MB/42/2015
Luxembourg, 25.9.2015

Update from the Advisory Group on Dissemination

39th Meeting of the Management Board 24-25 September 2015

Item	12.3
Action	For information
Status	Final - Public

Key messages

The Management Board is invited to take note of a report from the activities of the advisory group on dissemination.

The advisory group met on 16 June 2015. Apart from receiving a general update on dissemination activities, the group was consulted on the dissemination of endpoint study summaries and the publication of life-cycle information for dossier evaluation cases. Furthermore, the group exchanged views how on-line third party consultations can be improved.

Background

The advisory group on dissemination was set up in 2009 and is mandated with:

- monitoring the progress made on dissemination and other publication on the Agency's website of information on chemical substances;
- assisting the ECHA management by giving advice when needed;
- acting as "ambassadors" to civil society, in particular by reporting back to their respective stakeholders (and raising awareness);
- reporting to the Management Board on its activities.

The three members of the Management Board appointed by the Commission to represent interested parties are by default be members.

The current composition is as follows:

1. Mr Antonello LAPALORCIA (CHAIR)	(September 2009)
2. Mr Martin FÜHR	(September 2009)
3. Mr Kestutis SADAUSKAS	(December 2014)
4. Ms Gertraud LAUBER	(December 2011)
5. Mr Hubert MANDERY	(June 2010)
6. Mr Antti PELTOMAKI	(June 2013)
7. Mr Anastassios YIANNAKI	(June 2015)

The last report from the advisory group to the Management Board was given in 2013 after the group had reviewed its achievements since 2009 and concluded on a number of outstanding issues[1].

[1] http://echa.europa.eu/documents/10162/13608/final_mb_48_2013_report_advisory_group_dissemination_en.pdf

Rationale

1	**Update on dissemination relevant activities** The Secretariat briefed the advisory group on the developments since the last meeting, including the current dissemination status, the progress made in 2014/2015 with improving the ECHA website, the transparency of the regulatory decision making as well as the handling of confidentiality claims. The advisory group welcomed that the outstanding requirements from the last meeting were addressed. As regards the specific issue of disseminating exposure scenario information, the group took note of the progress made in general as well as of the interlinks with the development of the next version of IUCLID (version 6). A consultation of the advisory group on relevant dissemination relevant modalities is planned for Q4 2015/ The advisory group furthermore welcomed that the dissemination of information under the Biocidal Product Regulation is progressing well with all biocides substances (685 active substance-product type combinations and 4653 authorised biocidal products published), providing for improved search and export functionalities. The Secretariat informed that the vision for the dissemination activity is to provide tailored access to all information on chemicals contained in ECHA databases (in scope of REACH, BPR, CLP and PIC), in one single point of access. With the forthcoming overhaul of the dissemination architecture, a number of enhancements to the usability and presentation of the published data are to be introduced. Key among these are the substance centric approach and the introduction of substance Brief Profiles and Info-cards, which will contain a summarisation of all of the scientific data submitted to ECHA in REACH registrations[2]. The new functionalities are planned to be available for the public by the end of 2015. The advisory group welcomed the progress made by ECHA. A representative of interested parties highlighted that from a citizens' perspective it would be most desirable that the plans are implemented as this would be a big step forward and provide a visible benefit of all the efforts done by all actors under REACH.
2	**Dissemination of endpoint study summaries** The Secretariat informed the group that in the context of creating Brief Profiles for substances, the publication of endpoint summaries had been raised at stakeholder workshops on the issue in 2013 and in 2014, recognising the potential value of this publication. By way of background explanation it was reminded that REACH registration data is submitted to ECHA in IUCLID dossiers, structured in broad sections (Physical and chemical properties, environmental fate, ecotoxicology, toxicology). Each of these sections contains many different endpoints. Each endpoint is made up of potentially many separate studies, the non-confidential parts of which are disseminated on the ECHA website. From those studies, the registrant can summarise the key information and provide expert judgement on how results were derived in the endpoint summaries. ECHA plans from Q4 2015 to publish data (results) from registrant's endpoint summaries. The information will be used in the "Brief Profiles" and the publication will be progressive in time to reduce potential pressure to update by industry. The Secretariat outlined the publication plan in more detail and asked the group for advice on the matter, highlighting as a main consideration that in the course of the publication of the endpoint summaries an undue burden on registrants should be avoided, for example by requiring large scale updates to previously submitted registrations to resolve potential confidentiality concerns. This would be especially relevant in the run-up to the 2018 deadline. Thus the publication should be done in

[2] See annex for a mock-up

	such a way that the impact is minimised. The Secretariat explained that it intends to achieve this by focusing on the type of information to be published and scheduling. More precisely the Secretariat explained that the Agency plans to publish, from each endpoint summary the key endpoint summary (numerical or picklist) result field, including any measurement condition field(s). The implementation would follow the indicative timeline below[3]:  The advisory group discussed the approach and supported the publication of the endpoint Summaries information as outlined by the Secretariat. The group did not consider that the proposal to have a phased publication of the information to be an issue in terms of different treatment of registrants and supported the overall approach.
3	**Publication of life-cycle information for dossier evaluation cases** The Secretariat explained the plans for increasing the publicly available information related to dossier evaluation information, more specifically how more information can be published before, with and after the final evaluation decision. The aim is to provide public information about the life cycle of an evaluation decision and thereby increase transparency. The following additional information is planned to be structurally made public during 2016: • The scope of the evaluation case (targeted or general compliance check, or a testing proposal evaluation) • The status and outcome of the evaluation case (under evaluation, case concluded with no action /decision taken, under follow-up, evaluation closed) • The deadline in the final decision • The information requested in the decision (searchable) • Pending information requested (open issues) • The evaluation closing date ECHA's stakeholders were consulted on the approach during the ECHA Compliance Check Workshop 2015. The advisory group discussed the envisaged improvement and gave positive feedback, even though individual members expressed a preference for more detailed public information in relation to evaluation decisions.
4	**On-line third party consultations** The last topic discussed by the advisory group was proposed by an interested party representative. By way of introduction, the Secretariat gave an overview how third party consultations are organised currently by ECHA, highlighting that the amount of published information from authorisation applications has evolved since 2013. Compared to the first applications the published part of the authorisation has significantly increased. In the subsequent discussion, the impact of third party consultations on innovation and substitution was highlighted. A member of the group emphasised that it is important for potential suppliers of alternatives to know that a consultation is ongoing. The 2nd layer would be the presentations of the case which should allow an outsider to understand what is at stake in order to give targeted input into the process. Once all

[3] Note: This timeline was presented to the advisory group on 16 June and afterwards adjusted to the progress of the technical implementation and aligned with the development of IUCLID 6. Accordingly, the first endpoint study summaries will be published in Q1 2016 instead of November 2015.

	information is received, it may be worthwhile to extract conclusions for third parties so that they better understand how the Agency uses the information obtained from third parties. The Secretariat welcomed the proposal, explaining the limitations related to the current role and mandate of ECHA, and committing to look into how the public consultations have influenced the decision making. It was highlighted that the authorisation trialogues play an important role which should be added to the discussion. Furthermore, a possible cooperation with OECD in this area could open new ways of presenting the data in a more comprehensive way.

Attachments:

- Annex 1: Mock-up of brief profile of a substance (no real data)
- Annex 2: NGO paper on third party consultations
- Annex 3:Overview of disseminated information in 2015
- Annex 4: Reflections of Mr FUEHR in relation to the function of a "Third Party Ambassador"

For questions mb-secretariat@echa.europa.eu

Annex 1 Mock-ups (no real data) of Info-cards and Brief Profiles DOUBLE CLICK TO OPEN

InfoCard mock-up

Brief profile Mock-up

The following is a brief profile summarising the non-confidential data on this substance held in the database of the European Chemicals Agency (ECHA). Please note that this brief profile is generated automatically based on the data available at the time of generation. The data has been submitted to ECHA by third parties and ECHA cannot be held liable for the quality and correctness of the information. The type of uses and classifications for a particular substance may vary between different substances in ECHA. For a full understanding of the data it is recommended to consult the source data. Information regulatory actions under different legislative frameworks included in the brief profile may not be up to date and complete and it is responsibility of the substance manufacturer and importer to consult official sources. This brief profile is covered by the ECHA Legal Disclaimer.

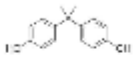
4,4'-isopropylidenediphenol

Short substance description. Lorem ipsum dolor sit amet consectetur adipiscing elit nullam at metus magna.

Brief Profile – Last updated: 03/12/2014

Substance Description

Substance Identity



EC Name: 215-627-8

IUPAC Name: 2,2-bis (4-hydroxyphenyl) propane

Other names

EC Number:	80-05-7
CAS Number:	C15H16O2
Index Number:	604-030-00-0
Molecular Formula:	C15H16O2

Smiles:	Oc1ccc(cc1)C(c2ccc(O)cc2)(C)C
InChI:	1S/C15H16O2/c1-15(2,11-3-7-13(16)8-4-11)12-5-9-14(17)10-6-12/h3-10,16-17H,1-2H3
Type of substance	Mono constituent substance
Origin	Organic
Registered compositions	7
Of which contain:	2 impurities relevant for classification
	0 additives relevant for classification
Substance Details	ENECS

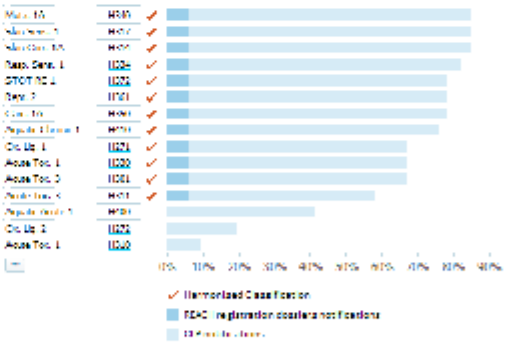
Safety Classification & Labelling

Danger! According to the Harmonised Classification and Labelling (ATP 1) approved by the European Union this substance is fatal if inhaled, may cause genetic defects, causes damage to organs through prolonged or repeated exposure, may cause cancer, is very toxic to aquatic life with long lasting effects, is toxic in contact with skin, is toxic if swallowed, causes severe skin burns and eye damage, may cause fire or explosion (strong oxidiser), is suspected of damaging fertility or the unborn child, may cause an allergic skin reaction, and may cause allergy or asthma symptoms or breathing difficulties if inhaled.

Additionally, the Classification provided by companies to ECHA in SLP notifications identifies this substance is very toxic to aquatic life, may intensify fire (oxidiser) and is fatal in contact with skin.

Lorem ipsum dolor sit amet.

Breakdown of all 2 606 C&L notifications submitted to ECHA



At least one notifier has indicated that an impurity or an additive present in the substance impacts the notified classification.

Critical Properties

C M R S PBT

Annex 2: NGO proposals for dissemination of on-line third party consultations

On-line third party consultations on authorisation and restriction proposals provide very valuable information on potential safer alternatives to replace the use of hazardous chemicals. If this information would be presented in a more effective way it could more effectively promote substitution and support companies' process of substitution.

Information provided on alternatives during the public consultation of applications for authorisation is publically available at ECHA's website. However, these alternatives are difficult to find and not linked to the substance itself. Moreover, the information on alternatives from the Restriction dossiers and provided through the public consultation is not extracted as specific information on alternatives although it is also available in ECHA's website.

In our view information about alternatives should be possible to find easily on ECHAs website in order to guide companies in their substitution work and to promote substitution of substances of very high concern. One of the NGO proposals taken on board by ECHA is to develop a substitution and innovation portal.

As agreed during the fourth ECHA-NGO discussion platform meeting on 10 April 2014[4], a lot of information is already available through the public consultation process which could be useful to convert to a more structured format. This structured information could fill the substitution and innovation portal easily and without requiring a substantial amount of resources once the format is properly set and used by third parties during the commenting process.

A substantial number of public consultations (for both applications for authorisation and restriction proposals) have already taken place. Third parties have provided overwhelming information on alternatives which could be used as information on potential alternatives to individual hazardous chemicals and specific uses for the substitution portal.

As mentioned in the 4th ECHA-NGO meeting, the challenge would then be to restructure and extract the information in a way that brings added value for companies looking to substitute. In our view, the Advisory group on dissemination is the best platform to work on this.

Regarding the accuracy of the data, we acknowledge that ECHA cannot be responsible for the reliability of the information provided by third parties. However, similarly to the information provided by companies in the registration phase, a statement by ECHA clarifying the ownership of the data should be sufficient.

[4] Meeting note available at:
http://echa.europa.eu/documents/10162/13587/ngo_meeting_note_20140410_en.pdf

Annex 3: Disseminated information – overview June 2015

ECHA
EUROPEAN CHEMICALS AGENCY

ECHA information on chemicals

- Registered substances information (13 149 substances; 50 797 registrations; > 2 million study summaries on properties and effects of chemicals)
- Public C&L inventory (120 867 substances; > 6 million notifications)
- EC Inventory (106 213 substances)
- Community rolling action plan (CoRAP) (267 substances)
- Biocidal Active Substances (685 active substances-product type and 121 approved) & 4653 biocidal products
- Candidate list of Substances of Very High Concern (SVHC) (163 substances)
- Registry of intentions for risk management proposals (Restriction, SVHC and CLH)
- Dossier evaluation decisions (900 decisions)

echa.europa.eu

Annex 4: Reflections of Mr FUEHR in relation to the function of a "Third Party Ambassador"

Martin Führ 08.09.2015

Proposal to nominate a "Third Party Ambassador" (TPA) within ECHA *first draft*

Follow up to the Advisory Group on Dissemination 16 June 2015

Whereas:

1. The REACH Regulation – as well as the TFEU (i.a. in Art. 15 (1)) – is based on the principle of transparency and openness to the needs of the European citizens and the public at large.
2. REACH relies in certain areas substantially on the concept of "inclusive governance" (i.a. in the authorization and restriction processes) providing for input by "third parties".
3. The overall aims of REACH, as laid down in its Art. 1 and the affiliated recitals (including the "Johannesburg goals" and the SAICM process), include the promotion of innovation towards a high level of protection of human health and the environment and thus enhancing competitiveness.
4. The REACH Regulation is designed to make best use of input of the various third parties mainly by means of internet based public consultation but also through their role as accredited stakeholder.
5. The focus of the work of authorities, including ECHA, is mainly driven by the interaction with those actors with direct obligations against ECHA processes; thus the needs of "indirect clients" tend to be not visible at the same level of perception to ECHA staff and ECHA processes.
6. Third parties might be considered as providing – similar to SME´s – so called "diffuse interests" which are important in the process of reaching the general aims of the REACH regulation but difficult to address and involve in the processes handled by ECHA; thus additional efforts in order to promote effective and efficient processes are justified.
7. The installation of an SME ambassador created a momentum within ECHA to take into account the perspective and the needs of SME´s in a coherent and proactive manner.
8. In order to achieve the overall aims of REACH the future role of ECHA should be to a higher extent address the elements of inclusive governance embedded in the REACH instruments and processes. This should be reflected in the internal structure of the agency as well as in the different processes and in the overall attitude of ECHA towards the interaction with "third parties".

A "Third Party Ambassador" (TPA) within ECHA should be nominated and it´s role should include the following elements

1. The TPA supports the Executive Director (and the directorates within ECHA) in considering the perspective and the specific needs of third parties.
2. The TPA contributes to coordinated efforts by ECHA to address the perspectives and needs of third parties.
3. The TPA establishes contacts to the third parties (and organizations assembling third parties) known to ECHA on a regular basis.
4. The TPA takes part in the meetings of senior management of ECHA with the TPs and the TP-organizations.
5. The responsibilities of the directorates are not affected by the instalment of the TPA.

Attachment to Annex 4: Last round of the "ECHA 2020" workshop