Industry views on the DU notification for authorised uses (REACH Art 66)

1. Introduction – legal background

After an authorisation has been granted for a specific substance and a specific use, holders of an authorisation as well as downstream users referred to it have to comply with some obligations.

According to Art 65 of REACH - The holders and downstream users shall include the authorisation number on the label before they place the substance or preparation containing the substance on the market for an authorised use without prejudice to Directive 67/548/EEC and Directive 1999/45/EC. This shall be done without delay once the authorisation number has been made publicly available in accordance with Art 64(9).

According to Art 66 of REACH – Downstream users (DU) dealing with an authorised use shall notify the Agency within three months of the first supply of the substance. The Agency shall establish and keep up to date a register of DUs who have made a notification and the Agency shall grant access to this register to the Competent Authorities of the Member State.

2. Current status

More and more applications for authorisation have been/are submitted to ECHA and are now in the pipeline of the process. In the meantime, ECHA is currently working on the format of the tool DUs shall use to notify authorised uses and is open for constructive input.

Industry welcomes this opportunity to provide its contribution by sharing concerns and suggestions on the notification tool.

3. Industry concerns

a) Communication

Due to the complexity and the length of certain supply chains, some Downstream Users (DUs) are not yet fully aware of their duties regarding the notification of authorised use dealing with an authorised substance. A learning process would need to be implemented in the coming years.

b) Language

The biggest group of DUs of authorised substances will presumably be SMEs. In particular because of that the notification tool needs to be available in all EU official languages.

c) Meaning of the term “use”

Downstream users having to notify are not all aware of REACH complexity. For instance, the definition of the term “use” may be subject to different interpretation according to the context it refers to. Many fields are linked to the term “use” in REACH text calling for different obligations. A clear interpretation &/or support from a helpdesk might help DUs to define/clarify whether they have to notify yes or no and for which use exactly.

d) Data requirement

The data requirement will be addressed to a completely different community, not familiar with registration dossier, authorisation application and any other kind of (scientific) data submission. Those DUs (dealing with substance <1T/y) have never had the intention to submit such complex file. Their

priority remaining to comply with the legislation, by informing their own use is well covered by a granted authorisation.

Therefore it would be recommended to have a box in the notification web form stating for instance that:

"Company A confirms the use X (drop list of authorised uses) of the substance Y (drop list of authorised substances) under a specific granted authorisation (drop list of granted authorisation).

e) Confidentiality of submitted data - CBI

Another concern targets the confidentiality of the supply chain and the accessibility of the notification register.

- The composition of the supply chain (link between manufacturer/importer and their distributors/DUs) is considered per se as CBI (Art 118.2d of REACH).
- According to Art 66 of REACH, the list of notifiers should only be made available to the Member State Competent Authorities.
- As the authorisation number is not confidential as such, the final DUs will know who holds the authorisation. The source of the substance will be limited to those suppliers holding an authorisation. However, to avoid to easily trace the supply chain and that the final DU by-pass several levels in the supply chain, it is recommended to keep the register of notification accessible only to authorised MSCA (as foreseen by REACH) and to avoid to disseminate side by side the name of the holder of the authorisation and the notifying DU.
- Regarding the notification of substances present in mixture, from an organisational point of view, the notification system might be challenging for companies having to notify several authorised substances present in the mixture.
- It is also suggested to provide DUs having notified, a confirmation of their notification and ensure them, data will not be disclosed.

4. Suggestions

Industry is of the opinion that the tool used to submit a notification should remain as simple as possible:

- Indeed lot of DUs, SME's are not familiar with complex IT-tools, nor aware of the existence of such tool. Therefore the use of IUCLID or REACH IT should be avoided.
- Need to have a user friendly, easy and accessible tool.
- In order to minimize the burden on DUs, a direct access to the notification page/template is requested via a link easily accessible on ECHA and National website.
- On ECHA website, it is suggested to mention the notification link on different pages, such as:
    - The authorisation page describing the process
    - The substance specific page where all document related to this substance can be found (BiU, public CSR, SEA, AoA, Committees outcome, COM decision and finally DU obligation/notification).

  - On pages dedicated explicitly to DUs, explaining their obligation vis-a-vis of REACH.

- To keep the notification tool and template as simple as possible, it is highly recommended:
  - To develop an easy web form, focusing the request on simple basic information (Company details, number of the use, number of the substance as stated in Annex XIV, etc..).
  - To provide pre-filled drop list with authorised substance names and authorisation numbers which the DU can select to register himself easily as user of this substance.
  - Since uses for a specific substance are very restricted and all available to ECHA from the application for authorisation, those should be added for each substance accordingly to the notification tool in form of a pick-list.
  - Every tool and template should be available in all official languages.
  - In summary, DUs will just have to click in boxes, chose from pick lists and fill in company details

5. Conclusion

In the framework of the notification tool that will be developed by ECHA to allow DUs to comply with the regulation stating that DU shall notify the Agency within 3 months of the first supply of the substance, industry provided their concerns regarding:

- The kind of information DUs shall provide for the notification
- The confidentiality of the notification
- The easy accessibility /availability of the tool.
- The language regime of the tool.

Industry would suggest:

- To keep the web link accessible, multilingual and the web form user friendly to allow DUs not familiar with IT tools to remain compliant.
- The data requirement should be based on basic information already available to the DUs having sometimes no clue on the kind of data submitted in REACH dossier.
- To provide to the DUs, a confirmation of the notification and ensure them, notification data will not be disclosed to competitors.
