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A Comparison of Mandatory and Voluntary Approaches to the Implementation of Globally Harmonized System of Classification and Labelling of Chemicals (GHS) in the Management of Hazardous Chemicals

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Abstract: The European Union (EU) and the World Health Organization (WHO) have applied different approaches to facilitate the implementation of the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS). The EU applied the mandatory approach by gazetting the EU Regulation 1272/2008 incorporating GHS elements on classification, labelling and packaging of substances and mixtures in 2008; whereas the WHO utilized a voluntary approach by incorporating GHS elements in the WHO guidelines entitled 'WHO Recommended Classification of Pesticides by Hazard' in 2009. We report on an analysis of both the mandatory and voluntary approaches practised by the EU and the WHO respectively, with close reference to the GHS 'purple book'. Our findings indicate that the mandatory approach practiced by the EU covers all the GHS elements referred to in the second revised edition of the GHS 'purple book'. Hence we can conclude that the EU has implemented the GHS particularly for industrial chemicals. On the other hand, the WHO guidelines published in 2009 should be revised to address concerns raised in this paper. In addition, both mandatory and voluntary approaches should be carefully examined because the classification results may be different.

Key words: Classification, EU Regulations, UN GHS implementation, Hazardous chemicals, Labelling, WHO

Introduction

It is common to find hazardous chemicals used for various purposes all over the world. However, there is no common agreement as to what defines a chemical as 'hazardous'. The International Labour Organization (ILO) Chemicals Convention No. 170 defines a 'hazardous chemical' according to the assessment of relevant information on the type and degree of their intrinsic health and physical hazards[1)], whereas New Zealand and the European Union (EU) define a 'hazardous substance' as a substance that fulfils any of the criteria stipulated in their respective regulations, i.e. the Hazardous Substances and New Organisms (HSNO) Act 1996[2)] and the EU Regulation No. 1272/2008 on classification, labelling and packaging of substances and mixtures[3)]. The intrinsic hazards or criteria here refer to the cut-off

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values or concentration limits of a particular chemical, so chemicals that exceed cut-off values are classified as hazardous or less hazardous depending on the classification criteria. The problem is that the cut-off values often differ from one country to another[4]. Seguin indicated that different cut-off values will lead to different chemical classifications, e.g. the same chemical can be classified as 'flammable' in one country but 'very flammable' in another[5]. This was supported by findings reported by the EU in 2006: a chemical with an LD_{50}=257 mg/kg (oral) was found to be treated as having different toxicity hazards in different countries; thus the EU classifies chemicals with an LD_{50}=257 mg/kg as 'harmful', whereas India classifies the same chemicals as 'non-toxic'[6].

Efforts at establishing a worldwide acceptable chemical classification system (with harmonized classification criteria or cut-off values) were initiated at the General Conference of the ILO in 1990 via the Chemicals Convention No. 170 and Chemicals Recommendation No. 177[7]. These initiatives were discussed more explicitly at the United Nations Conference on Environment and Development (UNCED) in 1992, where one of the significant outcomes was the decision to establish a globally harmonized hazards classification and compatible labelling system, including material safety data sheets and easily understandable symbols[8]. With the culmination of more than a decade of work by multidisciplinary experts, the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (referred to as the GHS 'purple book' in this paper) was adopted in 2002 by the United Nations Economic and Social Council's Subcommittee of Experts on the GHS (UNSCEGHS) and endorsed by the United Nations Economic and Social Council (ECOSOC) in July 2003[9].

One of the intentions of establishing the UN GHS was to prepare harmonized and comprehensive chemical classification criteria and hazard communication elements. Unlike other chemical-related international conventions, such as the Basel Convention on the Control of Transboundary Movement of Hazardous Wastes or the Stockholm Convention on Persistent Organic Pollutants (POPs), the GHS is a voluntary system that does not require countries to become members. In other words, the GHS is a non-legally binding instrument. Considering the fact that different countries have different practices in managing chemicals, and also aiming to provide flexibility for countries in adopting the voluntary system, the GHS allows countries, or competent authorities, to adopt appropriate components in the GHS 'purple book'. Nevertheless, guidance is provided in adopting the 'building blocks approach'. The GHS hazard classes and hazard categories can be seen as building blocks, so competent authorities are allowed to adopt whichever building blocks they deem appropriate to them. As far as hazard categories are concerned, competent authorities should adopt at least the higher or severe hazards (i.e. category 1), and where more than one category is adopted, these categories will form an unbroken sequence[10].

Various researchers, such as Silk[4], Winder *et al.*[11] and Pratt[12] have discussed the development of GHS. However to date, the GHS implementation approaches have not been explicitly addressed. This paper focuses on the GHS implementation approaches practised by the EU and the World Health Organization (WHO). Although the GHS is a voluntary system, the EU has taken the initiative to incorporate the GHS principles into the EU legislation, by gazetting the EU Regulation No. 1272/2008 on classification, labelling and packaging of substances and mixtures (hereinafter referred as 'European Regulation 1272/2008') that replaces the existing EU Directive on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (i.e. European Directive 67/548/EEC) and preparation (i.e. European Directive 1999/45/EC). The WHO has also incorporated GHS elements into their latest WHO Recommended Classification of Pesticides by Hazard guide that was released in 2009 but the Guidelines is a non-binding document, allowing competent authorities to adopt these recommendations voluntarily.

This paper reports on a comparative analysis that was undertaken to examine the approaches practised by the EU and WHO in incorporating GHS elements into their respective systems, i.e. the mandatory approach by the EU and the voluntary approach by the WHO.

Materials and Methods

The GHS 'purple book', EU Regulation No. 1272/2008 and WHO Recommended Classification of Pesticides by Hazard were used to compare their definitions or descriptions of key terms, such as 'chemical' and 'hazardous chemical', as well as their respective approaches to GHS implementation.

Results

Definition of "chemical" in the GHS 'Purple Book'

The GHS 'purple book' was first published in 2003, with Revised Editions in 2005, 2007 and 2009. Copies are available from the United Nations Economic Commission for Europe (UNECE), which also pro-

vides secretarial services for GHS[10]. The 3rd Revised Edition of the GHS 'purple book' is the latest version to date. All the different editions of the GHS 'purple book' provide guidance for the classification and hazard communication for substances and mixtures, and the definitions of 'substance' and 'mixture' are well defined in the GHS 'purple book'. However the GHS 'purple book' does not define a 'chemical'. The text presentation of the GHS 'purple book' indirectly indicates that 'chemical' means 'substance' and 'mixture', and efforts have been made in the 3rd Revised Edition to define 'chemical', 'substance' and 'mixture'; for example, the definition of carcinogen was amended from 'carcinogen means a chemical substance or a mixture' in the 2nd Revised Edition to 'carcinogen means a substance or a mixture' in the later edition[13]. However it would be more appropriate if the GHS 'purple book' defines 'chemical' explicitly in the text, for example, 'chemical means substance or mixture', so that the definitions of 'substance' and 'mixture' can remain as it is in the current edition of the GHS 'purple book'.

In addition, it is also suggested that the GHS 'purple book' should provide guidance to define the term 'hazardous chemical'. The rationale for this is that one of the GHS parameters in the GHS 'purple book' states that 'GHS covers all hazardous chemicals'[10], but no guidance is given to define 'hazardous chemicals' in the current GHS 'purple book'. This has created ambiguity for users following the GHS parameters. Alternatively, instead of defining 'hazardous chemical' in the GHS 'purple book', perhaps the UNSCEGHS could amend the parameter to 'GHS covers all chemicals', and this parameter should be qualified by an explanation that 'all chemicals should be assumed to be hazardous unless the chemical is not assigned to any hazardous class or category after this particular chemical is classified based on internationally accepted data from reliable sources.'

GHS implementation by the EU: the mandatory approach

In 2001, the Commission of the European Communities prepared a 'white paper' for a strategy on future chemicals policy in EU with the overriding goal of sustainable development[14]. The 'white paper' proposed that the EU should simplify the current EU classification and labelling system and improve comprehensibility through application of the GHS. Two main factors are seen as driving forces for the EU to implement GHS. First, the REACh (Registration, Evaluation, Authorisation and Restriction of Chemicals) regulation, gazetted by the EU on 18 December 2006[15], requires that classification and labelling results of hazardous substances and mixtures that are placed on the EU market by importers and manufacturers, irrespective of tonnage, be brought to the official notice of the European Chemicals Agency (ECHA)[16]. The GHS criteria which are anticipated to be implemented worldwide will definitely ease the notification process in the EU because the classification criteria that are used for substances and mixtures imported from outside the EU are the same as those used in the EU, hence EU importers can easily transmit the classification and labelling results to ECHA. Second, in terms of the cost and benefit analysis of the GHS implementation in the EU, the results of a comprehensive study carried out by Risk and Policy Analysts Limited (RPA) in 2006 for the DG of Enterprise and Industry, European Commission, showed that the EU's delayed adoption of the GHS would result in losses of roughly € 224 million in exports and € 184 million in imports[17]. The results from this study are believed to have triggered some concerns within the EU, particularly among chemical industries.

In 2007, the Commission of the European Communities drafted a proposal for classification, labelling and packaging of substances and mixtures that incorporated GHS elements[18]. Within 18 months of the dissemination of the proposal, the European Commission agreed to it and subsequently gazetted the EU Regulation No. 1272/2008 on classification, labelling and packaging of substances and mixtures on 16 December 2008. The EU Regulation 1272/2008 is based on the 2nd revised edition of the GHS 'purple book' and this regulation would replace the EU Directive 67/548/EEC by 1 December 2010 for substances and the EU Directive 1999/45/EC by 1 June 2015 for mixtures. The EU Regulation 1272/2008 adopted most of the building blocks in the GHS 'purple book' except for the flammable liquid category 4, acute toxicity category 5, eye damage/eye irritation category 2B, skin corrosion/irritation category 3, aspiration hazard category 2, hazardous to the aquatic environment acute toxicity category 2 and category 3[19].

There are differences between the EU Regulation 1272/2008 and the GHS 'purple book' (Table 1). One of the significant differences is the 'cut-off value' and the 'concentration limit'. Although the GHS 'purple book' does not define the meanings of 'cut-off value' and the 'concentration limit', from the presentation of the health hazards classification in the text, it is clear that both phrases have the same meaning. The difference between a generic cut-off value and a generic concentration limit in the EU Regulation 1272/2008 is demonstrated through the example of the skin irritation hazard[20]: Annex I of EU Regulation 1272/2008 defines the generic cut-off value for skin irritant substances to be 1%, but a skin irritant substance which is present in a mixture and in a quantity above or equal to the con-

Table 1. Comparison between the EU Regulation 1272/2008 and the GHS 'purple book'

EU Regulation 1272/2008 on classification, labelling and packaging of substances and mixtures[3)]	Third revised edition of the GHS purple book[10)]
This regulation covers substances, mixtures and certain specific articles.	The GHS covers substances and mixtures.
'Waste' as defined in the EU Directive 2006/12/EC on waste is not a substance, mixture or article within the meaning of this regulation.	The definition of 'waste' is not addressed.
'Supplier' means any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a mixture, or a mixture (note: distributors and consumers are not downstream users as a downstream user means any person, other than a manufacturer and importer, who uses a substance, either on its own or in a mixture).	As the GHS is a voluntary guidance document, the GHS does not require legal compliance. In this regard, the term 'supplier' is being used in the GHS 'purple book' in its general meaning.
The meanings for 'cut-off value' and 'concentration limit' are different, but comparable.	The meanings for 'cut-off value' and 'concentration limit' are the same.
The cut-off value for acute toxicity category 1–3 is 0.1% and the cut-off value for acute toxicity category 4 is 1% (unless there is a reason to suspect that an ingredient present at a concentration of less than 1% is still relevant for classifying the mixture as having acute toxicity).	The cut-off value for acute toxicity (all categories) is 1% (unless there is a reason to suspect that an ingredient present at a concentration of less than 1% is still relevant for classifying the mixture as having acute toxicity).
The word 'label' is not defined.	The word 'label' is defined.
For the label, besides the six elements required by the GHS, this regulation requires two additional pieces of information, i.e. the nominal quantity of the substance and where applicable, the supplemental information as described in Annex II of the regulation.	For the label, there are six elements required by the GHS, i.e. product identifier, supplier information, signal words, pictogram, hazard statement, and precautionary statement. However, GHS allows supplementary information to appear on the label with the conditions that the supplementary information provides further details, and does not contradict the standardised hazard information, or that the supplementary information provides information about hazards not yet incorporated into the GHS.
As far as Confidential Business Information (CBI) is concerned, this regulation provides criteria that allow manufacturers, importers or downstream users to request the use of an alternative chemical name. However, the request must fulfil a few criteria before it is considered by the ECHA for approval.	Only general guidance for the protection of CBI is provided.
One of the principles of precedence for hazard pictograms states that if the explosive pictogram applies, the use of the flammable pictogram and oxidising pictogram shall be optional, except in cases where more than one of these hazard pictograms are compulsory. (For example, if a substance is classified as organic peroxide Type B, where two pictograms are required by the regulation, i.e. explosive pictogram and flammable pictogram, the flammable pictogram is optional when the explosive pictogram is depicted on the label.)	This specific precedence principle is not stated in the GHS 'purple book'. However, other precedence principles for the EU Regulation No 1272/2008 and the GHS purple book are the same.
The hazard pictograms, signal word, hazards statements and precautionary statements shall be located together on the label.	The hazard pictograms, signal word and hazards statements shall be located together on the label.
The dimensions of the labels are stated in the regulation. In addition, the hazard pictogram shall cover at least one fifteenth of the surface area of the label but the minimum area shall not be less than 1 cm^2.	The dimensions of the label and the pictogram are not stated in the GHS 'purple book'

European Commission 2008[3)],
UN 2009[10)].

centration limit of 10% in the mixture would cause the mixture to be classified as a skin irritant. However, the skin irritant substance at ≥ 1% and below 10%, may still result in the classification of the mixture as a skin irritant, since the concentration would be taken into account if other skin corrosive/irritant substances are present in the mixture below the relevant generic concentration limits. For example, a mixture containing 0.8% substance X (skin corrosive category 1A) and 5% substance Y (skin irritant category 2) should be classified as skin irritant mixture (although substance X is < 1% and substance Y is less than 10%) because by referring to the formula in the EU Regulation 1272/2008, this mixture contains 13% (10(0.8%) + 5%) of skin irritant substances, i.e. above the generic concentration limits of 10%.

The EU Regulation 1272/2008 also introduced the requirement for the specific concentration limit to be

set by the manufacturer, importer or downstream user in cases where adequate and reliable scientific information shows that the hazard of a substance is evident even when the substance is present at a level below the concentrations set for any hazard classes in the Annex I of EU Regulation No. 1272/2008. The specific concentration limit for a particular substance is shown in Annex VI of EU Regulation No 1272/2008. In order to demonstrate classification using specific concentration limits, we have selected a substance from Annex VI of EU Regulation No 1272/2008, namely hexamethylphosphoric triamide (CAS no: 680-31-9) with a specific concentration limit ≥ 0.01%. The intrinsic hazardous properties for hexamethylphosphoric triamide (HMPTA) are the carcinogen category 1B and the mutagen category 1B. Suppose we now have two mixtures with different compositions of HMPTA, i.e. 0.5% of HMPTA in mixture A and 0.05% of HMPTA in mixture B. As stipulated in Annex I of EU Regulation No. 1272/2008, the generic concentration limit for carcinogen category 1B and mutagen category 1B is 0.1%. There is no doubt that mixture A should be classified as a carcinogen category 1B and mutagen category 1B. However, for mixture B, although the composition of HMPTA is below the generic concentration limit, it is noted that the composition of HMPTA exceeds the specific concentration limit, thus mixture B must also be classified as carcinogen category 1B and mutagen category 1B. According to ECHA, the specific concentration limits take precedence over generic concentration limits[20]. In addition, the concept of specific concentration thresholds is also recommended by GHS, particularly in paragraph 1.3.3.2[10].

Although there are differences between the GHS and the EU Regulation 1272/2008, these differences actually fall within the provisions of the GHS that allow for GHS components to be 'translated' by competent authorities into their local settings.

GHS Implementation by WHO: the voluntary approach

The WHO first published the guidelines entitled 'WHO Recommended Classification of Pesticides by Hazard' (hereinafter referred as 'WHO Guidelines') in 1978, and the WHO guidelines have been revised and reissued at two to three-year intervals[21]. The WHO pesticide classifications are based on LD_{50} of acute oral and dermal toxicity on rats. Although the majority of the pesticide classifications are based on acute oral toxicity, dermal toxicity must also be considered since it has been found that under most conditions of handling pesticides, a high proportion of the total exposure is dermal[21]. The WHO Guidelines have classified pesticides into four categories, i.e. Class Ia (extremely hazardous), Class Ib (highly hazardous), Class II (moderately hazardous) and Class III (slightly hazardous).

The WHO Guidelines and Food and Agriculture Organization of the United Nations (FAO) Guidelines, such as the FAO Guidelines on Good Labelling Practices for Pesticides[22] (hereinafter referred to as 'FAO Guidelines') are international guidelines that provide recommendations for pesticide classification and labelling. Although both the WHO and FAO Guidelines are voluntary guidelines, these guidelines have played important roles at the national level, particularly in developing countries that have adopted these guidelines into their respective systems. Since the agriculture sector is one of the key sectors for GHS implementation[9], the WHO and FAO have seen this as an opportunity to harmonize the classification of pesticides with other chemicals, such as industrial chemicals, and ultimately enhance chemical hazards communication. Hence, the WHO has shown their interest and indicated that they are in the process of incorporating GHS elements into the next WHO Guidelines[21]; Similarly, FAO has also indicated that they will incorporate GHS labelling principles into the next set of FAO Guidelines[23]. However, it is anticipated that the WHO Guidelines must be revised before the FAO Guidelines because part of the WHO Guidelines are referred to by the FAO Guidelines.

In 2009, the WHO amended their Guidelines by incorporating GHS elements into the latest edition (hereinafter referred as 'WHO Guidelines 2009')[24]. Some of the GHS related changes/updates in the WHO Guidelines 2009 are as follows: (i) as the GHS does not make any distinction between solids and liquids classification (for acute oral and dermal toxicity) like the former WHO classification system (in 2004[21]), the WHO Guidelines 2009 has adapted the GHS criteria by removing different classification criteria for solids and liquids; (ii) the WHO Guidelines 2009 retains the former WHO Classes (e.g. WHO Class Ia for extremely hazardous pesticides and WHO Class Ib for highly hazardous pesticides). However, the WHO cut-off values are correlated with the GHS cut-off values, except for the cut-off values of Category 3 and Category 4 that have been merged into 'moderately hazardous' (Table 2); (iii) one of the main differences between the WHO classes and the GHS is that the WHO classes have incorporated both chronic toxicity and acute toxicity, especially for some of the active ingredients listed in the WHO Guidelines 2009. For example, Captafol (CAS no: 2425-06-1) is classified as GHS Category 5 for acute oral toxicity because its LD_{50} value = 5,000 mg/kg; however, based on the carcinogenicity of Captafol in both rats and mice, WHO has classified Captafol as a Class Ia pesticide, i.e. extremely hazardous[24]. Hence,

Table 2. Comparison of WHO and GHS cut-off values for acute oral toxicity

LD_{50} (mg/kg)	≤ 5	5–50	50–300	300–2,000	2,000–5,000
GHS[a]	Category 1	Category 2	Category 3	Category 4	Category 5
WHO Guidelines[b]	Ia (extremely hazardous)	Ib (highly hazardous)	II (moderately hazardous)		III (slightly hazardous)

[a]The GHS criteria are based on the GHS third revised edition, where a lower category indicates higher hazards.
[b]The WHO criteria are based on the 2009 WHO Recommended Classification of Pesticides by Hazard that has already incorporated GHS elements.

the WHO classes can be seen as a 'composite classification' of acute and chronic toxicity. To ease concerns on which active ingredients with high LD_{50} values should be classified in a more severe WHO class, the WHO has listed all the relevant active ingredients in the WHO Guidelines 2009 by assigning those active ingredients into appropriate WHO classes. These active ingredients are accompanied by their respective GHS acute toxicity classification[24]. It is important to highlight that the WHO classification system concerns only acute and chronic toxicity, thus other health hazards like skin sensitization and physical and environmental hazards are not classified.

Although WHO has incorporated GHS elements into the WHO Guidelines 2009, there are several elements which have caused ambiguity for GHS implementation in the agriculture sector. The first is related to the moderately hazardous pesticides (WHO Class II). Table 2 shows the correlation between the WHO Classes and GHS Classes for particularly acute oral toxicity, and it can be seen that WHO Class Ia, WHO Class Ib and WHO Class III are well correlated with the GHS' acute toxicity categories, i.e. acute toxicity category 1, acute toxicity category 2 and acute toxicity category 5, respectively. However, the WHO Class II is correlated with both acute toxicity category 3 and category 4, hence this is the challenge when it comes to GHS labelling. If the WHO Class II correlates with both GHS acute toxicity category 3 and category 4, then what should be the pictogram and signal word for WHO Class II pesticides? 'Skull and crossbones' or the 'exclamation mark'? Danger or warning? (note: GHS acute toxicity category 3 and category 4 have different pictograms and signal words). Perhaps WHO should review the WHO Guidelines 2009, or alternatively, perhaps FAO could clarify this ambiguity when incorporating GHS elements into the FAO Guidelines on Good Labelling Practice for Pesticides. It is important to highlight that if FAO decides to adopt the labelling requirements of the GHS acute toxicity category 3 (e.g. 'skull and crossbones' pictogram, signal word 'danger') for the WHO Class II pesticides, then some may argue about the pesticides classified as acute toxicity category 4, and whether this would be considered too high a category. A similar concern would arise if FAO decides to adopt the labelling requirements of the GHS acute toxicity category 4 (e.g. 'exclamation mark' pictogram, warning etc) for the WHO Class II pesticides.

Another concern with regard to the WHO Guidelines 2009 is the 'composite classification' of acute and chronic toxicity, where the WHO classes have incorporated chronic toxicity into the acute health hazard classification for pesticides. Our study found, however, that the 'composite classification' is only applicable to those substances listed in the WHO Guidelines 2009. For those substances that are not listed in the WHO Guidelines 2009, it is difficult to judge whether a substance would be classified based solely on acute toxicity or both acute and chronic toxicity. For example, substance 'X' (that is not listed in the WHO Guidelines 2009) which is assigned to GHS acute toxicity category 5 and carcinogenicity category 1B, might be classified as WHO class III (slightly hazardous) if the classifier was not aware of the 'composite classification' practice of the WHO. In addition, guidance for a classifier to 'upgrade' a substance into a higher degree of hazard is not available, e.g. whether the substance 'X' should be considered as WHO Class Ib or as WHO Class Ia.

In the case of pesticide mixtures, if a pesticide formulation or mixture is classified using the formula (recommended by the WHO as one of the possible approaches to classifying pesticide mixtures, and is known as additivity formula in the GHS) to obtain LD_{50}, then the classification result for the mixture is no longer a 'composite classification', particularly when there is a chronic active ingredient with high value of LD_{50} and high composition in the mixture. For example, the classification result of a pesticide formulation that contains 80% of Captafol (CAS no: 2425-06-1, LD_{50} = 5,000 mg/kg;

carcinogenic in both rats and mice) and 20% of Diniconazole (CAS no: 83657-24-3, LD_{50} = 639 mg/kg) would indicate a WHO Class III pesticide, i.e. slightly hazardous. In fact, if pure Captafol (i.e. 100%), is considered, it would be classified as a Class Ia pesticide under WHO guidelines 2009, i.e. extremely hazardous. Hence, the classification result for the pesticide mixture is acceptable only in the aspect of acute oral toxicity, but it does not include the aspect of chronic toxicity because carcinogenicity of Captafol is not being addressed in the formula. Hence the 'composite classification' does not apply here, particularly for the mixture.

Discussion

Due to the nature of institutional settings, the GHS implementation approaches practised by the EU and WHO are different. The European Commission is obligated to formulate regional regulations that benefit all EU member countries. As far as chemical classification and labelling is concerned, the EU has actually initiated regional chemical classification and labelling directives since 1967. Hence the GHS intervention in EU was not entirely a new mandatory requirement. In fact, it is more like the adoption and adaptation of international recommendations into regional settings. The gazetting of EU regulation 1272/2008 has proven that the EU has successfully incorporated GHS elements as regional mandatory requirements. At the same time, as the EU was the world's top chemicals importer in 2009[25], the EU regulation 1272/2008 also has implications for other countries, particularly those countries that export chemicals to the EU. Although the responsibility to comply with the EU Regulation 1272/2008 lies with the manufacturers, importers and downstream users in EU, the EU importers might tend to import chemicals from companies that have already classified their chemicals based on GHS criteria; hence EU importers would just need to translate the hazard statements, precautionary statements and other related information into their local languages and then relabel the chemicals instead of reclassifying the chemicals, which would require additional financial and technical resources.

Meanwhile, as the EU is also the world's top chemicals exporter[25], there is another implication of the mandatory GHS implementation by the EU for countries that are importing chemicals from the EU but have yet to incorporate GHS elements into their domestic regulations. For example, according to the study carried out by Choi and Jonai[26], only 7 out of 19 selected countries from southeast, east and central Asia have implemented GHS for industrial chemicals; which means that more than half of these countries, if they are importing chemicals from the EU, would have to reclassify and relabel these imported industrial chemicals based on their local requirements. This, in a way, defeats one of the purposes of the GHS, which is to facilitate international trade in chemicals. However, if these countries have already incorporated GHS elements into their domestic regulations, they just need to translate and relabel the imported chemicals from EU without reclassifying them. We are not implying that the GHS implementation has created barriers to the chemical trade, but if countries that import chemicals from the EU do not react appropriately and immediately, it may affect their competitiveness because the cost of their products will increase due to the additional cost needed to reclassify and relabel industrial chemicals in order to comply with the domestic requirements.

As far as the WHO Guidelines 2009 is concerned, it is important to note that the WHO is an international organization which does not have the mandate to formulate mandatory tools. Nonetheless, the earlier versions of the voluntary WHO Guidelines (that had not incorporated GHS elements) have already played an important role in assisting numerous countries in defining pesticide hazards. For example, Malaysia had adopted acute oral and dermal toxicity standards from the WHO Guidelines, as well as the components in the FAO Guidelines for mandatory pesticide classification and labelling even before the GHS intervention.

The agriculture sector has been identified as one of the GHS implementation sectors. Countries like Malaysia are anticipating the amendment of the WHO Guidelines and FAO Guidelines that will incorporate GHS elements. However, the ambiguity of the amended WHO Guidelines 2009 that we have discussed above, as well as the absence of amended FAO Guidelines (that incorporated GHS elements), may well delay the process of GHS implementation in the agriculture sector, particularly for pesticides classification and labelling at the national level, and especially for countries that already have incorporated elements of WHO and FAO Guidelines into their regulations before the introduction of the GHS.

Another interesting issue is the comparison of the GHS classification results. For this purpose, Captafol was selected for the comparison of GHS classification results (for health hazards) between the WHO, EU and Japan. Japan was selected for the comparison because GHS classification results for approximately 1,500 substances can be found at the Japan National Institute of Technology and Evaluation[27] and the GHS implementation in Japan was discussed earlier by Jonai[28] and Ta *et al*[29]. Table 3 shows the GHS classification results of

Table 3. Comparison of GHS classification on health hazards of Captafol carried out by the WHO, the EU and Japan

Chemical	WHO[a]	EU[b]	Japan[c]
Captafol (CAS no: 2425-06-1)	• Class Ia (GHS acute toxicity Category 5) • Captafol is carcinogenic in both rats and mice	• Carcinogenic Category 1B • Skin sensitization Category 1	• Acute toxicity Category 5 • Skin irritation Category 2 • Eye irritation Category 2A • Respiratory sensitization Category 1 • Skin sensitization Category 1 • Germ cell mutagenicity Category 1B • Carcinogenic Category 1B • STOT – repeated exposure Category 1
Pictograms	[d] 		
Signal word	'Not applicable'[d]	Danger	Danger

[a]WHO 2009[24],
[b]European Commission 2008[3],
[c]NITE 2010[27],
[d]Based on the FAO Guidelines on Good Labelling Practice for Pesticides that has not incorporated GHS elements[22].

Captafol for health hazards in the three different classification structures. Several observations can be made from Table 3: (i) the classification results are dependent on the scope of the classification system, for example, the WHO classification system concerns only acute and chronic toxicity, hence other health hazards like skin sensitization are not classified; (ii) the classification results are dependent on the source of information; for example, Japan has referred to sources that indicate different health hazards of Captafol, hence more hazard categories were classified; (iii) the 'exclamation mark' pictogram is missing in the EU classification. In addition, the hazard statements and precautionary statements between the EU and Japan are different because more hazard categories have been characterized by Japan.

Conclusion

In conclusion, GHS implementation is not a simple and straightforward process. Although findings from this paper indicate that the GHS can be implemented via both mandatory and voluntary approaches, the WHO Guidelines 2009 should be revised to address the concerns raised in this paper. In addition, both mandatory and voluntary approaches must be carefully compared because the classification results may well be different.

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References

1) International Labour Organisation (1990) Chemicals Convention, No.170. ILO, Geneva.
2) New Zealand (2010) Hazardous substances and new organisms Act 1996. http://www.legislation.govt.nz/. Accessed February 1, 2010.
3) European Commission (2008) Regulation No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, Official Journal of the European Communities L353.
4) Silk JC (2003) Development of a globally harmonized system for hazard communication. Int J Hyg Environ Health **206**, 447–52.
5) Seguin L (2009) Optimizing your company's GHS deployment. J Chem Health Saf **16**, 5–9.
6) EU Commission Services (2006) Analysis of the potential effects of the proposed GHS regulation on its EU downstream legislation.
7) International Labour Organisation (1990) Chemicals Recommendation, No.177. ILO, Geneva.
8) United Nations (1992) Agenda 21. United Nations, New York.
9) United Nations Institute for Training and Research (2005) Developing a national GHS implementation strategy: a guidance document to support implementation of the GHS. UNITAR, Geneva.
10) United Nations (2009) Globally harmonized system of classification and labelling of chemicals. 3rd revised Ed., United Nations, New York.
11) Winder C, Azzi R, Wagber D (2005) The development

of the Globally Harmonized System (GHS) of classification and labelling of hazardous chemicals. J Hazard Mater **A125**, 29–44.
12) Pratt IS (2002) Globally harmonization of classification and labelling of hazardous chemicals. Toxicol Lett **128**, 5–15.
13) Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals (UNECE) (2009) Report of the UNECE Fourth Session. Document ST/SG/AC.10/36/Add.3.
14) Commission of the European Communities (2001) White paper: strategy for a future chemicals policy, Brussels. http://europa.eu/legislation_summaries/other/l21275_en.htm Accessed December 8, 2009.
15) European Commission (2006) Regulation No 1907/2006 of the European Parliament and the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directive 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, Official Journal of the European Union L396.
16) European Chemicals Agency (2010) Practical guide 7: How to notify substances in the classification and labelling inventory. ECHA, Helsinki.
17) Risk and Policy Analysts Limited (2006) Impact assessment of implementing the GHS: work package 1, Final report for DG Enterprise and Industry. European Commission, Brussels.
18) Commission of the European Communities (2007) Proposal for a regulation of the European Parliament and the Council on classification, labelling and packaging of substances and mixtures, and amending directive 67/548/EEC and regulation (EC) No 1907/2006; 2007.
19) European Chemicals Agency (2009) Introductory Guidance on the CLP Regulation. ECHA, Helsinki.
20) European Chemicals Agency (2009) Guidance on the application of the CLP criteria. ECHA, Helsinki.
21) World Health Organisation (2004) WHO recommended classification of pesticides by hazard and guidelines to classification 2004. WHO, Geneva.
22) Food and Agriculture Organization of the United Nations (1995) Guidelines on Good Labelling Practice for Pesticides. FAO, Rome.
23) Food and Agriculture Organization of the United Nations (2007) The implementation of GHS: FAO position paper. http://www.fao.org/ag/AGP/AGPP/Pesticid/Code/Download/GHS%20paper06.pdf Accessed January 5, 2010.
24) World Health Organisation (2009) WHO recommended classification of pesticides by hazard and guidelines to classification 2009. WHO, Geneva.
25) The European Chemical Industry Council (CEFIC) (2011) Facts and figures brochure 2010, Brussels. http://www.cefic.org/Facts-and-Figures/Documents1/ Accessed August 1, 2011.
26) United Nations Institute for Training and Research (UNITAR) (2010) Status of GHS implementation in Southeast, East and Central Asia. UNITAR, Geneva. http://www.unitar.org/cwm/ghs/events/asia-stocktaking-workshop/background-documents Accessed August 9, 2011.
27) National Institute of Technology and Evaluation (NITE) (2010) Information about the status of the implementation of GHS in Japan. http://www.safe.nite.go.jp/english/ghs_index.html. Accessed April 27, 2010.
28) Jonai H (2008) Implementation of the GHS in Japan. Ind Health **46**, 443–7.
29) Ta GC, Jonai H, Mokhtar MB, Peterson PJ (2009) Model for the implementation of globally harmonized system of classification and labelling of chemicals: lessons learned from Japan. J Occup Health **51**, 526–30.