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

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Thirtieth session Geneva, 9 – 11 December 2015 Item 4 (b) of the provisional agenda **Hazard communication issues: Improvement of annexes 1 to 3 and further rationalization of precautionary statements**

Flexibility in the use of precautionary statements

Transmitted by the expert from the United Kingdom on behalf of the correspondence group on improving annexes 1, 2 and 3 of the GHS

Background

1. In line with its mandate for the 2015-16 biennium¹ the correspondence group has taken forward work under its Workstream 2: 'to consider giving more freedom to labelling practitioners and/or enforcement authorities in assigning precautionary statements and in the precise wording used in precautionary statements, including, to consider whether to address minor linguistic variations in hazard and precautionary statements which do not affect the obvious meaning of these statements and, if appropriate, to develop proposals.'

2. This paper presents the outcomes of this work to date in the form of a draft proposal to amend parts of section 3 of Annex 3 of the GHS.

Proposal

3. The proposal adds new text in Section 3 of Annex 3 to the GHS under the heading 'Flexibility in the use of precautionary statements'. The new text:

(a) Gives guidance on when precautionary statements triggered by the classification of a substance or mixture may be omitted from the label.

(b) Explicitly encourages combination or consolidation of precautionary statements to save label space, improve readability and so improve the clarity of safety messages. It notes that the combined precautionary statements listed in Sections 2 and 3 of Annex 3 are examples, and encourages those responsible for labels to use other combinations where this contributes to clarity and comprehensibility of label information.

(c) Notes that, subject to any requirements of competent authorities, minor departures from the exact text of precautionary statements in the GHS are acceptable in limited circumstances where the changes do not affect the safety message.

¹ Programme of work of the Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals for 2015-2016 (refer to ST/SG/AC.10/C.4/56, annex III).

(d) Provides guidance to rationalise and reduce the number of precautionary statements relating to first aid and medical advice that are triggered when a substance or mixture is classified in different health classes/categories and for different routes of exposure. This guidance addresses a significant practical problem for labelling practitioners in applying the matrix of precautionary statements in regard to medical advice.

4. Annex 2 to this paper illustrates the effect of the proposed guidance to rationalise and reduce the number of precautionary statements relating to first aid and medical advice.

5. The opportunity has also been taken to restructure without loss of content the existing text of Section 3 of Annex 3 to the GHS under three headings (Introduction, General precautionary measures, and Matrix of precautionary statements by hazard class/category).

6. The proposal as it presently stands is at Annex 1 to this paper. New text is denoted by underlined italics (*thus*), and deleted text by strikethrough (*thus*). Where existing text has been moved this is indicated by putting the new paragraph number in italics (e.g. A3.3.1.2) and by a note in square brackets (e.g. [Note: previously in A3.3.2.3]).

7. The proposal is a work in progress, and a number of issues are still under discussion in the correspondence group. These include:

(a) The extent to which the text of precautionary statements can be varied, and the circumstances in which this is acceptable;

(b) Whether the text of hazard statements should be open to variation, and if so to what extent;

(c) Whether there should be any General Precautionary Statements for GHS target audiences other than consumers.

Action requested

8. The Sub-Committee is invited to note and comment on the proposal in Annex 1 to this paper as it presently stands, and on the issues noted in paragraph 7. Subject to the Sub-Committee's views, the Correspondence Group will take forward this work and prepare a formal document for the next session.

Annex 1

"Annex 3

Section 3

USE OF PRECAUTIONARY STATEMENTS

A3.3.1 Introduction

A3.3.1.1 This section provides guidance on the use of precautionary statements consistent with the GHS, including advice on the selection of appropriate statements for each GHS hazard class and category. This section should be seen as a living document and therefore <u>It will be</u> subject to further refinement and development over time. The basic concepts of the matrix and the philosophy given <u>though the overall approach set out</u> below will remain. [Note: previously A3.3.1.6.]

A3.3.1.2 Precautionary statements should appear on GHS labels along with the GHS hazard communication elements (pictograms, signal words and hazard statements). Additional supplemental information, such as directions for use, may also be provided at the discretion of the manufacturer/supplier and/or competent authority (see Chapter 1.2 and Chapter 1.4, para. 1.4.6.3). [Note: previously in A3.3.2.3]

A3.3.1.3 The starting point for assigning precautionary statements is the hazard classification of the chemical product. The system of classifying hazards in the GHS is based on the intrinsic properties of the chemicals involved (see 1.3.2.2.1). In some systems, however, labelling may not be required for chronic hazards on consumer product labels if information shows that the respective risks can be excluded under conditions of normal handling, normal use or foreseeable misuse (see Annex 5). If certain hazard statements are not required then the corresponding precautionary statements are also not necessary (see A5.1.1).

A3.3.1.4 The guidance for assigning the phrases in this section has been developed to provide the essential minimum phrases linking precautionary statements with relevant GHS hazard classification criteria and type of hazard.

A3.3.1.5 Existing precautionary statements have been used to the maximum extent as the basis for the development of this section. These existing systems have included the IPCS International Chemical Safety Card (ICSC) Compilers Guide, the American National Standards (ANSI Z129.1), the EU classification and labelling directives, the Emergency Response Guidebook (ERG 2004), and the Pesticide Label Review Manual of the Environmental Protection Agency (EPA) of the United States of America.

A3.3.1.6 The presumed observation of precautionary label information, specific safety guidelines, and the safety data sheet for each product before use are part of the labelling requirements and occupational health and safety procedures. [Note: previously A3.3.3.2] The goal of this section is to promote a more c-Consistent use of precautionary statements. Their use will reinforce safe handling procedures and will enable the key concepts and approaches to be emphasized in *workplace* training and education activities.

A3.3.1.7 In order to correctly implement precautionary measures concerning prevention, response, storage and disposal, it is also necessary to have information on the composition of products at hand, so that information shown on the container, label and safety data sheet can be taken into account when asking for further specialist advice. [Note: previously A3.3.3.]

A3.3.1.8 To protect people with different reading abilities, it might be useful to include both precautionary pictograms and precautionary statements in order to convey information in more than one way (see 1.4.4.1 (a)). It should be noted, however, that the protective effect of pictograms is limited and the examples in this annex do not cover

all precautionary aspects to be addressed. While pictograms can be useful, they can be misinterpreted and are not a substitute for training. [Note: previously A3.3.4.7]

A3.3.2 Matrix of precautionary statements by hazard class/category Allocation of precautionary statements

A3.3.2.1 This section sets out a matrix <u>listing</u> the recommended precautionary statements for each hazard class and hazard category of the GHS by type of precautionary statement (see A3.2.2.1). <u>The matrix</u> which guides the selection of appropriate precautionary statements, <u>and</u> It includes elements for all categories of precautionary action. All specific elements relating to particular hazard classes should be used. <u>In addition</u>, general elements <u>precautionary</u> <u>statements</u> not linked <u>in particular</u> to a certain hazard class or category should also be used where relevant (<u>see A3.3.3</u> <u>below</u>). [Note: Includes part of previous A3.3.5.1. However, the sentence 'In each case the precautionary statement has the applicable code on the line immediately above' is of limited value and has been omitted. A3.3.2.2 to A3.3.2.6 below were previously A3.3.4.1 to A3.3.4.5.]

A3.3.2.2 The tables making up the matrix show the core part of the precautionary statements in bold print. This is the text, except as otherwise specified, that should appear on the label. [Note: additional text in A3.3.4.1 moved to A3.3.4.3 under 'flexibility']

A3.3.2.3 Text in italics that starts with "- *if*" or "- *specify*" is intended to be an explanatory conditional note for the application of the precautionary statements and is not intended to appear on the label.

A3.3.2.4 When a forward slash or diagonal mark [/] appears in a precautionary statement text, it indicates that a choice needs to be made between the phrases they separate. In such cases the manufacturer or supplier can choose, or competent authorities may prescribe, one or more appropriate phrase(s). For example, "Wear protective gloves/protective clothing/eye protection/face protection" could read "Wear eye protection" or "Wear eye and face protection".

A3.3.2.5 When three full stops [...] appear in a precautionary statement text, they indicate that all applicable conditions are not listed. In such cases the manufacturer or supplier can choose, or the competent authorities may prescribe the other conditions to be specified. For example, in the statement "Use explosion-proof [electrical/ventilating/lighting/...] equipment", the use of "..." indicates that other equipment may need to be specified.

A3.3.2.6 In the majority of cases, the recommended precautionary statements are independent, e.g. the phrases for explosive hazard do not modify those related to certain health hazards and products that are classified for both hazard classes should bear appropriate precautionary statements for both.

A3.3.3 General precautionary measures

A3.3.3.1 General precautionary measures should be adopted for all substances and mixtures which are classified as hazardous to human health or the environment. To this end the needs of, and the information sources available to three groups of users or applicators should be taken into account: <u>consumers, employers and workers, and</u> <u>emergency responders</u> the general public, the commercial user and the industrial worker. [Groups aligned with relevant target audiences in 1.4.3 of the GHS.]

A3.3.3.2 In addition to the appropriate precautionary statements in the matrix, taking into account the guidance in this section, the following general precautionary statements on the GHS label are appropriate under the given conditions and should also appear on GHS labels:

General public Consumers	GHS label, supplemental label information	P101	If medical advice is needed: Have product container or label at hand
		P102	Keep out of reach of children
		P103	Read label before use

Industrial Employers and worker <u>s</u>	GHS label, supplemental label information, Safety Data Sheet, workplace instructions	None of the above [For discussion in the correspondence group.]
<u>Emergency</u> <u>responders</u>	GHS label, supplemental label information, Safety Data Sheet, confidential information on composition (in some jurisdictions)	[For discussion in the correspondence group.]

A3.3.4 <u>Flexibility in the use of Structure of the precautionary statements matrix</u>

A3.3.4.1 *Omission of precautionary statements where the advice is not relevant*

Subject to any requirements of competent authorities, those responsible for labelling may decide to omit a precautionary statement specified in the matrix for a hazard class and category where the information is clearly not appropriate or is adequately addressed by other information on the label, taking into account the nature of the user (e.g. consumer, worker), the quantity supplied to the user, and the intended and foreseeable circumstances of use. Examples where it may be appropriate to omit precautionary statements are:

a. P241, Use explosion-proof [electrical/ventilating/lighting/...] equipment, where flammable liquids or flammable solids are supplied in small quantities to the general public;

b. P243, Take action to prevent static discharges, where flammable liquids are supplied in small

c. P272, Contaminated work clothing should not be allowed out of the workplace, where the substance or mixture is only supplied to the general public;

d. P283, Wear fire resistant or flame retardant clothing, where flammable liquids are supplied in small quantities to the general public;

e. <u>P501</u>, **Dispose of contents/container to ...**, where the substance or mixture is not supplied to the general public and where there are no specific requirements for disposal other than those normally applicable to workplace chemicals.

Where a decision is made to omit a precautionary statement the supplier of the substance or mixture should be able to demonstrate that the precautionary statement is not appropriate for the intended and foreseeable use, including potential emergency situations.

A3.3.4.2 <u>Combination or consolidation of precautionary statements</u>

quantities;

<u>To provide flexibility in the application of precautionary phrases, combinations or consolidations of</u> <u>precautionary statements are encouraged to save label space and improve readability.</u> [Note: previously in A3.3.2.2] <u>The matrix and the Tables in Section 2 of Annex 3 include a number of combined precautionary statements. However,</u> <u>these are only examples and those responsible for labelling should further combine and consolidate phrases where this</u> <u>contributes to clarity and comprehensibility of label information.</u>

Combinations of precautionary statements can also be useful for different types of hazard where the precautionary behaviour is similar. Examples are P372+ P370+ P380, Explosion risk. In case of fire: evacuate area, and P210+ P403, Keep away from heat, sparks and open flame and store in a cool well ventilated place. [Note: previously in A3.3.2.2]

A3.3.4.3 *Variations of text not affecting the safety message*

<u>Subject to any requirements of competent authorities, the precautionary statements that appear on</u> labels may incorporate minor textual variations from those set out in the GHS where these variations assist in communicating safety information and the safety advice is not diluted or compromised.

Examples include:

a) In P260, **Do not breathe dust/fume/gas/mist/ vapours/spray** the word 'vapour' may be spelled 'vapor' where the substance or mixture is supplied in North America.

b) In P234, Keep only in original packaging may appear on the label as Keep only in original partainer

<u>container.</u>

<u>c)</u> In the French text of P210: **Tenir à l'écart de la chaleur, des surfaces chaudes, des étincelles, des** flammes nues et de toute autre source d'ignition. Ne pas fumer, 'source d'ignition' may be replaced by 'source <u>d'inflammation'.</u>

d) [Other examples, e.g. different orders of combination statements?]

However, it is not necessary to insist on identical sets of words in all situations. Derogations from the recommended labelling statements are at the discretion of competent authorities. In all cases, clear plain language is essential to convey information on precautionary behaviour. [Note: previously A3.3.4.1] *Furthermore, to ensure clarity of safety messages any variations should be applied consistently on the product label and in the safety data sheet.* [The correspondence group may wish to discuss whether similar flexibility is appropriate for hazard statements.]

A3.3.4.4 Application of precautionary statements concerning first aid and medical attention

First aid measures for acute toxicity or skin corrosivity take precedence over those for longer term effects. However, medical attention to delayed health effects may be required in cases of incidental exposure, even if not associated with immediate symptoms of intoxication. [Note: previously A3.3.4.6] For some specific chemicals, supplementary first aid, treatment measures or specific antidotes or cleansing materials may be required. Poisons Centres and/or medical practitioners *should be consulted* or specialist advice should be sought in such situations and *appropriate information* included on labels [Note: previously A3.3.2.3]

<u>Applying the matrix to substances or mixtures classified for several health effects will often trigger a</u> <u>number of precautionary statements relating to first aid and medical attention. To ensure clear advice on the response</u> <u>to be taken, particularly where rapid action may be crucial, the following principles may be applied:</u>

<u>A) Use combinations of precautionary statements where the immediate response is similar. For</u> <u>example, P332+P308+P313, If skin irritation occurs or IF exposed or concerned: Get medical advice/attention for a</u> <u>chemical classified both as skin irritation category 2 and reproductive toxicity category 2.</u>

B) Use precautionary statements calling for medical or first aid response (P310, P311, P312, P313) in combination with the appropriate 'IF' statements for exposure (P301, P302, P304, P305 or P308) or with the appropriate combined precautionary statement. However, P301 and P302 need not appear on the label when the chemical is classified only as acute toxicity category 5 [oral or dermal]. [Question for the Group: is it known why GHS gives P304+P312 for acute category 5 inhalation, and P312 only for the category 5 oral and dermal routes? Should P304 here be removed?]

C) Where the classification of a substance or mixture triggers several different precautionary statements for first aid or medical attention, use the precautionary statement calling for the more urgent or rapid response. For example, P301+P304+P310, IF SWALLOWED OR INHALED: Immediately call a POISON CENTER/doctor/... for a chemical classified as acute toxicity category 2 (oral) and category 3 (inhalation). This principle leads to a precedence system; for example, P304+P310, IF INHALED: Immediately call a POISON CENTER/doctor/... would have precedence over P304+P312, IF INHALED: Call a POISON CENTER/doctor/... if you feel unwell; and either would have precedence over P308+P311, IF exposed or concerned: Call a POISON

<u>CENTER/doctor/...</u> or P308+P313, IF exposed or concerned: Get medical advice attention or P342+P311: If experiencing respiratory symptoms: Call a POISON CENTER/doctor/.... [Note: C) builds on A3.3.4.6]

D) Where three or more of the precautionary statements P301, P302, P303, P304 or P305 are triggered, they may be replaced by IF EXPOSED:. For example, P301+P302+P304+P312, IF EXPOSED: Call a POISON CENTER/doctor/... if you feel unwell for a chemical classified as acute toxicity category 4 for all three routes of exposure; and P301+P303+P304+P305+P310, IF EXPOSED: Immediately call a POISON CENTRE/doctor/..., for a chemical classified as skin corrosion, category 1, 1A, 1B or 1C. [Question for the Group: should we allow / encourage use of IF EXPOSED for two or more routes of exposure?]".

Annex 2

Example - Formaldehyde (37 %) stabilised with 10% Methanol and 1% Papain

Pictograms



Signal word: Danger

Hazard statements:

H301+H311+H331 - Toxic if swallowed, in contact with skin or if inhaled

- H314 Causes severe skin burns and eye damage
- H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled
- H317 May cause an allergic skin reaction
- H341 Suspected of causing genetic defects
- H350 May cause cancer
- H370 Causes damage to organs (Eye)

Precautionary statements: Response statements involving first aid/medical advice triggered by these hazard statements according to the precautionary statement matrix:

P301+P310, IF SWALLOWED: Immediately call a POISON CENTER/doctor/...;

P312, Call a POISON CENTER/doctor/...if you feel unwell.

P311, Call a POISON CENTER/doctor/...

P310, Immediately call a POISON Center/doctor/...

P342+P311, If experiencing respiratory symptoms: Call a POISON CENTER/doctor/...

P333+P313, If skin irritation or rash occurs: Get medical advice attention

P308+P313, If exposed or concerned: Get medical advice/attention*

P308+P311, If exposed or concerned: Call a POISON CENTER/doctor/...

* Discretion possible under existing A3.3.4.6

Other response statements: P321; P330; P302+P352; P321; P361+P364; P304+P340; P301+P330+P331; P303+P361+P353; P363; P304+P340; P305+P351+P338; P326+P324

Based on the proposed principles only one precautionary statement referencing a poison center or doctor would be used:

P301+P302*+P304+P305+P310: IF EXPOSED: Immediately call a POISON CENTER/doctor/...

[Note: Correspondence Group to check whether any consequential changes are needed to the label in Example 7 in Annex 7.]