

Paris, 25 January 2008

Dear Laurence,

As the official business and industry advisory committee to the OECD, BIAC has participated in the OECD programme on the harmonisation of classification and labelling from the very start.

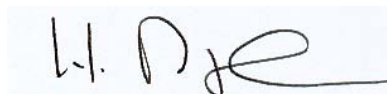
With this letter and the attached comments, we would now like to convey BIAC's views on developing a globally harmonized terrestrial classification scheme to the Secretariat and to OECD members. At the meeting of the Expert Group, which was held in Washington, DC, October 23-24, 2007, some reservations and concerns about of the concept and approach were expressed. These issues were briefly addressed in the follow-up conference call and were raised in detail in a short report that CropLife International, which is an active member of BIAC, sent to the Secretariat. Many of the points raised in this report are also relevant to other sectors of the chemical industry. Therefore, I am pleased to attach a short paper from BIAC covering the views of the whole industry.

I would be grateful if you would distribute the paper and this covering letter to the Members of the OECD Expert Group ahead of the upcoming OECD Group conference call in February.

We appreciate that it may not be possible to include the complete BIAC report in the papers the OECD Expert Group is currently drafting. However, we hope it will at least be possible to include the full summary from the attached paper. It is particularly relevant to the part of section (a) of the UN mandate concerned with evaluating the potential benefits of harmonizing classification.

We remain committed to the concept of GHS and its implementation, but we question the benefits that will be derived from expanding the system to include terrestrial classification.

Sincerely Yours



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25 January 2008

**BIAC VIEWS ON BENEFITS OF GLOBALLY HARMONISING
TERRESTRIAL HAZARD CLASSIFICATION OF CHEMICALS**

Summary

1. In general, BIAC believes there are negligible benefits to be derived from this programme. There are already existing procedures for presenting terrestrial hazard information in Safety Data sheets (SDS). For data rich substances, particularly crop protection chemicals, there are also well developed, more comprehensive, procedures for presenting hazard and risk based information on labels which have the advantage of taking into account local needs. Many of the metals (and organic substances) have now undergone extensive risk assessments under the Existing Substances Directive in the EU or are undergoing similar testing for REACH. These data are being incorporated into SDS and labels. It is not clear that adoption of a terrestrial classification approach in the GHS would indeed lead to harmonization. It may simply put one more approach to labelling in place and cause further dis-harmonization.
2. Standardised hazard based classification for terrestrial effects could reduce safety. Additional terrestrial hazard statements on labels, e.g. for pesticides, would detract from the other key safety messages and could cause confusion with existing risk based label safety phrases.
3. There are no terrestrial data for the vast majority of chemicals because generally such testing is done on those substances intended to be used in terrestrial applications and, therefore, is not needed for most substances. The inclusion of this endpoint in the GHS could mislead government regulators, those in industry responsible for classification and labelling, and chemical users to believe this is or should be a routinely assessed endpoint, when in fact testing and assessment for this endpoint should be done in a targeted manner.
4. Data available for information rich groups of chemicals, such as metals and pesticides, is designed for use in risk assessments. These data are often not suitable for use in hazard based classifications, based on simple LD50/EC50 values for the chemical. For examples: Data on metals reflects their complex chemical state in the environment. Special procedures had to be devised to allow the test methods to be useful for risk assessments. Most of the methods were developed to derive chronic endpoints and not acute toxicity values. Methods would have to be developed or modified to accommodate massive metals or sparingly soluble metal compounds for classification. Pesticide data for some groups of organism, such as soil micro-organisms, predator/parasitic arthropods, and plants are related to their rates of application and often only available for the formulated product.
5. Introducing a harmonised terrestrial classification system would be costly and time consuming.

6. Given the desire of the UN Subcommittee of Experts on the GHS to restrict changes to the GHS to a minimum in order to facilitate adoption by countries, there does not appear to be sufficient benefit to all sectors at this moment to justify introducing a completely new class to the GHS

Lack of Benefits

Terrestrial hazard information can already be presented in harmonised Safety Data Sheets (SDS), in addition to that on the label and is particularly relevant to those involved with manufacture, transport and dealing with accidents.

Groups dealing with transport labels have not expressed any desire/plans to introduce globally harmonised terrestrial hazard transport labels.

During the past 50 years, detailed procedures have been developed for making terrestrial data for pesticides available to all relevant groups and this is implemented and enforced through National Laws. The National/Regional requirements take into account local cultural needs. With this in place, there would be no benefit from international harmonisation of Terrestrial Hazard Classification. Pesticides predominantly reach the terrestrial environment through deliberate application. (Although the current debate is concerned solely with substances there would be no logic in producing a GHS if it was not to be extended to formulated products). Product labels make extensive use of risk based instructions on how to use the product safely. Many countries, for example in the EU, use solely risk based terrestrial labels and after careful consideration rejected the use of terrestrial hazard phrases. Some countries, such as USA, also use a small number of hazard phrases but in most of these countries they are restricted to wild mammals, birds and honeybees. Introduction of more hazard based classifications could reduce safety (see below).

Most of the massive metal and metal compounds have now been classified in the EU. The approach is based on aquatic organism tests and requires special procedures for massive metals and sparingly soluble metal compounds. The approach required 12 years to develop. We now observe that nearly all of the soluble metal salts are classified as Acute I and Chronic I (most hazardous). The massive metals are generally not classified and the sparingly soluble metal compounds are somewhere between. The addition of terrestrial organisms is not expected to change the metal classification outcomes. The time and effort to develop the test procedures and perform the additional tests will provide no tangible benefit. We acknowledge that a terrestrial classification system might identify a few more organic substances as hazardous. We question the value of the effort required to achieve this. For example, it is self evident that a herbicide is toxic to plants and there is no benefit from additional classification/labelling.

Potential for Use of Standardised Terrestrial Hazard Based Classifications to Reduce Safety

In order to be effective, labels must not be overloaded. Adding more hazard-based terrestrial signal words/phrases would compete for much needed label space at the expense of other information and attract the reader's attention away from the main safety messages. There would be greater clarity and transparency by making full use of the SDS. The SDS can be used to make available any existing relevant data, rather than a very restricted harmonised terrestrial classification system based on very simple criteria, such as the LC/LD50 toxicity values.

Additional hazard based labelling of pesticides can confuse the user. For example, the UK abandoned using hazard based classification/labelling for honey bees because it caused confusion when a product was labelled as very toxic to honey bees although it was labelled for use on crops where bees are present because a detailed risk assessment had shown there was no risk to bees at the recommended rate and/or time of application. The European Union recognized this potential for confusion when it decided not to include any terrestrial related hazard phrases in Annex IV to Directive 91/414/EEC. Instead it focused on safety phrases, describing how to prevent risks, in Annex V.

Lack of Data for Use in a Hazard Based Classification Procedure

There are no terrestrial data for the vast majority of organic chemicals because generally such testing is done on those substances intended to be used in terrestrial applications and, therefore, is not needed for most substances. This will continue to be the case even under REACH. Low and moderate volume chemicals will not be tested for terrestrial organisms to any extent. We note that GHS does not require additional testing.

For the data rich groups of chemicals, such as metals and pesticides the information is mainly produced for use in risk assessments and much of it is not suitable for use in simple hazard based classification schemes, based on simple criteria such as LC/LD50 toxicity values. Additional testing methods would have to be developed and designed to accommodate difficult to test substances.

Metal compounds, massive metals and alloys have very complex interactions in the terrestrial environment and hazards/risks/safety can not be related to simple toxicity values. Levels and rates of solution, speciation and complex formation have all to be taken into account. Issues, such as background levels in soils have also to be resolved. The issue of testing “difficult substances” is one that goes well beyond metal substances and also includes many organic based chemicals. There have been significant scientific advances in developing test methods for these “difficult substances” over the past few years. The tests do not yield a simple LC/LD50 for the chemical to e.g., soil organisms. Thus, much of the data are not suitable for use in a simple hazard based classification system, based on simple substance toxicity values. The primary focus of the research for the past 6-8 years has been on development of chronic test methods.

Pesticide testing requirements are driven by the data required for human and environmental risk assessments. They are normally specified in the National and Regional legislation for the approval of specified uses. Some terrestrial studies are not suitable for use in hazard, based classification procedures based on the LD50/EC50 of the chemical substance, because they do not generate such values.

- Rather these studies are used to determine whether unacceptable effects occur at field use rate or some multiple of it. This is the case for soil micro-organisms and non-target arthropods. These rates will vary from pesticides to pesticide. For example effects on soil micro-organism activity are normally studied at 2 rates of application, equivalent to one and five times the maximum level of soil residues resulting from the recommended rates of application.
- For some groups of organisms, such as plants and non-target arthropods, only the formulated product is tested and data are not available for the active substance.
- The species to be tested may depend on the crop to be treated, for example, the species of non-target arthropods.

Further, the inclusion of this endpoint in the GHS could mislead government regulators, those in industry responsible for classification and labelling, and chemical users to believe this is or should be a routinely assessed endpoint, when in fact testing and assessment for this endpoint should be done in a targeted manner. OECD should be cautious about the potential to stimulate unwarranted testing, particularly animal testing.

Large Cost of Globally Harmonising Terrestrial Hazard Classifications

There will be large, un-quantified, costs in producing and introducing a terrestrial GHS system, particularly if it is extended to mixtures (products); including;

- Cost of developing the system,
- Cost of introducing the system into national laws,
- Cost of training industry and government staff who will be responsible for making the classifications,
- Cost of changing, for example pesticide labels (to both industry and the registration authorities); this is in addition to the changes that will have to be made in the near future to accommodate the adoption of GHS in its current form,
- Cost of training product users, particularly millions of consumers and farmers, on how to interpret and use the new labels and
- Cost of development and implementation of the changes in GHS to accommodate terrestrial classification in developing countries.

We thank you in advance for taking these comments into consideration and stand ready to provide any additional information that would be helpful.

The Business and Industry Advisory Committee to the OECD (BIAC) was created in 1962 as an independent organisation recognised by the OECD as the official representative of the OECD business community. BIAC's members are the major industrial and employers' organisations in the 30 OECD member countries. Via its 31 standing committees and policy groups, BIAC mirrors all economic policy issues the OECD covers and examines their potential impacts on business in both member and an increasing number of non-member countries.