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Report from the advisory group on dissemination

Meeting of the Management Board 26-27 September 2013

Item	14
Action	For information
Status	Final - public

Action requested

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

The advisory group held three meetings since its last report to the Management Board (March 2012[1]). Together with the ECHA management, the group focused on reviewing the progress made with the implementation of ECHA's dissemination activity and looked into emerging issues. The advisory group was also consulted on the dissemination of information generated in the context of new Agency activities, such as data from authorisation applications and Biocides processes. Furthermore, the group was involved in an important study on the future development of ECHA's dissemination portal for which an external consultant was contracted.

At its last meeting of 3 July 2013, which was the 13th meeting since 2009, the group reviewed its achievements since its establishment and concluded on a number of outstanding issues.

Background

The advisory group was set up in 2009 and reports regularly to the Management Board[2]. It is composed of Mr Lapalorcia (IT, Chair), Ms Dimitriou (EL), Mr Kwisthout (NL), the representatives from DG ENTR and DG ENV as well as the Board members appointed by the Commission to represent interested parties (Ms Lauber, Mr Fuehr and Mr Mandery).

The advisory group was equipped with the following mandate:

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

Main issues discussed in 2012/2013

Dissemination of further information from the REACH Safety Data Sheet

The dissemination of information that is usually contained in a Safety Data Sheet in accordance with the REACH Regulation was one of the major issues discussed in the advisory group since 2009. The outcome of these deliberations was, for example, the conclusion to publish the name of the registrant (if no request for confidentiality is made and accepted as valid.)

[1] 16 May 2012, 20 March and 3 July 2013.
[2] See documents MB/48/2009, MB/65/2009, MB/85/2009, MB/42/2010, MB/76/2010, MB/67/2011 and MB/M/01/2012 (agenda item 19).

In its 13th meeting the advisory group received an updated overview on the status of the various pieces of information contained in safety data sheets (see Annex 2). The Secretariat explained that most of the data that are available to ECHA[3] are published with the notable exception of exposure scenarios. For the exposure scenarios a planning was developed to arrive over time at an improved dissemination of relevant information (see Annex 3). It was noted that the exposure scenario information ECHA holds in the Registration dossiers (in the Chemical Safety Report) is not the same as the exposure scenario information which is part of the safety data sheets. Resolution of this point was seen as an important element of implementing the plan.

The advisory group noted with satisfaction that most of the issues discussed could be solved, noting that the analysis part of the work is done and the implementation can now be tackled.

Dissemination from information in authorisation applications
The advisory group was consulted on the publication of information from authorisation applications, based on groundwork done by the Secretariat in consultation with relevant stakeholders. Issues discussed here included the publication of the name of the applicant where it was concluded that this information will, as a rule, be public. However, certain aspects, such as the relation to approved confidentiality claims under Article 119 of the REACH Regulation will require analysis and possibly justify exceptions in order to not undermine legitimate rights of companies.

Dissemination under the Biocides Regulation
In its last meeting, the advisory group concluded on some outstanding issues related to the dissemination of data under the Biocidal Product Regulation. This followed discussions at the 12th meeting and a subsequent written consultation. The dissemination of Biocides data started on this basis with the entry into operation of the new Regulation. Issues discussed in this context concerned, for example, the publication of legacy data from the previous Biocides legislation, the dissemination of the summary of the biocidal product characteristic (SPC) and the publication of names of study directors.

Study report on the development of the dissemination portal
The outcome report of the study for improving the ECHA dissemination portal is attached to this note. (See Annex 4 and 5). The advisory group had been involved in the concept of the study and some of its members contributed to the work of the external consultant.

The overall conclusion from the study is that an integrated approach should be pursued which allows access to all relevant information on substances via one entry point with increased usability and simplified navigation. The advisory group supported the Secretariat's conclusions from the study, in particular the ambition to make access more user friendly. It was pointed out that the project has close links to data quality, since the public availability allows a wide audience to scrutinise and contribute. At the same time a call was made to keep the priority of simplicity for average citizens in the mind.

The next steps will be divided in technical and content-wise implementation, including an IT architecture review and the development of a new user interface. For the user interface and navigation improvements a workshop with stakeholders is planned in the second half of 2014. Another workshop is planned still for 2013 for defining the content of a brief profile of properties / key information of substances (see recital 117 REACH). ECHA's aim is to make available an improved dissemination portal online in 2015.

[3] Safety Data Sheets are circulated in the supply chain but ECHA does not receive copies of the actual documents. Not all the data which should be in the sheets is also available to ECHA.

Attachments:

Annex 1 Overview of the main achievements of the Advisory Group on Dissemination

Annex 2 Overview of the information in a safety data sheet

Annex 3 Planning concerning the dissemination of exposure scenarios

Annex 4 Stakeholder’s Engagement Study next steps

Annex 5 Stakeholder’s Engagement Study full study report

Annex 1. Overview of the main achievements of the Management Board Advisory Group on Dissemination

Topic	Main achievements
Policy on handling of confidentiality claims	Development of criteria in collaboration with stakeholders (technical meeting), including the concept of a 5-step workflow and set of assessment factors. Advice on the development by ECHA of a practical guide for registrants. The group endorsed the proposal that an adequate public name needs to be provided by the registrant for ECHA to accept a confidentiality claim on the IUPAC name as valid.
Strategy for automated dissemination	The group endorsed a proposed strategy and timelines to phase-out the review by registrants before dissemination, enabling ECHA to reduce the time between submission and dissemination.
Scope of the information disseminated under REACH, and in particular article 119(2)(d)	Supported by the opinion of the Commission's Services, the group advised to enlarge the scope of the information disseminated under article 119(2)(d) (Safety data sheet (SDS) information) with: • Company name • Registration number • Result of the PBT/vPvB assessment • Generic exposure potential • Whether a CSA was performed ECHA adapted its IT-systems and – after a transitional period for the registrants – started to disseminate this information in November 2012. Remaining point: dissemination of exposure scenarios attached to the safety data sheet (see Annex 3). The group endorsed a proposal to disseminate more information on the derivation of DNEL/PNEC from the dossiers. This was also implemented in November 2012. Feedback on the experience with confidentiality requests on SDS information was positive and no indication that registrants would systematically claim this information confidential for substances not requiring a safety data sheet.
Dissemination of the tonnage band	Supported by the opinion of the Commission Services, the group advised to calculate the tonnage band by summing up the tonnages of all registrants in the joint submission, unless claimed confidential, and converting this sum into a tonnage band. Following a written consultation with the group, ECHA concluded on balance that the originally foreseen "four registrant rule" shall not be applied. Additionally, ECHA implemented further tonnage bands than the ones listed in REACH, and published the tonnage

	information in July 2012.
Dissemination of information from authorisation applications	The group endorsed an approach for the dissemination of the applicant's name and the information to be disseminated in the context of the public consultation on applications for authorisation.
Publication of notifiers' names in the C&L Inventory	The group recommended to apply the highest degree of transparency in the CLP platform enabling contact between notifiers of the same substance. This was implemented and released in February 2013.
Stakeholder engagement study	Following the group's endorsement, ECHA in cooperation with an external contractor launched a Stakeholders' Engagement Study for investigating ways to improve the readability and user friendliness of ECHA's Dissemination website and thereby reviewing the roadmap to be implemented over 2013-2015.
Biocides Dissemination	Following discussions in March 2013, the group concluded in July 2013 on its view on the dissemination of Biocides Data. Issues discussed included the interpretation of Article 22 of the BPR, the dissemination of the SPC, the publication of names of study directors and the publication of legacy data for active substances.

Annex 2. Overview of the information in a safety data sheet

Requirements for the compilation of safety data sheet (SDS) Commission Regulation (EU) No 453/2010, Annex II		Where the information can be entered in the registration dossier (IUCLID Section)	Status of the Dissemination of this information	Legal basis (REACH article)
0.1 **0.2** 0.2.5.	**Introduction** **General requirements for compiling a SDS** The date of compilation of the safety data sheet shall be given on the first page as well as the version number, revision number and for revisions any other indication of what version is replaced.	not	Publication of the date of the latest version of the aggregated dossier by end 2013.	
1 1.1	**Identification of the substance or mixture** Product identifier "In the case of a substance, the product identifier shall be provided in accordance with Article 18(2) of Regulation (EC) No 1272/2008 and as provided on the label in the official language(s) of the Member State(s) where the substance is placed on the market, unless the Member State(s) concerned provide(s) otherwise." "For substances subject to registration, the product identifier shall be consistent with that provided in the registration and the registration number assigned under Article 20(3) of this Regulation shall also be indicated. (...) the part of the registration number referring to the individual registrant of a joint submission may be omitted (...)" "Other names or synonyms by which the substance or mixture is labelled or commonly known, such as alternative names, numbers, company product codes, or other unique identifiers may be provided."	1.1. contains IUPAC name, EC name/number and CAS number 1.3 for updates; for initial registrations, the registration number is not in the dossier, but available in REACH-IT 1.1 (reference substance) contains the synonyms, molecular/structural formula, SMILES notation and InChI. 1.1 contains trade name	**Done** **Done** **Done** **Done**	Art. 119(1)(a), 119(1)(b), 119(2)(f) and 119(2)(g) Art. 119(2)(d) Art. 119(1)(a), 119(1)(b), 119(2)(f) and 119(2)(g) Art. 119(2)(e)
1.2	Relevant identified uses of the substance and uses advised against What substance is intended to do (like "flame retardant")	3.5 (Identified uses) and 3.6 (Uses advised against)	**Done**	Art. 119(2)(d)
1.3	Details of the supplier of the SDS			

	"The supplier, whether it is the manufacturer, importer, only representative, downstream user or distributor, shall be identified. The full address and telephone number of the supplier shall be given as well as an e-mail address for a competent person responsible for the safety data sheet." "If the supplier is not located in the Member State where the substance or mixture is placed on the market and he has nominated a responsible person for that Member State, a full address and telephone number for that responsible person shall be given." "For registrants, the information shall be consistent with the information on the identity of the manufacturer or importer provided in the registration."	1.1 contains the registrant's name and address. 1.7 contains the suppliers of the OR. 1.1 Contact person tab contains the information for the competent person responsible for the SDS	**Done** **Done** – (clarification ongoing with some OR/ suppliers (on permission of supplier that his name is published instead of the OR's name) **Done**	Art. 119(2)(d)
1.4	Emergency telephone number	not		
2	**Hazards Identification**			
2.1	Classification of the substance of mixture	2.1 & 2.2	**Done**	Art. 119(1)(c)
2.2	Label elements	2.1 & 2.2	**Done**	Art. 119(1)(c)
2.3	Other hazards "Information on whether the substance or mixture meets the criteria for PBT or vPvB in accordance with Annex XIII shall be provided." "Other hazards which do not result in classification but that may contribute to the overall hazards of the substance"	2.3 2.1 "additional hazard statements"	**Done** **Done**	Art. 119(2)(d) Art. 119(1)(c)
3	**Composition / information on ingredients**			
3.1	Substances Main constituent: at least the product identifier or one of the other means of identification in 1.1. Impurities: when itself classified and contributing to the classification of the substance, the product identifier shall be provided in accordance to Art 18(2) of Regulation (EC) No 1272/2008 or one of the other names or identification numbers. "Suppliers of substances may choose to list in addition all constituents including non-classified ones."	1.2 1.2 1.2	**Done** **Done** **Done**	Art. 119(1)(a), 119(1)(b), 119(2)(f) and 119(2)(g) Art. 119(2)(a) Art. 119(1)(a), 119(1)(b), 119(2)(f) and

				119(2)(g)
3.2	Mixtures	not		
4 4.1 4.2 4.3	**First-aid measures** Description of first-aid measures Most important symptoms and effects, both acute and delayed Indication of any immediate medical attention and special treatment needed.	11	**Done**	Art. 119(1)(g)
5 5.1 5.2 5.3	**Fire-fighting measures** Extinguishing media Special hazards arising from the substance or mixture Advice for fire-fighters	11	**Done**	Art. 119(1)(g)
6 6.1 6.2 6.3 6.4	**Accidental Release Measures** Personal precautions, protective equipment and emergency procedures Environmental precautions Methods and material for containment and cleaning up Reference to other sections	11	**Done**	Art. 119(1)(g)
7 7.1	**Handling and Storage** Precautions for safe handling	11	**Done**	Art. 119(1)(g)
7.2	Conditions for safe storage, including any incompatibility	11 and 4.18	**Done**	Art. 119(1)(g) and (d)
7.3	Specific end use(s) "For substances and mixtures designed for specific end use(s), recommendations shall relate to the identified use(s) referred to in subsection 1.2 and be detailed and operational. If an exposure scenario is attached, reference to it may be made or the information as required in subsections 7.1 and 7.2 shall be provided." (...) "If industry or sector specific guidance is available, detailed reference to it (including source and issuing date) may be made."	3.5 11 3.7.1 as of IUCLID 5.4 11	**Done** see Annex 2 **Done**	Art. 119(2)(d) and Art. 119(1)(g) Art. 119(1)(g)

8 8.1 8.2	**Exposure controls/Personal protection** Control parameters Exposure controls	11	**Done**	Art. 119(1)(g)
9 9.1	**Physical and chemical properties** Information on basic physical and chemical properties	4	**Done**	Art. 119(1)(d)
9.2	Other information	4.23	**Done**	Art. 119(1)(d)
10 10.1. 10.2. 10.3. 10.4. 10.5. 10.6.	**Stability and reactivity** Reactivity Chemical stability Possibility of hazardous reactions Conditions to avoid Incompatible materials Hazardous decomposition products	11 and 4	**Done**	Art. 119(1)(g) and (d)
11 11.1 11.1.1 11.1.1.1	**Toxicological information** Information on toxicological effects Substances Relevant hazard classes for which information shall be provided	2 and 7	**Done**	Art. 119(1)(c) and (e)
11.1.1.2	"For substances subject to registration, brief summaries of the information derived from the application of Annexes VII to XI shall be given, including, where appropriate, a reference to the test methods used. For substances subject to registration, the information shall also include the result of the comparison of the available data with the criteria given in Regulation (EC) No 1272/2008 for CMR, categories 1A and 1B, following point 1.3.1 of Annex I to this Regulation."	4-8 2 and 7	**Done** **Done**	Art. 119(1)(e) and Art. 119(2)(c) Art. 119(1)(c) and (e)
11.1.2	Mixtures	not		
11.1.3	Information shall be provided for each hazard class, differentiation of effect. If stated that the substance or mixture is not classified for a particular hazard class, differentiation or effect should be clearly indicated why.	2 and 7	**Done**	Art. 119(1)(c) and (e)

11.1.4	The data included in this subsection shall apply to the substances or mixtures as placed on the market. If available the relevant toxicological properties of the hazardous substances in a mixture shall also be provided such as the LD50, acute toxicity estimates or LC50.	7	**Done**	Art. 119(1)(e)
11.1.5	Where substantial information on test data for a substance or mixture exist, it may be necessary to summarise results of the critical studies, for example by routes of exposure.	endpoint study summary	**Done** for DNEL and PNEC	Art. 119(1)(f)
11.1.6	Where the classification criteria for a particular hazard class are not met, information supporting this conclusion shall be provided.	2	**Done**	Art. 119(1)(c)
11.1.7	Information on likely routes of exposure	7 and 3.7.3 (generic exposure potential)	**Done**	Art. 119(1)(e) and Art. 119(1)(d)
11.1.8	Symptoms related to the physical, chemical and toxicological characteristics	not		
11.1.9	Delayed and immediate effects as well as chronic effects from short and long-term exposure	not		
11.1.10	Interactive effects -should be included if relevant and available	not		
11.1.11	Absence of specific data -when data on the specific substance or mixture are not available, data on similar identified substances or mixture, if appropriate, may be used.	category members, test material identity	**Done**	
11.1.12	Mixture versus substance information	not		
11.1.13	Other information	7.12	**Done**	Art. 119(1)(e)
12	**Ecological information**			
12.1	Toxicity	6	**Done**	Art. 119(1)(e) and (f)
12.2	Persistence and degradability	**~** 5 and 6.5	**Done**	Art. 119(1)(d)
12.3	Bioaccumulative potential	5.3	**Done**	Art. 119(1)(d)
12.4 12.5	Mobility in soil Results of PBT and vPvB (where a chemical safety report is required)	5.4.1 2.3	**Done** **Done**	Art. 119(1)(d) Art. 119(1)(d)
12.6	Other adverse effects	6.6	**Done**	Art. 119(2)(c)
13	**Disposal considerations**	11	**Done**	Art. 119(1)(g)

14 14.1-14.6 14.7	**Transport information** UN number, UN proper shipping name, Transport hazard class(es), Packing group, Environmental hazards, Special precautions for user Transport in bulk according to Annex II of Marpol 73/78 and the IBC Code	11	**Done**	Art. 119(1)(g)
15 15.1	**Regulatory information** Safety, health and environmental regulations/legislation specific for the substance or mixture	not	Via the Search for Chemicals, information is available on whether the substance is identified as a SVHC, has a harmonised C&L, is subject to authorisation, etc.	
15.2	Chemical safety assessment It shall be indicated if a chemical safety assessment has been carried out for the substance or the mixture by the supplier	13	**Done**	Art. 119(2)(d)
16	**Other Information** This section describes other information relevant to the compilation of the SDS including information on revision of the SDS.	not	Intention to publish a "dissemination history" for each substance in the dissemination portal (new website in 2015).	

Annex 3: Dissemination of exposure scenarios

Current situation

An exposure assessment is to be carried out for substances that fulfil certain Classification criteria or are assessed to be a PBT or vPvB (REACH Article 14). The exposure assessment includes the generation of exposure scenarios, which must be placed in an annex to the SDS for communication in the supply chain.

ECHA receives the exposure scenarios as part of the CSR, in chapter 9 or 9/10 (new Chesar format). It is important to note that there may be differences between the exposure scenarios submitted in the CSR and exposure scenarios attached to the SDS and communicated in the supply chain. For example, the latter can be further standardised to improve usability by the downstream users. In addition, Section 9 of the CSR also contains other elements (exposure estimation) which are typically not included in exposure scenarios attached to the SDS.

The fact that exposure scenario information is currently only available to ECHA in the CSR poses several practical difficulties for their immediate dissemination:

- As the format specified in Annex I of the REACH Regulation for the CSR is only defined at a high level, registrants structure section 9 in different ways. It is thus not always straightforward to identify and extract the relevant exposure scenario information. This would require a manual, case-by-case assessment.

- Experience from ATDs to CSRs shows that registrants, across all sections of the CSR, frequently report potentially confidential business information (e.g. details on the precise use, manufacturing process or internal know-how). This is on the one hand due to the fact that registrants did not expect the CSR to be automatically disseminated when submitting it to ECHA. On the other hand, certain calculations in the CSR may in some cases allow recalculation of potentially confidential business information (e.g. precise tonnages). Filtering out this information from a CSR in its current format would always require a manual screening and assessment.

- The exposure scenarios are part of the information that can be claimed confidential (Article 119(2)(d)), provided that a fee is paid and the justification provided is considered valid by ECHA. As currently registrants did not have the possibility to indicate a confidentiality claim on information contained in the CSR, ECHA would need to contact each registrant and process such claims outside established procedures.

- The CSR can be in any technical format but is usually submitted as a Word or PDF document attached to the IUCLID technical dossier. In some cases, it is submitted as an "image", which means that it cannot be processed further (e.g. by text mining software).

Therefore, from the above, there is currently no straightforward way of publishing information contained in exposure scenarios, which currently is present in the CSR. Even if we would technically be able to extract the sections for publication on ECHA website, interaction with the registrant would still be needed to verify whether they want to claim confidentiality and, if not, whether they would need to "clean" their CSR and remove certain data that should not be published (such as precise tonnage or specific use conditions).

It is also worth noting that, in March 2013, i.e. before the arrival of the majority of the 2013 dossiers, the database contained approximately 15 000 dossiers with a section in the CSR on exposure scenarios (i.e. there was a section 9 or 10) that would need to be handled.

ECHA's strategy to publish information contained in exposure scenarios

ECHA proposed, in its long-term strategy towards improving the quality of information, to assess whether a structured CSR could be developed with the benefit that it would improve the readability and consistency of the CSRs and would potentially facilitate better data mining for substance prioritisation purposes. For the registrants, it should facilitate the maintenance of the CSR if they use a CSA tool, in particular Chesar and would also probably improve the safety advice circulating in the supply chain via the exposure scenarios.

The proposal was submitted to CARACAL in March 2012, explaining that as a first attempt towards more structured CSR information, a new section had been created in IUCLID (section 3.7) where exposure information could be reported. The document also highlighted that the development of a structured CSR would be done in cooperation with the concerned actors: registrants and MSCAs and that the impact on existing dossiers would be assessed.

Within ECHA, the activity is performed under the "CSA Development programme" which covers many work packages related to the preparation of the CSR, the exposure scenarios, the DU obligations, etc. and involves experts from several directorates.

The aim is to assess for which parts of the CSR there would be a benefit to provide the information on exposure scenarios, exposure estimates and risk characterisation in structured fields or whether it would be better to keep flexibility for the registrants, in particular to ensure that the assessment of substances that do not fit in the standard structure can still be reported efficiently. In parallel, there is also the analysis of which of these structured fields could be candidates for inclusion in the completeness check and further published on ECHA website, i.e. those which would be similar to the exposure scenario data attached to the SDS and would be in scope of Article 119(2)(d). This assessment is still on-going. The outcome will be presented to the stakeholders at a later stage.

Further to the consultation with stakeholders, changes in the CSR would need to be reflected in the version 6 of IUCLID (probably version 6.1) that will be released in 2015. In parallel there would be an upgrade of the completeness check tool and the dissemination filter tool. The new tool ("Dossier Quality Assistant") would also be updated to support correct filling of the fields.

The success of the strategy requires that existing dossiers and CSRs are updated to follow the new format.

In conclusion, the publication of exposure scenarios on ECHA website is linked to the successful execution of the process outlined above, and the launch of IUCLID 6, i.e. in 2015. This coincides with the launch of the redesigned Dissemination website.

Annex 4: Stakeholder's Engagement Study

1. Background

Dissemination as one of the pillars of REACH is at the core of both mission and values of ECHA. It plays a pivotal role in assuring transparency, efficiency, trustworthiness and supports the safe use of chemicals, in terms of human health and environment, by placing information under the scrutiny of industry, downstream users and the general public.

During 2011, the amount of information on chemicals disseminated on the ECHA website was enormously increased. Concerning REACH registrations, it now contains detailed information on more than 8.400 substances from over 33.000 registration dossiers. This information is searchable by EC number, CAS number and chemical name. Additionally, via the link to the eChemPortal[4] developed by ECHA in cooperation with OECD, users can query directly the properties of the registered substances.

Furthermore, the C&L inventory has information on the classification and labelling of ~110.000 substances as well as EU harmonised classification for ~4500 substances.

In addition, information and lists of the various regulatory processes such as Candidate List, REACH Annex XIV ("Authorisation List") and Annex XVII ("Restriction List"), CoRAP for substance evaluation, Registry of intentions, Evaluation decisions, etc. are constantly being populated and published in various sections of the ECHA website.

At the end of 2011, a dedicated search engine was launched for all information related to a queried chemical substance. This "one-stop-shop" (hereafter "Single Point of Access") provides links to most of the data on chemical substances contained in the ECHA databases, including the before mentioned lists of regulatory processes. This search engine is available at http://echa.europa.eu/web/guest/search-chemicals.

This information resource is unique in the world, hence the importance of implementing a user-friendly navigation and layout, efficient and easy query functionalities, and understandable publication format for all possible interested parties.

Dissemination represents an ECHA's long term activity and it is vital to streamline the process(es) in a long-term sustainable way. This is even more relevant with the addition of the biocidal information for which publication will start in Q4/2013.

Following ECHA's vision "(…) to become the world's leading regulatory authority on the safety of chemicals.", the Dissemination website should aspire to be the world leading source of information on chemicals.

2. Stakeholder consultation

ECHA's databases contain an extensive amount of information on chemical substances and stakeholders' expectations on easy access to this information have been growing. ECHA in cooperation with an external contractor launched a Stakeholders' Engagement Study for investigating ways to improve the readability and user friendliness of ECHA's Dissemination website and thereby reviewing the roadmap to be implemented over 2013-2015. User groups from NGOs (environmental, consumers, workers etc.), industry (EU and non-EU), third party service providers, academia, a number of EU/EEA Member State Authorities and other non-EU partners (e.g. Regulatory Authorities of US, Canada etc.) were consulted.

The objective of the study was to identify, in collaboration with the stakeholder user groups, what information on substances will be of most interest and how best the Agency can make it available online. More specifically:

[4] eChemPortal (http://www.echemportal.org) makes available web links to information on properties of chemicals (physical chemical properties, environmental fate and behaviour, ecotoxicity, toxicity) submitted to government chemical review programmes at national, regional, and international levels.

- Understand the behaviour (needs, affordances, preferences) of the ECHA web audiences when searching for chemicals
- Synthesise the stakeholders' insights in order to identify opportunities for the redesign of ECHA's Dissemination website
- Provide comparisons with known portals on chemicals (including ESIS, ACTOR, SIN List, eChemPortal, Haz-Map, ChemIDplus and Risctox) so that users could highlight their preferences
- Propose a new set of concepts that would address the above and would propose the transition of ECHA's Dissemination website to a new capability level

The insights were gathered via primary and desk research methods and resulted in a total of 380 responses to an online survey (submitted by organisations based in 46 countries) and 16 semi-structured stakeholder interviews (with 20 participants in total).

2.1 Main findings

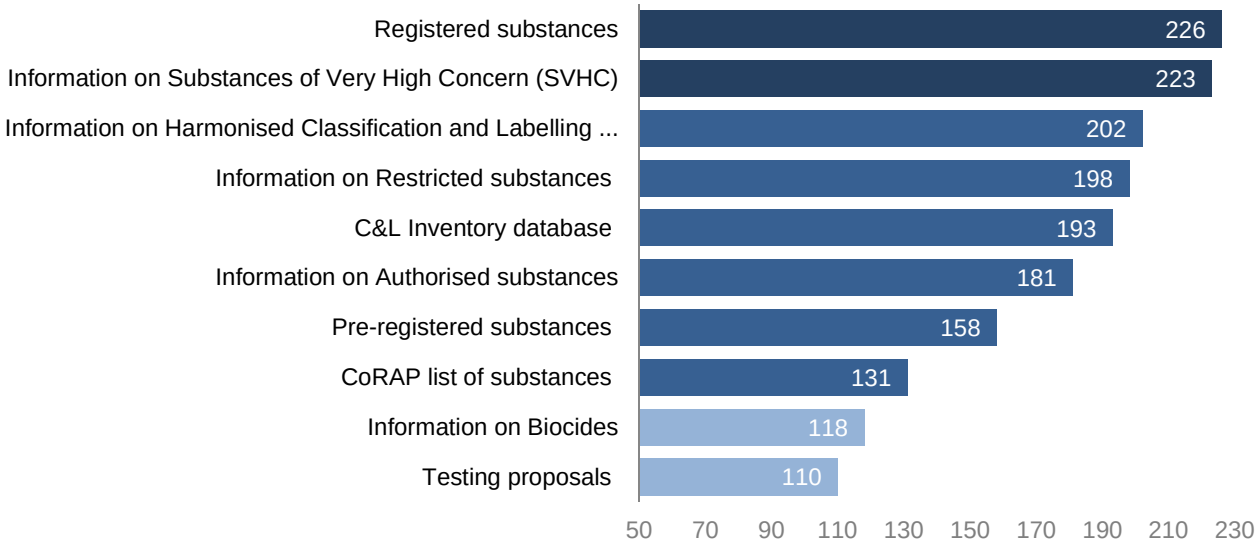
The study revealed good options for improving ECHA's Dissemination services and identified a number of web audiences' usage patterns, beliefs and opinions. Overall, it can be argued that the ECHA web audiences are to a certain extent satisfied with the Registered Substances database and the "Single Point of Access" functionality.

However, the users' targeted interests and work processes put forward a set of data search, presentation and data manipulation expectations which are currently not adequately addressed by the existing ECHA web applications. A summary of the main findings divided by category can be found in attachment I to this document. The categories include:

- Navigation
  - design and structure
- Search function
  - integrated search, reliability and advance filtering
- Integration of data sources / Display of results
  - direct inter-linkage between several regulatory processes
- Availability of information
  - Exposure Scenarios, Chemical Safety Report, brief substance profiles, acknowledgement of confidential claims
- Download functionalities / Reporting
  - advance reporting tools and download functionalities (e.g. per property)

Stakeholders were also asked to specify their information needs concerning the regulatory processes under ECHA's responsibility. As can be observed in Figure 1, the majority of the ECHA databases were specified by more than 50% of the respondents. The replies confirm that, in the users' view, the concept of Dissemination is broader than just the registered substances and the C&L Inventory.

Figure 1. Information needs of ECHA's Stakeholders



As a key outcome of the study, ECHA should consider moving forward with data consolidation, interoperability (between processes, databases and systems) and optimisation initiatives (including substance identification) aiming at delivering interfaces that allow efficient data exchange and querying.

In addition, a high level of data interoperability will reduce support and maintenance overheads caused by the lack of standardisation during the design of the process in the past.

2.2 Addressing the main findings

Immediate actions

Taken into account previously identified needs expressed by ECHA stakeholders and internal users, several improvements are already taking place for the Dissemination of registration dossiers that already address the results of the Stakeholders' Engagement Study. They cover:

- Improve filtering and search functions
  - Filtering NONs substances available
  - Wild card searching available
- Improve data display and availability
  - Confidentiality claims visibility improving
  - DNELs/PNECs assessment factors and justifications published
- Download / printing features
  - Printer friendly html implemented

Other findings

Although some results of the study can easily be accommodated, many others require an adaptation of the website architecture (e.g. central point of access to all substance-related data, inter-linkage between processes, data download, different views on the data, brief profiles etc.).

Indeed, the current technical infrastructure of the Dissemination pipeline(s) sets limitations on the way the data are being displayed/published. The reason for this is that the Dissemination project was initiated as an IT project and focused primarily on REACH registration aspects. The C&L inventory was also mostly addressed as an IT project, involving other technology and processes than for registration. This is an important legacy constraint to take into consideration in the future architecture.

The foundation was/is based on existing IT tools (in particular IUCLID), which impacts the display format of the disseminated data. On the other hand, it allows the registration dossiers and the C&L data to be made available on the website swiftly. The need for a more user-friendly interface and a holistic/integrated approach of data (not only registration and C&L data) has become evident in the results of the study (i.e. all needed data in one place/search). The complexity of disseminated information being scattered in various sections of the ECHA website needs also to be tackled.

Further requirements like availability of Exposure Scenarios (ES) are currently being handled in the context of the CSA Development programme, which also covers many actions aiming at improving the quality of CSR and the usability of ES to be communicated in the supply chain, and the IUCLID 6 development. While extracting CSR information poses several practical difficulties for their immediate dissemination (please see AP5 support documentation "*Update on dissemination of information on substances under Article 119(2)(d) of REACH*"), efforts are made to structure ES information in IUCLID 6. Subsequently ECHA would be able to automate publication and integration of ES information into ECHA's dissemination website in the future, depending on the strategy decided in the context of the CSA Development programme.

Other requirements such as Brief profiles are deeply dependent on the substance-centred model (see Section 3.1) and are being further analysed to address the challenges associated with data availability and format and to assure meaningful display of information considering different user profiles.

3. Way forward

3.1 Integrated approach

The aim is to allow stakeholders to:

- access all information related to a substance of interest independently of the entry point: dossiers submitted by companies (whatever the legislation, REACH, CLP, Biocides), lists (such as SVHC Candidate list, Annex XIV, XVII, CoRAP, etc.), consultations, results of regulatory processes (e.g. evaluation decisions, biocidal products approvals, etc.)
- increase usability by simplifying the navigation (e.g. reducing the number of pages to browse for finding the information)

This concept was already presented in previous documents as the "Single Point of Access" approach. In practice, this requires that progress must be achieved on two aspects:

- business perspective: better integrate all substance dissemination activities within ECHA since many activities are taken place under individual regulatory processes but not always under the coordination of the Dissemination team: A different organisation will be put in place to ensure integration.
- IT perspective: progress on the architectural review of the website, to ensure that the technology enables interlinking of the information (substance-centred model – see diagram in attachment II) and implement other functionalities (such as download of search results or different views on the data or brief profiles). An IT architectural study was launched recently with expected outcomes as of August 2013.

The IT development is in coherence with the large integration effort ECHA has undertaken based on the on-going Data Integration Project (DIP). DIP is aiming at linking together information arising from different sources to better support the work of ECHA and the Member States Competent Authorities. To this extent, DIP represents the opportunity to interlink the information produced and collected by ECHA for dissemination purposes as well.

The IT architectural study will allow ECHA to better understand the challenges and constraints for revamping the website and subsequently make an informed decision on which of the requirements expressed by the stakeholders in the study can be implemented. The aim of launching the new Dissemination website is in 2015.

3.2 Next steps

The Dissemination website improvement entails four main developments:

- Architectural review in order to integrate the scattered information and legislative processes, to facilitate the presentation of data under different views and to enable data download
- Review of the Dissemination pipelines (system enabling the filtering from CBI information, the aggregation of dossiers submitted for the same substance, etc.) to further streamline the processes and gain efficiency as well as integrate the dossiers submitted for the Biocidal Product Regulation (BPR)
- Development of user interface
    - Information display (type, structure and design)
    - Search engines and filters
- Content-related aspects such as definition of what should be presented in the Brief profiles of substances or improvement of data quality

While the first two developments will be carried in parallel for all processes and in connection with the Data Integration Project, the third development can be implemented in a step by step approach based on the priorities (to be defined). Finally, the quality of the information improvement will be an Agency's continuous task within the first strategic objective set in the multi-annual work programme.

The precise timeline will be decided based on the outcome of the IT Architectural study.

Attachment I to Annex 4

Summary of main findings from Stakeholders' Engagement Study

Navigation

- Easy to use when accustomed to IUCLID format, not straight forward for non-experts users who would be mostly interested in brief substance profiles (recital 117 in REACH regulation)
- Custom set of icons with explanatory information for each field could be considered a more user-friendly approach
- User interface is perceived as 'quite complicated' and 'still not very intuitive'. It requires too many clicks to find the required info (for example on the dossier page), which leads to user fatigue
- The left sidebar on the Registered Substances database provides proper navigation throughout the dossier but cumbersome due to the content volume and Information Architecture

Search function

- Additional filters would be helpful. Examples for filters would be the possibility to choose the database to search or ability to indicate whether the search should also return similar terms
- Filter for NONs substances (NONS/Not NONS) and Nano (Nano/Not Nano)
- Missing functionality for searching by synonyms and use of wildcards
- When performing a query the system should provide suggestions. Partial name searches are feasible but should be supported by the appropriate search options (e.g. 'starts with', 'matches exactly' and 'contains' options). Suggestions should be provided as well for misspelt names in order to avoid that no result is showing
- Search by substance properties/classification
- Searching for groups of substances/family of substances

Integration of data sources / Display of results

- Results list to indicate hazard statement codes
- In case of a unique substance match the intermediary page should also present the substance summary factsheet/one-pager (recital 117 of REACH)
- Single Point of Access widely used - links/'redirects' to a number of ECHA sources and applications. The fact that it presents a multiplicity of links/'redirects' to a number of ECHA sources and applications was largely considered to be problematic:
    - Need to click on the "view" button for each one of the search results (time consuming) and it is not apparent how the user can go back to the list of search results after having clicked on one of the "view" buttons. A more integrated approach on the display of results is deemed appropriate
    - Possibility to choose the database to search or all databases to be combined into one search interface, which would allow users to select filters applicable for all
    - Synergies on the search criteria between the various databases. As an example it was proposed that the Registration substance database triggers further searches in the C&L Inventory with the same criteria in case the user is interested in 'jumping' between the two databases
    - Linking between various databases (e.g. between REACH-based and Biocides systems) needs to provide clarification on under which regime each substance is regulated
    - Important to know what chemicals are in restriction or in the Candidate List. Overview of the various regulatory processes that the substance is going through and in which stage (i.e. public consultation, final decision etc.)
- The issue of global alignment was raised by some interviewees, especially by those who work in globally operating enterprises (i.e. linking with external databases). These organisations were interested in receiving and comparing data generated in the US, Australia, Europe etc.

Availability of information

- Present meaningful justifications and visual indicators when data are missing/not available:

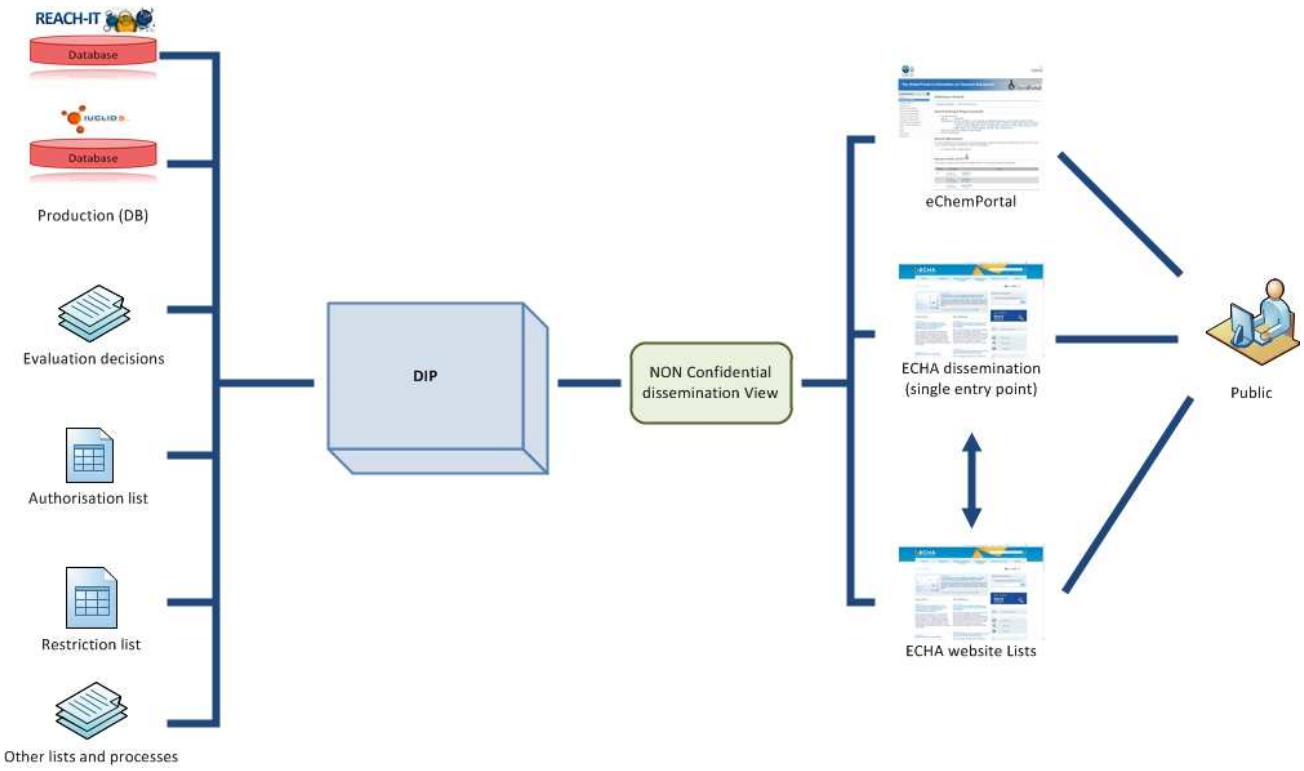
  - Several stakeholders requested empty areas to be indicated as "empty due to missing data", "empty due to a confidentiality claim that has been accepted", or "empty due to a confidentiality claim that is pending", with the possibility of using colour coding in order to distinguish between each case
- Searching for specific date fields:
  - Searching for the registration date of a substance (i.e. the date that the substance is used / traded legally in the market)
- Dossier/data updates:
  - It should be possible to search and retrieve content versions through an update history
  - Detailed justification of the update of the dossiers (e.g. "compliance with regulation" and "detailed reason/information") and the specific fields or sections that have been updated
- "Information about the justifications for the DNELs /assessment factors is missing"
- "Non - availability of ESs and CSRs"
- "Brief substance profiles (recital 117 in REACH) and/or generic substance summaries/factsheets are missing"
  - Some interviewees mentioned that there is a case for segmenting the data-set and search interfaces in order to meet the needs of the different visitor types. This layered approach would aim to satisfy the needs of non-specialised public and specialised visitors by providing:
    - Two views of the search interfaces
    - Two views of the underlying data (one-pager factsheets and IUCLID compliant full dossiers)

Download functionalities/Reporting

- Downloadable content: more flexibility sought, difficult to use data for statistical purposes currently, custom data exports not possible
  - The possibility to use .csv and .xls exporting in order to execute the 'Search, extract and export' usage scenario is considered very important. At the moment users are resorting to downloading the Excel file that contains the full results and then searching it locally since, (a) some searches are not possible on the website and (b) some of the search results on the website are perceived as wrong. These users view the ECHA databases as a 'library' of substances that they need to refer to (to the latest updated substance information) in order to complete 'external workflows'. The above usage scenario applies to both searches for groups of substances (such as a list of PBTs, a list of high tonnage substances or a list of proposed SVHCs) as well as searches for individual substances
- Personalisation and subscription to information
  - A number of stakeholders mentioned that they would like to maintain a personalized list of substances and queries that would provide quick access to the desired substances as well as automated alerts when updates in the data are available.

Attachment II to Annex 4

Figure 1. Integrated approach to Dissemination



Note: The diagram is voluntarily simplified. In practice, there are different "layers": data stored in the data integration platform (normally only integrated data), data exposed through the data virtualisation system (specific source system data) and data provided directly by the source system (systems allowing direct data exchange).

Figure 2. User navigation to disseminated data