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Original Article

Classified Chemicals in Accordance with the Globally Harmonized System of Classification and Labeling of Chemicals: Comparison of Lists of the European Union, Japan, Malaysia and New Zealand

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ABSTRACT

Background: The Globally Harmonized System of Classification and Labeling of Chemicals (GHS) was developed to enhance chemical classification and hazard communication systems worldwide. However, some of the elements such as building blocks and data sources have the potential to cause “disharmony” to the GHS, particularly in its classification results. It is known that some countries have developed their own lists of classified chemicals in accordance with the GHS to “standardize” the classification results within their respective countries. However, the lists of classified chemicals may not be consistent among these countries.

Method: In this study, the lists of classified chemicals developed by the European Union, Japan, Malaysia, and New Zealand were selected for comparison of classification results for carcinogenicity, germ cell mutagenicity, and reproductive toxicity.

Results: The findings show that only 54%, 66%, and 37% of the classification results for each Carcinogen, Mutagen and Reproductive toxicants hazard classes, respectively are the same among the selected countries. This indicates a “moderate” level of consistency among the classified chemicals lists.

Conclusion: By using classification results for the carcinogenicity, germ cell mutagenicity, and reproductive toxicity hazard classes, this study demonstrates the “disharmony” in the classification results among the selected countries. We believe that the findings of this study deserve the attention of the relevant international bodies.

1. Introduction

The Globally Harmonized System of Classification and Labeling of Chemicals (GHS) is an internationally accepted system that outlines the criteria for chemical classification and hazard communication [1]. Inconsistencies in chemical classification and labeling systems can affect public health, the environment and trade [2], hence the implementation of the GHS is expected to produce a consistent chemical classification and hazard communication system within a country and across borders, helping to ultimately reduce and eliminate chemical risks. The GHS can also be used by those countries without proper chemical management systems, specifically for the purpose of establishing a recognized framework for chemical classification [3].

The implementation of the GHS was expected to improve uniformity of chemical classification and hazard communication worldwide. However, some flexible elements in the GHS have created inconsistencies among countries adopting the system. One of the elements is the “building block”. The building block gives countries flexibility in adopting hazard classes and hazard categories, but it must follow the guidelines stated in the GHS. For example, if more than one hazard category is adopted, a continuous unbroken sequence should be adopted among the hazard categories [1]. However, the building block is not intended to limit the classification of chemicals; rather, it is meant to provide flexibility in the GHS implementation for countries [4]. Although these building blocks seemed to create inconsistencies in chemical classification at the beginning of GHS implementation, it was observed

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that such inconsistencies could be easily overcome once the competent authorities have determined the building blocks in their respective countries. By taking into account the safety and trading aspects, the building blocks adopted by countries implementing the GHS are almost similar. Thus, those building blocks that have not been adopted will be exempted or become irrelevant for that particular country.

Besides building blocks, another source of inconsistencies in chemical classification involves the data used for chemical classification. The inconsistencies here refer to the classification results derived from the same classification criteria but different data sources. The GHS encourages the use of existing data for classification purposes, as this would reduce unnecessary animal testing [1]. This data can be obtained from reliable databases such as the International Programme on Chemical Safety INCHEM, International Agency for Research on Cancer (IARC), International Chemical Safety Cards, and Environmental Health Criteria Monographs and so on. The GHS does not specify the data sources. So long as the data is reliable and is consistent with the classification criteria stated in the GHS, it can then be used for chemical classification. However, data used from multiple sources, the roles of expert judgment, and the weight of evidence can lead to different chemical classification results. Experts such as toxicologists or ecotoxicologists are not only responsible for generating data from toxicological and ecotoxicological studies that will be used in the classification process, but they also play a key role in the interpretation of such data to ensure classification decisions are made accurately [5]. Therefore, classifiers are facing problems with data selection and interpretation and, without expertise in decision making, this can potentially lead to less accurate chemical classification results.

Building blocks, data sources, expert judgment, and weight of evidence are potential challenges to the "harmony" in the GHS, particularly in chemical classification results. Inconsistencies in chemical classification results will then lead to inconsistencies in hazard communication, which might lead to confusion among chemical users on the proper protection required when using and handling those chemicals. In this regard, establishing a list of the classified chemicals based on the GHS can be seen as one of the potential solutions to avoid this "disharmony" in the implementation of the GHS. Some countries which are aware of the benefits of listing classified chemicals based on the GHS have developed their lists, some to meet mandatory requirements and others on a voluntary basis. Nevertheless, as these lists are developed by individual countries, there are also inconsistencies among them. This issue was highlighted by the United Nations Institute for Training and Research (UNITAR) during the 15th session of the United Nations Sub-Committee of Experts on the GHS (UNSCEGHS) in 2008. The article submitted by UNITAR highlighted the different classification results for toluene based on four existing lists; it also proposed to UNSCEGHS to consider whether there was a need for an internationally developed and maintained list for classified chemicals based on the GHS [6].

In the 18th session of UNSCEGHS held from 9 to 11 December 2009 in Geneva, the UNSCEGHS initiated discussions to consider the development of a harmonized classification list [7]. However, till today, the mechanism to establish an internationally harmonized classification list is still not clear, hence the progress is relatively slow. In the 34th session of UNSCEGHS in 2017, the majority of experts and industry representatives supported the concept of a nonbinding list of chemicals classified in accordance with the GHS [8]. However, it was reported in the 36th session of UNSCEGHS in 2018 that "no discussion took place" under the section of 'development of a list of chemicals classified in accordance with the GHS' [9].

Although an internationally harmonized classification list in accordance with the GHS is still nonexistent, some countries, such as those in the European Union, and Malaysia, have each gazetted a list of classified chemicals, and the maintenance of this list of classified chemicals is mandatory [10]. Some other countries have also developed lists of classified chemicals on a voluntary basis, such as the list of classified chemicals established by the Japan National Institute of Technology and Evaluation (NITE). By taking into account several existing lists of classified chemicals in accordance with the GHS, this study aims to assess the consistency of chemical classification results among countries, as well as to compare chemical classification results established by international bodies. The classification results were obtained from countries with mandatory requirements for lists, as well as those lists made on a voluntary basis, where both types of lists are acceptable for GHS implementation because the GHS has not determined a specific approach for implementation [11]. These results are expected to provide some perspective on the implementation of classified chemicals lists in different countries, and the findings of this study can also contribute to the UNSCEGHS.

2. Method

In this study, four countries, namely the European Union (note: in this study, EU is considered as a country for comparison purposes), Japan, Malaysia, and New Zealand, were selected for a comparison of their classified chemicals lists. The criteria for this selection were: (i) these countries have developed a list of classified chemicals in accordance with the GHS (the lists may have been either mandatory or made voluntarily); and (ii) these countries are located in different regions. In addition, these selected countries are considered to have full or partial GHS implementation from the legal perspective [12]. Although differences exist in the definition of 'chemicals' (for example, Malaysia uses the term "chemicals" to refer to substances and mixtures whereas New Zealand uses the

Table 1
References and authorities in the selected countries that developed hazard classification criteria in accordance with the GHS [13–16]

Country	References	Authorities
European Union	EU Regulation EC No 1272/2008 –Amended by Commission Regulation 2017/776 – 4 May 2017	European Commission, European Union
Japan	GHS Classification Guidance for Enterprises 2013 Revised Edition	Ministry of Economy, Trade and Industry (METI), Japan
Malaysia	Occupational Safety and Health (Classification, Labeling and Safety Data Sheet of Hazardous Chemicals) Regulations 2013 and Industry Code of Practice on Chemicals Classification and Hazard Communication 2014	Department of Occupational Safety and Health Malaysia
New Zealand	Hazardous Substances and New Organisms (HSNO) Act 1996	Environmental Protection Authority, New Zealand

GHS, Globally Harmonized System of Classification and Labeling of Chemicals.

Table 2
Obligations and number of chemicals listed in the four lists of classified chemicals in accordance with the GHS

Country	Sources of classified chemicals	Obligation	Number of classified chemicals
European Union	EU Annex VI – Adaptation to Technical Progress (ATP) 10	Mandatory	4251
Japan	GHS Classification Results, NITE (Japan)	Nonmandatory	1407
Malaysia	Part 1, Industry Code of Practice on Chemicals Classification and Hazard Communication 2014	Mandatory	229
New Zealand	Chemicals Classification and Information Database (CCID), EPA New Zealand	Mandatory	approximately 5000

GHS, Globally Harmonized System of Classification and Labeling of Chemicals; NITE, National Institute of Technology and Evaluation.

term "hazardous substance" to refer to substances and mixtures), this will not affect the analysis of this study because the hazard classification criteria used in these countries are in accordance with the GHS [13–16]. Table 1 shows the references and authorities in the selected countries that developed hazard classification criteria in accordance with the GHS.

This study was conducted by only taking into account hazard classes of carcinogenicity (C), germ cell mutagenicity (M) and reproductive toxicity (R), generally known as CMR chemicals in the list of classified chemicals of the European Union, Japan, Malaysia, and New Zealand. The CMR chemicals here refer to the chemicals classified under the GHS as having carcinogenicity (category 1/1A/1B and 2), germ cell mutagenicity (category 1/1A/1B and 2) or reproductive toxicity (category 1/1A/1B, 2 and via lactation) [1]. The comparison in this study is among chemicals with the same classification results, whether both are CMR chemicals or chemicals not classified as CMR (also known as "Not Classified" or NC). It is important to note that chemicals that are not classified as CMR might still be classified under other hazard classes such as acute toxicity, skin corrosion or skin irritation. For the comparison among the countries, hazard category 1, 1A and 1B under the hazard classes of CMR are treated as a hazard category 1. This will not affect the communication hazard of the class because the pictogram, signal word and hazard statement for the hazard sub-categories 1A and 1B are the same as the hazard categories [1]. The comparison among the four countries was conducted from 1 June to 31 July 2018 using existing data sources, namely the EU Annex VI – Adaptation to Technical Progress 10, the Malaysia Industrial Code of Practice on Chemicals Classification and Hazard Communication 2014 (Part 1), the Japan NITE GHS Classification Results and the New Zealand Chemicals Classification and Information Database. Besides, this study also compares those with the classification results established by an international body, namely the IARC.

3. Results

3.1. Reference for comparison

Based on the data collected from the EU, Japan, Malaysia, and New Zealand, Table 2 shows the obligations and numbers of chemicals listed in their respective lists of classified chemicals in accordance with the GHS.

In this study, Malaysia was chosen as a reference point for comparison because it has the smallest number of classified chemicals (i.e. 229 chemicals) compared with the other three countries. This means that all the classified chemicals in Malaysia's list were used for comparison without taking into account whether the chemicals are listed on the EU, Japan, and New Zealand lists. In other words, the maximum number of chemicals selected for comparison in this study is 229, although the lists of the EU and Japan have a higher number of chemicals. As discussed earlier, this study only focused on CMR chemicals or chemicals not classified as CMR (i.e. NC). This means that any chemical which had at least one hazard class—either carcinogenicity, germ cell mutagenicity or reproductive toxicity, or not classified as CMR by any of the countries—was selected for comparison in this study. In addition, if any CMR chemical from Malaysia's list was not found in the lists of the other three countries, it would still be considered for the purpose of comparison. This was done by assuming that the particular chemical had not been classified yet or that the current category of such hazards had not yet been determined in the other countries.

3.2. Comparison of the same classification results for CMR chemicals among the 4 countries

In Malaysia's list of 229 classified chemicals, 82 are CMR chemicals, i.e. chemicals that have been classified with at least one hazard class—either carcinogenicity (category 1/1A/1B and 2), germ cell mutagenicity (category 1/1A/1B and 2) or reproductive toxicity (category 1/1A/1B, 2 and via lactation). The list of classified chemicals in Malaysia is established by the Department of Occupational Safety and Health (DOSH), and amendment of the list will take into account technical inputs from a technical committee comprising members from industry, professional bodies and academia.

Out of the 229 chemicals in Malaysia's list [17], 147 chemicals are found to fall under at least one hazard class - either CMR, or 'not classified' (NC), when compared with chemical lists developed by the European Union, Japan and New Zealand. Of these 147 chemicals, 143 chemicals have the same classification results under carcinogenicity, 146 chemicals have the same classification results under germ cell mutagenicity and 145 chemicals have the same classification results under reproductive toxicity (Table 3). A more detailed comparison was conducted, where countries that have the same classification results (i.e. 4 countries, 3 countries and 2 countries) for the hazard classes of carcinogenicity, germ cell mutagenicity and reproductive toxicity were analyzed. Table 3 also shows the number and percentage of chemicals with the same classification results for CMR using Malaysia's list as reference. Table 3 shows that for carcinogenicity and mutagenicity, about 50%-60% of the classification results are the same across the 4 countries, i.e., 54% for carcinogenicity and 66% for mutagenicity. This shows some connection among the 4 countries, for example, all these countries might have referred to the IARC for classification results for carcinogenicity. However, this is just an assumption and it is difficult to justify because the rationale for classification is not stated in their official documents nor on their websites. On the other hand, the similarity between classification results for reproductive toxicity has a relatively low percentage, i.e. only 37% of the classification results are the same across the 4 countries. However, it is noted that there is a 45% similarity in the classification results for reproductive toxicity for 3 countries, and the highest proportion

Table 3
Number and percentage of chemicals with the same classification results for carcinogenicity (C), germ cell mutagenicity (M) and reproductive toxicity (R) using Malaysia's list as reference

Countries					Numbers and percentage of chemicals with the same classification results for:					
Number of countries	Countries with the same classification results				Carcinogenicity		Mutagenicity		Reproductive toxicity	
	MY*	EU†	JP‡	NZ§	n¦	%	n¦	%	n¦	%
4 countries	✓	✓	✓	✓	77	54%	96	66%	53	37%
3 countries	✓	✓	✓		21	30%	12	25%	14	45%
	✓	✓		✓	21		23		52	
	✓		✓	✓	1		1		0	
2 countries	✓	✓			21	16%	14	9%	25	18%
	✓		✓		1		0		0	
	✓			✓	1		0		1	
Total					**143**	**100%**	**146**	**100%**	**145**	**100%**

* MY – Malaysia (as reference).
† EU – European Union.
‡ JP – Japan.
§ NZ – New Zealand.
¦ n – number of chemicals.

(i.e. n = 52) is contributed by Malaysia, the European Union, and New Zealand (Table 3).

Of the 147 CMR chemicals, several chemicals have different CMR classification results comparing Malaysia with either the European Union, Japan or New Zealand. These include, for carcinogenicity, 3 chemicals (i.e. formaldehyde, tetrahydrofuran, vinyl acetate), for which three countries (the European Union, Japan, and New Zealand) have the same classification results; and one chemical (i.e. dieldrin) for which two countries (Japan and New Zealand) have the same classification results; for mutagenicity, one chemical (i.e. formaldehyde) for which three countries (the European Union, Japan, and New Zealand) have the same classification results; for reproductive toxicity, one chemical (i.e. chloroform) for which three countries (the European Union, Japan, and New Zealand) have the same classification results, and one chemical (i.e. styrene) for which two countries (the European Union and New Zealand) have the same classification results.

3.3. Comparison between Malaysia and other countries

The Malaysian Ministry of International Trade and Industry is the chair for the National Coordinating Committee for GHS Implementation in Malaysia, whose role is to facilitate and coordinate GHS implementation across various sectors in Malaysia, namely the industrial workplace, agriculture, transport and consumer products [18]. As part of this Coordinating Committee, the DOSH is given the responsibility of implementing the GHS in the industrial workplace in Malaysia.

Over the years, DOSH has made significant efforts to implement the GHS at the industrial workplace in Malaysia, and one of its achievements is the gazetting of the Occupational Safety and Health (Classification, Labeling and Safety Data Sheet of Hazardous Chemicals) Regulations 2013 that is consistent with the GHS [19]. In addition, DOSH has also carried out numerous outreach and training programmes related to the GHS. Although DOSH has gazetted a mandatory list of classified chemicals in accordance with the GHS, being in a developing country and with limited technical resources, it might have referred to other international lists of classified chemicals to develop its own list. Hence in this study, the CMR hazard classes are used as a tool to compare classification results between Malaysia and the other countries, i.e. the European Union, Japan, and New Zealand. Fig. 1 shows the percentage of the CMR chemicals with the same classification results for Malaysia and the other countries. The results indicate that a high percentage (>98%) of the classification results for CMR hazard classes are the same for Malaysia and the European Union: 98% for carcinogenicity, 99% for mutagenicity and 99% for reproductive toxicity, respectively. In this respect, we can conclude that the CMR hazard classes listed in Malaysia's list is consistent with the list established by the European Union.

3.4. Comparison between countries and IARC

One of the findings above indicates that about 54% of the classification results for carcinogenicity is the same across the 4 countries (the European Union, Japan, Malaysia, and New Zealand), and the reason could be that they had referred to the IARC for classification results for carcinogenicity. In this study, a more detailed analysis was carried out to find out the possible reason.

The IARC is the specialized cancer agency of the World Health Organization. Its objective is to promote international collaboration in cancer research. IARC has assessed almost 1,075 agents and the results have been published in IARC monographs [20]. The IARC has a different method for classification compared to the GHS, but the classification criteria of the two systems are the same (Table 4). As such, the method of classification utilized by IARC needs to be converted to the GHS format before it can be used for comparison of classification results of related countries. The conversions were made based on the same classification criteria between the IARC and the GHS. Thus, the correlation between the IARC and the GHS results, as shown in Table 4 in the following context, are: Group 1 correlates with Category 1A; Group 2A correlates with Category 1B; and Group 3 correlates with Category 2. The correlations are in line with the GHS Classification Guidance for Enterprises 2013 Revised Edition issued by the Ministry of Economy, Trade and Industry of Japan [15].

In this study, the comparison of classification results was conducted between IARC and the European Union, Malaysia and Japan. New Zealand was not included in the comparison because there was no subcategory classification result in the Chemical Classification and Information Database. Any CMR chemical selected in this study not found in the list of the IARC is considered as "Not Classified".

In accordance with Table 3, 77 chemicals have the same classification results among the four countries. Hence all the 77 chemicals were selected for comparison. Table 5 shows the comparison results between the IARC and the three countries (Malaysia, the European Union, and Japan). It is observed that all three countries selected for comparison with the IARC have more than 85 % (of 77 chemicals)

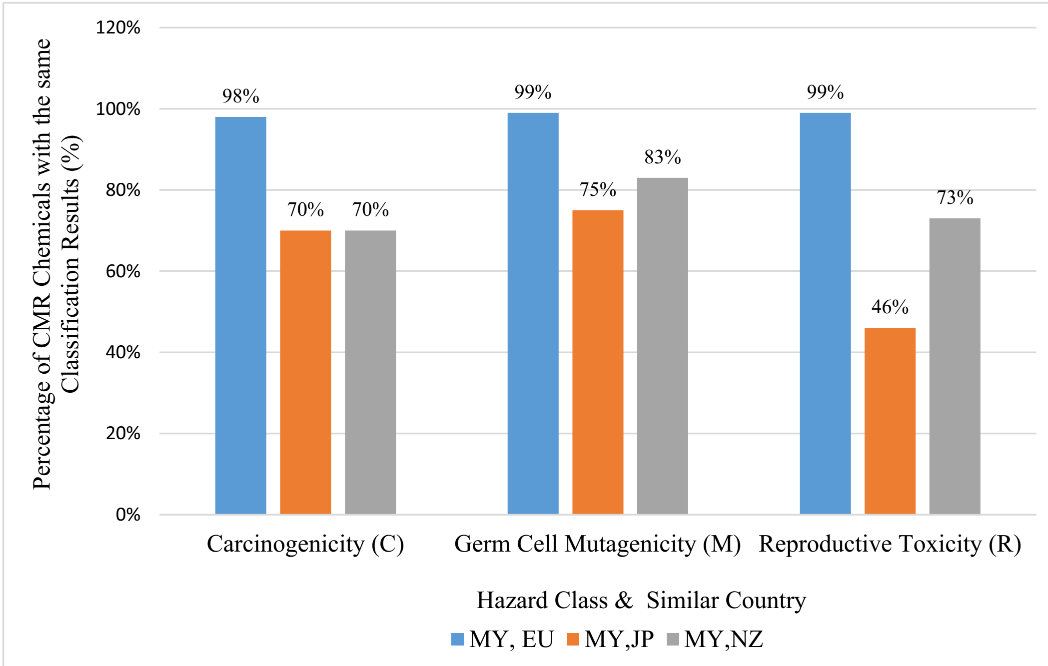

Fig. 1. Percentage of the CMR chemicals with the same classification results for Malaysia (MY) and other countries, namely the European Union (EU), Japan (JP), and New Zealand (NZ). CMR, carcinogenicity, germ cell mutagenicity, and reproductive toxicity.

consistency, i.e. the same classification results with the IARC. This indicates that to a certain extent, the selected countries have been referring to the IARC for the classification of carcinogenicity.

4. Discussion

Unlike any other international convention related to chemicals management, such as the Stockholm Convention on Persistent Organic Pollutants, the GHS is a voluntary system [21]. To ensure global acceptance of this voluntary system, implementation of the GHS is anticipated to protect chemical users by providing an internationally comprehensible system for hazard communication, as well as to facilitate international trade [1]. Owing to the benefits of GHS, countries have adopted GHS into their legal framework, and the status of GHS implementation is also discussed in various international and regional forums, including the Chemical Dialog under the Asia Pacific Economic Cooperation [22].

Table 4
Classification criteria for IARC and GHS

IARC	GHS
Group 1: Carcinogenic to humans Group 2A: Probably carcinogenic to humans Group 2B: Possibly carcinogenic to humans Group 3: Not classifiable as to carcinogenicity to humans Group 4: Probably not carcinogenic to humans	Category 1: Known or presumed human carcinogen Category 1A: Known to have carcinogenic potential for humans Category 1B: Presumed to have carcinogenic potential for humans Category 2: Suspected human carcinogens

GHS, Globally Harmonized System of Classification and Labeling of Chemicals; IARC, International Agency for Research on Cancer.

When countries adopt GHS into their legal framework as a mandatory requirement, the competent authorities in the respective countries have determined the responsibility for chemical classification and hazard communication. It was found that the responsibility is on the chemical manufacturers/suppliers [13,14]; hence it is not the responsibility of the competent authority to classify and label the chemicals. Nonetheless, to ensure consistency of the hazard communication, even before GHS, the EU had established a list of harmonized classification and labeling for chemicals, stipulated in the Annex I of the European Commission Council Directive 67/548/EEC gazetted in 1967 [23]. Later, the harmonized list was incorporated into the EU regulations in line with GHS, where the list takes into account chemicals with the following criteria: respiratory sensitization category 1; germ cell mutagenicity category 1A, 1B or 2; carcinogenicity category 1A, 1B or 2; and reproductive toxicity category 1A, 1B or 2 [14].

The list of classified chemicals developed by a competent authority is only applicable within its country boundaries, not beyond. For example, a listed chemical must follow the classification results stipulated in the list of classified chemicals when the chemical is manufactured or imported into the EU, however, once the chemical is exported from EU to Japan, the importer in Japan can make the decision whether to retain the EU classification result, or to adopt the classification result (nonmandatory) established by the Japan NITE. Such circumstances would definitely lead to inconsistency: among importers in Japan of the same chemical, some might adopt EU classification results and others might adopt Japan classification results. For example, for the chemical N,N-dimethylanilinium tetrakis(pentafluorophenyl)borate (CAS number: 118,612-00-3), the EU classification results indicate that this chemical is classified as carcinogenicity category 2, acute toxicity 4, skin irritation and serious eye damage [14], but the same chemical is considered as 'classification not possible' due to no data available [24]. Hence, if a chemical importer in Japan adopts the EU

Table 5
Comparison results between IARC and three countries (Malaysia, the European Union, and Japan)

Classification of carcinogenicity by IARC		Classification of carcinogenicity by countries			Number of chemicals that have same classification results as IARC		
IARC	Convert to GHS category	MY[*]	EU[†]	JP[‡]	MY	EU	JP
1	1A	1A	1A	1A	2	2	2
	1A	1B	1B	1A	0	0	4
2A	1B	1B	1B	1B	5	5	5
2B	2	1B	1B	1B	0	0	0
	2	2	2	2	1	1	1
3	NC[§]	2	2	2	0	0	0
	NC	NC	NC	NC	12	12	12
NC	NC	2	2	2	0	0	0
	NC	NC	NC	NC	46	46	46
Number of chemicals with the same classification results (of 77 chemicals)					66 (or 86%)	66 (or 86%)	70 (or 91%)

GHS, Globally Harmonized System of Classification and Labelling of Chemicals; IARC, International Agency for Research on Cancer.
[*] Malaysia.
[†] European Union.
[‡] Japan.
[§] Not classified (NC).

classification results for this chemical, then the chemical users are aware of the hazards posed by chemicals; but if the importer adopts the Japan classification results, no hazard information might be available for that particular chemical. In this regard, it is possible that in the same workplace, the same chemicals may bear different labels, hence confusing the chemical users who would not be able to take the necessary protective measures. This, in a way, has defeated the purpose of the establishment of GHS.

Different levels of consistency (of classification results) derived from different classified chemicals lists that are in accordance with the GHS are expected to cause some challenges. The classified chemicals lists work well for their respective countries, particularly for the respective competent authorities responsible for GHS implementation, because the list is expected to (i) harmonize classification results for chemical substances; (ii) enhance hazard communication and user protection for chemical substances; and (iii) facilitate chemical mixture classification (non-laboratory testing) using concentration limits, additivity formulas, summation methods, etc. However, different lists of classified chemicals will lead to confusion among chemical users, and potentially lead to inconsistent hazard communication, thus, appropriate control measures cannot be determined. Since the main objective of GHS is to protect chemical users by providing an internationally comprehensible system for hazard communication, we would like to propose that UNSCEGHS expedite the process of creating a harmonized GHS classification list. The list might not possibly cover all chemicals, but at least the CMR chemicals would be harmonized for the protection of workers against long term exposure to chronic chemicals.

5. Conclusion

At present there is no guidance nor implementation mechanism adopted internationally to establish a list of classified chemicals in accordance with the GHS. The proposal to create a harmonized GHS classification list that was discussed at UNSEGHS serves as a good starting point. The development of an international list of classified chemicals is long overdue; although the discussion was initiated in 2009, there is still no concrete decision on this matter ten years on. As some countries have already developed their own lists of classified chemicals, this study does not intend to make a thorough comparison among these existing lists. Indeed, by using classification results for the CMR, this study demonstrates the 'disharmony' in classification results among the selected countries. We hope that the findings of this study will get the attention of UNSCEGHS to expedite the progress of establishing an international list of classified chemicals.

Conflicts of interest

All authors have no conflicts of interest to declare.

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