

COMMITTEE OF EXPERTS ON THE TRANSPORT OF DANGEROUS GOODS AND ON THE GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS

Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals

Fourteenth session,

Geneva, 12-14 December 2007

Item 4 of the provisional agenda

DEVELOPMENT OF GUIDANCE ON THE APPLICATION OF GHS CRITERIA

Application of GHS criteria to UVCBs¹, in specific petroleum substances

Transmitted by the International Petroleum Industry Environmental Conservation Association (IPIECA)

Background

1. The GHS currently lacks a suitable and consistent methodology for the classification of the hazards of UVCBs which include among other substance types, petroleum substances. Consequently, as GHS is being implemented by UN Member States several different approaches have emerged for the classification of petroleum substances, resulting in different hazard classification. Differences may arise due to (a) the complex composition of petroleum substances, (b) differences in interpretation of the experimental data, and (c) divergent application of the GHS criteria.

2. As part of the proposed workplan (UN/SCEGHS/13/INF.4) IPIECA presents an overview of anticipated issues that can result in divergent classification of petroleum substances within UN Member States.

Domain of applicability

3. This paper addresses crude oil and petroleum substances produced from oil and gas operations and the process streams derived from them in refinery operations.

Petroleum substances

4. Crude oil is a complex combination of hydrocarbons extracted in its natural state from the ground. It consists predominantly of aliphatic, alicyclic and aromatic hydrocarbons, but may also contain small amounts of nitrogen, oxygen and sulphur compounds. It is used as a feedstock for petroleum refining operations, which separate and convert it into fractions (streams). Petroleum refinery streams are used in a variety of applications, with the major proportion being used in the production of hydrocarbon transport fuels (for example gasoline and diesel). Hydrocarbon fuels are traded internationally.

¹ Substances of unknown or variable composition, complex reaction products or biological materials.

5. Due to their method of production, and complex composition, it is not possible to characterise petroleum streams in terms of their exact chemical composition, molecular formula or structure. They can be grouped together according to the process by which they are being manufactured and basic physico-chemical properties. Similar conversion and/or separation processes will result in streams of broadly similar composition. It should be noted that as a result of variation in the crude oil used and the specific conditions of the refining process, levels of individual constituents of a petroleum stream (defined by a single Chemical Abstracts Service Registration Number [CAS RN]) may vary quantitatively.

6. Grouping of petroleum substances has been used by the European Commission for the purposes of compiling Annex 1 to the Existing Substances Regulation and also Annex XVII of REACH. In the USA, petroleum substances have also been grouped into similar categories for the purposes of the High Production Volume (HPV) Chemicals programme. Commonly used groups of petroleum streams are:

- Petroleum gases (used as LPG)
- Naphthas (used as gasoline)
- Kerosines (used as jet fuel)
- Gasoils (used as diesel/gasoil)
- Heavy fuel oils (used as marine fuel)
- (Lubricating) base oils (many applications, e.g. lubricating greases)
- Bitumen (used in the production of asphalt)
- Aromatic extracts (used for example as process oils and in tyre production)
- Petroleum waxes (used for example as food coatings and in cosmetic products)
- Petroleum coke (used in electric power stations)
- Crude oil

Issues that can result in divergent classification of petroleum substances among UN Member States

7. IPIECA has compiled an inventory of issues that can result in divergent classification of petroleum substances among UN Member States. The inventory is based on experience with current legislation, implemented or proposed GHS legislation and the UN GHS text.

(a) Although petroleum streams are complex in composition, they are described by individual CAS RN and considered as “substances” rather than “mixtures”.

All existing Chemical Control Laws regard petroleum process streams as substances. More specifically, for classification and labelling purposes petroleum streams are considered to be ‘substances’ in the EU, the U.S., Australia, Canada, Philippines, Korea, Japan, South-Africa, China and New Zealand. In addition many countries have established inventories or lists of ‘permitted or notified’ chemical substances, that include petroleum substances under their CAS RN. Thus these CAS RNs have significance not only for classification and labelling, but also for purposes of trade.

The UN GHS text sets guidelines for the classification and labelling of substances and mixtures, but not specifically for UVCBs. As different rules apply to substances vs. mixtures, it is of pivotal importance to agree on and define the status and appropriate rules for classifying UVCBs, particularly for petroleum substances.

(b) Although petroleum streams are considered as “complex substances”, mixture rules are applied by some national authorities for specific endpoints.

As one example, UN GHS text indicates that the primary data for substance classification are available data on the substance itself. However, some authorities require that data on levels of specific hazardous constituents within complex substances be considered as part of the overall substance classification, e.g., complex substances containing constituents classified as carcinogenic at levels > 0.1% must themselves be classified as carcinogenic. However, this is not required by all authorities.

As a corollary to the above, UN GHS text indicates that if reliable data are available on a substance, retesting of the substance for classification and labelling purposes is not required. However, the national authorities that give constituent data precedence in classification forbid testing (or the use of test data) as a basis for over-ruling classifications. These differing views in the precedence of primary test data, particularly for classification of substances as carcinogenic, mutagenic and teratogenic, could lead to large regional differences in classification for these endpoints.

(c) There are currently no provisions in the UN GHS text to deal with UVCB substances described by a single CAS RN that may have different hazard classifications.

The EU GHS proposal takes into account that levels of specific components may vary within a single CAS RN. For specific petroleum substance constituents (which may themselves be hazardous and require classification) a European methodology (Notasystem) applies when classifying the petroleum substance. For example: a petroleum gas is by default classified as a carcinogen (since petroleum gas may contain the carcinogen 1,3-butadiene), unless the substance contains <0.1% 1,3-butadiene.

A fixed classification for a CAS RN representing a petroleum substance may, as a result of the (variable) composition of the petroleum substance, overestimate the actual hazard. If hazards are not correctly reflected, the confidence in the system could be compromised. In addition, if less hazardous substances are not differentiated from more hazardous substances, the incentive to produce less hazardous substances is removed.

(d) There are different approaches for the carcinogenicity classification of petroleum substances.

In the US carcinogenicity classification of petroleum substances is driven by process/refining history and takes into account assessments by other authorities such as IARC. The Japanese carcinogenicity classification is derived by a committee of experts and also takes into account assessments by other authoritative bodies such as IARC. In the EU, carcinogenicity classifications have generally been based on hazard assessment by EU technical committees and harmonised classifications incorporated into Annex I to the Dangerous Substances Directive (which will become Annex VI to the EU GHS Regulation). Specific classified constituents are taken into account for petroleum substances. UN GHS text contains clear criteria for carcinogenicity classification of substances based on availability of epidemiological and/or animal data. Mixtures are classified based on the classification of the ingredients of the

mixture, or (on a case-by-case basis) if data on the mixture as a whole are available. Experts often come to divergent classifications even when using the same guidance framework for weight of evidence evaluations.

(e) There are different lists with classifications available.

The EU maintains a list of classifications for certain substances: Annex I (Annex VI under EU GHS). These classifications are to be maintained at implementation of EU GHS. The Japanese authorities have published a list of GHS classifications, derived by the Japanese expert committee. The existence of National lists, with potentially different classifications will lead to divergent GHS classifications around the world for petroleum substances.

(f) Authorities have different approaches towards the use of human data in the evaluation of human health hazards of a chemical.

UN GHS text indicates that reliable epidemiological data and experience on the effects of chemicals on humans should be taken into account in the evaluation of human health hazards of a chemical. However, as one example where some UN Member States have interpreted the UN GHS text in a very restrictive manner, the EU GHS text proposal states that available experience on effects on humans may only be given priority over data derived from animal studies when the human data demonstrate hazards not identified from the animal studies, but does not allow the use of human data to override the results of animal studies when human data demonstrates a lack of effect observed in animals.

Considering the plethora of available human data for petroleum substances, the GHS classification may consequently differ among UN Member States based on the ability of industry to take full account of the available human data which are of direct relevance and should take precedence over animal data.

Next steps

8. The above are the main identified issues associated with petroleum substances that can lead to divergent GHS classifications around the world. IPIECA acknowledges that some differences arise due to different regulatory frameworks in which competent authorities are operating. Realising regulatory differences may continue to exist, IPIECA will try to provide the greatest level of consistency in the application of GHS criteria to petroleum substances. This guidance will be based on available scientific guidance and developed in the next months. It aims to provide a harmonised approach for the classification of petroleum substances.

9. IPIECA aims to provide draft guidance by July 2008 for consideration by the UNSCEGHS. It is believed that the work product of the IPIECA GHS Task Force if adopted will have benefits in the following areas: (i) greater global harmonization on products broadly traded in international commerce, (ii) enhanced credibility of the GHS framework with regard to petroleum and (iii) improved certainty of classification, less complexity and lower cost for industry and country authorities. We acknowledge that achieving these benefits is dependent on the pursuit of a credible approach, which is well communicated and understood by the affected parties.