



THIS WEEK IN HELPDESK

Toll formulators and PCN

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Toll formulators are downstream users. If they supply and make a mixture available on the market, they are duty holders in accordance with Article 45 and have the obligation to generate a UFI and make a notification – even if they do not own the product or the intellectual property rights of the mixture they formulate.



What obligations does the toll formulator's customer have? The toll formulator's customer will not have any notification obligations if they only store and place the mixture on the market, meaning, they act as a distributor. However, they do have obligations under Article 4(10) of CLP.

What if the customer makes a change? If the customer performs any activities as a downstream user (formulation, re-packaging, re-filling) then they also have the obligation to make their own notification under Article 45. If as distributor, they re-label, re-brand or place on a market that their toll formulator supplier has not notified, then they can make their own notification or request the toll formulator to include in their submission the additional details.

Does it matter who generates the UFI? No, but ideally, the toll formulator generates the UFI and includes it on the label and in the notification. In general, the same UFI can be also used by different companies as long as the composition is the same. Because the UFI is a means to identify a mixture composition, and not a legal entity, it is also permissible for the customer to generate the UFI and provide it to the toll formulator. The customer can generate a different UFI for their use, and help keeping their business relationship confidential.

How are the legal entities differentiated in a notification? The toll formulator as a duty holder must provide their legal entity details in the notification as the '**Legal submitter**'. There is no requirement for them to indicate the customer's details in the notification. The details of a '**Contact point**' should be indicated in the notification if the submitter is not in possession of additional information in case of follow up by authorities. See section 5.1.2 of the Guidance on Annex VIII <https://echa.europa.eu/guidance-documents/guidance-on-clp>

Can the toll formulator delegate responsibility to the customer? In theory, yes. In example 16 (option 3) of the Guidance on Annex VIII, the toll formulator's customer may take the responsibility for the notification and submit the information using their own legal entity – relieving the toll formulator from the obligation of making a notification. However, the toll formulator will remain the duty holder under Article 45 therefore this assumes an agreement from both parties has taken place. Note that this is outside the remit of ECHA and this may be enforced differently in each Member State.

Can the foreign user functionality help? In some cases, yes. A 'foreign user' can perform actions on behalf of an account holder, such as preparing and submitting a poison centre notification. If there are no confidentiality concerns, a foreign user can be, for example, the customer of the toll manufacturer. See "This week in Helpdesk – legal submitters and foreign users" for most commonly asked questions on this topic https://poisoncentres.echa.europa.eu/documents/22284544/29721445/legal-submitters-foreign-users_en.pdf/