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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

Forty-seventh session Geneva, 4-6 December 2024 Item 2 (a) of the provisional agenda Work on the Globally Harmonized System of Classification and Labelling of Chemicals: Recommendations made bythe Sub-Committee at its forty-fourth, forty-fifth and forty-sixth sessions

Consolidated list of draft amendments adopted by the Sub-Committee at its forty-fourth, forty-fifth and forty-sixth sessions

Note by the secretariat*

This document contains the consolidated list of draft amendments to the tenth revised edition of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (ST/SG/AC.10/30/Rev.10) adopted by the Sub-Committee at its forty-fourth, forty-fifth and forty-sixth sessions.



^{*} A/75/6 (Sect. 20), par. 20.51.

Chapter 1.2

In the definition of "Ozone Depleting Potential", delete "(ODP)" in the first sentence and replace "ODP" with "ozone depleting potential" in the second sentence.

Insert the following new definition in the alphabetical order:

"Global warming potential is a metric that compares the ability of a substance or mixture to trap heat in the atmosphere as compared to a benchmark gas (generally carbon dioxide). The formal definition of global warming potential is the cumulative radiative forcing, both direct and indirect effects, over a specified time horizon resulting from the emission of a unit mass of gas relative to that of carbon dioxide (as the reference gas)."

Chapter 2.2

2.2.2 In note 2 under table 2.2.1, replace "Aerosols" with "Aerosols and chemicals under pressure".

Chapter 2.3

2.3.1.1 Amend to read as follows:

"2.3.1.1 Definition and general considerations

2.3.1.1.1 *Aerosols, this means aerosol dispensers*, are any non-refillable receptacles made of metal, glass or plastics and containing a gas compressed, liquefied or dissolved under pressure, with or without a liquid, paste or powder, and fitted with a release device allowing the contents to be ejected as solid or liquid particles in suspension in a gas, as a foam, paste or powder or in a liquid state or in a gaseous state.

2.3.1.1.2 Aerosols do not fall additionally within the scope of section 2.3.2 (chemicals under pressure), chapters 2.2 (flammable gases), 2.5 (gases under pressure), 2.6 (flammable liquids) and 2.7 (flammable solids). Depending on their contents, aerosols may fall within the scope of other hazard classes.

NOTE: Some sectors, e.g. transport, may have other specific provisions regarding the applicability of additional hazard classes. For the transport of aerosols, see special provision 63 of the UN Model Regulations.".

2.3.1.2.1 Delete current notes 1 and 3 under table 2.3.1.

2.3.1.2.2 (new) Current Note 2 under table 2.3.1 becomes new paragraph 2.3.1.2.2 as amended to read as follows:

"2.3.1.2.2 Aerosols containing more than 1 % flammable components or with a heat of combustion of at least 20 kJ/g that have not been tested according to 2.3.1.2.1, third indent, must be classified as aerosols, Category 1."

2.3.2.1 Amend to read as follows:

"2.3.2.1 Definition and general considerations

2.3.2.1.1 *Chemicals under pressure* are liquids or solids (e.g. pastes or powders), pressurized with a gas at a pressure of 200 kPa (gauge) or more at 20 °C in pressure receptacles other than aerosol dispensers and which are not classified as gases under pressure.

NOTE: Chemicals under pressure typically contain 50 % or more by mass of liquids or solids whereas mixtures containing more than 50 % gases are typically considered as gases under pressure.

2.3.2.1.2 Chemicals under pressure do not fall additionally within the scope of section 2.3.1 (aerosols) and chapters 2.2 (flammable gases), 2.5 (gases under pressure), 2.6 (flammable liquids) and 2.7 (flammable solids). Depending on their contents, chemicals under pressure may fall within the scope of other hazard classes."

NOTE: Some sectors, e.g. transport, may have specific provisions regarding the applicability of additional hazard classes differing from those in 2.3.2.1.2 and the related note. For the transport of chemicals under pressure, see special provision 362 of the UN Model Regulations.".

2.3.2.2.2 Delete notes 1 and 2.

Chapter 2.6

2.6.2 In note 4 under table 2.6.1, replace "Aerosols" with "Aerosols and chemicals under pressure".

Chapter 2.7

2.7.2 In note 2 under table 2.7.1, replace "Aerosols" with "Aerosols and chemicals under pressure".

Chapter 2.8

2.8.1.1 Amend the end of the second sentence to read "... as explosives, organic peroxides, or oxidizing liquids or solids in accordance with 2.8.2.1."

Chapter 2.17

2.17.2.2 Amend the note as follows:

"**NOTE:** Phlegmatized explosives which do not meet the criteria of 2.17.2.2 should not be classified as a desensitized explosive and should be classified as an explosive in accordance with chapter 2.1.".

Chapter 3.4

3.4.2.2.3.1 In the fourth sentence, replace "in the radioisotopic local lymph node assay" with "in the radioactive local lymph node assay".

3.4.2.2.5.1 Replace "3.4.5.3.5" with "3.4.5.3.1.5" in the last sentence.

3.4.2.2.5.3 Replace "3.4.5.3.6.2" with "3.4.5.3.1.6.2" in the first sentence and the related footnote 4.

3.4.2.2.7.2 Replace "3.4.5.3.2" with "3.4.5.3.1.2" in subparagraphs (a), (b) and (c). Replace "3.4.5.3.3" with "3.4.5.3.1.3" in subparagraph (d), "3.4.5.3.4" with "3.4.5.3.1.4" in subparagraph (e), and "3.4.5.3.5" with "3.4.5.3.1.5" in subparagraph (f).

3.4.2.2.7.3 Replace "3.4.5.3.5" with "3.4.5.3.1.5" in subparagraph (a).

3.4.3.1 Replace with the following:

"3.4.3.1 Classification of mixtures when data are available for the complete mixture

3.4.3.1.1 In general, the mixture should be classified using the criteria for substances taking into account the tiered approach to evaluate data for this hazard class (see 3.4.3.1.2 and figure 3.4.1). If classification is not possible using the tiered approach, then the approach described in 3.4.3.2 or, if that is not applicable, in 3.4.3.3, should be followed. For supplemental labelling required by some competent authorities, see the note to table 3.4.5 and 3.4.4.2.

3.4.3.1.2 Care should be exercised in evaluating data on mixtures that the dose used does not render the results inconclusive and that the test methods used to generate such results are appropriate for predicting the skin sensitizing properties of the mixture (see 3.4.5.3.2). Further, for both standard test methods (in vivo, *in chemico*, in vitro) and defined approaches, data can only be used for classification when all ingredients fall within their applicability domain. Specific limitations regarding applicability domains are described in the respective test methods and defined approaches and should be taken into consideration as well as any further information on such limitations from the published literature. A competent authority may decide which *in chemico/*in vitro test method or defined approach may be accepted for mixtures (see 3.4.5.3.2.4 and 3.4.5.3.2.5). A more detailed overview of factors to consider in the classification of mixtures can be found in guidance section 3.4.5.3.2 and the test methods.".

- 3.4.5.3 Insert the following new heading beneath "3.4.5.3 Background guidance":
 - "3.4.5.3.1 Guidance on substances skin sensitization".

3.4.5.3.1 to 3.4.5.3.2 Current sections "3.4.5.3.1" to "3.4.5.3.2" become new sections "3.4.5.3.1.1" to "3.4.5.3.1.2".

3.4.5.3.1.2 (former 3.4.5.3.2) Replace with the following:

- "3.4.5.3.1.2 Guidance on the use of human data
- 3.4.5.3.1.2.1 This guidance is relevant to substances and mixtures.

3.4.5.3.1.2.2 The classification of substances and mixtures can be based on human evidence generated from a variety of sources. These sources include human predictive patch testing, epidemiological studies, case studies, case reports or histories, diagnostic patch testing and medical surveillance reports, and poison control centre information. This data may have been generated for consumers, workers, or the general population. Guidance for evaluating human evidence and the criteria in 3.4.2.2.2 is provided by some competent authorities (e.g., ECHA Guidance on the Application of the CLP Criteria, 2017). Further valuable information which should be considered for classification purposes (e.g., on use of appropriate concentrations and vehicles, as well as mixture evaluation) is also available (see U.S. Consumer Product Safety Commission (U.S CPSC), 2013; European Society of Contact Dermatitis guidance, 2015; Frosch et al., 2015).

3.4.5.3.1.2.3 When evaluating existing data, its quality should be taken into consideration. Criteria for a "well conducted" study would include validated outcomes, relevant dosing and route of administration and use of appropriate controls. Special attention should be applied to ascertain that exposure to the relevant substance or mixture is established with sufficient reliability. Studies should, where applicable, be carried out according to national and/or international test guidelines and according to good laboratory practice (GLP), compliance with good clinical practice (GCP), and good epidemiological practice (GEP) (U.S. CPSC, 2013; Hoffman, 2019; Alba, 2020; World Health Organization, Council for *International* Organizations of Medical Sciences (WHO CIOMS), 2009).

3.4.5.3.1.2.4 Positive data from well-run epidemiological studies (in accordance with WHO CIOMS guidelines, 2009) can be used for classifying substances and mixtures for skin sensitization. Some examples of epidemiological studies may include case control studies, cohort studies, cross-sectional studies, or longitudinal studies. These studies should have large sample sizes with well-documented exposures to a substance or a mixture.

3.4.5.3.1.2.5 When using human epidemiological data for classification, consideration should be given to available data from a number of sources: (a) well-conducted clinical and diagnostic studies; (b) epidemiological studies, either general population studies or occupational studies; (c) cross-reactivity data; (d) case histories. Positive data from well-run epidemiological studies (which should also comply with WHO CIOMS guidelines, 2009) can be used for classifying substances and mixtures for skin sensitization. The incidence and severity of sensitization in occupational epidemiological studies may be higher than in general population studies due to the higher exposure levels (both in time and concentration). The exposure, the incidence and the severity in the study populations should be taken into account especially when deciding on the subcategory (see 3.4.2.2.2).

3.4.5.3.1.2.6 A specific type of epidemiological study (such as randomized control studies or trials) may include information from diagnostic patch testing. Diagnostic patch testing is considered by some competent authorities to be the gold standard in diagnosing contact allergy in dermatitis patients (Johansen et al, 2015; Frosch et al., 2015). Importantly, due consideration needs to be given to the appropriate selection of vehicle, test material composition, and patch test concentrations for the purpose of not causing false negatives, false positives, irritant reactions or inducing contact allergy (skin sensitization). Positive data from experimental, clinical or diagnostic studies in humans and/or well-documented episodes of allergic contact dermatitis may be used to classify substances and mixtures for skin sensitization, when it can be assumed with sufficient confidence that the tested substance or mixture was indeed the most likely cause for induction of sensitization. Therefore, it should be established that there is at least a general likelihood that the respective patient(s) had been previously exposed to the substance or mixture. On the other hand, negative results from such tests are not sufficient to prove that the test substance or mixture should not be classified as a skin sensitizer.

3.4.5.3.1.2.7 For some substances and mixtures, predictive patch test data in human volunteers are available (e.g. Strickland et al., 2023). Two test designs for predicting whether the substance or mixture will induce sensitization are the Human Maximization Test (HMT) and the Human Repeated Insult Patch Tests (HRIPT).

3.4.5.3.1.2.8 Positive data from predictive patch testing (HRIPT or HMT) showing allergic contact dermatitis caused by the test substance or mixture can be used to classify for skin sensitization. These studies are generally conducted in controlled clinical settings and in general the study outcome is considered more reliable the larger the test panel size. Criteria for evaluating these data are provided in 3.4.2.2.2.2 and 3.4.2.2.2.3. When evaluating the data from HRIPT, consideration should be given to the appropriate use of vehicle as this can affect the outcome of testing (Johansen et al., 2015; Frosch et al., 2015).

3.4.5.3.1.2.9 The HMT is no longer in use, due to ethical concerns about its potential to create adverse health consequences for the person being tested. In cases where such data exist, they can nevertheless be used for classification.

3.4.5.3.1.2.10 Special consideration should be given to negative human data as full dose-response information is generally not available. For example, a negative result in an HRIPT or HMT at a low concentration may not allow

for the conclusion that the substance or mixture does not have skin sensitizing properties, as such effect at a higher concentration may not be excluded. In addition, negative human data should not necessarily be used to negate positive results from animal studies and/or defined approaches but can be used as part of a weight of evidence assessment. For both animal and human data, consideration should be given to the impact of the vehicle (e.g. Wright et al, 2001 and Kligman, 1966).

3.4.5.3.1.2.11 For example, negative results from substances or mixtures tested in a predictive patch test at a DSA (dose per skin area) of $< 500 \ \mu g/cm^2$ imply that a classification for skin sensitization might not be needed at all, however, classification as sub-category 1A or 1B cannot be ruled out, because the concentration tested was not high enough to exclude these possibilities. The same holds for test results for which it is unknown whether the test concentration corresponded to a DSA $< 500 \ \mu g/cm^2$. Negative results from substances or mixtures tested at a DSA \geq 500 µg/cm² suggest that classification might not be needed. However, while classification as subcategory 1A can be ruled out, classification as sub-category 1B cannot, because a higher test concentration might have resulted in a positive test result. However, a negative test result at a concentration of 100% (i.e. the undiluted substance or mixture) can justify no classification (based on this test). Nevertheless, negative results at low concentrations may be informative for classification of mixtures containing the substance or mixture at similar or lower concentrations.

3.4.5.3.1.2.12 Human data not generated in controlled experiments with volunteers for the purpose of hazard classification (e.g. case studies, case reports and case histories, and poison control centre information) can be used with caution. Consideration should be given to the frequency of cases, the inherent properties of the substances or mixture, as well as factors such as the exposure situation, bioavailability, individual predisposition, cross-reactivity and preventive measures taken.".

3.4.5.3.1.3 to 3.4.5.3.1.6 (new, former 3.4.5.3.3 to 3.4.5.3.6) Current sections "3.4.5.3.3" to "3.4.5.3.6" become new sections "3.4.5.3.1.3" to "3.4.5.3.1.6". Renumber the paragraphs within each section accordingly.

3.4.5.3.1.5 (former 3.4.5.3.5) In the second sentence, replace "criteria" with "methods" and insert "for this purpose" at the end of the sentence.

3.4.5.3.1.6.1 (former 3.4.5.3.6.1) Replace "3.4.5.3.6.2" with "3.4.5.3.1.6.2".

3.4.5.3.2 (new) Insert the following new section after 3.4.5.3.1.6 (former 3.4.5.3.6):

"3.4.5.3.2 *Guidance on mixtures – skin sensitization*

3.4.5.3.2.1 General considerations

3.4.5.3.2.1.1 Mechanistic information in the OECD document on the "Adverse Outcome Pathway for skin sensitization" can be helpful in understanding the value of the individual *in chemico* and in vitro methods compared to the in vivo methods (see OECD (2014)).

3.4.5.3.2.1.2 Most of the standard animal test methods, defined approaches, in vitro and *in chemico* methods were developed and formally validated for identifying sensitizing substances and not mixtures. Nevertheless they are technically applicable to mixtures (see 3.4.3.1.2). However, there is limited data indicating whether there is a difference in the predictive capacity between standard animal test methods and defined approaches for the classification of mixtures. Sometimes, standard animal tests (see 3.4.2.2.3) on mixtures are required by competent authorities or applied voluntarily and the results are

internationally accepted for classification. Therefore, the results of standard animal test methods can be used for the classification of mixtures. The defined approaches were first introduced in OECD Guideline 497 in 2021 without a clear statement on the applicability of the defined approaches for mixtures (see also 3.4.5.3.2.4.1). Human data can also be used for the classification of mixtures (see 3.4.5.3.2.2).

3.4.5.3.2.2 Guidance on the use of human data

See the guidance on the use of human data in 3.4.5.3.1.2 which is also applicable to mixtures.

3.4.5.3.2.3 Guidance on the use of standard animal data

3.4.5.3.2.3.1 Animal tests have been developed to identify sensitizing substances and not mixtures. Therefore, the results obtained on mixtures need to be evaluated with care. The following considerations can be relevant for mixtures because of dilution effects, in particular for borderline cases, but can also be applicable for substances.

3.4.5.3.2.3.2 For example, a stimulation index of three or more in the radioactive local lymph node assay (LLNA) (OECD Test Guideline 429) should be seen as a regulatory threshold for identification of a sensitizing mixture rather than as a threshold for sensitization as such. If a sensitizing substance is present at a low concentration in a mixture, a stimulation index of three may not be reached in the LLNA, but the substance in that mixture may still act as a sensitizer at population level. For this reason, a conclusion on the absence of sensitizing potential of a mixture based on the negative outcome in a test must be taken with great caution.

3.4.5.3.2.3.3 Where the mixture is tested undiluted, contains sensitizing ingredients and there is an increase in positive animals (Buehler, guinea pig maximisation test (GPMT)) or in the response (LLNA) which does not fulfil the criteria for a positive result, an overall weight of evidence assessment is required including the indicators included in tier 3. This should also include available data on the sensitizing ingredient(s) regarding their potency, bioavailability, accumulation in the skin and interaction with the other ingredients. When the result is inconclusive, where applicable the bridging principles should be applied, otherwise the ingredient-based approach should be followed according to the tiered approach for mixtures (see 1.3.2.3).

3.4.5.3.2.3.4 Test data on a mixture takes into account effects of possible interactions of its components. For instance, it is known that the presence of a vehicle may significantly influence the skin sensitizing potency, by altering the penetration of the sensitizing component(s) through the skin, (Basketter et al. 2001, Dearman et al. 1996, Heylings et al. 1996) or through other mechanisms involved in the induction of sensitization (Cumberbatch et al. 1993; Dearman et al. 1996). These mechanisms may differ between animals and humans. Especially where differences are known or suspected that could lead to the underestimation of sensitization, negative outcomes may not be reliable.

3.4.5.3.2.3.5 If the classification of a mixture based on a standard animal test (or tests) is inconsistent with the classification based on the concentration and potency (e.g. from standard animal test(s) or human data) of a sensitizing ingredient (or ingredients) (see table 3.4.5), additional considerations may need to be taken into account for the classification of the mixture (see OECD Test Guideline 429). This could include, for example, test concentrations, difference in vehicle and purity of the test material.

3.4.5.3.2.3.6 Where the mixture contains corrosives or potent irritants resulting in unacceptable irritation in the pilot study with the mixture, either a

dilution has to be used or the results may be a false positive. If a dilution is tested, the lower tested dose of the potential sensitizer(s) in the mixture may lead to false negative results for classification. In such cases, where applicable the bridging principles should be applied, otherwise the ingredient-based approach should be followed according to the tiered approach for mixtures (see 1.3.2.3), unless evidence is provided that the negative result is not caused by the dilution. This could for example be shown by testing the mixture without the corrosive or irritant ingredients at the actual concentration. Also, the validity of a well conducted LLNA on a mixture with a negative outcome can scientifically be confirmed by spiking the test mixture with another sensitizer (positive control) at different concentrations, or by showing a dose-response relationship.

3.4.5.3.2.4 Guidance on the use of defined approaches

3.4.5.3.2.4.1 Defined approaches may not have been formally validated for mixtures according to international procedures. Several defined approaches require upfront consideration to whether such testing will yield results that are predictive of the skin sensitizing properties of the mixture (see 3.4.5.3.2.4.3). This upfront consideration could include a comparison of the classification based on the results of a defined approach with existing classifications of similar mixtures. Where the comparison shows that the defined approach is predictive of certain types of mixtures, the outcome of the defined approach can be used for other mixtures of the same type for classification.

3.4.5.3.2.4.2 *In chemico* and in vitro methods used in defined approaches do not account for dermal penetration. Therefore, results from defined approaches may lead to false positive predictions compared to the standard animal tests that account for dermal penetration.

3.4.5.3.2.4.3 Also, it is necessary to exercise care when evaluating whether the dose used will yield results that are predictive of the skin sensitizing properties of the mixture. For example, in some in chemico and in vitro methods, the limited solubility of the ingredients of the mixture or limited stability of any suspension formed in the exposure medium or solvent may not allow testing at a dose that corresponds to the test requirements. In such a case, no valid outcome can be obtained for a negative result. Also, where the mixture is tested at lower concentrations in the in vitro methods due to the presence of cytotoxic ingredients, a positive result can be used for classification. However, a negative result is considered inconclusive as the concentration of the sensitizing ingredient(s) could have been too low unless evidence is provided that the negative result is not caused by the dilution. In such cases, where applicable the bridging principles should be applied, otherwise the ingredientbased approach should be followed according to the tiered approach for mixtures (see 1.3.2.3). Approaches to address cytotoxicity are suggested in the relevant OECD test guidelines 442D and 442E.

3.4.5.3.2.4.4 In some methods, e.g. in silico predictions in the defined approaches for skin sensitization listed in OECD Guideline 497, all ingredients have to be assessed individually and the outcome from the in silico component of the defined approach is considered positive, if one ingredient is positive. However, it is noted that this may provide overly conservative or false positive predictions, as the in silico methods currently do not take into account the concentration at which the ingredient is present in the mixture.

3.4.5.3.2.5 Guidance on the use of non stand-alone *in chemico*/in vitro methods

3.4.5.3.2.5.1 Individual *in chemico/*in vitro methods such as those reported in OECD test guidelines 442C, 442D and 442E, due to their limited mechanistic coverage, cannot be used on their own to conclude on Category 1

or no classification. In addition, although some of these methods provide quantitative information, these cannot be used for the purposes of subcategorization into sub-categories 1A and 1B since the methods have not been validated according to international procedures for this purpose. Nevertheless, such quantitative information may be accepted by a competent authority when used in a weight of evidence assessment under tier 2 for the purpose of subcategorization. This is also in line with the statement in these test guidelines that "Depending on the regulatory framework, positive results generated with these methods may be used on their own to classify a chemical into UN GHS Category 1." Therefore, the GHS also allows a competent authority to decide that a positive result with one of these non stand-alone in chemico/in vitro methods, may be used on its own to classify in Category 1 and whether test guideline 442C (Appendix III) kinetic Direct Peptide Reactivity Assay (kDPRA) can be used to differentiate between sub-category 1A and no sub-category 1A.

3.4.5.3.2.5.2 In chemico/in vitro methods may not have been formally validated for mixtures according to international procedures. Several *in chemico/*in vitro methods require upfront consideration to whether such testing will yield results that are predictive of the skin sensitizing properties of the mixture (see 3.4.5.3.2.5.4). This upfront consideration could include a comparison of the classification based on the results of an *in chemico/*in vitro method with existing classifications of similar mixtures. Where the comparison shows that the *in chemico/*in vitro method is predictive of certain types of mixtures, the outcome of the *in chemico/*in vitro method may be used for other mixtures of the same type for classification.

3.4.5.3.2.5.3 *In chemico/*in vitro methods do not account for dermal penetration. Therefore, results from *in chemico/*in vitro methods may lead to false positive predictions compared to the standard animal tests that account for dermal penetration.

3.4.5.3.2.5.4 Also, it is necessary to exercise care when evaluating whether the dose used will yield results that are predictive of the skin sensitizing properties of the mixture. For example, in some in chemico and in vitro methods, the limited solubility of the ingredients of the mixture or limited stability of any suspension formed in the exposure medium or solvent may not allow testing at a dose that corresponds to the test requirements. In such a case, no valid outcome can be obtained for a negative result. Also, where the mixture is tested at lower concentrations in the in vitro methods due to the presence of cytotoxic ingredients, a positive result can be used for classification. However, a negative result is considered inconclusive as the concentration of the sensitizing ingredient(s) could have been too low unless evidence is provided that the negative result is not caused by the dilution. In such cases, where applicable the bridging principles should be applied, otherwise the ingredientbased approach should be followed according to the tiered approach for mixtures (see 1.3.2.3). Approaches to address cytotoxicity are suggested in the relevant OECD test guidelines 442D and 442E."

3.4.5.3.3 (new, former 3.4.5.3.7) Current section "3.4.5.3.7" becomes new section "3.4.5.3.3". Renumber the paragraphs within the section accordingly.

Insert the following references in the alphabetical order in the current list at the end of the chapter:

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^{*} References:

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Chapter 4.2

Chapter title Amend to read "HAZARDOUS TO THE ATMOSPHERIC SYSTEM"

4.2.1 Amend the heading to read "**Definitions and general considerations**".

Insert a new paragraph beneath the amended title to read:

"This chapter covers substances and mixtures that are hazardous to the atmospheric system due to their ozone depleting and/or global warming potential. For the purposes of this chapter, the following definitions apply:"

Move the existing definition "*Montreal Protocol* is ..." to place it before the existing definition for "*Ozone Depleting Potential*"

In the existing definition of "Ozone Depleting Potential" delete: "(ODP)" in the first sentence and replace "ODP" with "ozone depleting potential" in the second sentence.

Insert the following new definition for "Global warming potential" after the definition for "Ozone Depleting Potential" to read:

"Global warming potential is a metric that compares the ability of a substance or mixture to trap heat in the atmosphere as compared to a benchmark gas (generally carbon dioxide). The formal definition of global warming potential is the cumulative radiative forcing, both direct and indirect effects, over a specified time horizon resulting from the emission of a unit mass of gas relative to that of carbon dioxide (as the reference gas)."

4.2.2 Move footnote reference "1" from the heading of 4.2.2, to the end of the first sentence under the new heading for 4.2.2.2 (see amendment to 4.2.2.2 below).

Insert a new paragraph 4.2.2.1 under the heading "Classification criteria" to read as follows:

"4.2.2.1 Substances and mixtures are classified into the hazardous to the ozone layer hazard class due to their ozone depleting potential in accordance with 4.2.2.2 and/or hazardous by contributing to global warming hazard class by their global warming potential in accordance with 4.2.2.3, independently."

4.2.2.2 Place the existing sentence under "Classification criteria" ("A substance or mixture...") under a new heading 4.2.2.2 and amend as follows:

"4.2.2.2 Hazardous to the ozone layer

A substance or mixture shall be classified in Category 1 hazardous to the ozone layer according to the following table¹:"

In the text of footnote 1 (previously assigned to 4.2.2) replace "ozone layer" with "atmospheric system".

Table 4.2.1, column "Criteria":

Replace "listed in annexes to" with "listed with an ozone depleting potential in annexes to" and "listed in the annexes to the" with "listed with an ozone depleting potential in the annexes".

4.2.2.3 Insert the following new section after table 4.2.1:

"4.2.2.3 Hazardous by contributing to global warming

A substance or mixture shall be classified in Category 1 hazardous to global warming according to the following table ¹:

Table 4.2.2: Criteria for substances and mixtures that are hazardous by contributing to global warming

Category	Criteria
1	Any of the controlled substances listed with a global warming potential in annexes to the Montreal Protocol; or Any mixture containing at least one ingredient listed with a global warming potential in the annexes to the Montreal Protocol, at a concentration ≥ 0.1 %

Footnote 1: Reproduce the text of footnote 1 assigned to 4.2.2.2, as amended.

4.2.3 Renumber the paragraph preceding the table as "4.2.3.1". In the last sentence of that paragraph, replace "Table 4.2.2" with "Table 4.2.3".

Amend current table 4.2.2 (renumbered 4.2.3) and insert a new paragraph 4.2.3.2 to read as follows:

"Table 4.2.3:	Label elements for substances and mixtures hazardous to the
	atmospheric system

	Category 1	Category 1
	Hazardous to the ozone layer	Hazardous by contributing to global warming
Symbol	Exclamation mark	Exclamation mark
Signal word	Warning	Warning
Hazard statement	Harms public health and the environment by destroying ozone in the upper atmosphere	Harms public health and the environment by contributing to global warming

4.2.3.2 Some substances and mixtures meet the criteria for classification as hazardous to the ozone layer and hazardous by contributing to global warming. In these cases, the principles outlined in A3.1.2.5 for combining hazard statements can be used to combine the hazard statements for both hazard classes into a single hazard statement (i.e. "Harms public health and the environment by contributing to global warming and destroying ozone in the upper atmosphere.")."

4.2.4 Amend to read as follows:

"4.2.4 Decision logics for substances and mixtures hazardous to the atmospheric system

The decision logics for hazardous to the ozone layer (see 4.2.2.2) and hazardous by contributing to global warming (see 4.2.2.3) which follow are not part of the harmonized classification system but are provided as additional guidance. It is strongly recommended that the person responsible for classification study the criteria before and during use of these decision logics.





Decision logic 4.2.2 for hazardous by contributing to global warming



Annex 1

Table A1.30

Amend to read as follows:

"A1.30 Hazardous to the atmospheric system (see chapter 4.2 for classification criteria)

Classification			Labelling				GHS hazard
GHS hazard class	GHS hazard category	UN Model Regulations class or division	GHS pictogram	UN Model Regulations pictograms	GHS signal word	GHS hazard statement	statement code
Hazardous to the ozone layer	1			Not applicable		Harms public health and the environment by destroying ozone in the upper atmosphere	H420
Hazardous by contributing to global warming	1	Not applicable			\checkmark	Not applicable	Warning

Annex 3, section 1

Table A3.1.3

Insert the following new entry under H420:

(1)	(2)	(3)	(4)
H421	Harms public health and the environment by	Hazardous by contributing to global	1
	contributing to global warming	warming (chapter 4.2)	

Annex 3, section 2

Table A3.2.2

P260, column (4)

For "Acute toxicity, inhalation (chapter 3.1)": Insert ", 3" after "1, 2".

For "Specific target organ toxicity, single exposure (chapter 3.8)" and "Specific target organ toxicity, repeated exposure (chapter 3.9)": Delete: ", 2".

P261

For "Acute toxicity, inhalation (chapter 3.1)", column (4): delete "3,".

Insert the following new row below the entry for "Skin sensitization (chapter 3.4)":

(1)	(2)	(3)	(4)	(5)
		Specific target organ toxicity, single	2	
		exposure (chapter 3.8)		

Insert the following new row below the entry for "Specific target organ toxicity, single exposure, narcotic effects (chapter 3.8)":

(1)	(2)	(3)	(4)	(5)
		Specific target organ toxicity, repeated exposure (chapter 3.9)	2	

In column (5), at the end of the current condition for use (applicable to all entries), replace "applicable conditions" with "applicable physical state(s)."

P284, row "Acute toxicity, inhalation (chapter 3.1)", column (4)

Insert ", 3" after "1, 2".

Table A3.2.3

P320

In column (2), replace "(see ... on this label)" with "(see information on this label and safety data sheet)".

Insert the following rows before the existing entry for "Acute toxicity, inhalation (chapter 3.1)":

(1)	(2) (3)		(4)	(5)
		Acute toxicity, oral (chapter 3.1)	1, 2, 3	
		Acute toxicity, dermal (chapter 3.1)	1, 2, 3	

For "Acute toxicity, inhalation (chapter 3.1)", column (4): insert ", 3" after "1, 2".

In column (5) amend the current condition for use (applicable to all entries) to read as follows:

"- if immediate measures that can be easily applied, such as the administration of antidote or other specific treatment are required. These measures must be specified on the label and safety data sheet, recognizing additional detailed instructions, including any training requirements, should be provided on the safety data sheet, if appropriate. "

P321

In column (2) replace "(see ... on this label)" with "(see information on this label and safety data sheet)".

In column (4):

- For "Acute toxicity, oral (chapter 3.1)": replace "1, 2, 3" with "4".
- For "Acute toxicity, dermal (chapter 3.1)": delete "1, 2, 3".
- For "Acute toxicity, inhalation (chapter 3.1)": replace "3" with "4".

In column (5), replace all conditions for use with the following (applicable to all entries):

"- if immediate measures that can be easily applied, such as the administration of antidote or other specific treatment are required. These measures must be specified on the label and safety data sheet, recognizing additional detailed instructions, including any training requirements, should be provided on the safety data sheet, if appropriate.

- may be omitted if P320 is given on the label."

P322 and P323 (new)

(1)	(2)	(3)	(4)	(5)
P322	2 Specific treatment is urgent (see	Acute toxicity, oral (chapter 3.1)	1, 2, 3	Manufacturer/supplier to reference on the
	information on the safety data sheet).	Acute toxicity, dermal (chapter 3.1)	1, 2, 3	safety data sheet detailed instructions,
		Acute toxicity, inhalation (chapter 3.1)	1, 2, 3	including any training requirements, to administer an antidote or other specific treatment. - may be omitted if P320 is given on the label.
P323	Specific treatment (see information on	Acute toxicity, oral (chapter 3.1)	4	Manufacturer/supplier to reference on the safety
	the safety data sheet).	Acute toxicity, dermal (chapter 3.1)	4	data sheet detailed instructions, including
		Acute toxicity, inhalation (chapter 3.1)	4	any training requirements, to
		Skin corrosion (chapter 3.2)	1, 1A, 1B, 1C	other specific treatment. - may be omitted if P321
		Skin irritation (chapter 3.2)	2	or P322 is given on the
		Skin sensitization (chapter 3.4)	1, 1A, 1B	label.
		Specific target organ toxicity, single exposure (chapter 3.8)	1	

Insert the following new precautionary statements after P321:

P340, row "Acute toxicity, inhalation (chapter 3.1)", column (4)

Add ", 5" after "1, 2, 3, 4".

P352, row "Acute toxicity, dermal (chapter 3.1)", column (4)

Add ", 5" after "1, 2, 3, 4".

P302+P317, column (2)

Replace current text with "[Deleted]" and delete the text under columns (3) and (4).

P302+P352, row "Acute toxicity, dermal (chapter 3.1)", column (4)

Add ", 5" after "1, 2, 3, 4".

P304+P317, column (2)

Replace current text with "[Deleted]" and delete the text under columns (3) and (4).

P304+P340, row "Acute toxicity, inhalation (chapter 3.1)", column (4)

Add ", 5" after "1, 2, 3, 4".

Table A3.2.5

P501, row "Acute toxicity, inhalation (chapter 3.1)", column (4)

Add ", 4" after: "1, 2, 3".

P502

Insert the following new row after the existing row for "Hazardous to the ozone layer (chapter 4.2)":

(1)	(2)	(3)	(4)	(5)
		Hazardous by contributing to global warming (chapter 4.2)	1	

Annex 3, section 3

Table for "Acute toxicity, oral (chapter 3.1)", hazard categories 1, 2, 3, column "Response"

Delete the P321 entry, and insert the following P320 and P322 entries (current entries for P301+P316 and P330 remain unchanged):

"P320

Specific treatment is urgent (see information on this label and safety data sheet).

- if immediate measures that can be easily applied, such as the administration of antidote or other specific treatment, are required. These measures must be specified on the label and safety data sheet, recognizing additional detailed instructions, including any training requirements, should be provided on the safety data sheet, if appropriate.

P322

Specific treatment is urgent (see information on the safety data sheet).

Manufacturer/supplier to reference on the safety data sheet detailed instructions, including any training requirements, to administer an antidote or provide other specific treatment.

- may be omitted if P320 is given on the label."

Table for "Acute toxicity, oral (chapter 3.1)" hazard category 4, column "Response"

Insert the following P321 and P323 entries (current entries for P301+P317 and P330 remain unchanged):

"P321

Specific treatment (see information on this label and safety data sheet).

- if immediate measures that can be easily applied, such as the administration of antidote or other specific treatment, are required. These measures must be specified on the label and safety data sheet, recognizing additional detailed instructions, including any training requirements, should be provided on the safety data sheet, if appropriate.

- may be omitted if P320 is given on the label.

P323

Specific treatment (see information on the safety data sheet).

Manufacturer/supplier to reference on the safety data sheet detailed instructions, including any training requirements, to administer an antidote or other specific treatment.

- may be omitted if P321 or P322 is given on the label."

Tables for "Acute toxicity, dermal (chapter 3.1)" hazard categories 1, 2 and 3

Delete the current table for category 3.

In the current table for categories 1 and 2, insert a row for category 3 under the existing row for category 2 as follows:

Hazard Symbol		\sim	Signal	Hazard statement		
category			word			
3	Skull and crossbones		Danger	H331	Toxic in contact with skin	

Column "Response", delete the P321 entry, and insert the following P320 and P322 entries (current entries for P302+P352, P316 and P361+P364 remain unchanged):

"P320

Specific treatment is urgent (see information on this label and safety data sheet).

- if immediate measures that can be easily applied, such as the administration of antidote or other specific treatment, are required. These measures must be specified on the label and safety data sheet, recognizing additional detailed instructions, including any training requirements, should be provided on the safety data sheet, if appropriate.

P322

Specific treatment is urgent (see information on the safety data sheet).

Manufacturer/supplier to reference on the safety data sheet detailed instructions, including any training requirements, to administer an antidote or provide other specific treatment.

- may be omitted if P320 is given on the label."

Table for "Acute toxicity, dermal (chapter 3.1)", hazard category 4, column "Response"

Amend P321 and insert a new entry for P323, to read as follows (current P302+P352, P317 and P362+P364 remain unchanged):

"P321

Specific treatment (see information on this label and safety data sheet).

- if immediate measures that can be easily applied, such as the administration of antidote or other specific treatment, are required. These measures must be specified on the label and safety data sheet, recognizing additional detailed instructions, including any training requirements, should be provided on the safety data sheet, if appropriate.

- may be omitted if P320 is given on the label.

P323

Specific treatment (see information on the safety data sheet).

Manufacturer/supplier to reference on the safety data sheet detailed instructions, including any training requirements, to administer an antidote or other specific treatment.

- may be omitted if P321 or P322 is given on the label".

Table for "Acute toxicity, dermal (chapter 3.1)" hazard category 5, column "Response"

Amend to read:

"P317 Get medical help.

P302+P352

IF ON SKIN: Wash with plenty of water/...

...Manufacturer/supplier or the competent authority may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate."

Tables for "Acute toxicity, inhalation (chapter 3.1)" hazard categories 1, 2 and 3

Delete the current table for category 3.

In the current table for categories 1 and 2, insert a row for category 3 under the existing row for category 2 as follows:

Hazard Symbol category			Signal Hazard statement word		tement
3	Skull and crossbones	3	Danger	H331	Toxic if inhaled

Column "Response", amend P320 and insert a new P322 entry as follows (current entries for P304+P340 and P316 remain unchanged):

"P320

Specific treatment is urgent (see information on this label and safety data sheet).

- if immediate measures that can be easily applied, such as the administration of antidote or other specific treatment, are required. These measures must be specified on the label and safety data sheet, recognizing additional detailed instructions, including any training requirements, should be provided on the safety data sheet, if appropriate.

P322

Specific treatment is urgent (see information on the safety data sheet).

Manufacturer/supplier to reference on the safety data sheet detailed instructions, including any training requirements, to administer an antidote or other specific treatment.

- may be omitted if P320 is given on the label."

Table for "Acute toxicity, inhalation (chapter 3.1)" hazard category 4

Column "Prevention", for the P261 entry replace ".... to specify applicable conditions." with "... to specify applicable physical state(s)." (current entry P271 remains unchanged).

Column "Response", insert the following new P321 and P323 entries (current entries for P304+P340 and P317 remain unchanged):

"P321

Specific treatment (see information on this label and safety data sheet).

- if immediate measures that can be easily applied, such as the administration of antidote or other specific treatment, are required. These measures must be specified on the label and safety data sheet, recognizing additional detailed instructions, including any training requirements, should be provided on the safety data sheet, if appropriate.

- may be omitted if P320 is given on the label.

P323

Specific treatment (see information on the safety data sheet).

Manufacturer/supplier to reference on the safety data sheet detailed instructions, including any training requirements, to administer an antidote or other specific treatment.

- may be omitted if P321 or P322 is given on the label."

Column "Disposal", insert a new entry for P501, to read as follows:

"P501

Dispose of contents/container to...

... in accordance with local/regional/national/international regulations (to be specified).

Manufacturer/supplier or the competent authority to specify whether disposal requirements apply to contents, container or both."

Table for "Acute toxicity, inhalation (chapter 3.1)" hazard category 5, column "Response"

Amend to read:

"P317 Get medical help. P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing."

Table for "Skin corrosion/irritation (chapter 3.2)" hazard categories 1, 1A, 1B, 1C, column "Response"

Replace P321 and insert a new P323 entry, as follows (current entries for P301+P330+P331, P302+P361+P354, P363, P304+P340, P316 and P305+P354+P338 remain unchanged):

"P321

Specific treatment (see information on this label and safety data sheet).

- if immediate measures that can be easily applied, such as the administration of antidote or other specific treatment, are required. These measures must be specified on the label and safety data sheet, recognizing additional detailed instructions, including any training requirements, should be provided on the safety data sheet, if appropriate.

- may be omitted if P320 is given on the label.

P323

Specific treatment (see information on the safety data sheet).

Manufacturer/supplier to reference on the safety data sheet detailed instructions, including any training requirements, to administer an antidote or other specific treatment.

- may be omitted if P321 or P322 is given on the label."

Table for "Skin corrosion/irritation (chapter 3.2)" hazard category 2, column "Response"

Amend P321 and insert a new P323 as follows (current entries P302+P352, P332+P317 and P362+P364 remain unchanged):

"P321

Specific treatment (see information on this label and safety data sheet).

- if immediate measures that can be easily applied, such as the administration of antidote or other specific treatment, are required. These measures must be specified on the label and safety data sheet, recognizing additional detailed instructions, including any training requirements, should be provided on the safety data sheet, if appropriate.

- may be omitted if P320 is given on the label.

P323

Specific treatment (see information on the safety data sheet).

Manufacturer/supplier to reference on the safety data sheet detailed instructions, including any training requirements, to administer an antidote or other specific treatment.

- may be omitted if P321 or P322 is given on the label.".

Table for "Skin sensitization (chapter 3.4)" hazard categories 1, 1A, 1B

Column "Prevention":

For the P261 entry replace ".... to specify applicable conditions." with "... to specify applicable physical state(s)." (current entries P272 and P280 remain unchanged).

Column "Response":

Amend P321 and insert a new P323 as follows (current entries P302+P352, P333+P317 and P362+P364 remain unchanged):

"P321

Specific treatment (see information on this label and safety data sheet).

- if immediate measures that can be easily applied, such as the administration of antidote or other specific treatment, are required. These measures must be specified on the label and safety data sheet, recognizing additional detailed instructions, including any training requirements, should be provided on the safety data sheet, if appropriate.

- may be omitted if P320 is given on the label.

P323

Specific treatment (see information on the safety data sheet).

Manufacturer/supplier to reference on the safety data sheet detailed instructions, including any training requirements, to administer an antidote or other specific treatment.

- may be omitted if P321 or P322 is given on the label.".

Table for "Specific target organ toxicity (single exposure) (chapter 3.8)" hazard category 1, column "Response"

Amend P321 and insert a new P323, to read as follows (current entry for P308+P316 remains unchanged):

"P321

Specific treatment (see information on this label and safety data sheet).

- if immediate measures that can be easily applied, such as the administration of antidote or other specific treatment, are required. These measures must be specified on the label and safety data sheet, recognizing additional detailed instructions, including any training requirements, should be provided on the safety data sheet, if appropriate.

- may be omitted if P320 is given on the label.

P323

Specific treatment (see information on the safety data sheet).

Manufacturer/supplier to reference on the safety data sheet detailed instructions, including any training requirements, to administer an antidote or other specific treatment.

- may be omitted if P321 or P322 is given on the label.".

Table for "Specific target organ toxicity (single exposure) (chapter 3.8)" hazard category 2, column "Prevention"

Delete the P260 entry and insert a new P261 to read as follows (current entries for P264 and P270 remain unchanged):

"P261

Avoid breathing dust/fume/gas/mist/ vapours/spray.

- may be omitted if P260 is given on the label

Manufacturer/supplier or the competent authority to specify applicable physical state(s)."

Table for "Specific target organ toxicity (single exposure) (chapter 3.8)" hazard category 3, column "Prevention"

For P261 replace ".... to specify applicable conditions." with "... to specify applicable physical state(s)." (current entry P271 remains unchanged).

Table for "Specific target organ toxicity (repeated exposure) (chapter 3.9)" hazard category 2, column "Prevention"

Delete the P260 entry and insert a new P261 entry to read as follows:

"P261

Avoid breathing dust/fume/gas/mist/ vapours/spray.

- may be omitted if P260 is given on the label

Manufacturer/supplier or the competent authority to specify applicable physical state(s)."

Annex 3, section 3

Table for "Hazardous to the ozone layer (chapter 4.2)", amend the heading to read as follows: "HAZARDOUS TO THE ATMOSPHERIC SYSTEM (CHAPTER 4.2) (Hazardous to the ozone layer)"

Insert a new matrix table for the new "Hazardous by contributing to global warming" hazard class, after the renamed matrix table for "Hazardous to the atmospheric system (chapter 4.2) (Hazardous to the ozone layer)", to read as follows:

"HAZARDOUS TO THE ATMOSPHERIC SYSTEM (CHAPTER 4.2)

(Hazardous by contributing to global warming)

information on recovery or recycling.

Hazard category	Symbol	•	Signal word	Hazard statement	
1	Exclamation mark		Warning	H421	Harms public health and the environment by contributing to global warming
Precautionary statements					
Prevention	Response	S	torage		Disposal
				P502	
				Refer to	manufacturer or supplier for

Annex 7

Amend the introductory sentence to read as follows:

"The following examples are provided for illustrative purposes by arranging the GHS label elements in accordance with sections 1.4.10.4 and 1.4.10.5 and are subject to further discussion and consideration by the GHS Sub-Committee.

Example 1

Replace with the following:

"Example 1: Combination packaging for a chemical with the classification: Flammable liquids, Category 2

Outer packaging: Box with a Class 3 flammable liquids transport label* Inner packaging: Plastic bottle with GHS label



* Only the transport markings and labels as specified in the UN Model Regulations are required for outer packagings.".

Replace with the following:

"Example 2: Combination packaging for a chemical with the classification: Flammable liquids, Category 2 and specific target organ toxicity – single exposure, Category 1

Outer packaging: Box with a Class 3 flammable liquids transport label* Inner packaging: Plastic bottle with GHS label



* Only the transport markings and labels as specified in the UN Model Regulations are required for outer packagings.".

Replace with the following:

"Example 3: Combination packaging for a chemical with the classification: skin corrosion/irritation, Category 2 and serious eye damage/eye irritation, Category 2A

Outer packaging: Box with no transport label (not required) * Inner packaging: Plastic bottle with GHS label



*

Some competent authorities may require a GHS label on the outer packaging.".

Replace with the following:

"Example 4: Single packaging (for example a 200 l drum) for a chemical with the classification flammable liquids, Category 2



Note: The GHS label and the Class 3 flammable liquid pictogram (commonly referred to as label in transport regulations, see 1.4.10.4) as well as any other markings required by the UN Model Regulations may also be presented in a combined format (see also example 7).".

Replace with the following:

"Example 5: Single packaging (for example a 200 *l* drum) for a chemical with the classification: Flammable liquids, Category 2 and specific target organ toxicity-repeated exposure, Category 1



Note: The GHS label and the Class 3 flammable liquid pictogram (commonly referred to as label in transport regulations, see 1.4.10.4) as well as any other markings required by the UN Model Regulations may also be presented in a combined format (see also example 7).".

Replace with the following:

"Example 6: Single packaging (for example, a 200 *l* drum) for a chemical with the classification: Skin corrosion/irritation, Category 2 and serious eye damage/eye irritation, Category 2A"





Replace with the following:

"Example 7: Additional guidance when transport and other GHS information appear on single packagings

- (a) Where transport and other GHS information appear on a single packaging, consideration must be given to ensure that the label elements are placed in a manner that addresses the needs of the different sectors. The GHS pictogram does not appear on the GHS label when a transport label for the same hazard is already used (see 1.4.10.5.1);
- (b) Transport labels must convey information immediately in an emergency situation. They must be able to be seen from a distance, as well as in conditions that are smoky or otherwise partially obscure the package;
- (c) Transport labels are distinct in appearance from pictograms intended solely for non-transport purposes which helps to distinguish them;
- (d) Transport labels may be placed on a separate panel of a GHS label to distinguish them from the other information or may be placed adjacent to the other GHS information on the packaging; and
- (e) The pictograms may be distinguished by adjusting their size. Generally speaking, the size of the non-transport pictograms should be proportional to the size of the text of the other label elements. This would generally be smaller than the transport labels (the size of which is intentionally regulated), but such size adjustments should not affect the clarity or comprehensibility of the non-transport pictograms.

Following is an example of how such a label may appear for a chemical in a 200 l drum for transport and use in the workplace.

This example is not intended to cover all specific requirements which may have been included in national legislation implementing the GHS nor all possible supplemental information which may be voluntarily included (e.g. "Directions of use" or "Filling weight") or which may be required by some competent authorities. It takes account of the required basic GHS label information as described in section 1.4.10.

Single packaging using 3 adjacent panels to convey multiple hazards: A mixture with the classification: Flammable liquids Category 2; Acute toxicity (inhalation) Category 4, and Specific target organ toxicity - repeated exposure, Category 2

