

UN/SCEGHS/8/INF.10

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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Item 2 (c) of the provisional agenda

CLASSIFICATION AND LABELLING OF OZONE DEPLETING SUBSTANCES

Transmitted by the expert from Finland

INTRODUCTION

1. At its 6th session in December 2003, the Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals agreed to set up a Correspondence Group on Ozone Depleting Substances (ODS) (ST/SG/AC.10/C.4/12, para 48) to address the issues raised in the discussion on the proposal concerning classification and labelling of ozone depleting substances (ST/SG/AC.10/C.4/2003/6).

2. New members joined the Correspondence Group in July 2004 and the group now comprises experts from Australia, Austria, Brazil, Finland, France, Germany, Italy, Japan, Norway, Spain, Sweden, United States of America, International Council of Chemical Associations (ICCA) and European Chemical Industry Council (CEFIC). The Correspondence Group is lead by Finland.

3. ODS issue was discussed in the 7th Session of the SCEGHS on the basis of an informal document (UN/SCEGHS/7/INF.14) and the following issues were raised in the discussion:

- information on existing systems should be collected more extensively before making a proposal for harmonized criteria for classification and labelling on ODS;
- the countries were encouraged to take part in the work of Correspondence Group more actively;
- the views of members of the Correspondence Group should be further explored on the options for classification and labelling of ODS made by some EU countries;
- new proposals for classification and labelling of ODS should be invited, if any;
- the work should be continued in consultation with the Secretariat of the Montreal Protocol.

PROGRESS OF WORK

3. The chair of the Correspondence Group prepared a document (attached) based on discussion in the 7th Session of the SCEGHS for consideration by the Correspondence Group and asking for response by 13 September 2004. The Secretariat of the Montreal Protocol was consulted on the same document simultaneously. The chair requested response on the following issues:

- information on existing classification and labelling systems of ODS. This request does not apply

to representatives of the EU countries as the basic proposal (ST/SG/AC.10/C.4/2003/6) made to the SCEGHS already contained that information.

- positions on the options presented in the paper, if they are different, incorrectly reflected or not included in the attached working document on options
- possible new options on how to solve classification and labelling of ODS
- proposals on how to continue with the proposal at the 8th Session of the SCEGHS:
 - provide a report on the ongoing work , or
 - provide a report on the ongoing work and propose to finalize the work in the next biennium, or
 - provide a formal document including a proposal for decision making based on the consultation in the Correspondence Group information.

4. The chair of the Correspondence Group included in the note to the members also the positions of different countries on the options for harmonized classification and labelling of ODS, as expressed at the 7th Session of the SCEGHS.

5. Response to the inquiry were received from Japan, Spain, USA and from the EFCTC (European Fluorocarbon Producers Association) for the European industry. The responses are attached to this document.

6. Japan responded by emphasizing the importance of the link to the Montreal Protocol and questioning the mandate of the SCEGHS to work on the issue. Japan also pointed out that the effects of ODS on health and the environment are indirect, and asked that it would be first considered whether or not ODS is eligible to be added to the GHS. Japan informed the members of the Correspondence Group that Japan has no system in place for labelling of ODS.

7. Spain responded by suggesting to open up a more comprehensive chapter in the GHS for substances that may alter the atmospheric system, ODS being a small fraction of this issue. A wider context would leave door open to add other types of substances in the future to this chapter as necessary. Spain also provided their position on the options for classification and labelling of ODS: classification criteria for ODS, option 1 (lists of substances of Montreal Protocol); cut-off value for classification of mixtures as ODS, option 1 (0,1 %), but option 2 (1 %) could also be considered; labelling elements for ODS – pictograms, the already existing pictogram for dangerous for the environment should be used; labelling elements of ODS – product identifiers – identification of substances, option 1 which allows the use of names of Montreal Protocol is preferred.

8. USA responded by providing complete information on their existing legislative system on classification and labelling of ODS, and suggesting a template to collect information on existing systems for the GHS. USA proposes that harmonization of classification and labelling criteria would be considered on the basis of collected information on existing systems. USA emphasizes the importance of the coordination of the GHS activities with the Montreal Protocol. USA provided information that the present US legislation classifies and requires labelling of ozone depleting substances under the U.S. Clean Air Act. The information on the exact contents of the requirements is provided in the response of the USA.

9. USA proposes a template to collect information for Step 1 document of the GHS in accordance with the following template:

- Definitions/Basis of Classification under Existing Systems
 - information on countries,
 - information on systems,

- information Montreal Protocol,
- issues for consideration
- Scope of classification and labelling under existing systems
 - information on countries,
 - information on systems,
 - issues for consideration
- Classification of mixtures under existing systems
 - information on countries,
 - information on systems,
- Label elements required under existing systems
 - information on countries,
 - information on systems,
 - information on Montreal Protocol
- Elements for proposal
 - to be added on the basis of collected information
 - issues for consideration.

10. EFCTC responded by providing positions on the proposed options for classification and labelling of ODS. EFCTC supports option 1 (lists of substances under the Montreal Protocol) under issue 1 concerning classification criteria and option 2 (1 %) under issue 2 concerning cut-off values for classification of mixtures.

PROPOSAL TO CONTINUE THE WORK

11. As a result of the inquiry it has turned out that at least the USA in addition to the European Union has a legislative system in place for classification and labelling of ODS. This result provides a reason to continue the work to take account at least these two systems for development of the harmonized classification and labelling rules under the GHS.

12. It is proposed that the work on ODS is continued in the next biennium and completed by 2006 making a proposal for harmonized classification criteria and labelling provisions for ODS.

13. To this end it is proposed that the template suggested by the USA would be used for collecting information on existing systems on ODS forming the basis for further discussions when developing the harmonized rules.

APPENDIX 1

Note of the Chair sent to the Correspondence Group on 22 July 2004

OZONE DEPLETING SUBSTANCES

Thoughts for continuation of the work with ODS

In the 7th Session of SCEGHS the proposal of some EU countries for classification and labelling of ozone depleting substances was discussed on the basis of an informal paper (UN/SCEGHS/7/Inf. 14) which provided options to find solutions on outstanding issues.

Some new countries wanted to join the Correspondence Group. The Correspondence Group was agreed to continue its work taking into consideration what was said in the discussion. The countries were requested to provide the names and e-mail addresses of their representatives to the Secretariat of the SCEGHS.

Many experts of the SCEGHS expressed their interest in establishing the classification and labelling criteria for ODS. Some countries (USA, Australia) felt that more information is needed on existing systems. All agreed that the work should be continued in consultation with the Secretariat of the Montreal Protocol.

For continuation of the work on ODS the following issues should be borne in mind:

- international rules for classification and labelling of hazardous chemicals (covering health hazards, environmental hazards, physical hazards) belong to the scope of GHS, keeping in mind the fact that ODS are identified for bans and restrictions under the Montreal Protocol, and that the GHS should not be in conflict with the provisions of the Montreal Protocol.
- GHS is a flexible system consisting of building blocks which leave the possibility for systems and countries to choose whether to implement certain parts the classification and labelling rules of the GHS, for example ODS.
- there are existing systems (e.g. EU) which presently require classification and labelling of ODS; it is unlikely that any system would agree to remove a C&L requirement for ODS before a GHS equivalent is in place. GHS should not make continuation within these systems too difficult.
- as mentioned above, some systems already require C&L for ODS, and will not remove such a system without having a replacement under the GHS. Bearing in mind that the flexibility in REACH makes it possible for other systems to not apply all classes (e.g. ODS) in GHS, it would appear to be reasonable to vote in the SCEGHS if necessary on proposals for inclusion of ODS in GHS. Thus, if other systems decide in the future to include ODS in their systems there would be one ready in GHS to apply thereby increasing the degree of global harmonization.

How to continue the work of the Correspondence Group?

Members of the Correspondence Group are requested to provide:

- information on existing classification and labelling systems of ODS. This request does not apply to representatives of the EU countries as the basic proposal (ST/SG/AC.10/C.4/2003/6) made to the SCEGHS already contained that information.
 - positions on the options paper, if they are different, incorrectly reflected or not included in the attached working document on options;
 - possible new options on how to solve classification and labelling of ODS;
 - proposals on how to continue with the proposal at the 8th Session of the SCEGHS:
 - provide a report on the ongoing work , or
 - provide a report on the ongoing work and propose to finalize the work in the next biennium, or
 - provide a formal document including a proposal for decision making based on the consultation in the Correspondence Group.

The information is asked to be provided to the chair (anna-liisa.sundquist@stm.fi) of the Correspondence Group, and for information to the Secretariat of SCEGHS (catherine.masson@unece.org) as well as to the Secretariat of Montreal Protocol (via the Secretariat of the SCEGHS) by **13 September 2004**.

APPENDIX 2

ALS 22.07.04

Text of Annex 1 to informal document UNSCEGH/7/Inf.14 modified on 22.7.2004 for the use of the Correspondence Group

CLASSIFICATION AND LABELLING OF OZONE DEPLETING SUBSTANCES

ANNEX 1

**ISSUES AND OPTIONS TO BE DISCUSSED AND RESOLVED
FOR OZONE DEPLETING SUBSTANCES (ODS)**

Issues raised in the discussion at SCEGHS

Document ST/SG/AC.10/C.4/2003/6 submitted to the SCEGHS proposes classification criteria for ozone depleting substances (ODS) and subsequent harmonized labelling requirements for ozone depleting substances and mixtures. At the discussion in SCEGHS 6th Session in December 2003 the proposal was welcomed by many experts of the Subcommittee. The following issues were raised for further discussion:

- cut-off value for classification of mixtures (proposal 0,1 %)
- hazard communication elements of the label, in particular
 - the pictogram, taking into account that
 - the transport system is in the process of incorporating the GHS environment pictogram (dead fish and tree) for substances and mixtures that are dangerous for the aquatic environment
 - the pictogram should also pass the information that ODS may be hazardous to human health
 - identification of ozone depleting substances on the label, taking into account that the World Customs Organization is currently further developing customs codes for ODS's (informal document UN/SCEGHS/6/INF. 13 submitted after the December Session of the SCEGHS)
- the use of an exclusive list of ozone depleting substances for classification purposes within the GHS.

In addition it should be noted that ODS classification and labelling should be dealt in close cooperation, and agreement, with the experts and Secretariat of the Montreal Protocol.

Options for solving the issues raised

1 Classification criteria based on the list of ozone depleting substances as included in the Annexes of Montreal Protocol

Option 1

Substances listed in Annex A, B, C or E of Montreal Protocol are classified as ODS within GHS (as proposed in ST/SG/AC.10/C.4/2003/6).

This approach can be justified by the following:

1) Identification of ozone depleting hazards of substances is a very complicated process and requires special expertise. If classification within the GHS were recognised on the basis of the general definition of Montreal protocol without lists of substances, a conflict might occur between the two international instruments, the GHS and Montreal Protocol. If some substances not included in Annexes of Montreal Protocol were recognised as such within the GHS, this might cause confusion among the users of such chemicals around the world.

2) The general definition of the ozone depleting substances within the EU legislation has not, as far as is known, led to classification of any other substances than those listed in Annexes to Montreal Protocol.

3) The proposed way of classification of ODS's would be simple for everyone to follow.

4) The general definition of ozone depletion is not always unambiguous (for example the ozone depletion potential for very short lived compounds depends on the specific location of the emission on earth surface).

Experts in favour of option 1:

- *Germany, France, Finland, Japan, Sweden, Denmark, Norway (can live with both 1 and 2), Spain, South Africa, UK (dti), CEFIC.*

Option 2

Substances fulfilling the criteria of ozone depleting substances of Montreal Protocol would be classified as ODS's within the GHS.

This option can be justified by the following:

1) GHS does not use lists of hazardous substances in any other context, but is based on the general definitions and criteria for classification to be applied by the suppliers or users of chemicals.

2) The general definition included in the present EU legislation has not led to application of criteria more widely than to those substances listed in Annexes of Montreal Protocol.

3) CA's and systems would still have the option available to provide the lists of Annexes of Montreal Protocol as guidance.

Experts in favour of option 2:

- *Italy, Norway (can live with both 1 and 2)*

2 Cut-off value for classification of mixtures as OD

Option 1

Mixtures are classified as ozone depleting when at least one ingredient has been classified as ozone depleting and is present at or above the cut-off concentration limit of 0,1 %.

This option can be justified by the following:

- 1) This cut-off concentration is used in one existing system (EU). GHS is supposed to be based on existing systems without lowering the level of protection.
- 2) The general cut-off concentration has no scientific background, but is based on the similar principle as setting of general cut-off's for other hazardous end-points, e.g. for aquatic hazards. The general cut-off's most often used within the GHS are 10 %, 1 % or 0,1 %.
- 3) Ozone depleting hazard is a serious hazard that would warrant application of cut-off concentration 0,1 %.

Experts in favour of option 1:

- **Germany, France, Finland, Sweden, Denmark, Norway, Spain**

Option 2

Mixtures are classified as ozone depleting when at least one ingredient has been classified as ozone depleting and is present at or above the cut-off concentration limit [$\geq 10\%$] [1 %].

This option can be justified by the following:

1) only one system in the world is presently applying classification and labelling requirements for ozone depleting mixtures. There is too little experience on application of 0,1 % cut-off concentration. A more cautious solution to take account the interests of the industry would justify higher limit, like [10 %][1 %].

2) there is no scientific justification for application of 0,1 % cut-off concentration.

Experts in favour of option 2:

- **Italy, UK (dti), CEFIC**

3 Labelling elements for ODS – Pictogram

Option 1

Ozone depleting substances and mixtures are labelled with the existing pictogram (fish and tree) for dangerous for environment as specified by the GHS.

This option can be justified by the following:

1) Fish and tree pictogram describes well that the chemical may be dangerous for the environment. This is sufficient information for all target audiences. The pictogram intended for transport will be bigger in size and can mostly be differentiated as necessary for the transport purposes also by other means (the label information is different for transport and supply purposes).

2) Fish and tree pictogram covers sufficiently well also the needs to include possible hazardous effects on human health caused by ODSs. The human effects are only secondary effects. In the case of ODS, the secondary effects are in principle not different from the secondary effects of substances hazardous to the aquatic environment, where secondary effects are not taken into account in the pictogram.

Experts in favour of option 1:

- *Italy, South-Africa, Sweden, Denmark, Norway (could consider also other options), Spain*
- *no clear stand: CEFIC, Germany, France, Finland*

Option 2

Ozone depleting substances would warrant a different pictogram (suggestions included in Annexes) from the existing pictogram (fish and tree) as specified by the GHS.

This option can be justified by the following:

- 1) Fish and tree pictogram should be reserved for chemicals hazardous to the aquatic environment, in particular, because the transport system is traditionally using one pictogram for one hazard only. Use of the same pictogram for other end points would cause confusion within the transport system.
- 2) Different pictogram would provide better information to all target audiences on the specific hazard of ODS's.

Experts in favour of option 2:

- *Japan*

4 Labelling elements of ODS – product identifiers – identification of substances

Option 1

Ozone depleting substances would be named in accordance with the normal rules of labelling of the GHS (see para)

This option can be justified by the following:

- 1) Normal rules of the GHS would allow naming of substances by their exact chemical names, technical names or identification codes¹. This would not prevent using of the identification specified within the Montreal Protocol.

Experts in favour of option 1:

- *Germany, France, Finland (flexible), Sweden, Denmark, Spain, South-Africa (?),*

Option 2

Ozone depleting substances should be named by using the technical names or designations specified by the Montreal Protocol ¹.

1. ¹ example:

customs codes	Montreal Protocol designation	Chemical name/technical name
2903 41	CFC-11	trichlorofluoromethane
2903 42	CFC-12	dichlorodifluoromethane
2903 43	CFC-113	trichlorotrifluoroethanes
2903 44	CFC-114 and CFC-115	dichlorotetrafluoroethanes ja chloropentafluoroethane

This option can be justified by the following:

- 1) It would be user friendly to apply the same identification methods for ODSs in both international instruments (GHS and Montreal Protocol).

Experts in favour of option 2:

- *Italy, Germany (could consider), Finland (flexible)*

APPENDIX 3

Appendix containing responses to the inquiry of 22.7.2004 of the chair of the Correspondence Group

A. *Japanese Comments on the Memorandum of Finland (Sept. 13, 2004)*

1. General Comments

In accordance with the Decision XIV/8 of the Meeting of the Parties to the Montreal Protocol, the Montreal Protocol Secretariat requested the GHS Subcommittee to consider whether to add ozone-depleting substances to the work program on GHS. Based on this request, the GHS Subcommittee created a Correspondence Group and it has been discussing specific issues such as criteria, and the design of pictograms and cut-off values of ODS. Although these specific discussions are progressing on the assumption that ODS can be added to GHS, the request of the Parties to the Montreal Protocol to examine the possibility of adding ODS to GHS's program has not yet been discussed at the group. ODS destroys the ozone layer by being emitted into the atmosphere, therefore an increased amount of ultraviolet rays reaching the earth's surface, which will harm human beings and other living things. We should examine this matter from the viewpoint of adding ODS to GHS, since ODS has the characteristic of not being a substance that directly influences the health of people and other living organisms. For this reason, before conducting technical arguments on the conditions of the addition of ODS to GHS, whether or not ODS is eligible to be added as an object of GHS should first be considered.

Moreover, at the open-ended working group of the Montreal Protocol in July, the parties expressed the following concern: the Subcommittee should not begin work on the issue until it had received full guidance from the Meeting of the Parties to the Montreal Protocol; however, the Subcommittee decided to go ahead regardless. Since Japan understands that this work is based on the request by the Montreal Protocol and the Montreal Protocol is the most important scheme for protecting the ozone layer, we suggest that this work should be based on regular contact with the Secretariat of the Montreal Protocol.

2. Request for information on existing classification and labeling systems of ODS

Though gasses with high-pressure request to be labeled or sealed by a law, there is no labeling system exclusively for ODS gases in Japan.

B. *Comments from SPAIN*

A first general comment about the scope:

Some of the issues considered by the GHS are hazardous to the aquatic environment and now is being discussed the inclusion of the hazardous to terrestrial ecosystems. Compared to these ones, substances that deplete the ozone layer may seem a small fraction of substances that alter the atmospheric system. It might be useful to consider a new title that leave an open door for, in the future, be able to include substances regulated under Kyoto Protocol as HFCs, PFCs, etc.

1 Classification criteria based on the list of ozone depleting substances as included in the Annexes of Montreal Protocol

From the practical point of view, option 1 is the most adequate: Substances listed in Annex A, B, C or E of Montreal Protocol are classified as ODS within GHS (as proposed in ST/SG/AC.10/C.4/2003/6).

Nonetheless, if we would like in the future to take into account the first comment about the scope, a wider approach should be taken.

2 Cut-off value for classification of mixtures as ODS

Option 1, a cut off of 0.1% seems more reasonable because is the figure most used in EU legislation. Nonetheless option 2 (1%) could be accepted taking into account the lowering use and controls over these substances.

3 Labelling elements for ODS – Pictogram

Environmental hazard pictogram should be used to avoid creating a new one, avoiding confusions linked to a great number of different pictograms

4 Labelling elements of ODS – product identifiers – identification of substances

Option 1 seems correct, because it doesn't prevent using the Montreal Protocol names, which should also be used.

C. *Comments from the United States of America and Suggested Draft Template for “Step 1” GHS Analysis Document on Ozone Depleting Chemicals (ODC)*

As indicated in our comments at the GHS Sub-Committee meetings, the U.S. believes it is advisable that proposals for new GHS hazard classes be based on thorough analyses of existing systems and development of consensus proposals, following the procedures described in Chapter 1.3 of the GHS document. In the case of a proposed new hazard class for ozone depleting chemicals (ODC), it is also important to coordinate closely with both the Secretariat and the parties to the Montreal Protocol (many of whom are not represented in the GHS Sub-Committee).

The purpose of this paper is to describe, in general terms, the U.S. system for the classification and labeling of ozone depleting chemicals and the framework of the Montreal Protocol on Substances that Deplete the Ozone Layer (MP). We have included some information on labeling in the European Union previously provided to the Sub-Committee, and invite the European Union (Commission or Member States) and other countries with ODC labeling schemes in place to fill in parallel information. We also raise some initial issues for consideration by the working group. The paper is intended to facilitate discussion about the possibility of including ODS in the GHS following the procedures described in Chapter 1.3; however, we do not, at this time, believe there is sufficient information to make such a decision in the near term. We look forward to further discussion with interested countries and stakeholders.

Draft Template for “Step 1” GHS Analysis Document on Ozone Depleting Chemicals (ODC)

I. Introduction

The purpose of this paper is to describe existing systems of classification and labelling of ozone depleting chemicals (substances and mixtures, abbreviated ODC) with a view toward possible development of a consensus proposal to harmonize classification and labelling under the GHS.

Currently, the European Union, the United States, [and others?] classify and require labelling of ODC

under the [insert law/directive numbers] and the U.S. Clean Air Act, respectively. In addition, many countries, including the U.S. and EU member states, are parties to the Montreal Protocol (MP).

The GHS is a voluntary international system that establishes common and consistent approaches to chemical hazard classification for the purposes of hazard communication. Its scope does not include harmonization of risk assessment or risk management. The MP is an international control/risk management regime that will eventually phase out production and use of ozone depleting substances. The Protocol can, and has, been adjusted to accelerate phase-out schedules and amended to introduce other kinds of control measures and add new controlled substances. Parties are legally bound to comply with Protocol and Amendments after ratifying them. To date, there are 188 Parties to the MP. Information concerning the status of ratification for the various Amendments is available from the Ozone Secretariat. It is important to be mindful of ongoing work under the MP and to coordinate as appropriate with MP Parties in the development of any proposals for classification and labeling under the GHS.

II. Definitions/ Basis of Classification under Existing Systems

U.S.: The U.S. Environmental Protection Agency defines ozone-depleting potential (ODP) as a factor established to reflect the ozone-depletion potential of a substance, on a mass per kilogram basis, as compared to CFC-11. The factor is based upon the substance's atmospheric lifetime, the molecular weight of bromine and chlorine, and the substance's ability to be photolytically disassociated as well as other factors determined to be an accurate measure of ozone-depleting potential. Using established ODPS permits the U.S. to divide the substances into two classes that reflect higher and lower ODPS and further permits a phase-out schedule based on the relative ODPS of each substance, focusing on phasing out the higher ODPS first. Class I substances have ODPS of ≥ 0.2 . Class II substances currently include only HCFCs.

E.U.: [current definition/s used in creating EU list]

Other countries/systems:

Montreal Protocol: The MP is not a classification system. Rather, it conducts periodic scientific assessments of the ozone depleting impacts of various substances that may or may not be included in the Protocol's Annexes. Parties may, by amendment, add or remove substances from control under the MP based on information included in the periodic assessments which consider a variety of factors including, among other things: ODP, magnitude of consumption, types of uses, availability of alternatives, and cost implications.

Issues for consideration: The GHS is a criteria-based system, not a listing system. Classification under GHS is based on hazard/intrinsic properties, not risk, and the GHS acknowledges specifically that risk management measures generally require additional considerations and risk assessment. MP listings are risk-based, so an important issue is how the hazard-based GHS might interface with this different framework and whether this would take the GHS in an appropriate direction.

III. Scope of classification and labelling under existing systems

U.S.: Under U.S. law, chemicals classified as Class I or Class II under the Clean Air Act, as well as products manufactured with or containing Class I chemicals, are required to be labeled currently. (In addition, the U.S. is obligated to promulgate regulations to require labeling of products manufactured with or containing Class II products by 2015.)

EU: Chemicals listed under.... are required to be labeled.

Other countries/systems?

Issues for consideration: (1) The GHS scope excludes “articles,” while the U.S. labelling scheme requires products manufactured with some ODS to bear ODS labels. (Nothing in the GHS restricts other types of labeling for additional, non-chemical products, however.) (2) There may be “exceptions” in existing systems that should be captured in any GHS system. (3) The Montreal Protocol adopted the London Amendment in 1990 (adding several controlled substances), the Copenhagen Amendment in 1992 (adding methyl bromide as a controlled substance) and the Beijing Amendment in 1999 (adding bromochloromethane as a controlled substance). An important issue to consider is whether the GHS would apply to these substances for a country that had not ratified the associated amendment under the MP. Conversely, countries may include ozone depleting substances under national systems before they have been officially added to the MP lists.

IV. Classification of mixtures under existing systems

U.S.: Classification under the CAA is based on the presence of an ozone depleting substance in the mixture, without regard to any minimum cut-off level or concentration percentage.

EU: Mixtures that contain an ozone depleting substance at levels greater than 0.1% are classified and labelled.

Other countries?

Issues for consideration: Is there an appropriate cut-off level for classification of mixtures that will not create problems in terms of reasonable detection levels, etc.? Is there any other reasonable basis for classifying mixtures, beyond based on their ingredients?

V. Label elements required under existing systems

U.S.: The U.S. CAA requires containers of Class I and Class II ODC and products manufactured with or containing Class I substances to bear the signal word “warning” and the hazard statement “may contain....[insert name of substance] a substance which harms public health and the environment by destroying ozone in the upper atmosphere.” (Since ozone is a pollutant to be prevented in the ambient air, this statement makes the distinction that depleting the upper atmosphere ozone layer is harmful rather than beneficial to public health.) No symbol or pictogram is required.

EU: The EU requires the dead fish and tree pictogram, no signal word, and the hazard statement “dangerous for the ozone layer.” Certain additional precautionary statements are also required. Ingredient disclosure is not required.

MP: The MP does not require labeling.

Other countries?

Issues for consideration: The GHS provisions on ingredient disclosure/identifiers call for labels to include the chemical identities of ingredients that contribute to certain health hazards only. Countries/systems are free to require labelling of other ingredients as well (e.g., in the U.S.,

pesticide active ingredients must be identified by name and percentage regardless of hazard), but it is not part of GHS. Is there any issue with combining ingredient statements and hazard statements, as is current U.S. practice?

VI. Elements for a proposal

[Elements and/or options would need to be further developed for working group consideration once the template is filled in and all major issues have been resolved.]

Issues for consideration: In addition to the usual issues involved in crafting compromise approaches and the particular points raised above, the working group and GHS bodies will need to consider the practical utility of creating a new GHS hazard class given plans for phasing out ODS under the MP and the time required to translate, publish, disseminate, and implement changes under the GHS, including conforming changes to other sections of the document as appropriate.

D. ***EFCTC Position on ODS Classification at UN/SCEGHS Level (9 July 2004)***

The European Fluorocarbon Producers Association (EFCTC) would like to submit the following comments and position to the Committee of Experts on the transport of dangerous goods and on the globally harmonized system of classification and labeling of chemicals, concerning the classification and labeling of ozone depleting substances (ODS).

For ISSUE 1 - Classification Criteria

Option 1 is necessary as there is a process under the Montreal Protocol to add new substances if appropriate. This would allow harmonization between the Montreal Protocol and the UN classification processes.

For ISSUE 2 - Cut-off value for classification of mixtures as ODS

Option 2 is preferred using 1% (2% would be better) and makes sense for a global harmonized system.

Justification: As far as we are aware, there are no deliberate preparations that use 1% (or 2%) ODS. Therefore using a 1% (2%) cut-off would not create issues of deliberate supply of ODS.

The substance and preparation definitions used in the EU Directive 1999/45/EC exclude ODS from the process used to manufacture a substance, from the requirement to label preparations (see Annex 1: Preparations Directive Definitions).

This Directive in Article 3 “Determination of dangerous properties of preparations” sets out that >0.1% ODS should be labelled.

However we have a real concern depending on interpretation of the requirements for recovered and recycled HFC refrigerants if they contain greater than (>0.1%) ODS.

Recovered HFCs that are contaminated with other ODS refrigerants at the (>0.1%) level (if that level is adopted) might be interpreted as requiring labelling. In this case the source of the ODS would not be the production process used but contamination that occurs during use. Contamination at the (>0.1%) level of e.g. CFC 12 in HFC 134a might be interpreted as requiring labeling as the source of the CFC 12 would not in this case be the production process to make the HFC 134a.

Such labelling in these circumstances would discourage recycling and lead to confusion for international trade, and the potential labelling of HFCs as ODS.

It is not possible to easily separate e.g. CFC 12 and HFC 134a as they form an azeotrope (distil at the same temperature- difficult to separate by distillation).

An unintended consequence of a low (i.e. 0.1%) % cut-off could be a reduction in recycling of HFCs and a greater necessity to destroy thereby inadvertently leading to increased production and acting against the principle of sustainable development.

Although the 0.1% cut-off is currently in place in the EU there is no reason to propose it if it is inappropriate. Globally the HFC industry wants to encourage recovery and recycling. A 0.1% cut off for ODS, will if our interpretation is correct, discourage this activity. Moving and using recycled HFCs internationally will be difficult without a (2%) cut-off.

A 2% cut-off limit would be preferred, as a minimum a 1% limit is necessary.

APPENDIX 4

DIRECTIVE 1999/45/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations

Definitions

1. For the purposes of this Directive:

- (a) 'substances' means chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the products and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;
- (b) 'preparations' means mixtures or solutions composed of two or more substances;

Determination of dangerous properties of preparations

Dangerous for the environment ozone gaseous preparations % vol/vol $\geq 0,1$ other preparations % w/w $\geq 0,1$

APPENDIX 5

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