Task Force on Existing Chemicals

DRAFT SUMMARY RECORD


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1. The IUCLID User Group Expert Panel met on 23-24 September 2008 at OECD headquarters in Paris. This was the first meeting of the Expert Panel since the release of the new IUCLID 5 software [see http://iuclid.eu]. The list of participants is attached in the Annex.

2. The Draft Agenda was approved.

**Coordination between the ECHA IUCLID Management Group and the OECD IUCLID User Group Expert Panel**

3. The Secretariat presented the document [ENV/JM/EXCH(2008)1] outlining the coordination between activities at the European Chemicals Agency (ECHA) and at OECD regarding IUCLID in light of the fact that, in 2008, the ownership of the IUCLID 5 software will be transferred from the European Commission to ECHA. The IUCLID web site and responsibility for future developments will also be transferred to ECHA. The Expert Panel noted the mandate of the OECD IUCLID User Group Expert Panel and the roles of the ECHA IUCLID Management Group, comprised of ECHA staff, and the IUCLID Coordination Group, comprised of staff from ECHA and the OECD Secretariat.

**Progress Report**

4. ECHA reported on developments of the IUCLID 5 software since its release in June 2007 as well as short term plans for additional upgrades. The IUCLID 5 Pre-registration Tool and the SNIF Migration plug-in have been released, and the following are under development: Service Release 1, IUCLID 5 Query Tool plug-in, web services, CSR plug-in, translations of chapters A, B, C and D of the user manual (both internal help system in IUCLID and the pdf version).

5. The Expert Panel noted the progress made. The planned development of web services allowing for query and data access services and integration of IUCLID 5 with external systems was well received by the panel. The Expert Panel commented that dossiers of biocidal substances should be used in performance testing in order to test how new developments handle the large amount of data they contain. BIAC indicated their willingness to take part in future testing.

**The development of CSR and SIAR plug-in specifications for IUCLID**

6. ECHA presented the project to develop a plug-in for IUCLID 5 that will generate Chemical Safety Reports (CSR) for submission under REACH and the specifications for a plug-in that would generate OECD SIDS Initial Assessment Reports (SIARs). The Expert Panel noted the information. BIAC suggested that future development of plug-ins for reporting on biocidal and pesticidal substances could be useful. The Secretariat reminded the meeting that pre-defined executive summaries used within the pesticides programmes of Canada and the United States are available on the OECD Harmonised Template web site.

**The eChemPortal project and its relationship with IUCLID 5**

7. The Secretariat presented the eChemPortal project and in particular two elements of the eChemPortal project, (1) IUCLID web interface, (2) IUCLID provider agent, and the project’s relationship to IUCLID 5. Appropriate users of IUCLID 5 will be able to participate in eChemPortal through a IUCLID web interface that has been developed by the European Commission and with a IUCLID 5 data provider in eChemPortal catalogue format which will be developed in the context of the eChemPortal project.

Setting priorities for improvements of the functionalities of IUCLID 5

9. In advance of the Meeting, stakeholders submitted requests and ideas concerning the IUCLID 5 software for improvements of the functionalities and user-friendliness of IUCLID 5 as well as first indications of priorities. Stakeholders were also invited to identify:

- Endpoints which are relevant for IUCLID for which there are currently no OECD Harmonised Templates.
- Additional regulatory settings or voluntary programmes that could use IUCLID as a data gathering and submission tool and the potential role of OECD to facilitate the use of IUCLID in those new settings.

10. Proposals for improvements were submitted by Germany, BIAC, ECHA and the OECD Secretariat. The Meeting set priorities and discussed actions for moving forward the proposals.

11. Stakeholders are particularly interested in developments which facilitate the use of IUCLID 5 as a tool to gather and submit data on properties of biocidal and pesticidal substances and products.

12. The Secretariat will revise the document based on the Meeting discussions and consult with ECHA on what can be implemented. Priority user needs which cannot be financed by ECHA will come back to the Panel for discussion and requests for stakeholder funding. The revised document including input from ECHA will be made available to the Expert Panel via an electronic Committee Discussion Group (CDG).

13. Regarding the changes proposed to existing OECD Harmonised Templates or proposals for the development of new templates, the Secretariat will submit the proposals for consideration to the OECD Expert Group on Harmonised Templates.

14. The Secretariat will set up the electronic Committee Discussion Group (CDG) in order to disseminate general information, training and guidance materials to the Panel. The CDG will also allow Panel members to post newly identified issues and hold “forum” style discussions on questions and issues. However, all urgent questions regarding the use of IUCLID 5 should still be sent to the IUCLID Help Desk at ECHA.

15. The following action items emerged from the discussion of this agenda item:

- ECHA will investigate whether it would be possible to implement the function allowing to branch off directly to the substance data set relating to the active substances and formulants and at a minimum whether this function could be made available to “distributed” versions of IUCLID 5 containing biocidal product data. If requested, Germany offered to deliver a complete sample of the proposal.


- BIAC will submit more details regarding the failure of the IUCLID Workstation Installation Procedure when installing the application at “My Documents” folder.
• **ECHA** will investigate whether it is possible to use LDAP Authentication to define IUCLID 5 users.

• The Secretariat will send the Panel a web link to the prototype of the IUCLID 5 Browser and invite the Panel to comment on the Browser screen as a possible model for an improved print layout for IUCLID 5.

• **ECHA** will inform the Panel of the existing workaround to differentiate headings of different IUCLID 5 installations.

• The Secretariat will re-investigate the issue regarding editing a copied and pasted record from another substance for read-across.

• **Germany** offered to make draft proposals of the following templates for circulation to the OECD Expert Group on Templates:
  - Acidity/alkalinity and if necessary pH value
  - Storage stability - stability and shelf-life
  - Technical characteristics of the biocidal product, e.g. wettability, persistent foaming, flowability, pourability and dustability
  - Physical and chemical compatibility with other products including other biocidal products with which its use is to be authorised

• **BIAC** will inform the Secretariat and ECHA of the Physical Chemistry fields that do not allow an adequate number of digits.

• **ECHA** will investigate whether the XML file validation tool developed by ECHA can be made available.

**New OECD Harmonised templates for residue chemistry for pesticides**

16. The OECD Secretariat reported on the status of developments of new OECD Harmonised templates for residue chemistry for pesticides. Five new templates have been developed:

- 85-2: Livestock metabolism
- 85-3a: Crops metabolism
- 85-3b: Rotational crops metabolism
- 85-4: Livestock residues
- 85-5: Rotation crops residues

The corresponding XML schemas for these templates will be developed when resources are found.

17. The Expert Panel agreed to implement these new templates in IUCLID 5.

18. **BIAC** commented that there is a need for more structured data in tables for reporting summary information for chemicals for pesticides and biocides (for example, allowing to store tables in tables and to export the tables in XML format). This issue is being investigated by the OECD Expert Group on the Electronic Exchange of Pesticides Data. The Expert Panel will be kept informed of this work.
Setting priorities for improvements of the training course materials for instructing new users on using the IUCLID software.

19. The Secretariat presented the document outlining proposals submitted by member countries and other stakeholders for improvements to the training course materials of IUCLID 5 as well as first indications of priorities. No proposals were submitted, other than the Secretariat proposal to post video tutorials on the IUCLID 5 site in other formats than the current WebEX format; this has already been planned by ECHA.

20. The Secretariat encouraged the Expert Panel to share existing training material on IUCLID 5. Germany offered to share with the Secretariat relevant information from its experience with e-learning tools and Intranet blogs and wikis. France offered to share with the Panel the “IUCLID 5 - guidance for beginners” (in French) developed by France’s Helpdesk for REACH.

Setting priorities for additional guidance documents for users for entering data into IUCLID using the OECD Harmonised Templates.

21. The Secretariat presented the document outlining the proposals submitted by member countries and other stakeholders for additional guidance documents for entering data into IUCLID using the OECD Harmonised Templates as well as first indications of priorities. Proposals were submitted by Germany, BIAC and ECHA. The Secretariat will revise the document based on the Meeting discussions and consult with ECHA on what can be implemented. Priority user needs which cannot be financed by ECHA will come back to the Panel for discussion and requests for stakeholder funding. The revised document will be posted on the CDG.

22. At its next technical meeting on biocides, the European Commission will raise the issue that the IUCLID manual and the online help may be incomplete regarding filling in a data set for an active biocidal substance or product. The European Commission will communicate the outcome to the Expert Panel.

Translation of the IUCLID 5 End User Manual

23. ECHA reported on the initiative to translate chapters A-D of the IUCLID 5 End User Manual into European Languages. The translations will be integrated as plug-ins to IUCLID 5. The aim is to make the translations available by the end of 2008.

24. Non-European languages are also possible. If the translations are developed using the XML format and the guidance prepared by ECHA, it will facilitate the development of the corresponding plug-ins by interested stakeholders. Non-European language translations can be published on the OECD website. The Secretariat invited the Expert Panel to inform stakeholders who may be interested in pursuing the development of a non-European translation.

Relationship with the IT tool for new substance notifications

25. BIAC reported on the status of the development of an IT tool for new substance notifications and its relationship to IUCLID. The tool will accept and store the information elements required for the notification of a new substance in many different jurisdictions in OECD member countries and generate the completed notification forms for submission to the different jurisdictions, both as a printed hard-copy and as an electronic XML file specific to the different electronic systems for submission of notifications in member countries. The first versions of the system will not yet implement the OECD Harmonised Templates.
26. The Secretariat invited Expert Panel members to volunteer to test the beta-test version of the IT tool for new substance notifications.

27. The Expert Panel agreed to work more closely with the OECD Task Force on New Chemicals responsible for this project in order to investigate possible synergies, e.g. harmonising XML formats.

28. BIAC suggested that it would be beneficial to investigate the possibility to harmonise XML schema for administrative information in the context of regulatory submission of data.

**Any Other Business**

29. The Secretariat invited the Expert Panel to express any further ideas that it may have regarding development of IUCLID 5. BIAC suggested that it would be beneficial to develop different modules of IUCLID 5 adapted to the needs of different programmes, e.g. biocides, pesticides. The IUCLID 5 application could offer entry points to these modules.

30. Germany would like to see all legislative reporting requirements brought under one tool. For example, pharmaceutical product data could be stored and exchanged using IUCLID 5. In addition, Germany proposed that, if making IUCLID 5 source code available to member states is not possible, financing of specific IUCLID developments by member countries should be considered in order to allow to adopt IUCLID 5 for their own uses.

31. BIAC suggested that Industry may be interested in funding application programming interfaces (APIs) that would work with IUCLID 5 web services to develop functionalities to meet specific programme requirements.

32. The Expert Panel found the Meeting particularly useful for discussing topics outside the scope of REACH. The Secretariat encouraged participation of non-European countries.

33. The Expert Panel will meet again in a year, allowing time for users to gain experience with IUCLID 5 and allowing time for ECHA to implement planned changes.
ANNEX 1: PARTICIPANTS LIST

Participants list for the IUCLID User Group Expert Panel / Liste des participants pour Groupe d'étude sur les produits chimiques existants

23/9/2008 - 24/9/2008

(This information is available to governments only)