19 September 2013

Downstream user webinar
Navigating ECHA´s website for information on chemical substances – Questions and Answers

This document is the collated and revised version of the questions and answers covered during the webinar hosted by ECHA on 19 September 2013. It is meant to accompany the presentations and video recordings of the event.

The content has been edited to merge related topics and for increased clarity.

Is the information of all registered substances open to the public or are there some restrictions (such as legal or supplier related restrictions)?
All of the non-confidential information on registered substances is made public by ECHA in accordance with Article 119 of REACH. Article 119 specifies which information is always to be published, and which can be claimed confidential.

Can the information published be used for purposes other than REACH? How can I contact the data owner, who is not identified as this information is not disseminated in the ECHA web site?
The data from dossiers is published on ECHA's website for general information purposes. Any other use of the information without obtaining the permission from the owners might violate their rights. To contact the data owner, you need to send your question via the ECHA Helpdesk contact form for the specific data you need (http://echa.europa.eu/contact/helpdesk-contact-form). Once you have permission from the data owner, you can use the data.

Why do we find other types of results (Toxicology/Ecotoxicology) in addition to the "Key test" in the published information in the dissemination portal? Can we use these results as well?
All non-confidential results submitted to ECHA are published on the ECHA website. For your information, those indicated as key tests are those for which the registrant considered the results as key for their own purposes. For details on naming of test results, see the Data Submission Manual 15 on dissemination: http://echa.europa.eu/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals.
As for the use of results, please remember that use of the information without obtaining the permission from the owner(s) of the respective information might violate the rights of the owner (see legal notice).

Where on the ECHA website can I find publicly available information on the Assessment Factors of published DNELS if that information has been made available in the submitted IUCLID dossiers? Is there any way that a user looking at the Registered Substances site for a material can determine how the published DNEL's (in the Toxicological Information section) were derived or which identified use of a substance results in the exposure that is driving the listed DNEL?
Since November 2012 ECHA has made public the Assessment Factors (AF) of all published DNELS, where this information has been made available to ECHA in the

submitted IUCLID dossiers. DNELs, including AF if available, are given in the endpoint study summaries of section 7 of disseminated dossiers.

For more information check the Data Submission Manual 15 (see link below). Also check the article in the latest ECHA Newsletter on making use of DNELs generated under REACH: http://newsletter.echa.europa.eu/home/-/newsletter/entry/4_13_making-use-of-derived-no-effect-levels-generated-under-reach.

ECHA has made public any non-confidential details on extrapolation methods - full details of which fields in IUCLID are made public can be found in the technical annexes of Data Submission Manual 15 on dissemination: http://echa.europa.eu/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals.

However, the very specific details of how DNEL values were calculated are often highly confidential, and thus are not made public. At the moment it is not possible to identify a more specific non-confidential use for a substance as the use driving the published DNEL value.

If we have the REACH registration number from our supplier, how can we check it on the ECHA website?

You can use the registration number as a search criterion when searching registered substances in the Information on Chemicals section of the ECHA website. Be aware however that in the published dossiers there is no way to know which registration number belongs to which registrant, unless you are dealing with an individual submission. ECHA does not provide any other service for checking registration numbers.

Some non-EU suppliers say that they have registered their substance but they do not want to give their REACH registration number before their downstream user places the first order. Is it legal? Can we require it from the supplier?

Non-EU companies cannot register substances. Registration is done either by their importers or their only representative.
Suppliers of registered substances must communicate the registration number down the supply chain at the latest at the time of the first delivery.
The legal obligation of supplying the registration comes from REACH Article 31 for situations where a Safety Data Sheet is required and from REACH Article 32 when no Safety Data Sheet is required.

Where can a downstream user find information of typical uses of substances of very high concern, to check if they might be contained in the articles he supplies?

ECHA does not have a database of this type but some information is available in the registration dossiers which you can search on our website. The background documents for substance of very high concern proposals or restriction proposals can also contain such information. ECHA publishes examples of articles containing substances included in the Candidate List, which are available for consumer use on the EU market. The data is based both on the notifications that companies have submitted to ECHA and on the information contained in the registration dossiers. This can be found in: http://echa.europa.eu/information-on-chemicals/candidate-list-substances-in-articles.

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Where can one find categories of application of chemicals that are being considered for inclusion on the Candidate List - e.g. softener, epoxy etc. as they are not always part of the dossier?
REACH and CLP deal with substances not with categories of substances. We recommend you approach the relevant sector organisations. Also, if a substance you are interested in appears in the Registry of Intentions for the identification of substances of very high concern, you can contact the authority who is planning to submit the dossier.

When a REACH registration has been submitted, will the relevant information automatically be transferred to the Classification and Labelling Inventory (C&L Inventory), or does the registrant also need to notify the substance to the inventory?
Yes, the C&L Inventory automatically contains all C&L notifications submitted as part of a REACH registration dossier. Therefore REACH registrants, if they have included a CLP C&L in their registration dossier, do not need to make a separate notification.

Is it possible to download the C&L Inventory or to access it with a web-service?
This is not possible. However, ECHA is investigating the possibility to export search results in to an Excel file. No access through a web-service is foreseen.

Could you please explain the Seveso information that is provided through the C&L inventory?
The categorisation according to the Seveso II directive is provided for most substances with harmonised classification. No Seveso information for substances without harmonised classification can be provided. Note that ECHA is not an authority for the Seveso Directive. For further information on Seveso, please ask your national authority: http://ec.europa.eu/environment/seveso/natautho.htm.

If a substance in the C&L Inventory shows a classification with a hazard statement (e.g. H315) and a label with a different hazard statement (e.g. H319), I think of an error. Is there another possible reason?
There are a number of notifications with technical errors, such as missing labelling elements. However, according to Article 21 of CLP the label shall include the relevant hazard statements in accordance with the classification. We encourage notifiers to check their notifications and update them if needed.

Why is there sometimes a discrepancy between the classification that should be assigned according to the CLP rules (e.g. based on study results of LD50) and the classification actually assigned by the registrant?
For the purposes of dissemination all submitted dossiers are processed automatically and made public as submitted. This information has not been reviewed or verified by the Agency or any other authority. Only afterwards are dossiers selected for evaluation which may detect deficiencies and request corrections from the relevant registrants.

How do I know which is the correct classification and labelling when there are many different ones submitted for the same substance?
There can be justified reasons for different self-classifications (such as impurities). ECHA does not verify whether the self-classification is correct but recommends that you contact your supplier if you are concerned. Note that according to Article 41 of CLP, notifiers and registrants shall make every effort to come to an agreed entry to be included in the inventory.

If notification to the C&L inventory results in different entries for the same substance, when can we consider that "every effort" has been achieved according to CLP Article 41 related to coming to an agreed entry?

This is based on a case-by-case analysis. In any event, if you have contacted the other notifiers and discussions have not led to an agreement, it would be recommended to make a record of the measures taken. In case an agreement cannot be reached you can contact your national enforcement authority.

What level of information about C&L classification is expected to be shared by notifiers via the C&L Platform? What about intellectual property protection and cost sharing?

No confidential information is shared on the C&L Platform. The C&L Platform is an easy solution for notifiers and registrants to contact each other. Once registrants and notifiers of the same substance come together, they can decide how and where they discuss the classification and labelling for their substances. The discussions in the C&L Platform are not actively monitored by ECHA.

Why is the harmonised classification sometimes different from registered or notified classification?

Differences between harmonised and registered or notified classifications can have different origins. A substance which is subject to harmonised classification and labelling (Part 3 of Annex VI to CLP) must be classified in accordance with that entry. In addition, the manufacturer or importer should self-classify the substance for those hazard classes where no harmonised classification is available. For example, a substance may have a harmonised classification for acute oral toxicity, but not for acute dermal toxicity. This means that the manufacturer or importer would have to use the available harmonised classification and then explore, using the information available, whether the classification criteria for acute dermal toxicity are fulfilled, and classify accordingly. The resulting classification and labelling should be introduced in the notification the manufacturer or importer submits to the C&L Inventory.

Self-classification can depend on the data each supplier has access to or on the impurities present in the substance. Therefore, differences in self-classification can have a firm basis.

For substances with a minimum harmonised classification (classification marked with an asterisk in Annex VI to CLP), notifiers must also classify them in a more severe hazard category if they have further information showing that this is more appropriate. Again, the result of this classification will depend on the data the notifier has access to and may give rise to different classifications.

When will substances with different classifications be harmonised? To which classification should we refer until then?

Harmonisation is not meant to apply to all substances. In accordance with Article 36 of CLP, substances of particular concern shall be harmonised to ensure adequate risk management throughout the European Union. Member States, manufacturers, importers and downstream users may propose a harmonised classification and labelling of a substance.

Note that in case of different entries in the C&L inventory for the same substance, according to Article 41 of CLP, notifiers and registrants shall make every effort to come to an agreed entry to be included in the inventory. Downstream users may use the classification from one of their suppliers otherwise they must self-classify the substance and notify ECHA.

Which classification must I use if I have two suppliers who have different classifications in their safety data sheet (SDS) and there is no harmonised one?
Downstream users may use the classification from one of their suppliers otherwise they must self-classify the substance and notify ECHA. We recommend that you contact your suppliers to clarify and agree on a classification, if possible. There could be justified reasons, such as impurities, that explain the difference. If no agreement can be reached we recommend taking a precautionary approach and using the more severe classification.

When does a supplier have to update an SDS after his registration and when does a downstream user have to update the SDS's after a registration of the substance?
Suppliers (including downstream users) shall update the safety data sheet without delay on the following occasions:

- as soon as new information which may affect the risk management measures, or new information on hazards becomes available;
- once an authorisation has been granted or refused;
- once a restriction has been imposed.

Regarding the four last digits of the registration number of a substance in the SDS, is it correct that manufacturers should include the last 4 digits? Only distributors/downstream users may omit part of the registration number by including XXXX.
Correct, only a distributor or downstream user can omit part of the registration number. See 1.1 of Annex II to REACH. This enables e.g. formulators to have multiple suppliers without needing to update the Safety Data Sheet.

In slide number 24 of the presentation "Information on registered substances" why are there different REACH registration numbers for different countries in the safety data sheet?
It shows that the substance was registered in different countries by different legal entities. Possibly the supplier uses different suppliers in different countries.

What to do when we receive a SDS with a registration number but no exposure scenario (the substance is registered above 10 tonnes per year and classification as H317 according to CLP)?
Write to your supplier to ask if you should have an exposure scenario and make a formal record of what you have written and when.

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A downstream user sells a mixture containing >1% of an unclassified substance of very high concern. The mixture is not classified. What obligation does the downstream user have concerning informing their customer? Do they need for example a SDS and labelling?

As the mixture and its components are not classified as hazardous, the mixture does not need to be labelled according to CLP. A SDS needs to be provided at the recipient's request according to Article 31(3) of REACH.

As for labelling, the CLP Regulation does not require the inclusion of a product identifier for a non-classified substance in a mixture on the label. If a substance of very high concern is not classified (e.g. it has been identified as a substance of very high concern on the grounds of fulfilling the PBT or vPvB criteria or "equivalent concern"), it need not be indicated on the label. However, it may be indicated as supplemental information (Article 25(3) of CLP).

Is it already mandatory to consider in the mixtures' SDS the exposure scenarios of the individual dangerous substances the mixture contains? If yes is there any guidance available to perform this?

Yes it is. According to Article 31(7) any downstream user shall include relevant ESs, and use other relevant information, from the SDS supplied to him when compiling his own SDS for identified uses. This is addressed in the downstream user guidance. The downstream user can:

- integrate the information into the main body of the SDS
- append safety use information for the mixture or
- attach relevant exposure scenarios for the substances in the mixture

Do we need to mention the registration numbers of components in section 3 of a mixture SDS provided these are hazardous components which need to be mentioned in chapter 3 according to the SDS-regulations?

Yes, a registration number shall be given if available (REACH, Annex II 3.2.4).

When writing own safety data sheets for mixtures, should REACH registration numbers be collected from the ECHA website or should the downstream user wait to receive the REACH registration number from the supplier?

The downstream user must wait for their supplier to provide them with the registration number. Each company has their own registration number, thus you cannot take one from the disseminated information on ECHA's website. According to Article 39 of REACH the receipt of the registration number communicated to the downstream user by his supplier in a SDS triggers the downstream user obligations pursuant to Article 37 and 38 of REACH. Suppliers shall update the safety data sheet without delay on the following occasions:

- as soon as new information which may affect the risk management measures, or new information on hazards becomes available;
- once an authorisation has been granted or refused;
- once a restriction has been imposed.

However, any updates following registration shall include the registration number.

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Should a supplier develop exposure scenarios for chemical products (not pure substances) produced less than 10 tonnes per year?

A supplier is not required to develop exposure scenarios for chemical products (mixtures) in any quantity. If he is required to provide a SDS, he should use relevant information, including from exposure scenarios, when compiling the SDS. He can:

- integrate the information into the main body of the SDS
- append safety use information for the mixture or
- attach relevant exposure scenarios for the substances in the mixture

Why doesn't ECHA require SDSs to be submitted as part of the info submitted to them and make these available on the database for users?

ECHA has no legal basis to request the SDS to be submitted as part of the information requirement for a REACH registration. ECHA only has access to, and can only make available, the information in the submitted IUCLID dossiers. However, according to Article 119(2)(d) of REACH, ECHA has to make the information which is contained in the safety data sheet, and which is not already disseminated under other articles of REACH available over the internet, unless the registrant successfully claims confidentiality. This "safety data sheet information" includes:

- registration number;
- registrant name;
- life-cycle description and uses advised against information;
- exposure scenario elements;
- result of the PBT (Persistent, Bioaccumulative and Toxic chemicals) and vPvB (very Persistent and very Bioaccumulative) assessment;
- indication of whether a chemical safety assessment (CSA) was performed.

Regarding both authorisation and restriction, at which stage does our supplier have an obligation to communicate information about the authorisation or restriction to us?

Suppliers shall update the SDS or the information provided according to Article 32 without delay when the authorisation has been granted or refused, or the restriction has been imposed.

Is ECHA providing help in ensuring that manufactures fulfil their obligation to inform on substance of very high concern in their mixtures?

ECHA cannot provide any direct help, but we can provide assistance via the ECHA Helpdesk. We also have several non-EU producers approaching us directly to ask what needs to be provided to their clients. There is also a useful German website where consumers can check if articles contain a substance of very high concern: http://www.reach-info.de/verbraucheranfrage.htm.
You can also contact your national enforcement authority, as enforcement is the responsibility of the Member States.

Does ECHA publish a list of all substances in Annex XVII?

Yes. Here is the link to List of Restrictions: http://www.echa.europa.eu/en/addressing-chemicals-of-concern/restrictions/list-of-restrictions.

The list of restriction has 105 entries. However, the Annex XVII and the appendix have many more. How can I find these substances?
Group entries or the appendix cannot yet be found by general substance search. Only single substance entries can be found. Currently, the best way is to make a text search in the REACH text (http://echa.europa.eu/regulations/reach/legislation).

Does a substance stay on the candidate list even if it is also added to the list of substances subject to authorisation (Annex XIV)?
Yes, an identified substance of very high concern will stay on the Candidate List. The Candidate List triggers specific obligations, also for downstream users, that remain even if the substance is also included in Annex XIV or other lists. See also the following link: http://echa.europa.eu/web/guest/candidate-list-obligations.

Are there fixed dates for updating the list of harmonised classification and labelling, Classification and Labelling Inventory, Candidate List, Authorisation List (Annex XIV) and the List of Restrictions (Annex XVII) or must they be monitored continuously?
The list of harmonised classification and labelling (Annex VI CLP) and the Authorisation List of REACH are updated about once a year and the List of Restrictions whenever a new restriction has been agreed and published. The Classification and Labelling Inventory is updated about once a month. The Candidate List is updated twice a year, in June and in December. The related public consultations are scheduled about three months before each update.

Some of the Annex XV reports do not contain any information on typical uses. Why not?
For the identification of a substance of very high concern, use information is not necessary (only hazard related). Information on uses is relevant for follow-up processes (such as authorisation). If information is not available in the report, it will be taken from registration dossiers, from the commenting round and other available sources.

What is the Registry of Intentions (RoI)?
The Registry of Intentions is a register where the following intentions of Member States and ECHA are collected:

- Identification of substances of very high concern;
- Restriction;
- Harmonised classification.

These three separate substance lists can be found on the ECHA website. The aim of the public Registry of Intentions is to inform interested parties of the substances for which the authorities intend to submit Annex XV dossiers. This helps them to prepare in time for the commenting.

Is a supplier obligated to communicate information to downstream users if a substance is added to Registry of Intentions, or later when authorisation or restriction is confirmed?
Suppliers shall update the SDS or the information provided according to Article 32 without delay when the authorisation has been granted or refused, or the restriction has been imposed. The requirement to communicate information applies specifically to authorisation and restriction, but also for new hazard information or information which may affect risk management measures.

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What modes of control are implemented to ensure that downstream users place articles on the market which comply with REACH obligations?
REACH enforcement is entirely in the remit of each EU/EEA Member State.

In which cases must one provide more than just the minimum information (substance name) when an article contains a Candidate List substance in concentration above 0.1%?
More than just the minimum information must be provided when it is essential for the safe use of the article (including the waste stage). Further information can be found in the guidance for substances in articles:
http://echa.europa.eu/documents/10162/13632/articles_en.pdf.

If a company produces substances and mixtures in EU and exports them to a non-EU producer of articles, is the obligation for providing the information valid?
In case of export, the obligations for providing information (Articles 31-33 of REACH) are not applicable as they are related to the placing on the market.

You encourage downstream users to participate in discussions, but in which way can we do so? What kind of information a formulator SME can provide, which can be useful?
The most useful information is on uses and conditions of use. Sector organisations often collate this. Also, see ECHA website on ENES, exchange network for exposure scenarios, where work is on-going regarding mixtures. Further information can also be found in the downstream user guidance.

If you recommend to downstream users to ask everything to their suppliers, what are the obligations of the suppliers? Is REACH not focussed on a top-down process within the supply chain?
REACH aims to encourage two-way communication between suppliers and users. When registrants and suppliers receive good information on the uses, they can generate better information to provide downstream (Article 37 of REACH).