

Substance Brief Profiles

Workshop Proceedings

Helsinki, 3 December 2013



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Table of Contents

1. INTRODUCTION	4
2. INFO CARDS AND SUBSTANCE BRIEF PROFILES	5
2.1 Most positive aspects of ECHA's proposal	5
2.2 Improvements required	5
2.3 Concerns	6
2.4 Open issues	7
2.5 Other suggestions	7
3. NEXT STEPS	8
APPENDIX 1 - BACKGROUND INFORMATION	9
APPENDIX 2 - AGENDA	10

1. Introduction

On 3 December 2013, the European Chemicals Agency (ECHA) hosted a workshop to discuss the type of information that should be included in a substance “brief profile”. The purpose of the workshop was to enable various user groups with different perspectives and needs to have focused discussions on how to design useful and user-friendly substance “brief profiles”. Based on the findings and recommendations from the workshop, ECHA will further improve the substance “brief profile”.

The workshop was attended by 15 representatives from the Member State competent authorities, Accredited Stakeholder Organisations (representing industry, trade unions and NGO’s) and international organisations.

The participants were welcomed by ECHA’s Director of Registration Christel Musset. Speakers from ECHA addressed the context and scope of substance brief profiles, followed by a detailed presentation of ECHA’s proposal.

Following these presentations, two break-out groups were formed to exchange views on the way forward for publishing meaningful substance brief profiles taking into account the expectations of the different user groups. The break-out groups discussed ECHA’s proposal in detail focusing on the tiered approach to information (info card and brief profile), the type of information available, structure and graphical representations.

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.

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

2. Info cards and substance brief profiles

2.1 MOST POSITIVE ASPECTS OF ECHA'S PROPOSAL

Tiered Approach

Participants found the tiered approach to information based on (1) search results, (2) info cards, (3) brief profiles and (4) raw (source) data as a good option to present the information progressively to users.

Approach for C&L and uses aggregation and display

The general principle on aggregating and displaying the hazard statements and uses of a substance was supported by the participants. Nevertheless, participants of the meeting stressed the importance of being able to review the algorithms to better understand the logic behind them and provide comments. The participants also stressed that such algorithms should be transparent to all users. Finally, if outlier notifications exist and must be removed, this should be done in a consistent and transparent way. A possible option would be to have a threshold applied in the notified classification and labelling hazard statements but not in the C&L inventory breakdown.

C&L notifications breakdown

The graphic representation of C&L notifications was one of the most valued features of the brief profile. ECHA was requested to include a clear description of the chart and interactive functionalities (mouse roll-over tooltips) to describe to users how the chart should be interpreted and the meaning of each hazard statement code.

Overview of regulatory processes

The concept of highlighting main regulatory processes was another element in the info card and brief profiles information appreciated by the participants. However, participants did not agree on the level of detail and which regulatory processes should be covered by this overview.

Icons for key concerns

The proposal to highlight key concerns such as SVHC, CMR and PBT was considered positive by the majority of the participants. However, there were concerns regarding the use of icons that could be confused with new legal/labelling requirements. In addition, other key concerns such as sensitising properties were regarded to be valid for inclusion.

2.2 IMPROVEMENTS REQUIRED

Phrases and labels

During the discussion, several participants stressed the need for reviewing the labels and sentences used in both the info cards and brief profiles to avoid ambiguity (e.g. "This substance is used in processes such as") and contradiction (e.g. Classified substance with hazardous properties in Safety Classification and Labelling section and the statement "There are at present no known concerns relating to this substance." in the Summary of Concerns section). The wording used should be precise and consistent with the legal text.

Contextualisation of information

Fields and information provided should be described either through a glossary or by means of a tooltip.

Links to other databases/regulations

Some participants suggested that the brief profile users could benefit from including both links to other sources of information on chemical substances (e.g. OECD eChemPortal) and to include information from other regulatory databases (e.g. WFD, ROSH, POPs, EU OELs).

2.3 CONCERNS

Minimised misleading communication of data

Participants of the meeting stressed the importance of finding ways of minimising misleading communication of data. While aggregating and summarising such amount of data, there is the risk of oversimplifying the information provided, removing it from its context, and increasing the risk of misinterpretation. Consequently, it is crucial that there are clear descriptions of what, how and where information is being used.

Scope and limitations of data

Participants highlighted the importance of being transparent at all levels (info cards and brief profiles) about the scope and limitations of the data provided. Due to dossier aggregation at substance level, it is not possible to highlight which endpoints have been compliance checked and those which have compliance issues (as this is done at dossier level). Therefore, by not having the required level of detail it should be clear that the Agency cannot guarantee the correctness of the information and not all EU regulatory information is included. To this end, it was considered to be very important to have the disclaimer available in both the info cards and brief profiles.

Use of framing sentences

The use of framing sentences to introduce the hazard statements was an issue of concern, as it may be confused with new signal words. Such framing sentences should be carefully reviewed to avoid misunderstandings and to be consistent with the legal text.

Data representation

A key aspect raised in the discussion was how the lack of data should be represented (either because data was not provided, it was provided in a non-usable format by the brief profile, it was claimed confidential or was considered scientifically not justifiable). The solution should be robust and consistent to be easily interpreted by users.

Intermediate uses

Concerns were raised by some participants on how uses from different registration types (full vs. intermediate) are aggregated and may lead to misunderstandings of the use conditions. Also, the example of a monomer substance registered as an intermediate but used as polymer by the end user that might have different hazards was given. The intermediate use should be clearly described to users to avoid misunderstandings.

Info card/brief profile review

Some participants considered that registrants should have the opportunity to review the brief profile before it is published or have a plug-in available to simulate an info card/brief profile. As the information is aggregated at substance level, a plug-in would fail to provide the complete overview of the published information, thus it would not be possible for the review of the information to be done by a single company. A dissemination plug-in is available to preview what gets filtered. Nevertheless, registrants would also welcome the possibility to preview the way their data would be presented.

Reporting inconsistencies

One of the issues raised by participants was the possibility to report inconsistencies and provide feedback on the info cards and brief profile information (e.g. related to self-classification, new scientific data, etc.). Such functionality needs to be further assessed.

Precautions and safe use

Some participants also highlighted the need to indicate that risk management measures can be taken and provide information on how the substance can be used safely.

2.4 OPEN ISSUES

During the plenary discussion some issues were identified. These are:

- Should info cards also be available for non-registered substances?
- Should information on dossier evaluation be accessible through the brief profile?

2.5 OTHER SUGGESTIONS

Other suggestions for improvement included:

- Display authorised uses
- Display use category titles in info card
- Have multiple info card print functionalities
- Display all substance names when printing the brief profile
- Implement different languages; at least be able to perform a search in different languages and have the info card available in different languages as well
- Provide information about the total amount of information being disclosed in the dissemination website (i.e. the proportions of published information, information claimed confidential, and information that is never public)
- Have a full history of updates
- Display uses advised against
- Display SVHC uses in consumers articles
- Highlight if the substance was registered as a nanomaterial
- Inform when data is validated/reviewed by ECHA
- Provide a link to the SDS or at least have a disclaimer to invite people to consult the company's SDS by contacting the company directly (i.e. contact points are illustrated in the third tier of information)
- Provide registrants' name (i.e. link to the third tier where all names are illustrated)

3. Next steps

At the end of the workshop, priorities for the development of the brief profiles/next steps were agreed:

- ECHA to consider sharing more examples of info cards and brief profiles for further consultation in beginning of 2014.
- ECHA should communicate about the process to registrants, applicants and notifiers in a timely and transparent manner.

Appendix 1 - Background information

Dissemination is one of the pillars of REACH aiming to increase the knowledge of the public about the properties of the chemical substances to which they may be exposed. It plays a pivotal role in assuring the safe use of chemicals, in terms of human health and the environment, by placing information under the scrutiny of industry, downstream users and the general public.

ECHA is already publishing a significant amount of information on chemicals on its website, such as information on more than 11 000 substances from over 41 500 registration dossiers, EU harmonised classification for approximately 4 500 substances and classification for more than 110 000 substances. In addition, information and lists of the various regulatory processes such as the Candidate List, REACH Annex XIV ("Authorisation List") and Annex XVII ("Restriction List"), the CoRAP list for substance evaluation, the registry of intentions, evaluation decisions, etc. are constantly being populated and published in various sections of the ECHA website.

REACH's goal is to increase the knowledge of the public about the properties of chemical substances.

In 2012, ECHA launched a Stakeholder Engagement Study aimed at better perceiving the requirements and needs of ECHA stakeholders when accessing ECHA's website. One of the main outcomes of the study was the need for user-friendly access to summarised information (or factsheets) and to download functionalities.

The access to summarised information is covered by recital 117 that defines that "EU citizens should have access to information about chemicals to which they may be exposed, in order to allow them to make informed decisions about their use of chemicals. A transparent means of achieving this is to grant them free and easy access to basic data held in the Agency's database, including brief profiles of hazardous properties, labelling requirements and relevant Community legislation including authorised uses and risk management measures (...)"

Giving stakeholders requirements and legal obligations, it is ECHA's ambition to improve the usability and user friendliness of the vast quantity of data on chemical substances that it has already published

Appendix 2 - Agenda

Tuesday 03 December 2013		
8:45	Registration	
PLENARY SESSION - K323		
9:00 15 min	1. Welcome and Introduction	ECHA
9:15 20 min	2. Previous consultations on disseminated information	ECHA
9:35 40 min	3. ECHA's proposal for tiered approach to substance brief profile	ECHA
10:15 20 min	Brief discussion on Agenda points 2 and 3	ECHA
10:35 15 min	Coffee Break	
10:50 10 min	4. Introduction to break-out groups	All
BREAK-OUT GROUPS		
11:00 2 h	5. Break-out groups to discuss in detail the brief profiles proposal	All
13:00 1 hour	Lunch	
PLENARY SESSION - K323		
14:00 1 hour	6. Report back from break-out groups	All
15:00 1 hour	Discussion on break-out groups findings and recommendations	All
16:00 30 min	Coffee Break	
16:30 30 min	7. Wrap-up and final Conclusions	ECHA
17:00	End of the workshop	

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