Organisation de Coopération et de Développement Économiques
Organisation for Economic Co-operation and Development

17-Nov-2016

English - Or. English

ENVIRONMENT DIRECTORATE
JOINT MEETING OF THE CHEMICALS COMMITTEE AND THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY

Cancels & replaces the same document of 15 November 2016

REPORT ON THE PILOT PROJECT ON ASSESSING THE POTENTIAL DEVELOPMENT OF A GLOBAL LIST OF CLASSIFIED CHEMICALS

Series on Testing & Assessment
No. 246

The corresponding annex is available in the following cotes:
ENV/JM/MONO(2016)43/ANN1/PART1 and ENV/JM/MONO(2016)43/ANN1/PART2

JT03405581

Complete document available on OLIS in its original format
This document and any map included herein are without prejudice to the status of or sovereignty over any territory, to the delimitation of international frontiers and boundaries and to the name of any territory, city or area.

ENV/JM/MONO(2016)43
Unclassified
English - Or. English

OECD Environment, Health and Safety Publications

Series on Testing & Assessment

No. 246

REPORT ON THE PILOT PROJECT ON ASSESSING THE POTENTIAL DEVELOPMENT OF A GLOBAL LIST OF CLASSIFIED CHEMICALS

Joint Pilot Project of the OECD and the UN Sub-Committee of Experts on the Globally Harmonised System of Classification and Labelling of Chemicals

IOMC

INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS

A cooperative agreement among FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD

Environment Directorate

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

Paris, 2016

ABOUT THE OECD

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation in which representatives of 34 industrialised countries in North and South America, Europe and the Asia and Pacific region, as well as the European Commission, meet to co-ordinate and harmonise policies, discuss issues of mutual concern, and work together to respond to international problems. Most of the OECD's work is carried out by more than 200 specialised committees and working groups composed of member country delegates. Observers from several countries with special status at the OECD, and from interested international organisations, attend many of the OECD's workshops and other meetings. Committees and working groups are served by the OECD Secretariat, located in Paris, France, which is organised into directorates and divisions.

The Environment, Health and Safety Division publishes free-of-charge documents in 11 different series: **Testing and Assessment; Good Laboratory Practice and Compliance Monitoring; Pesticides; Biocides; Risk Management; Harmonisation of Regulatory Oversight in Biotechnology; Safety of Novel Foods and Feeds; Chemical Accidents; Pollutant Release and Transfer Registers; Emission Scenario Documents; and Safety of Manufactured Nanomaterials.** More information about the Environment, Health and Safety Programme and EHS publications is available on the OECD's World Wide Web site (www.oecd.org/chemicalsafety/).

This publication was developed in the IOMC context. The contents do not necessarily reflect the views or stated policies of individual IOMC Participating Organisations.

The Inter-Organisation Programme for the Sound Management of Chemicals (IOMC) was established in 1995 following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. The Participating Organisations are FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organisations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

This publication is available electronically, at no charge.

For this and many other Environment, Health and Safety publications, consult the OECD's World Wide Web site (www.oecd.org/chemicalsafety/)

or contact:

OECD Environment Directorate,
Environment, Health and Safety Division
2 rue André-Pascal
75775 Paris Cedex 16
France

Fax: (33-1) 44 30 61 80

E-mail: ehscont@oecd.org

© OECD 2016
Applications for permission to reproduce or translate all or part of this material should be made to: Head of Publications Service, RIGHTS@oecd.org, OECD, 2 rue André-Pascal, 75775 Paris Cedex 16, France

FOREWORD

In 2014, the OECD Task Force on Hazard Assessment (TFHA) and the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology (JM) agreed to provide a coordination role for a pilot classification project upon invitation from the UN Sub-Committee of Experts on the Globally Harmonised System of Classification and Labelling of Chemicals (UNSCEGHS). This is a report of the Pilot Project of the OECD and the UN Sub-Committee of Experts on the Globally Harmonised System of Classification and Labelling of Chemicals detailing the process of the pilot project and learnings. It also contains a template for Proposals for Classification and Labelling (Annex 1). Accompanying the report are three case study chemicals where non-binding agreement on their classification have been reached.

1. Report on the Proposal for Classification and Labelling (C&L) of Dimethyltin Dichloride ENV/JM/MONO(2016)44, Series on Testing & Assessment No. 247.

2. Report on the Proposal for Classification and Labelling (C&L) of Dicyclopentadiene ENV/JM/MONO(2016)45, Series on Testing & Assessment No. 248.

3. Report on the Proposal for Classification and Labelling (C&L) of Dibutyl Phthalate ENV/JM/MONO(2016)46, Series on Testing & Assessment No. 249.

The results of this pilot project will be submitted to the UNSCEGHS for consideration in their deliberations on the potential development of a global list of classified chemicals.

This document has been prepared by a project team established for the Pilot Project under the OECD's Task Force on Hazard Assessment. It is being published under the responsibility of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology.

Background

1. In 2014, the OECD Task Force on Hazard Assessment (TFHA) and the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology (JM) agreed to provide a coordination role for a pilot classification project upon invitation from the UN Sub-Committee of Experts on the Globally Harmonised System of Classification and Labelling of Chemicals (UNSCEGHS).

2. These efforts would build upon the experience of OECD's pilot project on classification in the context of its Cooperative Chemicals Assessment Programme. The outcome of the OECD's pilot project are published (OECD, 2014a,b; OECD, 2016).

3. The pilot project objectives were to:

- To define the process for evaluating chemicals which should provide insight into the level of effort needed to create and maintain a global classification list
- To provide insight into the expertise needed to classify chemicals against the various endpoints, the process(es) to be used for evaluating data and making recommendations on a classification, and the process to be used to finalize and update a classification.
- To determine if non-binding agreement on classification and labelling could be reached on the pilot substances

4. It was also agreed that the following data would be tracked about resources used:

- Time reviewing data and preparing the assessment.
- Time spent in classification.
- Time spent in reviewing and responding to comments.
- Time spent in discussions with the working group on the classifications.

Organisation

5. In order to carry out the pilot project, it was agreed that the work would be organised as follows:

- A fixed number of chemicals would be selected by UNSCGHS
- The preparation of the collection of data and the draft C&L assessment for each nominated chemical would fall under the responsibility of the country or entity that nominated the chemical for the UN pilot exercise.
- To classify the chemicals for all relevant endpoints, as this was required by the guiding principles of UNSCEGHS and would give a better understanding of the resources needed.
- Countries and stakeholders would be invited to participate in the pilot exercise.
- The work would be coordinated by the OECD Secretariat.

Selection of Chemicals

6. Potential chemicals to be considered in the pilot were nominated to the UNSCGHS. Three chemicals were selected for the pilot:

- Dimethyltin dichloride, CAS No. 753-73-1 (Nominated by the European Chemicals Agency)
- Dicyclopentadiene, CAS No. 77-73-6 (Nominated by the Russian Federation)
- Di-n-butyl phthalate, CAS No. 84-74-2 (Nominated by the United States)

Process for Preparation of Reports and Review

7. In order to facilitate the pilot process the three countries nominating the chemicals (referred to in this report as 'sponsor' countries) developed a classification and assessment report form. This includes a Classification and Labelling Report and an Annex to the report for more detailed study information. (This template is available as an Annex (Part 1 and Part 2) to this document).

8. The information used for classification was required to be publically available in order to follow the guiding principles agreed by the UNSCGHS for a pilot on a global list (UNSCGHS, 2012).

9. Considering that a considerable amount of data is published only in the form of robust studies, it was also agreed that the data assessments may use robust summaries if the classifier (i) identifies the studies relied upon, (ii) provides sufficient detail about each study so that its reliability can be assessed, and (iii) obtains additional information about the study if requested by a participant in the classification exercise. It was suggested that summaries of data in IUCLID might be useful for classification, but care must be taken to ensure that those summaries provide enough information so that the reliability of the data can be assessed.

10. The steps of the drafting of the classification and labelling reports were as follows:

i) Sponsor countries drafted their respective classification and labelling reports (C&L reports) and associated Annexes.

ii) Draft C&L reports were circulated via an OECD project website to countries and organisations participating in the pilot project and comments on the draft C&L reports were submitted to the OECD using a standard template (Annex 1).

iii) OECD compiled the comments received on the reports and provided them to the sponsors and the participants of the project.

iv) The sponsor countries revised their draft C&L reports based on the comments and provided responses to the comments

v) The updated reports and response to comments were circulated to the experts participating in the pilot project and discussed through web-meetings (WebEx/teleconference)

vi) Outstanding comments and outcomes of the web-meetings were taken into account by the sponsors in updating the reports and a second web-meeting was scheduled, as needed, to complete the review process

Progression of the Pilot Project

11. The following outlines the general timeline it took for drafting, review and revision of reports. More specific information follows on resources utilised.

a) The three pilot chemicals were selected in October 2014 and a workplan was agreed by the UNSCGHS in December 2014.

b) The sponsor countries agreed on an initial reporting format in October 2014, which was refined throughout the drafting process.

c) The sponsor countries completed their draft classification and labelling reports July-August, 2015 and they were provided to reviewers on 2 September 2015 for a 6 week review period.

d) Comments were received from approximately 10 countries and organizations, and the comments were all uploaded to the OECD site by 5 November 2015.

e) The OECD has prepared comments summaries for each chemical. They show that 6 commenters provided a total of 217 discrete comments on the DCPD draft assessment; 7 commenters provided a total of 118 comments on the DBP draft assessment; and 5 commenters provided a total of 38 comments on DMTC.

f) The chemical sponsors updated their reports based on comments received and provided written responses to comments.

i. For DMTC, the sponsor (ECHA) provided a written response to comments and a revised report 15 December 2015, and on 22 January a teleconference call with was held with interested parties. Based on further feedback received on the call the report was revised, and an additional teleconference was held on 7 April at which time the report was agreed. A finalised report was received on 29 April, 2016.

ii. For DCPD, the sponsor (Russia) provided a written response to comments and revised report on 9 March and a teleconference was held 13 April, with interested parties. Based on further feedback received during the call, a revised report was received 13 May and commented on by written procedure. Following the provision and incorporation of these comments a finalised report was received on 4 July, 2016.

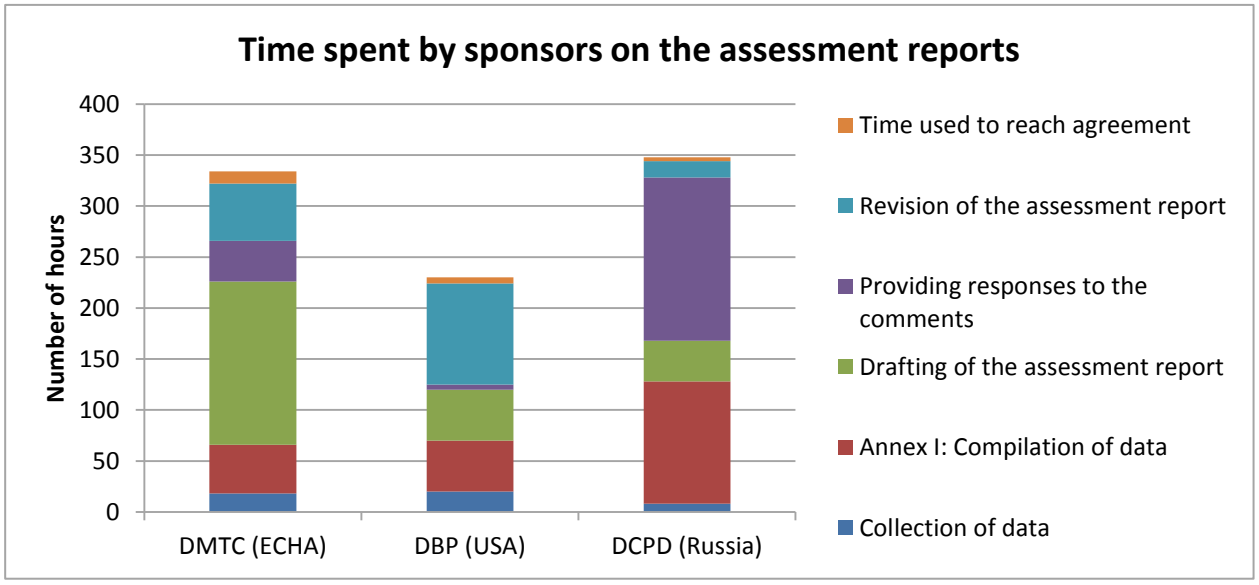
iii. For DBP, the sponsor (United States) provided written responses to the comments and a revised report on 7 March and 26 February respectively, and a teleconference was held 7 April, with interested parties. Based on further feedback received during a revised report was received 26 May and discussed during a teleconference on 8 June. Final comments received on the call were with respect to clarification of a few aspects of the report. A revised version was received on 9 July, 2016.

12. In summary, the timing from when the chemicals were selected to when the classification and labelling reports were finalised, ranged from 18 to 20 months, although this time also included refinement and discussion of the reporting template. The process was all conducted virtually through email correspondence, an on-line platform for sharing documents and through web-based teleconferencing.

Time Tracking for Pilot Project

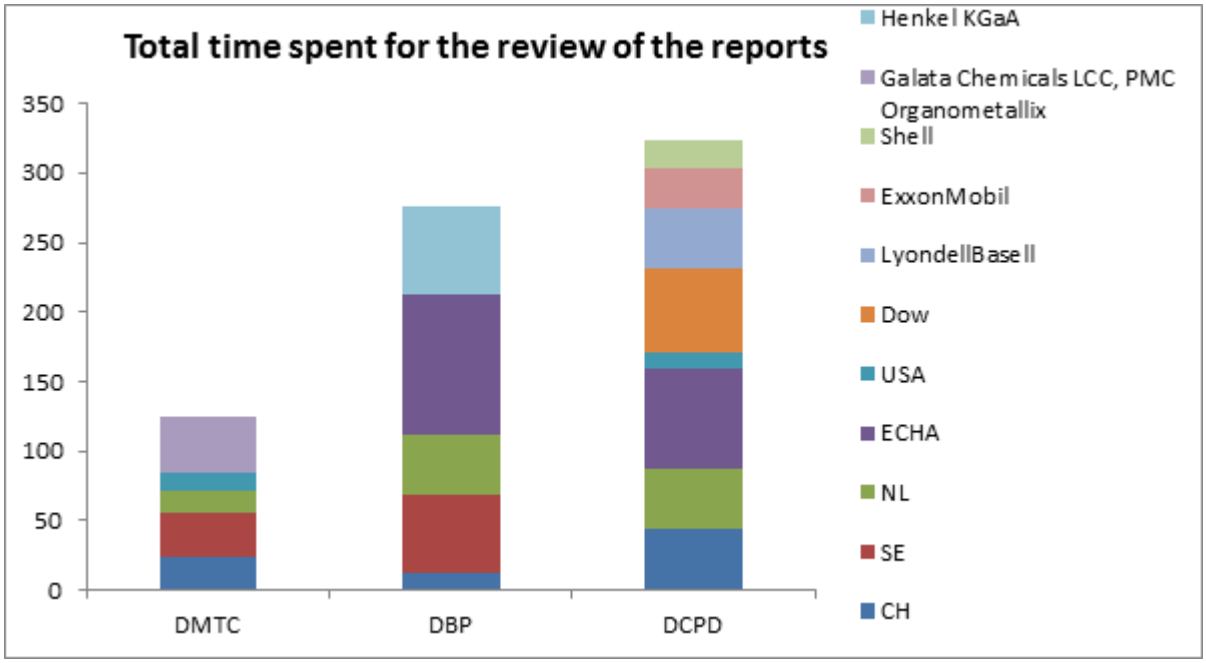
One of the objectives of this pilot exercise is to evaluate the resources needed to prepare the assessments, review them and to come to an agreement. A resource tracking form was filled by the sponsors and participant to the project.

Chemical	Time spent by Dossier submitter	Average time spent by reviewers
DMTC (ECHA)	41.75 days (8h/day)	3.1 days
DBP (USA)	28.5 days	6.9 days
DCPD (Russia)	43.5 days	5 days



13. The time spent in classification was not separately tracked because it was embedded in the drafting of the assessment report.

14. The average total time spent by sponsors is 38 days. They spent in average 21.4 days reviewing data and preparing the assessment and 16.6 days responding to comments and revising the assessment report. For reviewers, the average time spent was 5 days. For each chemical, agreement was reached by written procedure with one or two teleconferences with an average time of 6 hours.



Summary of Learnings from the Pilot Project

Drafting of the Initial Reports - General Comments

15. The drafting of the initial reports took a couple of months longer than anticipated. Contributing factors included large datasets, consistently reporting studies of various types, describing and tabulating the details of studies in the Annex to the report, consideration of the strength and quality of various studies and confidentiality/property rights issues. In the environment section of the template the denotation between "Key or Supportive study" was challenging to differentiate and the "Key and Supportive" column was therefore suggested to be deleted in the summarising tables in the C&L report template. Instead the text could include an evaluation of the use and relevance of the study for classification purposes.

16. In order to summarise information and propose classification and labelling for all GHS endpoints, the sponsors needed to draw from a wide range of expertise within their organisations. This adds to the complexity of drafting the report and underlines that necessity to bring together various technical capabilities to draft a report.

17. Particularly with sponsor authors who were newer to proposing classification and labelling, it was also a learning process as to how much information to provide in the report versus the Annex. Another challenge centred on how to communicate the comparison of the available information against the specific GHS criteria, particularly when there were conflicting data and a weight of evidence determination was needed to be used in order to apply the criteria.

Reviewing, Discussing and Revising of Draft Reports - General Comments

18. Several reviewers noted that it was at times difficult to determine which study, or group of studies, were critical to a classification proposal and commented that more clarity could be sought in this aspect. Related to this, the description of the quality of a study, whether by Klimisch scores, or denoting a study as "Key or Supportive", and the bearing of its quality on its contribution to a classification proposal, was at times lacking in clarity for the reviewer. However, it was noted by one party, that e.g. a given Klimisch score is not reflecting all aspects of the quality of a study. Also, it was suggested that if referred

to, it should be clarified who has assigned the score (as it is the result of a subjective assessment). In addition, this assessment was at times in the Annex of the report while some reviewers thought this would be better placed in the report for all the studies. Nevertheless, it is clear that reliability has to be included in some way in the C&L report and the decision logic and justification of the proposed classification needs to be clearly communicated.

19. In addition to the reliability of the studies, also other study details were sometimes absent or difficult to find. These include for example the guideline used, species, exposure route, and test concentrations. Especially for endpoints for which there are large data collections, a clear presentation of the studies is very helpful.

20. Some reviewers noted that they would have liked to have more information on particular studies that were cited in some cases from secondary sources, and others noted that only primary sources should be used, (which however, may restrict the data considered, as published reports are not always available). Note that in discussions of the UNSCEGHS, it was agreed that unpublished studies could be used in particular circumstances because if a C&L report "could only rely on published reports of data, the universe of substances that could be addressed in a global list was substantially narrowed" (UNSCGHS, 2014).

21. Also, there was a discussion on if previous Classification and Labelling decisions by authorities should be cited and incorporated in a report. If yes, where, and what information should be included? How does this help in deriving the current classification? Is there clarity on what data was used and under what classification system? Initial considerations include that it may provide a source of data and be of value if an independent expert committee has concluded on a classification proposal on the same data base or provided a hazard assessment on some of the same data.

22. A reviewer noted that the review process for DCPD triggered a discussion amongst global industry for proposed revised classification. Therefore the pilot project itself has led to further harmonisation.

23. It was helpful to have a template for comments, so that all comments could be provided to the sponsors to enable them to develop written responses to the comments. Due to the considerable amount of comments for some of the substances, the step of addressing comments took longer than anticipated. Although the development of written responses was time consuming for the sponsors, when completed in a detailed manner it provided reviewers with a clear sense of how their comments were taken on. This expedited dealing with a significant portion of the comments, focusing the web-meetings on key remaining issues.

24. The web-meetings proved necessary and helpful in discussing outstanding issues following the written process. It was through these discussions and dialogue that agreement on a number of more difficult issues was found. Therefore, either web-meetings or face to face meetings are necessary for a successful process.

Technical Learnings

25. There were a number of specific technical issues and learnings that were identified in the pilot process in relation to proposing specific classification and labelling. These are briefly summarized here.

- **Expert judgement -** The application of expert judgement in order to apply the criteria is necessary e.g. in borderline cases between two potential classification outcomes and in case there are contradicting results from the same type of data (e.g. within the same animal species) or

between different type of data (such as animal and human data). This may lead to differences in opinion on what a classification should be. An example of this manifested itself in the context of the DMTC pilot substance for the Reproductive Toxicity (developmental toxicity) - whether a Category 2 vs 1B was warranted. Although consensus was obtained on this issue for this substance, the discussion highlighted the need to bring specialised expertise to the discussion of such cases, and that such cases can lead to a variation in classification outcome.

- **Physical state of the substance -** In the case of DCPD, the physical state of the substance varies in the range of possible handling conditions, depending on its purity and temperature. This led to a discussion on whether a temperature range should be added to a classification. A possibility to use a split "entry" for the solid and liquid (only with regard to flammability) was also mentioned, if considered appropriate. It was agreed that this was impractical, as it would apply for all chemicals, but that the purity could be specified where it impacts the classification. For example, for DCPD a purity-dependent classification for "Flammable Liquids" could be proposed, as commercial grades with purity < 97% are liquids at room temperature (20° C/68° F), and those with higher purity are solids at 20° C/68° F and liquids above 32.2° C/90° F. Also, the temperature of testing, and hence physical state of the substance, can impact endpoints such as aspiration and therefore should be specified when the information is available.

- **Acute Toxicity (oral) -** There was some debate with regard to the selection of species for proposing a classification. Test guidelines typically denote that when selecting a species for acute toxicity testing, the rat is preferred in case of no available data justifying another species; however, when test results from more than one species are available, the general consensus was that the most conservative study should be selected, regardless of species, if there is no further information on species specificity and relevance to humans. This discussion took place in the context of classification proposal for DCPD for Acute Oral Toxicity, where using the mouse study is more conservative.

- **Irritation** –There are differences in reporting and interpretation of the scores for skin and eye irritation. For example, in the case of dibutyl phthalate, the scores for skin and eye irritation in one study were given as PDII scores: 0.54/8 for skin irritation and 0.11/110 for eye irritation. The PDII score is the overall score of a Draize test, calculated as the average of the scores of all animals and time points for erythema and oedema combined. However, classification under GHS is based on the scores of individual animals in combination with information on reversibility and exposure duration. This information cannot be derived from a single PDII score. To ensure consistency and transparency between classifications in the future, there should be consensus on the reporting and interpretation of irritation scores. For example, the result of a skin irritation study of DBP on the ECHA site is given as follows: "After 4 and 24 hours very slight (grade 1) erythema were observed for 2/3 animals. They were completely reversible within after 48 hours". Even where studies are reported through single PDII scores, they can support a weight of evidence approach; however, their limitations need to be accounted for during the classification process.

- **Specific Target Organ Toxicity - Repeated Exposure -** An issue was highlighted regarding what hazard statement to include with a classification for STOT-RE, particularly in terms of level of specificity. Should it be an organ system or the level of a specific organ(s)? This discussion was also supplemented with the sense that since the classification and labelling is used as a communication tool, the hazard statement should also be the most meaningful to the user, including workers and/or general public. This issue arose during the discussion for DMTC. The hazard statement of H372 (nervous system, immune system) for STOT RE 1 was proposed. It was agreed that effects on the thymus were observed; (and according to the dossier submitter,

also effects on the spleen were observed, but to a lesser extent) some participants brought forth the case that the effects on the thymus do not represent a general effect on the competence of the immune system and therefore the hazard statement should be limited to the thymus. A counter to this included that 'immune system' is easier to communicate to the public, in similarity with damage to “fertility” or to "the unborn child”. This issue was noted to be captured as a lesson from the pilot project that could result in different hazard statements being proposed.

- **Environmental hazards -** For the pilot substances there was discussion on how best to present and justify a proposal for environmental hazards classifications. It was suggested that the most practical approach is to conclude for all species at once using the most conservative approach by selecting the most sensitive species, instead of working through each individual species and comparing them to the GHS criteria. The proposed classification will anyhow derive from the most stringent classification across the species.

Other Learnings

26. The strength of the process is very much dependent on the active participation of both sponsors and reviewers, drawing from a breadth of expertise. The initial draft classification and labelling reports improved with the input of reviewers and active discussion amongst participants. Therefore a successful on-going process would need to entail commitment from a larger number of countries and other interested parties to put forward time and resources to both sponsor and actively review substances.

27. The GHS Subcommittee’s guiding principles require opportunities for stakeholders to provide input into the classification process, and industry participants provided comments on and participated in the teleconferences for each of the three pilot chemical classification and labelling reports. However, some stakeholders expressed concerns that they had learned of the exercise by chance, and that a more deliberate means to include to non-member participants be made in future classification exercises.

General Conclusions

28. This pilot project has demonstrated that it is possible to move towards agreement on proposed classification and labelling for substances in some cases as for 3 of 3 pilot substances consensus was reached on draft conclusions in a non-binding environment. However, as on average 38 days was spent drafting and updating reports per sponsor, and an average 5 days spent reviewing the reports per reviewer, this is feasible only with the sustained commitment of time and resources by countries and other interested parties.

REFERENCES

OECD, 2014a. Report of the Pilot Exercise on Classifications for Selected Chemicals Assessed at COCAM. Series on Testing and Assessment No. 210. ENV/JM/MONO(2014)31 http://www.oecd.org/env/ehs/testing/series-testing-assessment-publications-number.htm

OECD, 2014b. Annex 3 to the Report of the Pilot Exercise on Classifications for Selected Chemicals Assessed at COCAM. Series on Testing and Assessment No. 210. ENV/JM/MONO(2014)31/ANN http://www.oecd.org/env/ehs/testing/series-testing-assessment-publications-number.htm

OECD, 2016. Addendum to the Report of the Pilot Exercise On Classifications For Selected Chemicals. Series on Testing and Assessment No. 210. ENV/JM/MONO(2014)31/ADD http://www.oecd.org/env/ehs/testing/series-testing-assessment-publications-number.htm

UNSCGHS, 2012. Report of the Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals on its twenty-fourth session held in Geneva from 12 to 14 December 2012, Annex III 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. ST/SG/AC.10/C.4/48. http://www.unece.org/fileadmin/DAM/trans/doc/2012/dgac10c4/ST-SG-AC10-C4-48e.pdf

UNSCGHS, 2014. Assessing the potential development of a global list of classified chemicals. UN/SCEGHS/28/INF.22 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. http://www.unece.org/fileadmin/DAM/trans/doc/2014/dgac10c4/UN-SCETDG-28-INF22e.pdf