20 October 2021

Questions and answers from Poison centres session at ECHA Safer Chemicals Conference, 6 October 2021

Question	Answer
Hello, is the UFI code needed to be labeled before the product being imported to from nonEU the EU from the import side of controls? Or can the EU importer label the UFI themselves?	The responsibility to comply with the relevant obligations is on the importer. Importing means placing on the EU market and the product has to be compliant. The non EU supplier is expected to support
Can one formulation/product have more than one UFI code?	Thank you for your question, so as explained, yes a mixture can have more than one UFI code
Hello: harmonised PCN is now legally required since more than 9 months, when will all members states be ready to accept the harmonised submissions and have a final opinion on the submission procedure?	Indeed the onboarding took a bit longer than expected for some MSs. We are following up with the last still missing. We believe all MSs eventually will accept notifications via the Submission portal
Hello everybody! If a trader has a greater	Duty holders (DU/Importer) are required comply after the compliance date (unless the transitional period applies). It is different for distributors if the mixture was in compliance when supplied

quantity stored of a product prior to 2021 and wants to still sell the product on the market, how would you tackle this situation?	
what is the status of distributors now? Do they have any notification obligations?	As explained verbally, the status of distributors has not changed.
and clarify obligations for distributors to submit such information, through an only representative or other means." --> Modifications foreseen? Actions and timeline, please? Thank you	OR is not foreseen by CLP. Distributors, if needed, have to comply as duty holders. Normally their products should be covered by the supplier's notification. CLP is under review at the moment and changes may happen in this respect (e.g. duty holder definition and introduction of an OR). But the process is still in early stage
Are you aware of calls to poison centeres where the UFI was already used to identify the mixture in question? Is the use of a UFI in an emergency call something that is tracked for statistical	We are not systematically collecting this information, at least at the moment. But we will follow this up with our contact points in the PCs, who actually have this information

reasons?	
Why cant I see UFI codes on all the products?	Annex VIII includes a transitional period for mixtures already notified under national regimes before the relevant compliance date. cosmetics. You can find more information: https://poisoncentres.echa.europa.eu/why-the-ufi-matters-for-everybody
Our Turkish client has PCN&UFI for products. Can they send it without having the UFI on the label? Will it be ok to label UFI after clear goods from customs?	In principles products should be complaint with all relevant provisions before they are imported into the EU (import id deemed to be placing on the market). For a more elaborate answer, we would kindly ask you to submit the question via our ECHA contact form
Are there any thoughts of having one single emergency response phone number for calling EU poison centers?	This is something which goes beyond Article 45 and Annex VIII. We are not aware of such discussions so far. It would require coordination among PCs across EU
Is there a plan for future to have the ability to delete incorrectly submitted PCN dossier ? Since at the moment from my knowledge this is not possible.	By the end of the year, a new feature will be introduced in the submission portal and via System-to-system to disable submissions and flag them as "they should have never been submitted".
If I market a pen whose ink is hazardous, should I include the primary packaging, i.e. the pen	Thanks for the interesting question. This requires a more elaborated answer. We kindly ask you to submit the full question via the ECHA contact form

cartridge, in the PCN notification as packaging information?	
A non-EU company places products to the EU market through their EU subsidiaries and through distributors. Can one EU subsidiary submit PCN on behalf of all companies importing this product to the EU?	Each EU LE importing hazardous mixtures into the EU is supposed to notify. There is no OR role in CLP nor submission covering different duty holders
When registering an UFI on ECHA website the VAT number of the company is required. Is that any reason for that?	The VAT is used in the UFI generator to ensure uniqueness
Could the product identifier in the submission also the name in the CLP box (label)	The product name as it appears on the label is one of the main elements used by the PC to identify the mixture. This has to be provided in the submission
I produce a hazardous mixture notified for industrial and professional use. A customer informed me	It is about the MiM's UFI. If you use it to identify the MIM, this should have been previously notified by a supplier. Full list of current rules and description here https://poisoncentres.echa.europa.eu/documents/1789887/5577602/PCN+Validation+rules.pdf/6f7c90ce-dc2e-d937-e084-b8f58fa71314

now that he use my chemical for public use. I am trying to update but i am getting a warning QTL 516??? What is this warning?	
on ECHA website there is option to generate UFI without VAT number. If we choose this option does it mean that someone from other company can have the same UFI?	No the UFI generated in this way will also be unique - the system uses a unique code which acts as a sort of fake VAT number to generate the UFI each time.
If there is a product product in 2 different manufacturing sites for example in Europe and outside EU. Can I apply the same UFI for this product but produced in 2 different manufacturing sites please	The UFI is assigned to a mixture composition so as long as this remains identical then it is allowed to use the same UFI
The product name as it appears on the label is one of the main elements.Question is which label. Is this on Front of pack or could	We would need to understand better the case. Does the products have multiple names on the same packaging? The product id should be provided according to Art.18(3)(a).

it be also the back of pack where the name is listed in the CLP label	
The product name as it appears on the label is one of the main elements.Question is which label. Is this on Front of pack or could it be also the back of pack where the name is listed in the CLP label	In addition, Annex VIII requires other brand/trade names/variants as relevant
I have submitted a dossier for ammonia solution that we have classified as a hazardous mixture. What is the procedure to "retrieve" the submitted dossier if it is a substance instead of mixture ?	Note that solutions are, by definition, mixtures. Therefore should be notified if hazardous. Said so, a procedure to "disable" wrong dossiers will be available in the near future
Referring to the product name. E.g. name on FOP shows Brand and variant name .CLP label on BOP contains Brand, variant name including product type	The product name as it appears on the label is one of the main elements used by the PC to identify the mixture. This has to be provided in accordance with Article 18(3)(a) of the CLP regulation.

in different languages. Like toilet block, WC block. BOP name is listed on SDS and to our understanding this should be aligned with PCN	
When will the remaining member states (e.g. Belgium, Bulgaria, Slovakia) be connected to the ECHA Portal?	We publish the information about MSs preparedness as soon as we have it. Please refer to the Overview table on our website
for group submissions: do we need to indicate pH's as exact values or can we make use of ranges, i.e. >7 (as it as been evaluated in ECHA guidance doc.) ?	The information required for mixtures in a GS are the same as for standard submissions. A limited range can be provided (same validation rules apply)
what are the modifications of Poison Center Notification foreseen in the CLP revision? This point is mentioned in the CLP revision roadmap	Topics included in the upcoming CLP revision and relevant for PCN, are notification of substances and clarification of duty holders (i.e. certain distributors). Note, the process is at an early stage
Denmark, Netherlands, Czech rep,	MSs accepting notifications via Submission portal are indicated in our Overview table. Some of them are not fully connected (therefore the last

Romania, didn't receive any of our PCNs although ECHA indicates they are connected to PCN portal. Will ECHA do something about it ? If not, what shall industry do ?	event in the submission report is not displayed)
Can I be sure that my formulations are safe with poison centers since there is not signed NDA?	We can guarantee the confidentiality of the information as long as it remains in our systems and database. Once it is dispatched to PC/AB, we have no control anymore. Nevertheless all PCs/ABs confirm the information will be handled according to the applicable regulation its confidentiality
when we have this new, really fancy possibilities, to remove products from a specific market, will adding a new one also be so easy?	You can add a country the same way you are doing it now and flag the dossier as an update.
Belgium, Luxembourg received only PCNs sent from end September. Will ECHA do something to make sure they receive all previous PCNs ? If not, what is industry supposed to do ?	Please note that the acknowledgment of the received dossier is displayed when the dossier is processed into the BE database. As BE just finalised its technical set up, that may take some some time.
To add an extra question	As we replied earlier, ECHA has no mandate about fees. Each MSs has their

to Victoria v W.: how will the notification fees (different) be arranged if every member state will join the ECHA portal?	own policy
Italy and Hungary ask for fees, but DO NOT provide any invoice nor any interface for payment. Industry has some finance rules and can't pay without invoice. Any plans to address that?	ECHA does not have the mandate to support such a functionality as fee charging is a national process ECHA cannot create a general system for.
Do we need to update our notifications once format 4 is available via IUCLID to match the new PCN format?	It will be possible to submit dossiers created in previous IUCLID format provided that the new dossier does not fail business rules.
Can we submit voluntary PCN using the portal without assigning a UFI? Example: product only hazardous for environment, no need for UFI, but due to national regulation we want to do a PCN using	UFI is not necessarily required for voluntary submissions, even if is recommended

portal	
Would it be possible for ECHA tu publish the new validation rules (or at least a draft of them) before their implementaio n in the portal? It is important for S2S users to implement them in advance.	We are planning to publish a draft updated list of VRs as soon as it will be possible.
Can we submit voluntary submission (product only hazardous for environment) without entering toxicological information?	Tox info record is not mandatorily required for voluntary notification. We recommend consulting the VRs list document (on our website) which indicated when each rule applies
Is there a consensus that voluntary notification are free of charge?	This will depend on the Member State - we cannot really comment on that
Will a disabled PCN submission be transfered to the local authorities so that fees needs to be payed?	Yes. Authorities will be informed about the disabled submission.
How long will version 2 be accepted? Is there a timetable?	The submission of dossiers created with previous IUCLID versions will still be possible provided that the dossier does not trigger business rules.

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Name on FOP shows Brand and variant name .CLP label on BOP contains Brand, variant name and product type in different languages. Like toilet block,WC blok etc. What is required in the PCN submission?	Annex VIII requires complete trade name(s) and , where relevant, brand(s) and variant names as they appear on the label. The main point is to allow specific identification.
Should the name in PCN be aligned with SDS	The name of the notified mixture (i.e. the one in the notification) should tbe he one that is placed on the market.
Are there any plans to public search page at the ECHA homepage in order to search whether a product has been submitted? It would help users to check if suppliers made their duties.	There is no plan in this respect. We don't have mandate to publish such information at the moment
Could you remind how to manage imports from outside of EU, like UK and Switzerland? Do non-EU companies have to appoint an OR or could they use the ECHA portal (as	I would suggest you refer to our Guidance document for full details, (or the article Legal submitters & foreign users from our seriesThis week in Helpdesk here: https://poisoncentres.echa.europa.eu/questions-and-answers) but in brief, the non-EU company should arrange for an EU-based legal entity to make the notifications to which the EU importer can refer to the UFI in their mixture composition document

"foreign users"?)?	
If an ingredient gets a harmonised classification and labelling (or update of such), is this an update or do you need to do a new PCN (with new UFI)? Composition didn't change but classification did?	UFI needs to be changed when the composition changes. Other changes do not require a new UFI (but a simple update). Check Annex VIII B.4.1 in conjunction with A.5.1
if the single components are not classified in the same way due to lack of harmonization , is it acceptable to group the components using a worst case scenario classification for the ICG?	Components can be grouped is the classification is the same. In case of diverging classification the suppliers should be contacted to investigate the reason for the differences (it can justified)
disable a submission: how will it impact info received/ viewed by the AB/PC?	The end-to-end solution was presented at the last PCN users group meeting in September and slides were shared with participants. Happy to follow up if needed.
Will there be an easy way to check in what members states an UFI is notified? At the moment the only way is asking	No, this is not foreseen

trough the supply chain which takes a lot of time.	
What are the options for non-EU manufacturers for PCN submissions of the mixtures they put on EU market?	Due to limited possibilities for answer here we kindly recommend consulting the Guidance, which provide details on the issue. Non-EU legal entity do not have obligations but are expected to support
Is the lastest version of the member states overview really 8.0 from July. Somehow I cannot see any newer, no matter which browser I will use.	The latest version is 8.1 and we have made it available in our LinkedIn group - unfortunately we are having some issues with our website so it has not been uploaded there, but we expect it soon. If you are not a member of the LinkedIn group, the link is here: https://www.linkedin.com/groups/12364138/
Criteria set 2 - similar pH => can you please be more precise?	More information is available in the Guidance. it is eventually up to the submitter to assess
How does industry check that a MIMÂ´s UFI (ICG component) has been previously notified to a MS?	This is part of the checks we agreed with the WG and are already applying
Do you intend to provide a tool that could check automatically if a modification of an already notified	This seems what the exiting rules already do. According to the change, rules will make the dossier pass if the correct dossier is submitted (update or new notif for compo change)

formulation requires an update of the notification or not (includes the tolerance ranges)?	
Have you found a way to solve the speed issues iuclid has when working with larger databases (e.g. 1000 subsatances and 1000 mixtures)? At the moment the loading times are unbearable.	If you are facing technical issues, please write to ECHA's Contact form. From the question it is not clear whether the problem is in the IUCLID instance or in the submission portal. Thanks
Will dossier header be a part of dataset so you can transfer it easier in future?	There are no plans to allow copying of dossier header into other datasets as that is associated to a working context. You can send your requirement via Contact form including a business justification.
The issue is with iuclid: due to the database size it takes ages to complete a dataset for a PCN (long loading times). The issue has already been sent to you via contact form. Are you working on this?	If you have sent your question already, it will be replied as soon as possible. Thanks.
Could you please explain to us the difference of	Typical composition (IUCLID term) means exact composition. Otherwise you should provide a composition range according to the tables 1 or 2 in Annex VIII. There is no requirement about degree of purity

the terms range of composition, typical composition and degree of purity?	
When doing a PCN Notifications incl. MIM's with a UFI. You would notice the MIM UFI not being notified in the desired MS only at the end. Will there be options to notice this earlier in the process?	This information can be checked only upon submission as it is a comparison with wat has been submitted already to the central database
When we notify a product as MiM, not knowing the compositions because belongs to another company, do we need the exact tradename of the other company product we ferer to?	You need to indicate all of the known the information of the mixture in the Mixture in ixture (MiM) document, including it's tradename as supplied to you.
In case of products regulated by PPPR or BPR the mixture classification can be different depending on the member state evaluation.	Yes the same UFI can be used but different notifications required

What is the best approach for PCN? Same UFI across EU, but class diff	
Ceasing product from the market: if we only notify in one country do we indicate market, no country and previously the country where product is ceased?	In the dossier header, list of market areas remains as is: updates will be sent to all market areas regardless For each product information document, new list of market areas included to indicate that the product is ceased from one or more market areas
Would it be possible to cease in a single member state a batch/list of notified products at the same time?	Ceasing a product from the market is considered as an update of information contained in a notification - therefore this is done per product.