ECHA
EUROPEAN CHEMICALS AGENCY

Substance Brief Profiles

Workshop proceedings

Helsinki, 06 November 2014

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1. Introduction

On 6 November 2014, the European Chemicals Agency (ECHA) hosted a workshop with the purpose of reviewing the progress made in developing infocards and brief profiles (ICBP), providing an overview of the improvements made to the dissemination website and discussing future developments concerning dissemination. The workshop enabled various user groups with different perspectives and needs to discuss how to design useful and user-friendly access to substance information for EU citizens to use.

The workshop was attended by 13 representatives from the Member State competent authorities, the European Commission and accredited stakeholder organisations (representing industry, trade unions and NGOs).

The participants were welcomed by ECHA's Computational Assessment and Dissemination Head of Unit Mike Rasenberg. Speakers from ECHA reviewed the stakeholders' consultations process initiated in December 2013 with the first workshop on Substance Brief Profiles and the progress made with the developments of ICBP. The discussion was followed by a presentation on the need for new communication channels and an overview of ECHA's preliminary considerations to promote data quality through dialogue.

Following this presentation, two break-out groups were formed to exchange views on ECHA's proposal to promote data quality through dialogue. The break-out groups discussed ECHA's proposal focusing on the strengths and weaknesses, and the advantages and disadvantages of developing a communication channel between third parties and registrants.

In the afternoon, the rapporteurs reported on the findings of each break-out group to the plenary. The reports were followed by a plenary discussion.

Finally, ECHA presented the latest website developments to improve search functionalities and navigation as well as the infocards and brief profiles implementation plan, milestones and challenges.

A summary of the main points from the discussion during the workshop is presented below.

2. Progress made during 2014

2.1. STAKEHOLDERS CONSULTATIONS ON INFOCARDS AND BRIEF PROFILES

Following the Substance Brief Profile Workshop on 3 December 2013, a written consultation on the technical annexes of the infocards and brief profiles (ICBP) was initiated. The written consultation had two rounds focusing on different aspects of the ICBP.

2.1.1. First written consultation – substance description

The first written consultation took place from 18 February to 4 April 2014, where workshop participants were invited to comment on the extended background information on the substance infocards and brief profiles focusing on substance identity, safety classification and labelling, critical properties and regulations and the 'About this substance' sections.

ECHA received 31 comments from two accredited stakeholder organisations (CEFIC and EUROMETAUX) and two Member State competent authorities (French Helpdesk and Germany's Federal Office for Chemicals (BAuA)).

The outcome of this consultation was sent to workshop participants on 12 June 2014.

2.1.2. Second written consultation - scientific data processing

The second written consultation took place from 8 July to 8 September 2014. Stakeholders were requested to comment on the brief profiles' scientific data processing specifications, covering the proposed sections on physical and chemical properties, environmental fate and pathways, ecotoxicological information and toxicological information.

ECHA received 37 comments from three accredited stakeholder organisations (CEFIC, EUROMETAUX, ETUC and EEB) and one Member State competent authority (Germany's Federal Office for Chemicals (BAuA)).

2.1.3. Conclusions

Based on the comments received during the 2013 workshop and the two written consultations, the specifications for infocards and brief profiles were further developed:

- Examples from other websites were reviewed and taken into account to increase the usability of ICBP;
- Used terminology was improved and needs for further information to be displayed on screen (e.g. tooltips) identified;
- The feedback revealed concerns on the diversity of the notified information and how the proposed aggregation of the classification and labelling (C&L) could be misleading to the user:
    - Improvements were made to differentiate more clearly between notified under CLP and REACH registration data;
    - To keep the level of transparency on the data available and address the concerns, ECHA proposed a new approach and new display rules for C&L in the ICBPs (graphical design improvement will also take place);

- Usable/processable data for ICBP definition improved;
- Aggregation and prioritisation methods further described;
- Level of detail presented for each study result (data blocks) expanded to include repeated dose toxicity data.

2.2. IMPROVEMENTS MADE TO THE DISSEMINATION WEBSITE

ECHA informed about the latest developments on ECHA's website concerning the improvement of search functionalities and navigation:

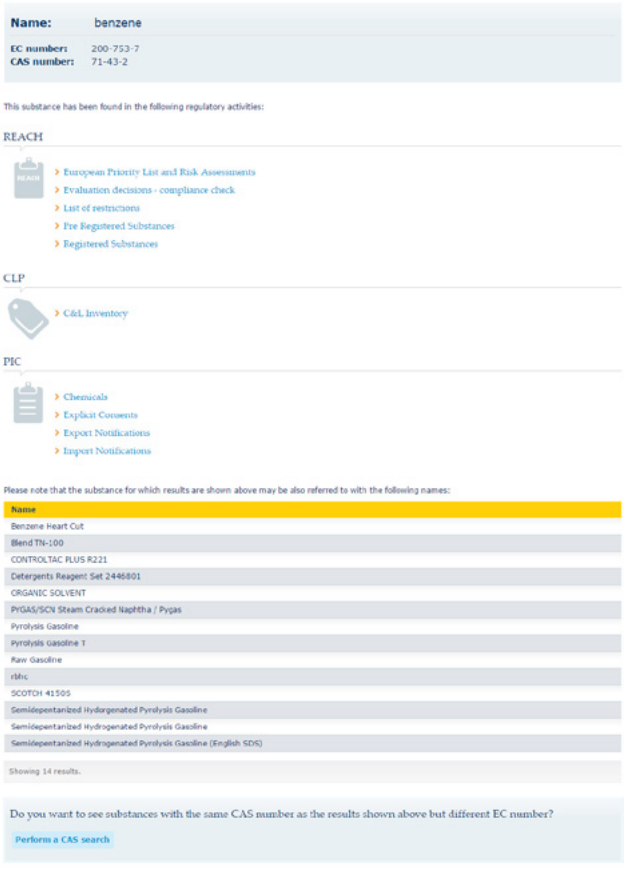
2.2.1. Substances search

- New autocomplete option for the search for chemicals;
- New "Substance page view" with matches per regulatory process improved;
- From the results view, a possibility to further search for substance(s) with the same CAS but different EC number, if any.

Figure 1: Search results for "Benzene" using the autocomplete option, before and after the new implementation

Before

After



2.2.2. Re-organisation of all sub items under the "Information on Chemicals" section

- Straight access from the main landing page to the lists;
- Only essential information presented in the list page;
- Additional details still available in sub-pages.

2.3. DISSEMINATION CHALLENGES AND NEXT STEPS

The implementation of Dissemination version 3.0 will require a complete overhaul of the dissemination IT infrastructure. This is required to be able to integrate in a unique system for REACH registrations, ICBP and key regulatory processes (e.g. authorisation, restriction, CoRAP, dossier evaluation and the Candidate List) based on a substance-centric approach, and prepare the dissemination pipeline to process IUCLID 6 dossiers.

2.3.1. Challenges

There are four main challenges to be dealt with:

- **Update of filtering rules from IUCLID 5 to IUCLID 6;**
- **Data sourcing** - Define the information requirements field-by-field and the processing details at every step. All scenarios must be covered and defined (e.g. incomplete data sets or confidential data);
- **Data volume** - Dissemination processes a high volume of information; a first release of 110 000 infocards and 15 000 brief profiles (counting for 1 000 – 2 000 IUCLID fields for ICBP and 100s of fields from other sources is anticipated, with thousands of millions of output values to be calculated);
- **Testing** - Due to the multiple sources and data volume, its integration, aggregation and summarisation, the testing procedure is rather complex with simulation in multiple input systems.

2.3.2. Next steps

Dissemination has a challenging year ahead. A concrete plan is in place to implement the required changes, based on the input collected from stakeholders.

- (Preliminary) IT analysis already ongoing;
- Graphic design interface started before the end of 2014;
- T development in place (analysis phase – implementation during 2015);
- Deployment should be complete by the end of 2015.

3. Future developments

3.1. PROMOTING DATA QUALITY THROUGH DIALOGUE

An issue raised by the stakeholders at the Substance Brief Profile Workshop was the need to be able to report inconsistencies and provide feedback on the infocard and brief profile (ICBP) information, e.g. related to self-classification, availability of new scientific data, etc.

The release of the ICBP will emphasise data quality, consistency and data gap issues in registered dossiers and the C&L Inventory due to their user friendliness and readability. It is therefore reasonable to assume that several sectors of society will have an increased interest and critical judgement on the information being disseminated, and as the aggregation of information from different registrants for the same substance highlights inconsistencies, the demand for channels to provide feedback by thirds parties may also increase. The interest from – and capability of – academia in providing new information on substances may also potentially rise.

Some tools are already available that address specific concerns and needs (e.g. the Pre-registered substances page, the Co-Registrants Page and the C&L Platform). However these channels are not the most efficient to communicate data inconsistencies, data quality or data gap issues in ICBPs as these tools and platforms have been implemented with specific aims and for specific users.

During the current workshop, ECHA presented an initial assessment made around this matter. The presentation focused on how feedback for ICBPs could be provided, with which aim, and to whom it should be targeted. The main purpose was to explore with all stakeholders what possibilities there are to facilitate communication on data quality, consistency and/or data gap issues by third parties, not only to ECHA but also directly to industry. This could foster efficiency and increase more effectively the dossier data quality. In this type of approach, ECHA could have a monitoring role potentially applying some level of moderation depending on the type of solution implemented (this analysis was not within the scope of the current workshop).

3.1.1. Break-out groups feedback

After the presentation, focused discussions followed in break-out groups including an analysis on the strengths and weaknesses, opportunities and threats (SWOT analysis) of developing such a communication channel for the ICBPs.

Possible actors

As possible actors for such a platform, the workshop participants identified: NGOs, companies, other registrants of the same substance, registrants of substitutes, downstream users, governments and other agencies (EU/Non-EU). The competent authorities where mentioned as a potential user who could make use of the channel for semi-official communications.

Possible types of information

The type of information in the ICBPs that could most likely trigger feedback was foreseen to be: spotting errors due to data aggregation methods and/or inconsistencies from multiple dossiers/studies (e.g. in classification, DNELs/PNECs, uses, safe uses) or providing information about new available studies.

Main comments

The discussions focused on how such a communication channel should be built to have added value and to help improve the data quality effectively and efficiently.

In this regard, for the system to be a success relevant contributions should be able to be filtered. ECHA presented an idea of having pre-defined interactive webforms with right questions to guarantee a minimum of information requirements; this approach of a structured dialogue would also support the receiving of consistent and meaningful contributions which again facilitates the processing of the feedback received.

It was also noted that it would need to be decided whether this type of a platform should be public – forum type of a channel – or a private platform. Monitoring and potential validation of the feedback would come into question depending on what type of an approach would be implemented (open forum vs private channel). All workshop participants agreed that a requirement to register (email address etc.) before submitting feedback should exist. It would then need to be decided within a potential implementation what the more precise requirements to submit a comment should be.

Figure 2 - Summary of the two break-out groups S.W.O.T analysis

Strengths	Weaknesses
Good tool to provide information on brief profiles' data aggregation [aggregation of information highlights inconsistencies]; Possible way to provide new information [e.g. availability of new studies]; Full open communication, all parties aware [if there is an open forum implementation].	If there is no reaction from industry, the tool loses value and may require follow-up; Resources needed from industry to respond and ECHA to monitor; Brief profiles not the place to do "compliance check" types of analysis, as they do not provide the level of detail needed; Challenge to make sure the feedback is relevant
Opportunities	**Threats**
Improvement of consumer's trust in use of chemicals; Stimulate industry to commit to REACH; Channel for manufacturers and/or importers with valid data to communicate; Potential channel for other non-EU states or other agencies to communicate with industry; Inform about new updates related to regulatory processes by registrant (e.g. compliance check) [if there is an open forum implementation]. Help industry in improving data quality; Improve the image/trust of industry.	Could end up in a work overload and waste of resources (to both ECHA and industry) if not well implemented; Competitors could misuse the tool; Too many irrelevant comments if there is not an effective way to filter the feedback.

3.1.2. Conclusions

A general consensus on the presented concept was found and it could be concluded that the quality of the received feedback defines the success of the system. If the concept is to be developed further, it is necessary to further clarify the scope of the system; how to relate it to the C&L Platform; and to what extent such a system would be useful to authorities. ECHA has not decided if and with what timelines implementation would be pursued. If a positive decision is made, stakeholders will be involved in the further definition.

4. Next steps

At the end of the workshop, it was agreed that:

- ECHA will further develop the brief profile technical specifications according to comments received and circulate them through the workshop participants when ready;
- Where the approach taken to compile a brief profile does not provide a satisfactory outcome, ECHA will further identify substance-type tailored improvements;
- ECHA will analyse the feedback received on the proposed communication platform and identify what the next steps would be.

APPENDIX 1 - Agenda

Thursday 6 November 2014	
8:45	**Registration**
	MORNING SESSION
9:00 30 min	**1. Welcome and introduction** *Outline of workshop objectives, overview of dissemination state-of-play and review of integrated approach to dissemination and brief profiles.*
9:30 50 min	**2. Stakeholders consultations on infocards and brief profiles** *Overview of the two written consultations on ECHA's proposal for infocards and brief profiles.*
10:20 30 min	**3. Discussion on Agenda point 2.**
10:50 20 min	**Coffee break**
11:10 20 min	**4. Promoting data quality through dialogue** *The infoCards and brief profiles will emphasise data quality, consistency and data gap issues. A direct communication channel between industry and society could be envisaged to promote a more efficient information flow and data quality improvement. The need for new communication channels was also emphasised during the previous workshop on brief profiles. An overview of ECHA's preliminary considerations will be presented.*
	BREAK-OUT GROUPS
11:30 1h30min	**5. Break-out groups: Promoting data quality through dialogue** *Focused discussions on strength and weaknesses, and advantages and disadvantages of developing a communication channel between third parties and registrants.*
13:00 1h00min	**Lunch**
	AFTERNOON SESSION
14:00 1h30min	**6. Report back from break-out groups and discussion**
15:30 30 min	**7. ECHA dissemination website: latest developments** *Presentation of the latest website developments to improve search functionalities and navigation.*
16:00 30 min	**8. Brief profiles next steps** *Implementation plan, milestones and technical challenges.*
16:30 30 min	**Coffee Break**
17:00 30 min	**9. Wrap-up and final conclusions**
17:30	**End of the workshop**

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