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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

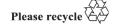
Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals

Report of the Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals on its forty-first session

held in Geneva from 8 to 10 December 2021

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I. Attendance

- 1. The Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals held its forty-first session from 8 to 10 December 2021, with Ms. Maureen Ruskin (United States of America) as Chair and Ms. Nina John (Austria) as Vice-Chair.
- 2. Experts from the following countries took part in the session: Argentina, Australia, Austria, Belgium, Brazil, Canada, China, Finland, France, Germany, Italy, Japan, Netherlands, New Zealand, Norway, Poland, Republic of Korea, Russian Federation, Serbia, South Africa, Spain, Sweden, United Kingdom of Great Britain and Northern Ireland, United States of America and Zambia.
- 3. Under rule 72 of the rules of procedure of the Economic and Social Council, observers from Chile, Mexico, Myanmar, the Philippines and Switzerland also took part.
- 4. Representatives of the United Nations Institute for Training and Research (UNITAR) and of the following specialized agencies were also present: Food and Agriculture Organization (FAO) and World Health Organization (WHO).
- 5. The following intergovernmental organizations were also represented: European Union and Organisation 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: Australian Explosives Industry and Safety Group Incorporated (AEISG); Compressed Gas Association (CGA); Croplife International; Dangerous Goods Advisory Council (DGAC); European Chemical Industry Council (Cefic); Fertilizers Europe (FE); European Industrial Gases Association (EIGA); Federation of European Aerosol Associations (FEA); Industrial Federation Paints and Coats of Mercosul (IFPCM); International Association for Soaps, Detergents and Maintenance Products (A.I.S.E); International Council on Mining and Metals (ICMM); International Dangerous Goods and Containers Association (IDGCA); International Organization of Motor Vehicle Manufacturers (OICA); International Petroleum Industry Environmental Conservation Association (IPIECA); Institute of Makers of Explosives (IME); Responsible Packaging Management Association of Southern Africa (RPMASA); Sporting Arms and Ammunition Manufacturers' Institute (SAAMI) and World Coatings Council.

II. Adoption of the agenda (agenda item 1)

Documents: ST/SG/AC.10/C.4/81 and ST/SG/AC.10/C.4/81/Add.1 (secretariat)

Informal documents: INF.1, INF.2 and INF.7 (secretariat)

- 7. The Sub-Committee adopted the provisional agenda prepared by the secretariat after amending it to take account of informal documents INF.1 to INF.19.
- 8. Regarding the status of publications, a member of the secretariat informed the Sub-Committee that the Spanish and Chinese versions of the ninth revised edition of the GHS had been finalised and would be made available on the website by the end of January 2022. It was noted that the Russian and Arabic versions were under preparation.

III. Work on the Globally Harmonized System (agenda item 2)

A. Work of the Sub-Committee of Experts on the Transport of Dangerous Goods (TDG) on matters of interest to the GHS Sub-Committee

- 9. The Sub-Committee considered the outcome of the discussions of the TDG Sub-Committee on informal document INF.10 and on document ST/SG/AC.10/C.4/2021/7 under agenda items 2 (b) and 2 (i) respectively.
- 10. Since no additional information was provided on any other matter of interest to the Sub-Committee dealt with by the TDG Sub-Committee, no further discussion took place under this agenda item.

B. Simultaneous classification in physical hazard classes and precedence of hazards

Informal document: INF.10 (Germany)

- 11. The Sub-Committee noted the progress of the work of the informal working group since the last session and was informed that the next meeting of the group was scheduled to take place on 26 January 2022.
- 12. On a question regarding the possibility that the outcome of this work had an impact on transport of dangerous goods provisions, the expert from Germany explained that this was not foreseen and that it would be up to the TDG Sub-Committee to consider whether the results of this work could be useful in the context of the transport of dangerous goods. It was noted that transport experts were participating in the work and that the TDG Sub-Committee would continue to be kept informed about the progress and outcome of the work of the group.
- 13. The expert from Germany invited all experts interested in participating in the informal working group to contact her (Ms. Cordula Wilrich).

C. Use of non-animal testing methods for classification of health hazards

Informal documents: INF.11 and INF.18 (United Kingdom, Netherlands)

- 14. The Sub-Committee took note of the information provided in informal documents INF.11 and INF.18, namely: the status report on the work of the informal working group; the information provided by OECD on the defined approaches; how defined approaches have been integrated in the review of chapters 3.3 and 3.4 so far; and current topics under discussion and challenges encountered by the informal working group during the revision of Chapter 3.4.
- 15. The Sub-Committee considered the general issues brought to its attention by the informal working group and concluded as follows:
 - (a) How much criteria and/or guidance should be provided in the GHS in case of conflicting results from different tests?
 - Guidance on the use of data should be provided both in the classification criteria part of the chapter and in the "guidance" section within the chapter(s), as it was done for chapters 3.2 and 3.3.
 - (b) To what extent changes to the already existing criteria would be acceptable when introducing criteria for new types of data?
 - Existing reliable and good quality evidence from human data should continue to be given high weight where relevant for classification and should be the first line of evaluation. In this regard, it was noted that there is a need to enhance the description of what is meant with reliable and good quality data. The proposals to review Chapter 3.4 to address classification using other types of data should not trigger changes in the existing classification criteria using human or animal data and may need clarification as part of the working group's update. It is acknowledged however that the current text in Chapter 3.4 may need to be reorganized and additional clarification provided, as it was the case for chapters 3.2 and 3.3, to accommodate the provisions addressing use of new types of data.
 - (c) How to handle technical issues with wider implications for other chapters in the GHS?
 - Technical issues identified as being beyond the mandate of the informal working group should be brought to the attention of the Sub-Committee who may decide whether to deal with them in plenary or entrust them to an existing or a new informal working group under the leadership of a delegation participating in its work.
- 16. The representative of OECD invited experts wishing to learn more about the implementation of the defined approaches on skin sensitization to watch a webinar held on

18 October 2021 on this topic ¹ following the publication of OECD Guideline 497 in June 2021.

D. Classification of skin sensitizers using the results of local lymph node assays test methods in accordance with OECD Test Guideline 442B

Informal document: INF.6 (Japan)

- 17. The Sub-Committee took note of the information provided by the expert from Japan on the progress of the work of the informal working group since the last session. It was noted that the criteria in table 3.4.3 as presented in the annex to informal document INF.6 for the local lymph node assay BrdU-FCM should be amended in accordance with the stimulation index value in OECD test guideline 442B (i.e.: "SI \geq 2.7" instead of "SI \geq 1.6") and that the text of section 3.4.2.2.3 should be checked against consistency with the terminology used in Chapter 3.4 for non-animal testing, currently under review.
- 18. The expert from Japan invited all experts wishing to provide additional comments on the proposal to send them to him (Mr. Masahiro Takeyoshi) in writing before the end of January 2022 so that they can be considered by the informal group when further developing the proposal.

E. Classification criteria for germ cell mutagenicity

Informal document: INF.14 (European Union)

19. The Sub-Committee took note of the update on the status of the work of the informal working group. It was noted that work on the criteria was not expected to be finalised on time for submission of a proposal for adoption by the Sub-Committee during the current biennium. Nevertheless, it was pointed out that the informal working group might be able to finalise a proposal addressing the review of terminology and the list of methods for adoption by the Sub-Committee by the end of 2022. However, some experts noted that further discussion was needed on several items, including definitions. The Sub-Committee invited the informal working group to submit a proposal for adoption in the current biennium, once the work on definitions was completed.

F. Practical classification issues (proposed amendments to the GHS)

Informal document: INF.15 (United States of America)

- 20. The Sub-Committee took note of the update on the status of the work of the informal working group and the draft proposal for new guidance in Chapter 3.1 and related examples on how to address the conversion of inhalation toxicity values for tests using exposure times other than 1 hour. Noting that this guidance may also be useful within the context of the Model Regulations on the Transport of Dangerous Goods, the Sub-Committee invited the expert from the United States of America leading this work to bring it to the attention of the TDG Sub-Committee for consideration.
- 21. The expert from the United States of America invited comments in writing on the proposals in the annex to informal document INF.15 and indicated that the informal working group will resume its meetings in January 2022.

G. Nanomaterials

22. As no document had been submitted under this agenda item, no discussion took place on this subject.

https://www.oecd.org/chemicalsafety/testing/webinars-on-testing-and-assessment-methodologies.htm

H. Improvement of annexes 1 to 3 and further rationalization of precautionary statements

Informal documents: INF.16 and INF.19 (United Kingdom)

- 23. The Sub-Committee took note of the update on progress of the work of the informal working group in informal document INF.16.
- 24. On the questions raised in informal document INF.16, the Sub-Committee concluded as follows:
 - (a) proposed options 1 and 2 for combined statement H315+H319 (Causes skin and eye irritation) in paragraph 12:

The Sub-Committee could not reach a consensus on any of the proposed options. Several experts expressed a preference for option 2, as they considered that it was clearer to understand and more suitable for workplace labelling than the text proposed under option 1. Others found that the text proposed under option 1 was more suited to address consumer products' labelling needs due the conciseness of the text. In the light of the comments made, the Sub-Committee invited those who had not yet done so, to inform the Chair of the informal working group of their preference.

(b) proposed options 1 and 2 for the footnote to table A.3.1.2 in paragraph 13:

The Sub-Committee expressed a preference for option 2, on the grounds that by specifying the hazard categories addressed (serious eye damage/eye irritation), it avoided possible misunderstandings as regards applicability to skin (corrosion/irritation).

(c) On the proposed three options addressing variations in the text of combined hazard statements and precautionary statements:

Several experts indicated that more time was needed to evaluate all options and their implications, taking into account in particular that option 3 was a recent proposal. The Sub-Committee invited them to provide comments in writing to the Chair of the informal working group.

- 25. The Sub-Committee expressed its appreciation for the work of the informal working group and noted the issues and challenges outlined in informal document INF.19. This included the need for additional support to the Chair of the informal working group in the form of leading some of the work within the work programme or developing thought-starters. It welcomed the offer from the representative of the European Union to consider the possibility of providing support to the informal working group. Other delegations were also invited to do so.
- 26. It was acknowledged that providing timely contributions to the informal working group and actively engaging on its work were key factors to ensure progress. However, it was noted that submission of detailed written comments on specific proposals was a time-consuming exercise, requiring multiple levels of review to evaluate all the implications of the proposed changes as well as time to consolidate the responses and comments. It was suggested that additional means of communication, e.g., conference or video calls, could be considered to facilitate a more dynamic exchange of views and opinions and help advance particularly complex technical issues.
- 27. The Sub-Committee noted the issues outlined in paragraph 45, item 2 of informal document INF.19 and invited experts to provide their contributions to the Chair of the informal working group (Ms. Deborah Traynor).

I. Other matters

1. Desensitized explosives

Document: ST/SG/AC.10/C.4/2021/7 (Germany)

- 28. Having heard the information provided by the Chair of the TDG Sub-Committee on the outcome of the discussions on this topic, the Sub-Committee concurred with the view of the TDG Sub-Committee to forward this proposal to the Explosives Working Group for consideration at its next meeting.
- 29. Concerning the proposal, several experts indicated that the terminology used in Chapter 2.17 may need to be reviewed to ensure consistency with the revised Chapter 2.1. It was noted in particular that the reference to "unstable" could be misunderstood and may no longer be appropriate following the revision of Chapter 2.1 of the GHS adopted during the last biennium. One expert considered, in addition, that more information was needed on how to convey test results and on nitrocellulose mixtures.
- 30. The expert from Germany pointed out that a general review of the terminology not directly related to the issue at hand, either in the current text of Chapter 2.17 or in other chapters of the GHS or the Manual of Tests and Criteria was out of the scope of her proposal and invited those who have identified additional terminology issues to consider addressing them separately.
- 31. The Sub-Committee invited the expert from Germany to consider the comments made and submit a revised proposal for consideration by the TDG Sub-Committee at its next session, on the understanding that it would be entrusted for consideration to the Explosives Working Group. The Sub-Committee invited all interested experts to submit any additional comments to her in writing (Ms. Cordula Wilrich) and welcomed more background information on the request regarding conveyance of test results and nitrocellulose mixtures.

2. Corrections to the ninth revised edition of the GHS

Informal document: INF.3 (secretariat)

32. The Sub-Committee adopted the corrections in informal document INF.3 (see Annex). However, it was pointed out that the guidance in note 3 to paragraph 2.1.2.1 as adopted during the last biennium may need to be further improved. The Sub-Committee invited interested experts to consider submitting a proposal to this end.

IV. Implementation of the GHS (agenda item 3)

A. Possible development of a list of chemicals classified in accordance with the GHS

Informal documents: INF.13 and 13/Add.1 (Canada, United States of America)

- 33. The experts from Canada and the United States of America presented the preliminary results of the GHS chemical classification list survey. It was noted that the responses were still being analysed and that the final conclusions were expected to be shared with the Sub-Committee at its forty-second session. Experts were invited to consider the questions under paragraph 27 in informal document INF.13 and provide feedback to the informal working group as soon as possible to facilitate its work when evaluating and presenting the information collected through the survey. It was pointed out that this work will play a key role to help deciding on the next steps for the work of the informal working group.
- 34. The expert from Japan informed the Sub-Committee of the availability of classification in accordance with the GHS (including the rationale for the classification) for about 3.200 substances.² The classifications are non-mandatory. To facilitate obtaining the latest information on substances that have been reclassified, the National Institute of Technology and Evaluation (NITE) is currently preparing the English version of the "one substance, one file integrated version" showing only the latest classification results.

² GHS Classification Results | National Institute of Technology and Evaluation (NITE)

B. Reports on the status of implementation

1. United States of America

Informal document: INF.12 (United States of America)

35. The expert from the United States of America informed the Sub-Committee about the changes in the Hazard Communication Standard (HCS) implementing the GHS for the workplace, since its adoption in 2012. It was noted that the 2012 HCS was based in the third revised edition of the GHS and that a proposal for alignment in accordance with the seventh revised edition had been submitted and was under public consultation until 22 December 2021. It was pointed out that the update also included a potential option to align some provisions with provisions from the eighth revised edition of the GHS, namely: the non-animal test methods for skin corrosion/irritation (Chapter 3.2); new classification criteria for aerosols, including the new hazard category for "chemicals under pressure", and updated precautionary statements. The final rule will reflect the comments provided during rulemaking. Once the final rule is published new guidance will be developed to facilitate its implementation.

2. Canada

36. The expert from Canada informed the Sub-Committee that proposed amendments to the Hazardous Product Regulations implementing GHS for the workplace (currently based on the fifth revised version of the GHS) was published in December 2020 and that the stakeholder comments' review was being finalized. The proposed update ³ includes provisions from the sixth and seventh revised editions of the GHS and aims to ensure, to the extent possible, alignment of implementation with the United States of America Occupational Safety and Health Administration HCS that is also under review.

3. Zambia

37. The expert from Zambia indicated that updated national standards on GHS and transport of dangerous goods were expected to be released in 2022.

4. European Union chemicals strategy

- 38. The Sub-Committee was informed about activities conducted in the European Commission in relation to the implementation of the European Union chemicals strategy.
- 39. It was noted in particular that new hazard classes would be introduced at European Union level. The representatives of Cefic, AISE and OICA said that in their opinion, new hazard classes should be introduced at GHS level first to ensure global harmonization. The representative of the European Union indicated that following adoption at European Union level, a proposal to seek the Sub-Committee's agreement to start work on these hazard classes would be submitted for its consideration.

C. Cooperation with other bodies or international organizations

Informal document: INF.9 (WHO)

- 40. The representatives of WHO and FAO informed the Sub-Committee about latest developments regarding WHO publications addressing classification and labelling in accordance with the GHS, as follows:
 - (a) WHO recommended classification of pesticides by hazard

Since 2009, the recommended classification incorporates the GHS criteria for acute oral and dermal toxicity. It is expected that availability of GHS classifications will support implementation of the GHS, particularly in countries that rely on the WHO classification scheme for pesticide management.

³ https://canadagazette.gc.ca/rp-pr/p1/2020/2020-12-19/html/reg4-eng.html

The latest revision of the WHO recommended classification was conducted in 2019. It includes approximately 100 new pesticide entries, provides classification for about 600 active ingredients and is available in several languages.

(b) FAO/WHO Guidance on Good Labelling Practice for Pesticides

The 2021 update of the guidance is about to be published. This new edition strongly recommends using GHS as the only classification scheme for pesticide labelling for acute and chronic health hazards (including GHS criteria for carcinogenicity, mutagenicity and reproductive toxicity). It was pointed out that the previous edition of the guidance offered multiple options for acute toxicity, but now the emphasis was only on GHS.

(c) International Safety Cards (ICSCs)

Cards on about 1700 chemicals are freely available in several languages and about 674 have been reviewed since 2006 to take account of GHS classification and labelling criteria.

(d) Nanomaterials

A pilot exercise for classification of nanoforms of three selected chemicals in accordance with the GHS was conducted in the ICSC project in 2019. As a result, cards for "Titanium dioxide (nanoform) P25" and "Zinc oxide (nanoform)" were published. Data for classification of the silver (nanoform) was considered insufficient and a card for the nanoform could not be issued.

41. Regarding recent developments related to Highly Hazardous Pesticides (HHPs) the representative of FAO indicated that FAO, WHO and ILO have prepared a draft action plan aiming at eliminating harm from HHPs in agriculture by 2030. It was noted that three out of the eight criteria used by FAO and WHO to define HHPs relate directly to GHS. The plan is under consultation by governments, with comments expected by mid-January 2022. Experts wishing to receive additional information on this topic were invited to contact the representative of FAO. She also mentioned that FAO and UNITAR were exploring possibilities to further engage the agriculture sector in GHS implementation.

D. Miscellaneous

Informal document: INF.4 (Sweden)

- 42. The Sub-Committee noted the information on activities to support GHS implementation in third countries conducted by the Swedish Chemicals Agency within the framework of development cooperation projects.
- 43. There was general support for the proposal to consider how the Sub-Committee could further support, promote and monitor GHS implementation worldwide. It was suggested that a specific agenda item could be added to address this topic and increase visibility, promote implementation and highlight the impact of the work of the Sub-Committee. It was also noted that there had previously been a GHS implementation issues working group, which could be revived. Several experts noted that it would be useful to share experiences on how different jurisdictions worldwide are keeping pace with the regular updates of the GHS. The representative of Cefic welcomed any initiative that may contribute to increase synchronisation in the implementation of different revised editions of the GHS.
- 44. The expert from Sweden was invited to consider the comments and suggestions made and work with other delegations who expressed interest in this topic on the development of a proposal for consideration by the Sub-Committee on possible ways forward.

V. Development of guidance on the application of GHS criteria (agenda item 4)

A. Alignment of Annex 9 (section A9.7) and Annex 10 with the criteria in Chapter 4.1

Informal document: INF.17 (ICMM)

45. The Sub-Committee took note of the update on the status of the work of the informal working group.

B. Practical classification issues

46. The Sub-Committee considered the information on guidance under preparation by the informal working group during the discussion of informal document INF.15 under agenda item 2 (f).

C. Practical labelling issues

- 47. The representative of the European Union informed the Sub-Committee about the preliminary results of a study on digital labelling for chemicals subject to the provisions of the Classification, Labelling and Packaging (CLP) regulation, which implements the GHS in the European Union. It was noted that a European Union initiative for a proposal for a regulation addressing simplification and digitalisation of labelling requirements for chemicals is open to public consultation until 16 February 2022⁴ (including to non-European Union citizens and organisations). The results of the study and the public consultation will feed into the European Commission Impact Assessment that is expected to be issued by mid-2022.
- 48. Noting that the possibility to consider digital labelling had already been raised in the past within the practical classification labelling issues informal working group led by Cefic, the representatives of the European Union and AISE indicated their willingness to share the findings of their studies on this topic and actively engage in the work of the informal group.
- 49. The representative of Cefic indicated that the group intended to resume its activities in 2022 and invited all those interested in contributing to this area of work to contact her (Ms. Liisi de Backer).

D. Miscellaneous

50. As no document had been submitted under this agenda item, no discussion took place on this subject.

VI. Capacity building (agenda item 5)

Informal document: INF.8 (RPMASA)

- 51. The Sub-Committee noted the information about capacity building activities conducted by RPMASA in South Africa.
- 52. The representative of UNITAR informed the Sub-Committee about capacity building activities conducted in Ghana and Kiribati in support to the development of regulation.
- 53. On guidance and training related activities, the Sub-Committee noted that:
 - (a) a document on lessons-learned from implementation, and guidance on developing legislation relevant to the GHS were released and are available at UNITAR's website.⁵
 - (b) e-Learning courses have been conducted in English and Spanish in 2021 with the next round expected to start in March-April 2022. Technical training

https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12992-Chemicals-simplification-and-digitalisation-of-labelling-requirements_en

⁵ The Global Partnership to Implement the GHS | UNITAR

webinars in Spanish and English, focusing on safety data sheets, labelling and information search have also been conducted to supplement the e-learning courses

54. The Sub-Committee welcomed the information provided and encouraged UNITAR to provide information to the Sub-Committee on challenges and issues related to GHS implementation that may have been identified capacity-building and training activities.

VII. Other business (agenda item 6)

A. Review of ECOSOC subsidiary bodies to be conducted during the 2022 session of Council

Informal document: INF.5 (secretariat)

55. The Sub-Committee took note of the request from ECOSOC for inputs on the review to its subsidiary bodies and agreed to the overview of its work and its linkages to the 2030 agenda provided in annex I to informal document INF.15. After discussion, the Sub-Committee agreed on the answers to the questionnaire in annex II to informal document INF.15.

B. Meeting dates and submission deadlines for the forty-second session

- 56. The Sub-Committee was invited to note the meeting dates and document submission deadlines for its forty-second session as follows:
 - (a) Meeting dates: 6-8 July 2022;
 - (b) Deadline for submission of official documents: 13 April 2022 (for documents submitted for consideration by the GHS Sub-Committee only) and 1 April 2022 (for documents submitted for consideration by both sub-committees, i.e.: TDG and GHS)

VIII. Adoption of the report (agenda item 7)

57. The Sub-Committee adopted the report on its forty-first session and its annex on the basis of a draft prepared by the secretariat.

⁶ *Note by the secretariat*: The secretariat, on behalf of the Sub-Committee, communicated the answers to the questionnaire agreed during the session to the ECOSOC secretariat on 13 December 2021.

Annex

[Original: English and French]

Corrections to the ninth revised edition of the GHS (ST/SG/AC.10/30/Rev.9)

1. Chapter 2.1, paragraph 2.1.2.1 starting with "The divisions are as follows:"

The paragraph number should read 2.1.2.2

In Note 3, first sentence, *for* test on solid substances or mixtures *read* test on explosive substances or mixtures

2. Chapter 2.1, table 2.1.2, Note

In the last sentence for and and Section 9 read and Section 9

3. Chapter 3.3, decision logic 3.3.1, third text box from the top on the right-hand side

For See decision logic 3.2.2 read See decision logic 3.3.2

4. Chapter 3.7, decision logic 3.7.4, "Modified classification on a case-by-case basis", question "Can bridging principles be applied?"

For applied?² read applied?³

5. Annex 1, table A1.1, column "UN Model Regulations pictogram"

