Use of “should”, “shall”, “may” and “must” in the GHS

Transmitted by the expert from the United States of America

Background

1. The use of “should”, “shall”, “may” or “must” recently arose in recent meetings of the informal working groups on the improvement of annex 1 to 3, the practical classification issues (PCI), the use of non-Animal test methods, and germ cell mutagenicity.

2. Using the discussion within the informal working group on the improvement of annexes 1 to 3 as an example to further illustrate the issue, the discussion was focused on the context of information on immediate specific measures that can be easily applied, such as an antidote or other specific treatment. The group considered changing “This information should be provided on the label and the safety data sheet” to “This information must be provided on the label and the safety data sheet.” The members considered that the use of “should” might result in the information not being provided. Members were to consult with their agencies on this point.

3. As the GHS is a set of non-binding recommendations rather than model regulations (such as the Model Regulations on the Transport of Dangerous Goods (TDG)), the framers of the GHS text agreed, at the time the GHS was developed, to a convention of using “should” or “may” in GHS text as this provided flexibility in implementing the GHS into national/regional laws. In some regulatory jurisdictions, the scope of changes that were needed to align with the GHS was significant. Also, the added flexibility given to authorities to transpose the non-binding GHS into mandatory legislation was considered necessary to be able to implement the GHS.

Information to support the proposed discussion

4. It is widely acknowledged that the issue is not merely an editorial matter involving a general replacement of “should” / “may” with “shall” / “must” and, as such, careful consideration should be given, in particular when it comes to testing for classification, given that the GHS does not require testing (see chapter 1.3, section 1.3.2.4).

5. According to one of the basic principles of the GHS, the criteria for health and environmental hazards in the GHS is test-method neutral (see chapter 1.1, paragraph 1.1.2.5 (b) (i) and chapter 1.3, section 1.3.2.4). Historically speaking, this was done to allow the use of existing data for classification when implementing the GHS for those hazard classes. This was an alternative to requiring retesting of chemicals using more recent tests/test guidelines specifically mentioned in the GHS (that may not have been available in the past).

6. The criteria for physical hazards are different because transport classification defines specific tests that shall be used to ensure transport safety and provide a common ground for classification. The tests used for classification for physical hazards are the only ones accepted to determine transport classification, and therefore, there is no other choice than to use the
ones specified in the transport regulations (and consequently in part 2 of the GHS). For instance, closed cup tests may trigger a different classification result than open cup tests for flammability for the same chemical. Classification of explosives is also very much dependent on the type of tests used.

7. It is worth pointing out that the original Recommendations on the Transport of Dangerous Goods were reformatted in 1996 in the form of “Model Regulations” to facilitate their direct integration into modal, national and international regulations. In that context, a paragraph was introduced to explain how “shall” and “should” were to be understood. The text is to be found in paragraph 2 of the Recommendations which states:

“Although only a recommendation, the Model Regulations have been drafted in the mandatory sense (i.e., the word "shall" is employed throughout the text rather than "should") in order to facilitate direct use of the Model Regulations as a basis for national and international transport regulations.”

8. Given that the GHS allows implementation in accordance with the building block approach, it differs from the approach in the Model Regulations for the transport of dangerous goods. In addition, the GHS includes guidance, explanatory text and other information (e.g., references and quotations from other texts) along with criteria. As a result, the text in GHS chapters cannot be copied into legally binding text without significant changes. Moreover, in the absence of guidance, the meaning of the terms “should”, “shall”, “may” and “must” in the context of the GHS may be subject to interpretation when translated into other languages or transposed into legally binding instruments for implementation.

9. A statement addressing the intended meaning of these terms in the GHS will help ensuring their understanding and consistent use and will also facilitate interpretation of the criteria while transposing it into legally binding instruments for implementation at national, regional or international level.

**Potential future work**

10. Discuss, with other interested parties, the development of a statement to clarify the intended meaning of the terms “should”, “shall”, “may” and “must” to help ensure consistency in the GHS.

11. Draft a proposal in the form of a working paper for the December 2023 meeting to include: text for the GHS to clarify the matter for future reference; and a mechanism to amend existing text, as appropriate.

**Action requested**

12. The Sub-Committee is invited to consider and discuss this issue. Interested parties are invited to contact the expert from the United States of America.