

## **Detailed Comparison of Classification and Labelling Systems for Ozone Depleting Chemicals**

### **Preamble**

1. The purpose of this paper is to describe existing systems of classification and labelling of ozone depleting chemicals (substances and mixtures, abbreviated ODCs) with a view toward possible development of a consensus proposal to harmonize classification and labelling under the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

2. The Parties to the Montreal Protocol requested the Ozone Secretariat to contact the UN Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling (SCEGHS) to evaluate the possibilities for and feasibility of including ozone-depleting substances on its work programme (Decision XIV/8).

3. At its 6<sup>th</sup> session in December 2003, the UN SCEGHS agreed to set up a correspondence group on Ozone Depleting Substances (ODS), under the leadership of Finland. This group identified issues and options to be discussed and resolved for ODSs.

4. At its December 2004 Session, the UN SCEGHS agreed on its work programme for the biennium 2005-2006, including the following item related to ozone depleting substances: "Examine possibilities to develop classification criteria for Ozone Depleting Substances in cooperation with the Conference of Parties to the Montreal Protocol (in cooperation with OECD)". Furthermore, the Sub-Committee requested that the OECD develop a detailed comparison of classification systems in countries/regions as the deliverable for this element of the work plan.

5. A new OECD Expert Group was established to work on this issue. It developed this document, on the basis of the information already provided to the UN SCEGHS or received from the Parties to the Montreal Protocol at the request of the Ozone Secretariat. The template was proposed by the US (See document UN/SCEGHS/8/INF.10).

6. On January 26, 2005, the Ozone Secretariat circulated to all Parties to the Montreal Protocol a letter requesting by 1<sup>st</sup> March 2005 information including:

- Definitions/Basis of classification;
- Scope of classification and labeling;
- Classification of mixtures; and
- Label requirements.

7. The OECD Secretariat received information with respect to the situation in the US, the EU Member States, Japan, Australia, Canada, New Zealand, Israel, Indonesia, Republic of Macedonia, Moldova, Fiji, Bulgaria and Oman.

8. Canada and Australia do not have existing chemical classification and/or labelling systems that cover ozone depletion hazards. Some countries (Indonesia, Canada, Bulgaria and Oman) provided information on the Harmonized System numbers, which are used to classify products for customs purposes. Some countries have requirements or standards for labelling of equipment (Fiji, the US, Bulgaria).

9. Fiji reported that labelling of containers for transportation and storage is part of the development strategy and framework for the National Ozone Unit 2005-2008 Work Programme. Republic of Macedonia reported that its future law on chemicals will be the basis for ODS classification and labelling. New Zealand reported that it is not currently a requirement to include information on the label about ozone depleting substances. However, most of its labelling requirements mirror GHS conventions, so it could easily integrate such labelling if required.

10. Considering the mandate “to examine possibilities to develop classification criteria for Ozone Depleting Substances”, the document includes some issues for consideration in developing classification criteria.

11. The Expert Group proposal was posted on the OECD website on 3<sup>rd</sup> June 2005 in order to facilitate comments by the Parties to the Montreal Protocol until end of August. The proposal was revised on the basis of the comments received and then circulated on 21 September 2005 to the OECD Task Force on Harmonization of Classification and Labelling, to the Sub-Committee on the GHS and to the Sub-Committee on the Transport of Dangerous Goods.

12. The term “Ozone Depleting Chemical” (ODC) is used in the document in addition to the term “Ozone Depleting Substance” (ODS) used by the Parties to the Montreal Protocol. There is a definition of “substance” in the GHS, which excludes mixtures; therefore, “Ozone Depleting Substance” should not be used in the context of the GHS.

## Detailed Comparison of Classification and Labelling Systems for Ozone Depleting Chemicals

### **IA. Introduction to Classification and labelling systems**

1. Depletion of the ozone layer, which absorbs most of the short-wavelength solar ultraviolet radiation (UV-B) has damaging effects on humans, such as sunburn, skin cancer and eye cataract, and important deleterious impacts on plants.

2. Currently, the United States classifies and requires labelling of ODS under the U.S. Clean Air Act (CAA). The European Union requires classification and hazard communication on ODS under Council Directive 67/548/EEC on the classification, packaging and labelling of dangerous substances and Directive 1999/45/EC of the European Parliament and of the Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations. Israel requires classification and labelling of ozone depleting substances under Israeli Standard 2302 (part 1) named: dangerous substances and preparations: Classification, Packaging, Labelling and Marking, which is based on the EU directives on classification and labelling. The Republic of Bulgaria has established a labelling system by Decree of the Council of Ministers No.254/1999 on the Control and Management of Ozone Depleting Substances. The Republic of Moldavia requires labelling of ODS in accordance with Law for approval of Regulation on commercial regime and settlement of use of halogenated hydrocarbons depleting ozone layer,

3. The GHS is a voluntary international system that establishes common and consistent approaches to chemical hazard classification for the purposes of hazard communication. It includes (i) harmonized criteria for classifying chemical substances and mixtures according to their health, environmental and physical hazards, and (ii) harmonized hazard communication elements, including labelling and safety data sheets. While the GHS covers all hazardous chemicals, the mode of application of the hazard communication components of the GHS may vary by product category or stage in the life cycle of a chemical. Its scope does not include harmonization of risk assessment or risk management. It is not intended to combat illegal trade or track movements of chemicals, as custom codes or export and import licenses do for ODCs. The GHS is a flexible system consisting of building blocks which leave the possibility for systems and countries to choose which elements of the GHS will be applied in different parts of their systems. For example, the transport system has not to date covered chronic effects due to the type of exposures expected to be encountered in that setting. (Where a system covers something that is in the GHS, however, that coverage should be consistent. For example, if a system covers carcinogenicity, it should follow the harmonized GHS classification scheme and use the harmonized label elements for that hazard class.)

### **IB. Introduction to Montreal Protocol**

4. The Montreal Protocol (MP) is an international control/risk management regime that will eventually phase out production<sup>1</sup> and consumption<sup>2</sup> of ozone depleting substances that are listed as controlled substances with their ODPs. It does not require hazard labelling.

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<sup>1</sup> “Production” means the amount of controlled substances produced, minus the amount destroyed by technologies to be approved by the Parties and minus the amount entirely used as feedstock in the manufacture of other chemicals. The amount recycled and reused is not to be considered as “production”.

5. Even after phase out, both developed and developing countries are permitted to produce and consume limited quantities of listed substances in order to meet the essential uses for which no alternatives have yet been identified. The phase-out schedules cover both the production and the consumption of the target substances. Some ODS are planned to be phased-out in the remote future (Phasing out of HCFCs will apply to developed Countries by 2030 and to developing countries by 2040). 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. Currently, 96 substances are listed; all isomers are covered unless specifically excluded. All ODS are substances that have non-zero ODPs; they contain chlorine and/or bromine, are volatile and have an atmospheric lifetime extending from more than several days up to hundreds of years. Parties are legally bound to comply with the 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 (<http://hq.unep.org/ozone/>). 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 labelling under the GHS.

## **IIA. Definitions/Basis of Classification under Existing Systems**

6. The definitions/basis for classification under existing systems are as follows:

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 generally based on the relative ODPs of each substance, focusing on phasing out the higher ODPs first. Class I substances generally have ODPs of  $\geq 0.2$ . Class II substances currently include only HCFCs.

EU: Substances which on the basis of the available evidence concerning their properties and their predicted or observed environmental fate and behaviour may present a danger to the structure and/or the functioning of the stratospheric ozone layer should be classified and labeled as dangerous for the environment. This includes the substances which are listed in Annex I to Regulation (EC) N° 2037/2000 on substances that deplete the ozone layer and its subsequent amendments. Substances listed in Annex I to that regulation are the same as those listed in the Montreal Protocol (with same ODP numerical values as in the Protocol). The present EU criteria are not literally limited to the substances included in Annex I to Regulation (EC) N° 2037/2000 and in the Annexes of the MP; however, there is no available information on non listed substances that would have been classified and labelled on the basis of the general criteria.

## **IIB. Procedure to Establish ODP-Values for Chemicals**

7. The Scientific Assessment Panel, established by the Parties to the MP under Article 6 of the Protocol, conducts periodic scientific assessments of the ozone depleting impacts, and estimates ODPs 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

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<sup>2</sup> "Consumption" means production plus imports minus exports of controlled substances.

things: ODP, magnitude of consumption, types of uses, availability of alternatives, and cost implications.

8. The Scientific Assessment Panel has provided in its 2002 report, Paragraph 1.4.4, the following description of ODP:

“The Ozone Depletion Potential (ODP) is an integrative quantity, distinct for each halocarbon source species, that represents the extent of the ozone depletion in the stratosphere expected from the halocarbon on a mass-for-mass basis relative to CFC-11. The formal definition of ODP is the ratio of integrated perturbations to total ozone, for a differential mass emission of a particular compound relative to an equal emission of CFC-11”. An extensive discussion of the details of the ODP calculation is given in WMO (1995)\*.

9. This corresponds to the definitions used in the US and the EU.

Issues for consideration: The GHS should not be in conflict with the provisions of the MP. 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. In this respect, information on ODP, as provided by the Scientific Assessment Panel for substances that may or may not be controlled by the MP, depending on other factors, may be more relevant.

### **III. Scope of Classification and Labelling under Existing Systems**

10. The scope for classification and labelling under existing systems is as follows:

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 labelled currently. (In addition, the U.S. is obligated to promulgate regulations to require labelling of products manufactured with or containing Class II products not later than 2015.)

EU: Substances listed in Regulation (EC) N° 2037/2000 and substances that fulfill the criteria described in point IIA, EU, are required to be classified and labelled. Preparations (mixtures) containing 0.1% or more of a substance that fulfills the criteria are required to be classified and labelled. The EC regulation does not require classification and/or labelling for articles.

Issues for consideration: (1) The GHS scope excludes “articles”(Section 1.3.2.1), while the U.S. labelling scheme requires products manufactured with some ODS to bear ODS labels. (Nothing in the GHS restricts other types of labelling for additional, non-chemical products, however.) (2) There may be “exceptions” in existing systems that should be captured in any GHS system. (3) Countries may include ozone depleting substances under national systems before they have been officially added to the MP lists. ODP values are used by the EU and the US to assess hazard of ODCs. Only very specialized experts can determine ODPs. If ozone depletion were to be included in the GHS, it might be reasonable to rely on internationally established ODPs; however, this could theoretically at least be perceived as a loss of protection.

#### **IV. Classification of Mixtures under Existing Systems**

11. The classification of mixtures under classification systems is as follows:

U.S.: Classification under the CAA is based on the presence of an ozone depleting substance in the mixture. There is no defined cut-off level or concentration percentage for mixtures.

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

Issues for consideration in the development of harmonized criteria: 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 Hazard Labelling Systems**

12. The label elements required under existing systems are as follows:

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. It is anticipated that a future labelling scheme for products manufactured with class II ODC would likely adopt the same requirements.

EU: The EU requires a “dead fish and tree” symbol that is very similar to the GHS symbol for chemicals (very) toxic to the aquatic environment, a signal word “Dangerous for the environment”, and the hazard statement “dangerous for the ozone layer.” Certain additional precautionary statements are also required:

- Refer to manufacturer for information on recovery/recycling;
- Use appropriate containment to avoid environmental contamination;
- Avoid release to the environment. Refer to special instructions/safety data sheet.

Ingredient disclosure is not required.

Bulgaria: Bulgaria requires labelling of each imported or exported package of substances. The label consists of information referring to the ODS, such as the trade name and composition of the ODS, human health and environmental hazard, and safety requirements, hazard symbols and signs, in conformity with international classification.

Moldova: Moldova requires labelling of the containers, where listed ODS are transported or stocked, with sustainable labels, situated on visible place, having the following inscription: “Contain substances depleting ozone layer”;

Japan: there is a requirement to label Methyl Bromide containers. The container is distinguished by uses. The colour of the label is blue for general use, red for quarantine and light purple for critical use. However, there is no clear statement that Methyl Bromide is an Ozone Depleting

Substance.

MP: The MP does not require hazard labelling. The Meeting of the Parties urged all Parties to introduce in their national customs classification system separate sub-divisions for the most commonly traded chemicals, as recommended by the World Customs Organization. The custom codes appear on import and export declarations; the objective is to combat illegal imports and exports of ODS and mixtures containing ODS.

Issues for consideration in the development of harmonized labelling: 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 (GHS Par. 1.4.6.3). 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**

13. Elements and/or options are already available in Document UN/SCEGHS/8/INF.10; however, further work would be needed to develop an harmonized classification system for ODCs.

\*Scientific Assessment of Ozone Depletion: 1994, Global Ozone Research and Monitoring Project - Report N° 37 , World Meteorological Organization, Geneva, 1995