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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 **7 December 2021**

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Work on the Globally Harmonized System (GHS): improvement of annexes 1 to 3 and further rationalization of precautionary statements

Annex 1-3 informal working group: Current issues and challenges

Transmitted by the expert from United Kingdom on behalf of the informal working group

1. This informal paper provides an overview of current issues and challenges faced by the informal working group.

General challenges of progressing working group work plans

Late contributions

2. Working groups of the Sub-Committee operate collaboratively in order to work through and resolve the issues on their respective work plans. This requires active participation of members of the working groups, through the development stage, and beyond to the submission of formal proposals for the consideration by the Sub-Committee.

3. Given the breadth of the work of the Sub-Committee, not all members either have an interest in particular issues or have the resource to be as actively involved as they would like given the number of working groups and issues that are being progressed during each biennium, in addition to other work commitments they may have. This means that the discussions in working group meetings, or via correspondence, to help resolve issues as proposals are developed is often limited to a few (often the same) members of a working group.

4. Notwithstanding the limitations outlined in paragraph 3, those who volunteered to participate in the work of an informal working group are expected to engage in the discussions and contribute to the development of proposals early in the process, particularly when they have fundamental issues. This allows the group lead(s) to ensure that all members views are fully taken on board when preparing a proposal on behalf of the informal group, for consideration by the Sub-Committee.

5. In addition, given the 3-month window between publication of formal proposals and their discussion in plenary, it is fundamental that informal working group participants submit their comments in writing as early as possible prior to plenary, so that they can be properly considered in preparation for the session. This may also assist with the discussion during plenary session and ensure a more efficient utilization of working group and Sub-Committee time.

6. The work of the informal working group on Annexes 1-3 has been facing some difficulties in the past to progress some of the items on its work program due to last minute contributions or comments that were not submitted on time for the informal working group to consider before a

formal proposal was sent for consideration by the Sub-Committee and sent back to the group for review.

7. Taking into account the workload of the informal working group, and the amount of work needed to develop a proposal, it would be advisable that those who engage in the work of the group commit to contributing and regularly and actively participate in its work, even though it is understood that their participation may fluctuate depending on the individuals' other commitments.

Need for additional support

8. Different working groups operate in different ways in relation to taking forward issues on their work plans. Some groups operate on the basis that if you put forward an issue for inclusion on their work plan that you lead on that issue. Other groups, like the Annex 1 to 3 working group, by default due to legacy items on their work plan, work on the basis of requesting volunteers to lead on particular issues.

9. Over the past 5 years and despite a number of requests, only 1 volunteer has stepped forward to lead on a particular issue on the Annex 1 to 3 work plan, the rest of the many issues and formal proposals that the group has taken forward for consideration by the Sub-Committee, have been led by the groups Chair. This has placed an inordinate amount of work on one individual to draft thought starters, resolve issues within the group and draft the associated informal and formal documents for the consideration of the Sub-Committee.

10. The expert from the United Kingdom, who has been leading the work of the Annex 1 to 3 group since July 2007, would like to invite other Sub-Committee members of this group to volunteer to take the lead on an issue on the groups' current work plan, particularly if historically they had originally put an issue forward for inclusion on the plan.

Current issues with respiratory sensitizers (categories 1, 1A, 1B) in Annex 3:

Background

11. The respiratory sensitization hazard class are considered to be of high seriousness and high urgency for receiving immediate medical help following exposure to such chemicals.

12. Respiratory sensitizers are listed under the following prevention and response precautionary statements:

- P261 **'Avoid breathing dust/fume/gas/mist/vapours/spray.'**
- P284 **'[In case of inadequate ventilation] wear respiratory protection.'**
- P304 '**IF INHALED:**'
- P316 **'Get emergency medical help immediately.'**
- P340 **'Remove person to fresh air and keep comfortable for breathing.'**
- P342 '**If experiencing respiratory symptoms:**'
- P304 + P340 '**IF INHALED: Remove person to fresh air and keep comfortable for breathing'**
- P342 + P316 '**If experiencing respiratory symptoms: Get emergency medical help immediately.**'

13. Currently there are no response precautionary statements to provide information on what specific immediate treatment should be provided to alleviate symptoms from exposure to a respiratory sensitizer. However, there are two precautionary statements that potentially could be used to provide such information and have been considered by the group, these are:

- P320 '**Specific treatment is urgent (see ... on this label).**' which is accompanied by conditions for use that refers to administration of an antidote.
- P321 '**Specific treatment (see ... on this label).**' which is accompanied by various conditions for use that refer to the administration of an antidote; specific measures; or use of a cleansing agent, depending on the specific hazard class.

14. Consequently, this issue was listed on the Annexes 1-3 IWG workplan (work item 3) for the 2021-2022 biennium and a thought starter on this issue was circulated to members of the group in July 2021 with the expectation that members consulted with their technical occupational health and safety and other relevant experts prior to their responding. Comments were received from group members from the United Kingdom, Canada, Germany, ECHA and the United States of America.

Considerations and issues:

(i) *Sensitized persons*:

15. Useful background regarding respiratory sensitization is provided as follows:

- A person who is not sensitized will not require any medical help;
- A person exposed to a respiratory sensitizer may become sensitized after an initial exposure, though they will not be aware they are sensitized until they are exposed to the respiratory sensitizer a second time. Hence, prevention of exposure is the best approach to ensure that they do not become sensitized;
- In workplaces using hazardous substances such as respiratory sensitizers, risk management measures and procedures should be in place to manage the risks from such substances to reduce the likelihood of and in the event of exposure incident occurring;
- For a sensitized person, the symptoms can vary widely (from mild to severe) depending on their individual susceptibility and the specific chemical involved. Often (but not always) people who are aware that they have a specific allergy/sensitization carry their own medication. However, it was also noted that once it is known that a person is sensitized to specific chemicals, they shouldn't be around those chemicals at all, which should be accounted for within their employers' assessment.

(ii) *First aid and legal considerations*:

16. In relation to specific immediate treatment following exposure to respiratory sensitizers, the group also considered the potential inclusion of a reference to the provision of first aid in the conditions for use for a relevant precautionary statement for this hazard class.

17. Firstly, the group considered the aim and definition for administering first aid. The aim of first aid treatment is to preserve life, prevent a condition worsening and promote recovery. However, there are slightly different definitions of the terms "first aid" and "first aider", two of these are:

- "Assessments and interventions that can be performed by a bystander (or the victim) with minimal or no medical equipment. A first aid provider is defined as someone with formal training in first aid, emergency care, or medicine who provides first aid."[1]
- "Initial assistance or treatment given to a person (the casualty) who is injured or taken ill. A first aider is a person who takes this action while taking care to keep everyone involved safe and to cause no further harm to anyone while doing so."[2]

18. Although there are varying levels of first aid qualifications for non-medical professionals and workplaces may have trained first aiders on-site, qualified first aiders may not always be available (for instance, outside the workplace) and consideration is required regarding whether

[1] Markenson, et al., 2010 (Part 17: First Aid 2010 American Heart Association and American Red Cross Guidelines for First Aid)

[2] St John Ambulance, St Andrew's First Aid and British Red Cross, 2021 (First Aid Manual, 11th Edition)

it is appropriate for a non-medically or non-first aid trained person to administer specific treatment following exposure to a respiratory sensitizer, noting that, legalities may vary between jurisdictions for non-medical professionals to administer medication or specific treatment on behalf of the casualty.

19. Although the group discussions on this issue are still on-going, the group welcomes initial views of the Sub-Committee on the issues raised in paragraphs 16 to 18.

(iii) ***Target audience and reference to specific treatment on the label:***

20. Before including a reference to specific treatment into the conditions for use for a precautionary statement for respiratory sensitizers, the following would need to be considered:

- What are the treatments that would be administered to a sensitized person?
- Whether the specific treatment would be readily available, for instance, on-site in the workplace;
    - in some countries, the workplace storage of epi pens, inhalers etc. on-site is not routinely recommend due to shelf life, accessibility, availability of those trained to use them, and that those who require quick access to such symptom relievers usually carry them.
- Who the target audience would be for the refence within the conditions for use of a relevant precautionary statement, which could encompass a range of people including:
    - the user or a person in the immediate vicinity who may be able to provide initial first aid assistance to the casualty;
    - emergency responders and medical professionals, who may provide the subsequent medical assistance to the person exposed following being contacted by the initial first aider on the scene.
- Whether it is necessary to include reference to a specific (rather than a generic) treatment on the label given the information that is already available or could be provided via alternative sources:
    - For instance, safety data sheet (SDS) section 4(c) includes “indication of immediate medical attention and special treatment needed if necessary” as part of the minimum information (see Table 1.5.2) so information on specific treatment could be provided in the SDS, if it is not already done so, or is not part of the precautionary statement;
    - other information that may already be available specifically to emergency responders and/or medical professionals

21. Although these issues are still under consideration, the group welcomes initial views of the Sub-Committee on the issues raised in paragraphs 20.

(iv) ***Order of action/treatment following exposure to respiratory sensitizers*****:**

22. There was general agreement that the first action to be undertaken, if a person is exposed, is to remove the person to fresh/clean air. This action is already covered by the combination statement P304 + P340: ‘**IF INHALED: Remove person to fresh air and keep comfortable for breathing**’.

23. Because only people who are already sensitized exhibit symptoms following exposure, any subsequent action would depend on whether the exposed person was exhibiting any respiratory symptoms, together with the severity of those symptoms. Hence the need for urgent treatment would depend on the symptoms exhibited by the sensitized person which can vary from mild to severe breathing difficulties.

24. However, whether a non-medical expert can properly distinguish between mild and severe breathing difficulties is an open question and given the potentially life-threatening nature of severe breathing difficulties, such as during a severe asthma attack, all respiratory symptoms

that are exhibited due to exposure to a respiratory sensitizer should always be double checked with a suitably qualified medical professional.

25. Furthermore, if an exposed person is experiencing respiratory symptoms, then the instructions in P342 + P316 '**If experiencing respiratory symptoms: Get emergency medical help immediately.**' (together with the associated conditions for use) direct the person (which could be the exposed person or someone going to their assistance) to get urgent help from the appropriate emergency medical help provider (e.g. a Poison Centre, Emergency Centre or Doctor) who will have access to the correct treatment information for that chemical, advise accordingly (e.g. to use an epi pen, inhaler, antihistamines, cortisone or some other readily available treatment) and who may (or may not) also dispatch emergency responders depending on the specific circumstances.

26. Hence, the group welcomes initial views of the Sub-Committee regarding whether the existing response combination precautionary statements of P304 + P340 and P342 + P316 already sufficiently addresses the concerns regarding the order of action to be undertaken.

(v) ***Reference to the use of an antidote in the conditions for use:***

27. In some countries, for most chemicals, the on-site storage and use of antidotes is not recommended and instead it is recommended to follow basic first aid principles (e.g. removing to fresh air/decontamination, calling emergency services for medical help (where applicable), give basic first aid treatment and wait for emergency services to arrive) rather than using an antidote. In addition to accessibility and availability of trained persons issues, the other main reasons for this approach include the limited shelf life of antidotes and the higher risk from trying to apply an antidote rather than following basic first aid principles and calling emergency services for medical help, and that some antidotes need to be given intravenously so only people with proper training can use them. The only exception would be where the site is very remote (e.g. off-shore oil rigs where there are highly trained technicians under video supervision from medical experts who could administer antidotes (if required).

28. Given the issues raised regarding antidotes, as outlined above, there was general agreement within the group that the use of an antidote would not be appropriate following exposure of a sensitised person to a respiratory sensitiser and hence there should be no reference to antidotes in any conditions for use for a precautionary statement that may be used for this hazard class.

29. Furthermore, the group noted that currently the conditions for use for some of the acute toxicity hazard classes/categories listed under P320 and P321 refer to the use of an antidote and may also require review.

30. Hence, the group welcomes initial views of the Sub-Committee regarding whether reference to antidotes in conditions for use in precautionary statements should be reviewed and whether this issue should be added to the work plan of the Annex 1 to 3 working group for future consideration.

(vi) ***Potential assignment of respiratory sensitizers under either P320 or P321:***

31. Although there were mixed views regarding whether it would be appropriate to place respiratory sensitizers under P320 or P321, and the group remained open to these options, overall, the group considered that neither option was ideal, even if specific treatment information were included within the conditions for use for this hazard class.

32. Given that the combination statement P342 + P316 (see paragraph 25 above) for respiratory sensitizers could potentially address the issue of urgency of obtaining medical help (where required), some members considered that there was unlikely to be any added value of including respiratory sensitizers under P320 or P321, unless there is an available in-date epi pen or other readily available medical treatment available on-site, which as mentioned in paragraphs 20 and 27 above, are not always available or recommended.

33. Furthermore, depending on views regarding the order of action/treatment following exposure to a respiratory sensitizer and the issues surrounding inclusion of specific treatment into the conditions for use for a precautionary statement, one option to address these concerns could be strengthen the message provided in the existing two response combination statements

for P304 + P340 and P342 + P316 through their amalgamation into a single four-statement combination that would be:

- P304 + P340 + P342 + P316: '**IF INHALED: Remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Get emergency medical help immediately**

34. This would require minimal amendment to the GHS and would not only strengthen the message by ensuring that the correct order of action was undertaken (specific to the needs of the exposed person) and that specific medical help would be urgently sort (if necessary) and provided by medical professionals which would avoid many of the issues raised above.

35. Hence the group welcomes the initial views of the Sub-Committee regarding whether it would be appropriate to amalgamate the current response combination statements for P304 + P340 and P342 + P316 into a single combination statement to address the concerns in relation to the order of action/treatment and obtaining specific treatment following exposure to a respiratory sensitizer.

(vii) ***P284 "[In case of inadequate ventilation] wear respiratory protection.":***

36. The conditions for use for P284 are as follows:

> "– *text in square brackets may be used if additional information is provided with the chemical at the point of use that explains what type of ventilation would be adequate for safe use.*
>
> Manufacturer/supplier or the competent authority to specify equipment."

37. However, some in the group believe that as currently written P284, together with its conditions for use, can be interpreted as being ambiguous and may not convey the correct message as intended. Others in the group believe that the condition of use refers to ventilation equipment and is not ambiguous.

38. According to the conditions for use, the text in square brackets in P284 may be used if information is provided. However, the information on safe use is not necessarily required to be provided) at point of use regarding the type of ventilation that would be adequate for safe use. Hence, if such information is not provided then P284 simply states: '**Wear respiratory equipment'.**

39. Normally respiratory protective equipment (RPE) would only need to be used when the type of ventilation for safe use is unknown (i.e. the information not provided) or it is inadequate (i.e. different from what the manufacturer/supplier or competent authority states should be used) or in a small number of cases where both adequate ventilation and RPE are both required to be used, which should be made clear in the information provided by the manufacturer/supplier or competent authority.

40. Further, the statement in the conditions for use '**Manufacturer/supplier or the competent authority to specify equipment**' is unclear regarding whether this pertains to type of ventilation and/or RPE. Some consider that this would cover just ventilation, others considered it could cover both ventilation and RPE (as this is currently mentioned in the text of the precautionary statement), while several members of the group also considered that the conditions for use should be made more explicit.

41. In addition, some considered that the text in the conditions for use could be further strengthened to ensure that such information is always provided i.e. change the emphasis from '*if additional information is provided*', which could be considered optional, to '*..to specify…*', which would make it a requirement to provide the information. Then if the ventilation at point of use was adequate (according to the information provided), normally there would be no need to wear RPE unless otherwise stated in the information supplied.

42. Some in the group considered that by providing greater clarity in the conditions for use and ensuring that the safe use information is provided, the text currently within the square brackets of P284 could remain but with the square brackets removed. This would retain the

current emphasis on wearing RPE when there is inadequate ventilation and ensure that the appropriate information is always provided on what the adequate ventilation and RPE should be used.

43. Although the group discussions regarding P284 issues are still on-going, given the issues outlined above, the group welcomes the views of the Sub-Committee regarding the following potential revised wording for P284 and its conditions for use (deleted text in strikethrough; new text in bold underlined):

> **"~~[~~In case of inadequate ventilation~~]~~, wear respiratory protection.**"
> ~~*– text in square brackets may be used if additional information is provided with the chemical at the point of use that explains what type of ventilation would be adequate for safe use.*~~
> "Manufacturer/supplier or the competent authority to specify **what type of ventilation would be adequate for safe use and provide additional information with the chemical at the point of use that explains what type of respiratory** equipment **may also be needed**."

44. This would ensure that the current ambiguity in the precautionary statement and conditions for use was removed, information is always provided on the type of adequate ventilation and the type of RPE that may be required for safe use and would also be consistent with the control measure hierarchy.

Action requested from the Sub-Committee

45. Although the work outlined in this document is still on-going within the informal working group, the Sub-Committee is invited to note and provide initial views on the issues outlined in this document as detailed in the following paragraphs:

1. **General challenges of progressing working group work plans:**
   - As provided in paragraphs 16 to 19.
2. **Current issues with respiratory sensitizers (categories 1, 1A, 1B) in Annex 3**:
   - Background on respiratory sensitizers and sensitized persons are provided in paragraphs 11 to 15;
   - First aid and legal considerations are provided in paragraphs 16 to 19;
   - Target audience and reference to specific treatment on the label are provided in paragraphs 20 to 21;
   - Order of action/treatment following exposure to respiratory sensitizers are provided in paragraphs 22 to 26;
   - Reference to the use of an antidote in the conditions for use are provided in paragraphs 27 to 30;
   - Potential assignment of respiratory sensitizers under either P320 or P321 are provided in paragraphs 31to 35;
   - P284 "[In case of inadequate ventilation] wear respiratory protection.': are provided in paragraphs 36 to 44.

46. The informal working group will then take on board the comments provided by the Sub-Committee with the view of resolving the outstanding issues regarding respiratory sensitizers (categories 1, 1A, 1B) in Annex 3 and providing a formal proposal for the consideration of the Sub-Committee at the forty-second session.