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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

<u>Sub-Committee of Experts on the Globally Harmonized</u> System of Classification and Labelling of Chemicals

REPORT OF THE SUB-COMMITTEE OF EXPERTS ON ITS TENTH SESSION 7 (p.m)- 8 December 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 tenth session in Geneva from 7 (p.m) to 8 December 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, Australia, Belgium, Brazil, Canada, China, Denmark, Finland, France, Germany, Ireland, Italy, Japan, Netherlands, New Zealand, Norway, Senegal, South Africa, 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, Mexico, Nigeria, Philippines, Romania, Russian Federation, Slovenia, Switzerland and Thailand.
- 4. Representatives of the United Nations Environmental Programme (Secretariat of the Basel Convention and UNEP Chemicals), of the United Nations Institute for Training and Research (UNITAR) and of the following specialized agencies were present: International Labour Office (ILO) and World Health Organization (WHO).
- 5. The following intergovernmental organizations were also represented: European Commission (EC) and 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: Compressed Gas Association (CGA), Croplife International, European Chemical Industry Council (CEFIC), European Fertilizer Manufacturers' Association (EFMA), European Industrial Gases Association (EIGA), Industrial Federation of Paints and Coats of Mercosul (IFPCM), International Association of the Soap, Detergent and Maintenance Products Industry (AISE), International Council of Chemical Associations (ICCA), International Organization for Standardization (ISO), International Paint and Printing Ink Council (IPPIC), International Technical Committee for the Prevention and Extinction of Fire (CTIF) and Soap and Detergent Association (SDA).

OPENING OF THE SESSION

- 7. The Director of the Transport Division of the Economic Commission for Europe, Mr. José Capel Ferrer, welcomed the participants. He informed the Sub-Committee of the status of the publication of the different linguistic versions of the first revised edition of the GHS and thanked those countries which made efforts to translate the GHS in their own language, emphasizing that an effective worldwide implementation of the GHS would only be possible when the system is available in a language understandable by those who have to apply it.
- 8. He also informed the Sub-Committee that the Council had adopted resolution 2005/53 without any changes to the original text of the draft resolution proposed by the Sub-Committee.
- 9. Focusing on implementation, he noted that irrespective of the efforts made by the Secretariat and organizations such as UNITAR, ILO, WHO and OECD and to promote the GHS through their programmes, Member States, and particularly those which are full members of the Sub-Committee, should show the example by taking the necessary steps to update their national legislation and by ensuring that their representatives participating in the work of treaty bodies in various sectors are

committed to the implementation of the GHS through international treaties concerned with the management of chemicals.

ADOPTION OF THE AGENDA

Document: ST/SG/AC.10/C.4/19

Informal documents: UN/SCEGHS/10/INF.1 and UN/SCEGHS/10/INF.2

10. 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).

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

(a) Physical hazards

<u>Document</u>: ST/SG/AC.10/C.4/2005/5 (Germany)

- 11. After a short presentation of the document by the expert from Germany, the Chairman of the Sub-Committee of Experts on the Transport of Dangerous Goods (TDG Sub-committee) said that the TDG Sub-Committee, as the focal point for physical hazards, had just examined the issues raised in document ST/SG/AC.10/C.4/2005/5 at its twenty-eighth session, and had agreed to carrying out the work if the GHS Sub-committee decided to pursue these matters. He also pointed out that experts from all sectors (workplace, storage, supply) should be invited to participate in the work and that the proposals contained in the German document should be further developed.
- 12. He also informed the Sub-Committee that, since most of the issued raised by Germany were related to substances having explosive properties, the TDG Sub-Committee felt that the Working Group on explosives who will meet in parallel to its plenary session next July could be entrusted with the work.
- 13. The GHS Sub-Committee finally agreed to request the TDG Sub-Committee to start considering these issues, on the understanding that the work will not be completed during the current biennium and would have to be carried forward to the next biennium.

(b) Health hazards

Respiratory and skin sensitization

<u>Document:</u> ST/SG/AC.10/C.4/2005/10 (OECD) <u>Informal documents:</u> UN/SCEGHS/10/INF.3 (OECD) UN/SCEGHS/10/INF.19 (Germany)

- 14. The Sub-Committee adopted the proposal for revision of Chapter 3.4 with one modification to paragraph 3.4.4.2 (see Annex 1).
- 15. The Sub-committee took note of the proposals for amendment of notes 1, 3 and 5 to table 3.4.1 and decision logics 3.4.5.1 and 3.4.5.2 and asked the expert from Germany to submit an official document to the July session.

Carcinogenicity potency estimation methods

Informal document: UN/SCEGHS/10/INF.4 (OECD)

16. The Sub-Committee took note of the conclusion of the OECD Task Force on Harmonization of Classification and Labelling that the work on carcinogenicity potency estimation methods should be discontinued for the time being. The representative of the OECD was requested to submit the conclusions of the OECD on this issue as an official document for the next session.

(c) Other matters

Document: ST/SG/AC.10/C.4/2005/7 (CTIF)

17. The proposal contained in the document was adopted with some modifications (see Annex 1).

Informal document: UN/SCEGHS/10/INF.6 (Secretariat)

18. There was no consensus on the exact interpretation of the terms "specific target organ/systemic toxicity" and related terminology used in Chapters 3.8 and 3.9 and the Sub-Committee felt that the question needed to be considered further to ensure consistency in the use of this terminology in the different language versions.

<u>Informal documents</u>: UN/SCEGHS/10/INF.20 (Secretariat)

UN/SCEGHS/10/INF.21 (Secretariat)

19. The Sub-Committee adopted the proposed corrections for the first revised edition of the GHS (except the one concerning the replacement of "hazard" with "toxicity" on pages 299 and 302 of the English version) with some additions and modifications (see Annex 2).

HAZARD COMMUNICATION ISSUES

(a) Hierarchy of labelling elements

Codification of hazard and precautionary statements

<u>Document</u>: ST/SG/AC.10/C.4/2005/8 (Australia)
Informal document: UN/SCEGHS/10/INF.7 (CEFIC)

- 20. There was general support for the introduction of a codification system for hazard and precautionary statements since the majority of experts considered that this would facilitate their translation and contribute to harmonization.
- 21. On the codification of hazard statements, many experts, while recognizing the merit of the Australian proposal, expressed their preference for the approach suggested by CEFIC on the understanding that a single alpha numerical code would not pose the same translation problems as a two alpha numerical code. Other experts noted that in the proposal for the development of a codification system, no consideration was given to the place where it would have to be inserted in the GHS. It was felt that the most appropriate place would be in the Annexes 2 or 3 and it was also noted that some text might be necessary in the main body of the GHS. The representative of CEFIC was requested to submit a proposal for the July session taking into account the comments received.

- 22. Regarding the codification of precautionary statements, some experts noted that since some of the proposed codes are already assigned and being used by the transport sector (i.e.: "P" for packing instructions; "PP" for special packing provisions and "PR" for particular requirements for gas cylinders and receptacles), the new codification system should avoid making use of them for different purposes.
- 23. The Sub-Committee agreed to set up of a correspondence working group, lead by CEFIC, who will submit a revised proposal for the July session.

(b) Building block approach: guidance and interpretation

<u>Document</u>: ST/SG/AC.10/C.4/2005/6 (Canada)
<u>Informal documents</u>: UN/SCEGHS/10/INF.9 (South Africa)
UN/SCEGHS/10/INF.13 (Sweden)

- 24. There was general agreement on the need to develop guidance on the interpretation of the building block approach.
- 25. Several experts shared the view of the expert from Canada that hazard classes and hazard categories are building blocks. Others, however, thought that this interpretation would be to stretch flexibility too far and would counteract harmonization within sectors.
- 26. With regard to hazard communication, many experts were concerned about the consequences of it being considered as a building block, in particular for those sectors where there are exemptions regarding labelling intended to tackle specific needs within that particular sector (for example, labelling of goods in limited quantities in transport).
- 27. In that regard, some experts thought that the exemptions applicable to each sector, if any, should be clearly identified in the GHS. Others were of the opinion that the system should focus on a general and agreed interpretation which could be shared and used by all sectors and all countries, in particular those without a system for the sound management of chemicals.
- 28. There was general support for the deletion of paragraph 1.1.3.1.5.6 in the Canadian proposal, on the grounds that risk based labelling is not a building block issue.
- 29. The Sub-Committee finally decided to establish a correspondence working group to deal with these issues (hazard classes and hazard categories as building blocks; further analysis of hazard communication elements as a building block, including transport exemptions) and to consider the need for the development of guidance material. The correspondence working group, lead by Canada, will start the work at the beginning of January 2006.

(c) Miscellaneous proposals

Labelling of very small packagings

Informal document: UN/SCEGHS/10/INF.8 (CEFIC)

30. The Sub-Committee agreed that the results of the questionnaire showed that harmonization of the requirements for the labelling of very small packagings was needed but would be challenging. However, some experts pointed out that the concept of "very small packagings" differed from one sector to another and that this should be taken into account.

- 31. On the question of possible conflict between existing transport labelling requirements and those applicable to other sectors (workplace/handling) raised by some experts, the representative of CEFIC explained that those concerns were not justified since the packagings addressed in his proposal would never be transported without being packaged in larger packagings which would bear the transport labels.
- 32. After consideration of this matter, countries were invited to study the answers given in the annex to document UN/SCEGHS/10/INF.8 and to send their comments to CEFIC by the end of January 2006. The representative of CEFIC was invited to submit a revised proposal for the July session taking into account the comments received.

Codification of GHS hazard classes and categories

Informal document: UN/SCEGHS/10/INF.15 (Australia)

- 33. There was no agreement on the proposal for the codification of hazard classes and categories in the GHS since many experts noticed that a number of codes and numbers were already used in transport regulations (for packing provisions: "B" for bulk transport, "T" for tank provisions, "M" for mixed packagings, or for class/division identification). In certain regulations, additional codes were used to reflect all hazards presented by a substance. Therefore, a more detailed analysis of existing codes might be necessary.
- 34. Several experts also felt that the purpose of this codification should be defined first, since developing a codification would present no added value if it was not used in practice.

IMPLEMENTATION OF THE GHS

(a) Reports from Governments or organizations

Pilot projects

Informal document: UN/SCEGHS/10/INF.5 (Germany/United States of America)

- 35. The Sub-Committee was informed of the results of a pilot project carried out by the European Union and the United States of America for the classification, preparation of SDS's and establishment of control banding approaches at the workplace, for methyl tert-butyl ether (MTBE) and glutaraldehyde, according to the GHS criteria.
- 36. The Sub-Committee welcomed the idea of conducting pilot projects as a useful tool to identify what guidance or assistance may be necessary to ensure the consistent application of GHS criteria worldwide.
- 37. The representatives of the OECD and WHO expressed their willingness to share with the GHS Sub-Committee the results of existing or future similar projects in their organizations.
- 38. Pursuant to the concern expressed by a member of the secretariat at the possibility that inconsistent classification lists be issued separately by several organizations as GHS validated classification lists without having been checked and endorsed by the GHS Sub-committee, it was made clear that the purpose of the pilot projects, at this stage, was not the generation of validated classification lists but the identification of possible areas for improvement in the application of the GHS classification criteria.
- 39. A number of countries expressed their wish to participate in the expanded pilot project.

GHS implementation status

Informal documents: UN/SCEGHS/10/INF.11 (South Africa)

UN/SCEGHS/10/INF.12 (Japan) UN/SCEGHS/10/INF.14 (Australia)

UN/SCEGHS/10/INF.16 and -/Corr.1 (Secretariat)

UN/SCEGHS/10/INF.18 (Brazil)

40. The Sub-Committee took note of the progress on the implementation of the GHS in various countries and through transport of dangerous goods regulations, on the basis of the information documents submitted.

- 41. The representative of the European Commission informed the Sub-committee that the preparation of a draft legal text on the GHS had already started and was expected to be ready for public internet consultation and comments during the second half of 2006. She also said that the target date for GHS implementation is 2008 and that a transitional period of some years is envisaged to enable industry to make the necessary arrangements to ensure compliance with the new classification and hazard communication provisions. During that transitional period, stakeholders will be allowed to use either the current system or the new one.
- 42. The Chairperson encouraged countries (especially developing countries) to keep the Sub-Committee informed of the progress on the implementation of the GHS in their countries, preferably in the form of informal documents, which would be made publicly available on the UNECE website.

(b) Cooperation with other international organizations

Strategic Approach to International Chemicals Management (SAICM)

Informal document: UN/SCEGHS/10/INF.22 (UNEP Chemicals)

- 43. The representative of the UNEP Chemicals presented UNEP activities concerning the development of a Strategic Approach to International Chemicals Management (SAICM) and its activities on implementation of the GHS. He also informed the Sub-Committee that the SAICM is expected to be adopted at the International Conference on Chemicals Management which will be held in Dubai in February 2006.
- 44. Some experts expressed concern at the possible overlapping between SAICM and GHS Sub-Committee activities. Others, on the contrary, were of the opinion that the SAICM will help promoting the implementation of the GHS worldwide.
- 45. A member of the Secretariat noted that the word "accompanied" in the phrase "to ensure that any hazardous material put into circulation is accompanied, at a minimum, by appropriate and reliable safety data sheets" may be misleading since in international transport it is not required that SDS accompany physically the shipments. The SDS are primarily intended for workplace safety, and emergency information during transport is obtained through other communication systems which may be specific to each mode of transport and which are consistent with the UN Recommendations on the Transport of Dangerous Goods.
- 46. The Chairperson concluded the discussion inviting countries to address their concerns, if any, on the Global Plan of Action to their respective representatives in the SAICM process.

47. The representative of UNITAR said that a GHS side-event is scheduled to take place during the International Conference in Dubai.

Secretariat of the Basel Convention

48. The representative of the Secretariat of the Basel Convention said that the GHS Basel Convention correspondence group on hazard characteristics had started its work and that the work programme and related documents were available on the Basel Convention website. He encouraged interested members of the Sub-Committee to take part in the work.

(c) Miscellaneous proposals

Informal document: UN/SCEGHS/10/INF.10 (South Africa)

- 49. Several experts, and in particular the representatives of the pilot countries of the UNITAR/ILO GHS Training and Capacity Building Programme, thought that a clear global implementation strategy should be developed, and a transitional period for implementation should be established.
- 50. In addition, they noted that in order to avoid differences in the degree of implementation among countries and sectors, a worldwide agreement on the implementation date is necessary.
- 51. Some others were of the opinion that since many countries have already taken measures for implementing the system by 2008, it could be considered that the transitional period has already started and that, in any case, the GHS being a non legally binding instrument, each country could define its own transitional period for the implementation depending on its own needs.
- 52. It was suggested that the Sub-Committee develop some guidance on transitional measures, prioritizing the goals for the implementation and defining the scope of the transitional measures. No consensus could be reached on this point and the Sub-Committee decided to revert to this issue at its next session.

CAPACITY BUILDING

Informal document: UN/SCEGHS/10/INF.17 (UNITAR)

- 53. The representative of UNITAR informed the Sub-Committee of the activities of the UNITAR/ILO Global GHS Capacity building Programme and UNITAR/ILO/OECD WSSD GHS Partnership. He encouraged the Sub-Committee to discuss implementation issues since pilot countries were looking forward to some guidance in that respect.
- 54. Representatives of the pilot countries informed the Sub-Committee of the various GHS related activities in progress in their respective countries. They underlined their difficulties to implement the system, mainly due to lack of awareness, knowledge and information about the GHS and chemicals hazards among stakeholders, numerous local languages and lack of training, resources and expertise. They also considered that the cooperation between the FAO and the GHS Sub-committee should be strengthened due to the outstanding importance of the agricultural sector in their countries.

COORDINATION AND WORK PROGRAMME

55. The representative of the OECD provided information on the status of the on-going work concerning toxic gas mixtures, strong-versus-weak sensitizers, chronic hazards for the aquatic environment, validation of the transformation/dissolution protocol and on the detailed comparison of

classification and labelling systems for ozone depleting chemicals.

- 56. For the validation of the transformation/dissolution protocol, she said that although the report of phase I had already been sent for comments, it was unlikely that the work would be completed during the current biennium.
- 57. For the work on terrestrial hazards, the expert from Austria said that the correspondence group had just started the discussions and he invited experts interested in participating in the work to contact him.

OTHER BUSINESS

Document: ST/SG/AC.10/C.4/2005/9 (Secretariat)

58. The Sub-Committee took note of the Council's resolution 2005/53, adopted on 27 July 2005, on the work of the Committee.

ADOPTION OF THE REPORT

59. The Sub-Committee adopted the report on its tenth session and the annexes thereto on the basis of a draft prepared by the secretariat.

* * * * *

Annex 1

<u>Draft amendments to the first revised edition of the Globally Harmonized System of Classification</u> and Labelling of Chemicals

Document: ST/SG/AC.10/C.4/2005/10 adopted, with some modifications, as follows:

3.4.1 Add "and general considerations" in the title after "Definitions";

Replace "induce" with "lead to" in the definition of "respiratory sensitizer" and in the definition of "skin sensitizer";

Add the following paragraphs after the definition of "skin sensitizer":

"For the purpose of this chapter, sensitization includes two phases: the first phase is induction of specialized immunological memory in an individual by exposure to an allergen. The second phase is elicitation, i.e. production of a cell-mediated or antibody-mediated allergic response by exposure of a sensitized individual to an allergen.

For respiratory sensitization, the pattern of induction followed by elicitation phases is shared in common with skin sensitization. For skin sensitization, an induction phase is required in which the immune system learns to react; clinical symptoms can then arise when subsequent exposure is sufficient to elicit a visible skin reaction (elicitation phase). As a consequence, predictive tests usually follow this pattern in which there is an induction phase, the response to which is measured by a standardized elicitation phase, typically involving a patch test. The local lymph node assay is the exception, directly measuring the induction response. Evidence of skin sensitization in humans normally is assessed by a diagnostic patch test.

Usually, for both skin and respiratory sensitization, lower levels are necessary for elicitation than are required for induction. Provisions for alerting sensitized individuals to the presence of a particular sensitizer in a mixture can be found at section 3.4.4".

- 3.4.2.1.1 and 3.4.2.2.1 In the box, replace "induce" by "lead to";
- 3.4.2.2.4.1 At the beginning of the second sentence, insert "Guinea pig" between "non-adjuvant" and "test method".
- 3.4.4 Insert "3.4.4.1" before the first paragraph.

Insert a new paragraph 3.4.4.2 after table 3.4.2 as follows:

"3.4.4.2 Some chemicals that are classified as sensitizers may elicit a response, when present in a mixture in quantities below the cut-offs established in Table 3.4.1, in individuals who are already sensitized to the chemicals. To protect these individuals, certain authorities may choose to require the name of the ingredient as a supplemental label element even though the mixture as a whole is not classified as sensitizer. Others may choose to classify and label the mixture as a sensitizer in accordance with notes 1, 3 and 5 to Table 3.4.1."

3.4.5 Decision logic 3.4.1 and 3.4.2

- In the central box, in the sentence starting with "is there evidence in humans..." replace "induce" with "lead to";
- In the last but one box on the left, after "sensitizer at ⁴", insert "⁵:" and a new footnote after current footnote 4 as follows:
- "5 See 3.4.4.2.".

<u>Document</u>: ST/SG/AC.4/2005/7 adopted with some modifications, as follows:

- A4.3.5.1 Replace (in the first sentence) 'type of extinguishers or fire-fighting agents' and (in the second sentence) "extinguishers", respectively, with "extinguishing media".
- A4.3.5.3 In the title, replace "equipment and precautions" with "actions".
- A4.3.5.3.1 In the first sentence, replace "precaution" with "protective actions".
- A4.3.5.3.2 Delete this paragraph.
- A4.3.6.1 Insert a new sub-paragraph A4.3.6.1 under current heading of A4.3.6.1, as follows:

"A4.3.6.1.1 For non-emergency personnel"

(Current text under A4.3.6.1 remains unchanged)

Add the following new sub-paragraph:

"A4.3.6.1.2 For emergency responders

Provide advice related to suitable fabric for personal protective clothing (e.g. "appropriate Butylene, not appropriate PVC)."

* * * * *

Annex 2

Corrections to the English version of the first revised edition of the Globally Harmonized System of Classification and Labelling of Chemicals

Chapter 1.3

Page 18

1.3.2.3 In the first sentence, replace "Parts 2 and 3" with "Parts 2, 3 and 4".

Chapter 1.5

Page 36

1.5.3.1.1 In table 1.5.1, replace "Serious damage to eyes/eye irritation" with "serious eye damage/eye irritation"

Chapter 3.3

Page 144

3.3.3.2.6 (d) Replace sub-paragraph (d) with the following:

(d) Data on irritation/serious eye damage for A and C are available and substantially equivalent, i.e. they are in the same hazard category and are not expected to affect the toxicity of B.

If mixture (i) is already classified by testing, mixture (ii) can be assigned in the same category. ».

Chapters 3.8 and 3.9

Pages 187 and 199 In 3.8.1.6 and 3.9.1.6, replace "acute lethality/toxicity", "skin corrosivity/irritation", "serious damage to eyes/irritation", "skin and respiratory sensitization" and "mutagenicity" with "acute toxicity", "skin corrosion/irritation", "serious eye damage/eye irritation", respiratory or skin sensitization" and "germ cell mutagenicity", respectively.

Annex 1

- Page 243 In the table for Explosives, in note (3), insert "and mixtures" after "Self-reactive substances" in the text in parenthesis.
- Pages 245 and 251 In the tables for Oxidizing gases (page 245), Oxidizing liquids and oxidizing solids (page 251), replace "Symbol and number: black. Background: yellow" with "Symbol (flame over circle): black; Background: yellow; Figure "5.1" in bottom corner: black".
- Pages 246 and 247 In the table for flammable solids (page 246) and in the first indent of note (2) in the table for Self-reactive substances and mixtures (page 247), replace "Symbol and figure: black. Background: white with seven vertical red stripes." with "Symbol (flame):

black; Background: white with seven vertical red stripes; Figure "4" in the bottom corner; black".

- Pages 248 and 249 In the tables for pyrophoric liquids and pyrophoric solids (page 248) and for self-heating substances and mixtures (page 249), replace "Symbol and figure: black, Background: upper half: white, lower half; red" with "Symbol (flame): black; Background: upper half white, lower half red; figure "4" in bottom corner: black".
- Pages 253 and 255 In the tables for Corrosive metals (page 253) and skin corrosion/irritation (page 255), replace "Symbol: black" with "Symbol (corrosion): black" and "Figure 8: white" with "Figure "8" in the bottom corner: white".
- Pages 254 and 255 In the tables for acute toxicity, replace "Symbol and figure: black, Background: white" with "Symbol (skull and crossbones): black; Background: white; Figure "6" in bottom corner: black".

Annex 2

Page 302

A2.28 (b) In the title, replace "Chapter 3.10" with "Chapter 4.1".

Annex 9

Page 487

A9.7.5.1.1 In the first sentence, replace "Figure A8.8.7.1" with "Figure A9.7.1".
