties to the Basel Convention

Informal documents: UN/SCEGHS/9/INF.11 (Secretariat)
UN/SCEGHS/9/INF.21 (Secretariat)

40. The Sub-Committee had before it INF.11 concerning decision VII/17 taken by the Conference of the Parties at its seventh meeting, on the establishment of a working relationship between the Open Ended Working Group (OEWG) of the Basel Convention and the Sub-Committee.

41. The representative of the Secretariat of the Basel Convention informed the Sub-Committee that the OEWG had agreed on the establishment of a correspondence group and that the agreed terms of reference were reproduced in document INF.21 for consideration and final endorsement, if agreed, by the Sub-Committee.

42. The Sub-Committee endorsed the terms of reference of the correspondence group submitted by the OEWG of the Basel Convention and invited all interested delegations to communicate the name of the nominated experts to the secretariat before the end of August.

United Nations Economic Commission for Europe

Informal document: UN/SCEGHS/9/INF.15 (Secretariat)

43. The Sub-Committee took note of the decision of the United Nations Centre for Trade Facilitation and Electronic Business (UN/CEFACT) Plenary to request the International Trade and Business Processes Permanent Group (TBG) to take into account the GHS provisions for the drafting of a revised document on Safety Data Sheet Business Specification which should be then submitted for review and approval of the Plenary.

CAPACITY BUILDING

Informal documents: UN/SCEGHS/9/INF.9 (Japan)
UN/SCEGHS/9/INF.10 (UNITAR)

44. The expert from Japan and the representative from UNITAR reported on progress and various events, seminars, workshops, training programmes and capacity building programme activities organized at national and regional level.

45. The representative of UNITAR said that pilot countries were looking forward to exchanging information on implementation issues, such as a transitional period for the implementation of the GHS, and that any guidance developed by the Sub-Committee would be of utmost help.

COORDINATION AND WORK PROGRAMME

Informal document: UN/SCEGHS/9/INF.3 (Secretariat) (Report of the 14th meeting of the Task Force on Harmonization of Classification and Labelling, Paris, February 2005).

46. The representative of the OECD briefly summarized the status of the work concerning toxic gas mixtures, sensitization/elicitation, chronic hazards for the aquatic environment and validation of the transformation/dissolution protocol. The fifteenth Task Force Meeting will be held in Rome, in March 2006.

ADOPTION OF THE REPORT

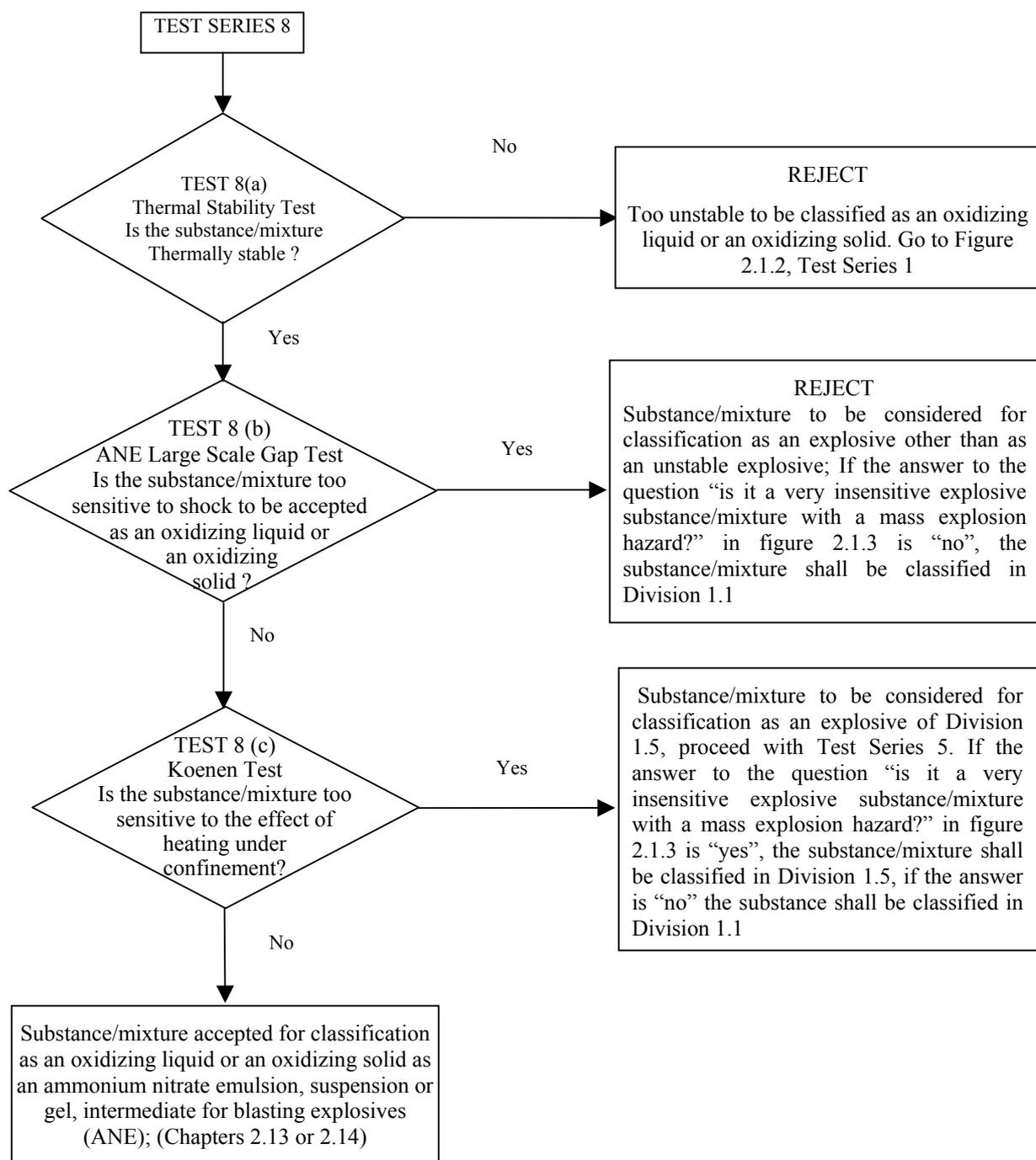
47. The Sub-Committee adopted the report on its ninth session and the annex thereto on the basis of a draft prepared by the secretariat.

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AnnexDraft amendments to the first revised edition of the Globally Harmonized System of Classification and Labelling of Chemicals

PART 2

Chapter 2.1 Figure 2.1.4 Amend to read as follows:



Chapter 2.16

Table 2.16.1 Amend the criteria to read as follows:
 “Corrosion rate on either steel or aluminium surfaces exceeding 6.25 mm per year at a test temperature of 55 °C when tested on both materials.”.

Add the following new note under the table:

“NOTE: Where an initial test on either steel or aluminium indicates the substance being tested is corrosive the follow up test on the other metal is not required.”

Consequential amendments: The same amendment as the one in table 2.16.1, applies to decision logic 2.16 (paragraph 2.16.4.1) and table A2.16 in Annex 2.

PART 3

Chapter 3.6

3.6.2.5.2 Add the following sentence at the end of the paragraph, after the last sub-paragraph:

“Guidance on how to consider important factors in classification of carcinogenicity is included in 3.6.5.3”.

3.6.5.3 Renumber the paragraph starting with “Excerpts from monographs...” as 3.6.5.3.1. Current paragraphs 3.6.5.3.1, 3.6.5.3.1.1, 3.6.5.3.1.2 and 3.6.5.3.2 become 3.6.5.3.1.1, 3.6.5.3.1.1.1, 3.6.5.3.1.1.2 and 3.6.5.3.1.2 respectively.

Move current footnote 4 (currently in the title, after “guidance”) to the renumbered paragraph 3.6.5.3.1, after “Excerpts”.

3.6.5.3.2 Insert the following new sub-section:

“3.6.5.3.2 Guidance on how to consider important factors in classification of carcinogenicity”*

The guidance provides an approach to analysis rather than hard and fast rules. This section provides some considerations. The weight of evidence analysis called for in GHS is an integrative approach which considers important factors in determining carcinogenic potential along with the strength of evidence analysis. The IPCS “*Conceptual Framework for Evaluating a Mode of Action for Chemical carcinogenesis*” (2001), the ILSI “*Framework for Human Relevance Analysis of Information on Carcinogenic Modes of Action*” (Meek et al., 2003; Cohen et al., 2003, 2004) and the IARC (Preamble section 12(b)) provide a basis for systematic assessments which may be performed in a consistent fashion internationally; the IPCS also convened a panel in 2004 to further develop and clarify the human relevance framework. However, the internationally available documents are not intended to dictate answers, nor provide lists of criteria to be checked off.

3.6.5.3.2.1 Mode of action

The various international documents on carcinogen assessment all note that mode of action in and of itself, or consideration of comparative metabolism, should be evaluated

on a case by case basis and are part of an analytic evaluative approach. One must look closely at any mode of action in animal experiments taking into consideration comparative toxicokinetics/toxicodynamics between the animal test species and humans to determine the relevance of the results to humans. This may lead to the possibility of discounting very specific effects of certain types of chemicals. Life stage-dependent effects on cellular differentiation may also lead to qualitative differences between animals and humans. Only if a mode of action of tumor development is conclusively determined not to be operative in humans may the carcinogenic evidence for that tumor be discounted. However, a weight of evidence evaluation for a substance calls for any other tumorigenic activity to be evaluated as well.

3.6.5.3.2.2 Responses in multiple animal experiments

Positive responses in several species add to the weight of evidence, that a chemical is a carcinogen. Taking into account all of the factors listed in 3.6.2.5.2 and more, such chemicals with positive outcomes in two or more species would be provisionally considered to be classified in GHS Category 1B until human relevance of animal results are assessed in their entirety. It should be noted, however, that positive results for one species in at least 2 independent studies, or a single positive study showing unusually strong evidence of malignancy may also lead to Category 1B.

3.6.5.3.2.3 Responses are in one sex or both sexes

Any case of gender-specific tumors should be evaluated in light of the total tumorigenic response to the substance observed at other sites (multi-site responses or incidence above background) in determining the carcinogenic potential of the substance.

If tumors are seen only in one sex of an animal species, the mode of action should be carefully evaluated to see if the response is consistent with the postulated mode of action. Effects seen only in one sex in a test species may be less convincing than effects seen in both sexes, unless there is a clear patho-physiological difference consistent with the mode of action to explain the single sex response.

3.6.5.3.2.4 Confounding effects of excessive toxicity or localized effects

Tumors occurring only at excessive doses associated with severe toxicity generally have doubtful potential for carcinogenicity in humans. In addition, tumors occurring only at sites of contact and/or only at excessive doses need to be carefully evaluated for human relevance for carcinogenic hazard. For example, forestomach tumors, following administration by gavage of an irritating or corrosive, non-mutagenic chemical, may be of questionable relevance. However, such determinations must be evaluated carefully in justifying the carcinogenic potential for humans; any occurrence of other tumors at distant sites must also be considered.

3.6.5.3.2.5 Tumor type, reduced tumor latency

Unusual tumor types or tumors occurring with reduced latency may add to the weight of evidence for the carcinogenic potential of a substance, even if the tumors are not statistically significant.

Toxicokinetic behaviour is normally assumed to be similar in animals and humans, at least from a qualitative perspective. On the other hand, certain tumor types in animals may be associated with toxicokinetics or toxicodynamics that are unique to the animal species tested and may not be predictive of carcinogenicity in humans. Very few such examples have been agreed internationally. However, one example is the lack of human relevance of kidney tumors in male rats associated with compounds causing α 2u-globulin nephropathy (IARC, Scientific Publication N° 147). Even when a particular tumor type may be discounted, expert judgment must be used in assessing the total tumor profile in any animal experiment.”.

* Cohen, S.M., J. Klaunig, M.E. Meek, R.N. Hill, T. Pastoor, L. Lehman-McKeeman, J. Bucher, D.G. Longfellow, J. Seed, V. Dellarco, P. Fenner-Crisp, and D. Patton. 2004. *Evaluating the human relevance of chemically induced animal tumors*. Toxicol. Sci., 78(2): 181-186.

Cohen, S.M., M.E. Mcke, J.E. Klaunig, D.E. Patton, P.A. Fenner-Crisp. 2003. *The human relevance of information on carcinogenic modes of action: overview*. Crit. Rev. Toxicol. 33(6), 581-9.

Meek, M.E., J.R. Bucher, S.M. Cohen, V. Dellarco, R.N. Hill, L. Lehman-McKeeman, D.G. Longfellow, T. Pastoor, J. Seed, D.E. Patton. 2003. *A framework for human relevance analysis of information on carcinogenic modes of action*. Crit. Rev. Toxicol., 33(6), 591-653.

Sonich-Mullin, C., R. Fielder, J. Wiltse, K. Baetcke, J. Dempsey, P. Fenner-Crisp, D. Grant, M. Hartley, A. Knapp, D. Kroese, I. Mangelsdorf, E. Meek, J.M. Rice, and M. Younes. 2001. *The Conceptual Framework for Evaluating a Mode of Action for Chemical Carcinogenesis*. Reg. Tox. Pharm. 34, 146-152.

International Programme on Chemical Safety Harmonization Group. 2004 *Report of the First Meeting of the Cancer Working Group*. World Health Organization. Report IPCS/HSC-CWG-1/04. Geneva

International Agency for Research on Cancer. *IARC Monographs on the Evaluation of Carcinogenic Risks to Human. Preambles to volumes*. World Health Organization. Lyon, France.

S.M. Cohen, P.A. Fenner-Crisp, and D.E. Patton. 2003. *Special Issue: Cancer Modes of Action and Human Relevance*. Critical Reviews in Toxicology, R.O. McClellan, ed., Volume 33/Issue 6. CRC Press.

C.C. Capen, E. Dybing and J.D. Wilbourn. 1999. *Species differences in Thyroid, Kidney and Urinary Bladder Carcinogenesis*. International Agency for Research on Cancer, Scientific Publication N° 147.”
