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Downstream user notifications of authorised uses: Information made public by ECHA

1. Purpose

This note explains what information from the notifications of downstream users of authorisation holders ECHA makes public on its website. It also describes what information ECHA shares with the respective authorisation holders.

2. Introduction

Downstream user notifications are required according to Article 66 of the REACH Regulation. The requirement to notify applies to companies that continue to use a substance included in the Authorisation List after its sunset date, based on an authorisation granted up their supply chain. After the publication of the authorisation decision in the Official Journal of the European Union, companies must notify ECHA within three months from when they receive their first delivery.

The approach has been developed by the ECHA Secretariat in consultation with the relevant Industry, NGOs/Trade Union stakeholders, and the Management Board Advisory Group on dissemination. It was adopted in June 2018. As of the time of publication of this note, ECHA is performing the necessary technical preparatory work for adapting the submission tool for notifications (REACH-IT) according to the adopted principles. The first data are foreseen to be published in mid 2018 at <https://echa.europa.eu/du-66-notifications>. Similar timelines are foreseen for sharing relevant data with the authorisation holders.

The following information is collected in the notifications:

- Companies notifying ECHA need to provide information on the company, the substance, and the authorised use. Information relating to the company includes the company name, the address of the sites where the substance is used, and the relevant contact information. The substance and the name of the authorised use are identified by the authorisation number selected by the downstream user during the notification. This number also identifies the supplier (direct or further up in the supply chain) that holds the authorisation covering the notified use.
- Companies can also voluntarily submit further information about their specific use of the substance, such as ranges for the typical annual quantity and the number of staff using the substance; a brief additional description of their use (e.g. the type of products they make or the sector where these products are used); and any involvement by the company in potential substitution activities.
- Finally, if the authorisation decision of the European Commission includes a requirement for downstream users to provide specific data to ECHA, e.g. on exposure or alternatives, then companies need to upload this information as an attachment to their notification, by the deadline set in the decision.

ECHA has been receiving notifications from downstream users since 2016, following the publication of the first authorisation decision covering actors down the supply chain, which was related to the substance hexabromocyclododecane (HBCDD).

3. Reasons for sharing information

As required under Article 66(2) of REACH, ECHA has established and keeps up to date a register of downstream user notifications, and forwards the notifications it receives to the relevant authorities in EU Member States. In essence, the notifications register complements the list of authorisation holders, and together the two encompass all companies benefiting from an authorisation.

The main aim of the notification system is to make it easier for authorities to ensure that only authorised uses of substances of very high concern (SVHCs) continue after their sunset date.

- The notification register makes it easy for enforcement authorities to identify companies that have not made a notification but are using a substance after its sunset date.
- Notifications help authorities to monitor the authorised uses of SVHCs while confirming that companies that have made a notification act in accordance with the authorisation's conditions.
- Notifications also support the review of authorisation decisions (preparation of a potential review report by the authorisation holder and its evaluation by ECHA and the Commission).

ECHA shares non-confidential information from the notifications with the public and specific anonymised information with authorisation holders. This approach to transparency aims to maximise the usefulness of notifications while respecting confidentiality concerns, such as confidential business information, information that would raise competition law issues and information subject to privacy.

The publication of the non-confidential part of the information in the Article 66 notification register is foreseen to bring a number of benefits. Furthermore, sharing specific anonymised information from the notifications with the authorisation holder is also considered beneficial. The foreseen benefits are described in an appendix to the note.

	Information published (Y / N / claims-dependent)	Information shared with AH (Y / N)
Company info	Company name	Company name
	Country of site	Country of site
	Address of site	Address of site
	Contact	Contact
Substance info	Substance name	
Use info	Use name	
	[Quantity - precise value/range] [- band]	[Quantity - precise value/range] [- band]
	[Number of staff - precise value/range] [- aggregate]	[Number of staff]
	[Brief additional description of use]	[Brief additional description of use]
	[Involvement in substitution activities]	[Involvement in substitution activities]
	Data attached as required by decision	Data attached as required by decision
Supplier	Authorisation holder (upstream supplier)	
Status	Current status (active/inactive) and inactivation reason	Current status (active/inactive)

Figure 1: Notification information made available by ECHA (left column: information published; right column: information shared with the authorisation holder)

Note: Fields in square brackets are optional and therefore are not be present for all notifications. Similarly, requirements for submission of specific data on exposure or alternatives (uploaded as attachments) do not apply for all authorisation decisions.

4. What information is published

ECHA handles the information in a notification at three dissemination levels (see Figure 1, left column).

Information always made public (in green):

- substance name;
- Member State where the use takes place;
- whether the notification's status is active or inactive (substituted/ceased use) and, if inactive, the stated reason of inactivation¹;
- tonnage band, if quantity information was provided.

ECHA also publishes aggregated information on the number of staff involved in the use, from all the notifications received per authorised use where such information was provided.

Information made public unless the downstream user has claimed this confidential with a valid justification (in grey):

- company name
- location of the site of use;
- name of the notified use;
- brief additional description of use;
- information on substitution activities.

Downstream users often wish to disclose such information. Therefore, for transparency, ECHA's approach is to make this information public unless justified objections are raised.

ECHA sometimes consults authorisation holders before publication of names or site locations of their downstream users that did not claim them confidential. This takes place if there are only one or two holders for the specific substance – or one or two holders for the specific use. In these cases it might be possible to deduce supply chain links (Article 118(2)(d) REACH) and thus, the authorisation holders would be consulted.

Information not made public (in red):

- name of the upstream supplier that holds the authorisation;
- personal information, such as the email address and telephone number;
- precise quantity and number of staff;
- attachments.

The publication of the authorisation-holding upstream supplier or personal information is not needed to achieve transparency in the process. Furthermore, information on quantities and staff will be published in bands or aggregates. The information included in attachments will be

¹ Companies can mark their notification as inactive in REACH-IT. This is relevant in case they have stopped use of the SVHC, e.g. because they have now implemented an alternative substance or technology.

included as part of the broad information on uses in case of a review report² by the authorisation holder.

Note that in some cases the name of the upstream supplier may be deducted from the substance name if the notified substance (or the notified use) has overall only one or two authorisation holders. It may also be possible to deduct the name of a confidential authorised use if overall only one use is authorised for the substance. In the first case, for protecting a confidential supply chain link downstream users may also wish to e.g. flag their use confidential. In the second case, for protecting a confidential use downstream users may also wish to flag their company name as confidential - mentioning the above reasoning in their justification.

5. How information is submitted, processed and published

The information from downstream user notifications is published at a dedicated page at ECHA's website, at <https://echa.europa.eu/du-66-notifications>. In addition to the public version of the register, ECHA displays on this webpage statistics on the number of notifications per Member State and substance.

Downstream user notifications are submitted through an on-line submission interface in REACH-IT, which has replaced an earlier web form. In REACH-IT, downstream users can claim certain information from their notification as confidential. There is a dedicated step for setting confidentiality flags during the on-line submission process. The companies must provide a clear justification along with any confidentiality claim.³

REACH-IT supports downstream users in this task, by offering specific templates for their justifications, visible as soon as a confidentiality flag has been activated. For these data fields where the reasons for confidentiality claims are rather obvious, REACH-IT offers predefined - still editable - standard justifications, to further simplify the input by downstream users.

ECHA publishes non-confidential information from the notification, based on the principles outlined above and any confidential claims by downstream users. ECHA publishes the information four times per year.

Where relevant ECHA consults with the authorisation holder before it first publishes the names and site locations of downstream users that have notified their use. In case the authorisation holder opposes publication of this information, ECHA decides about publication taking into account the legitimate interests claimed by the holder.

In the regular updates of its web site, ECHA makes sure that it presents the most up-to-date information from each notification, including its status, i.e. active vs. inactive. Downstream users should remember to keep the information in their notification up-to-date, including any confidentiality claims and the justifications for these.

6. Information shared with the authorisation holder

Authorisation decisions often include an obligation for downstream users to submit additional data to ECHA (e.g. on exposure or alternatives) and require ECHA to forward this information to the authorisation holder. This is because the authorisation holder needs to consider this information during the preparation of a possible review report, which is to be submitted 18 months before the expiry of the review period.

² The review report will include, for example, exposure data collected by the downstream users.

³ Companies that made their notifications using the earlier web form will receive a message from ECHA asking them to review their notifications in REACH-IT and set confidentiality flags if relevant. ECHA will allow sufficient time for making this update. A similar approach will be followed for allowing companies who have made their notifications in REACH-IT, to consider newly introduced confidentiality flags or amended disclosure rules.

In addition to such information⁴, ECHA periodically provides to the authorisation holder the information submitted by their downstream users in the notification (see above)⁵. The submission tool gives details clearly to the downstream users.

The above information is provided to the authorisation holder in an anonymised matter - only the country of the respective downstream user is indicated by ECHA, as well as whether the notification's status has been indicated as active or inactive (see also Figure 1, right column).

ECHA forwards the information 'as is', i.e. without any translation, editing, or further anonymisation (something to take into account in case the company's name appears e.g. in uploaded files).

⁴ Such files are automatically forwarded to the REACH-IT account of the authorisation holder.

⁵ Quantity information is provided to the authorisation holder in the form of tonnage bands, rather than precise values/ranges provided in the notification (similarly to the approach followed for publication).

Appendix: Benefits and features of the public notification register

The publication of the non-confidential part of the information in the Article 66 notification register is foreseen to bring a number of benefits. These are:

- Comprehensive knowledge about the status of continuing uses of SVHCs can facilitate active involvement and cooperation of various stakeholders towards the aims of further control of exposure and eventual substitution. This is in line with the view that it is not only for regulators and for enforcers to promote such aims.
- Notifying a use is in essence a statement by a company that it uses the SVHC in a responsible manner, in accordance with the authorisation conditions. This is of course also a legal requirement for being able to continue the use. Increased transparency regarding the companies that have – or have not - notified their use of a substance should further encourage compliance with authorisation and notification requirements by all companies. This in turn promotes a level playing field for all.
- Making available information on the actual scale of upstream authorisations⁶ promotes public scrutiny of the review process for these authorisations.
- A public version of the register enables companies to highlight the status of their specific use, e.g. the use of small amounts or a later substitution of the SVHC.
- Upfront clarification of the confidentiality status of the information in each notification and in particular of the publication principles employed, significantly increases the predictability of ECHA's handling of the notification data for downstream users and other actors in the supply chain.

ECHA understands that increased transparency about the identity of end users in supply chains could potentially facilitate disintermediation⁷ and/or enhance competition between suppliers for the downstream market. At the same time, these are supply chains of SVHCs and promoting eventual substitution (and therefore competition by alternatives suppliers) is in line with the aims of Authorisation.

Sharing specific anonymised information from the notifications with the authorisation holder serves the following purposes:

- Relevant information from downstream users is useful to the authorisation holder when deciding on whether to apply for an extension of the authorisation.
- Specific information about the use downstream can assist authorisation holders in preparing an accurate review report and covering the downstream use adequately: it helps refinement of both the authorised use and assessment reports (including the Chemical Safety Report, Analysis of Alternatives, and Socio-Economic Analysis).
- Considering that ECHA's Committees and the European Commission will take into account notification information when evaluating review reports for upstream authorisations, the transparency principle requires for a consolidated (anonymised) version of this information to be shared in a timely manner with the authorisation holder.

The information is provided without the downstream user's name⁸ so as to not further promote potential unintended effects on the structure of the supply chain (where this consists of several

⁶ Authorisations granted upstream, covering uses down the supply chain of the authorisation holder.

⁷ Possible bypassing of intermediary suppliers (intermediary downstream users and/or distributors) by upstream suppliers – which might be relevant for some multi-layer supply chains.

⁸ The use information to be provided to the authorisation holder will not include the company names. ECHA applies this principle also where downstream users' names are made public. The aim is to provide to the authorisation holder useful information about the downstream use rather than about the companies at the end of the supply chain. Of course, where names of notified companies are published, they may be possible to associate with own supply chain. Similarly, where the company name is visible in the file attachments that ECHA has to forward to authorisation holders, ECHA will not anonymise the files.

layers).

For the same reasons as listed just above, ECHA also recommends that downstream users who have notified their use do, as a standard practice, establish a contact and communicate with the authorisation holders – either directly or through potential intermediate suppliers.