



## Questions and answers transcript

ECHA organised a webinar on 12 February 2020 on poison centre notifications. It gave an update on the latest and upcoming developments for notifying hazardous mixtures to poison centres. These include changes to Annex VIII and improvements to ECHA's IT tools and available support.

This is an unedited transcript of the questions and answers from the webinar and will not be updated. For the most up-to-date advice on poison centre notifications, refer to our <u>support material</u>.

Which are the specific differences between a notification update and new 'notification record'? when I do need to prepare an update and when a new notification?	A new notification is due when there is a significant change of composition requiring a new UFI. Please cfr section 4
What do you see as difference between compliance date and deadline?	1 Jan 2021 is a compliance date, as the notification requirements according to Annex VIII of CLP start applying then for new mixtures for consumer use. It is not a deadline; mixtures notified with the current system dont need to be re-notified until 2025.
What, in practice, is the difference between a "compliance date" and a deadline?	1 Jan 2021 is a compliance date, as the notification requirements according to Annex VIII of CLP start applying then for new mixtures for consumer use. It is not a deadline; mixtures notified with the current system dont need to be re-notified until 2025.
You said that the company can develop an own UFI Generator when they have a large product portfolio, can you give an indication on what you mean with a large product portfolio?	According to the needs of the company, in case a lot of UFIs need to be generated, then the company has the possibility integrate the UFI generator into its own system.
With the UK leaving the EU what impact will this have on the notification procedure if submitting from the UK - will the UK be able to access the portal to notify products which will goon the EU market?	After the transition period UK will be a third country. The obligation to notify will therefore fall on the importer in the EU country.

I would like to know if fertilizers and biostimulant are in or out of socpe of Article 45 please.	All mixtures not exempted by CLP, classified for physical and health hazard and placed on the market, fall under the scope of Art45. Specific exemptions are listed in Part a.2 of Annex VIII
I meant the solutions on slides 25, 26, 27. Will all three go through or will it be one of those?	All three
Romania and Bulgaria -there is no available information for submission yet. Is there a time-limit for this desicion?	Annex VIII of CLP starts applying on 1 Jan 2021 for consumer use in all EU countries. We compile information in the table by country as soon as we get it. The table is only for information purposes, there are no deadlines attached to it.
We manufacture/formulate products that we sell under private label. Are we or our customers the duty holders to notify?	Any hazardous mixture placed on market is subject for notification obligation
for mixture packed as aerosol, classified only as an aspiration hazard, need not be labelled for this hazard. There is a need for UFI generation and PCN notification?	Article 45 applies to mixtures which are classified for physical and health hazards. Therfore these mixtures fall under the scope
roducts are transported from our one LE to another (in different EEA countries but same parent company) only for further formulation. These products are placed on the market only after formulation. Does it still fall under definition of placing on market?	Article 45 notification obligations for industrial use mixture apply.
Who is responsible for the PCN notification, the toll formulator or the brand owner of a product?	As explained in the Guidance (available on the ECHA website), the toll formulator is duty holder under Article 45
in case of private label products: who is responsible for submission (manufacturer or private label customer)?	As explained in the Guidance (available on the ECHA website), the toll formulator is duty holder under Article 45
A 'manufacturer' producing a caustic soda solution 50% in a chloralkali process is not an importer or a downstream user. The water solution comes directly from his chemical process and water is a reagent in this process. Does he need to notify?	As long as the operator manufactures a substance (and doesn't formulate a mixture), there are no sumission obligations. Questions on specific cases can be submitted via the contact form
e are a parent company and have several LEs in EU (100% owned by parent company). Sometimes we transport products/intermediates from one LE to another (both LEs are in EU) for further formulation or finishing. Do we also need to notify these intermediates?	As long as you are placing the mixture on market, notification obligation apply.
when making an update of one notification, will we need to create a new UFI?	As stated in article 5 of Annex VIII, a new UFI hall be created when a change in the composition of the mixture or group of mixtures fulfils one or more of the conditions foreseen in points (a), (b) and (c) of the fourth indent of Section 4.1 of Part B.

As you do not market in EU, you do not have obligation to notify under article 45 of CLP.
At the moment it is not possible to indicate different UFI and suppliers. The ICG solution foreseen with the 2nd amendment may address your case
Because it is possible to submit voluntary submissions related to mixtures that are not classified.
Can you please specify to which three solutions you are referring to?
Can you please use our contact forms, and elaborate on your scenario? Thank you.
Change of composition, change of MiM, supplier change
Change of UFI, change of composition, Change of supplier
CLP regulation applies in the UK during the transition period. However, note that the first compliance date for poison centre notifications is on 1 Jan 2021 and we don't have information from UK authorities on accepting notifications before that.
Currently it is available only in the guided dossier preparation tool in IUCLID Cloud. In the future it will be available also in IUCLID standard view in the new WebUI. Currently, it is not foreseen its implementation in the IUCLID Classic interface.
Currently the picklists are available in English only
Currently you can provide a H catagory without H statement associated. However, be informed that in the next versions of the tool a validation rule will be implemented to make sure that for each H category a H statement is associated.

In the first submission we only include 2 countries. Can we include more countries in the same submission later?	Currently you cannot add new countries. We are working towards that direction to ease the submission process for industry.
How do we know that our submission/notification in PCN is accepted by the member states?	Currently, only Germany and Estonia are accepting notifications submitted via the portal. Portal submissions already made to other Member States should not be considered as fulfilling the notification obligations.
Are already valid notifications in current version of PCN portal?	Currently, only Germany and Estonia are accepting notifications submitted via the portal. Portal submissions already made to other Member States should not be considered as fulfilling the notification obligations. Contact the relevant Member States if you have any doubt.
We are formulating and manufacturing products under our client's brand. He is the distributor. We understand that we have to make the notification because we are the duty holder according to CLP definition. Which address must we indicate in the notification?	Details of the duty holders have to be provide as required by Part B.1.2. The amended Annex VIII provides the possibility to include an additional contact point
If we import or send a hazardous development sample (non-commercial), do we need to do PCN?	Do you mean a mixtures for R&D/PPORD - these mixtures are out of scope.
a formulator and a rebrander, who must send the transmission and put UFI on the label? only formulator or also rebrander?	Duty holder have obligation to notify and put UFI. Same UFI could be used in supply chain and notification can be done by formulator on behalf of other actor as long as composition remains same.
Is it foreseen to getting more apointed bodies from the member states into the online submision?	Each Member State can chose if and when start us
Is it foreseen to getting more apointed bodies from the member states into the online submision?	Each Member State can chose if and when start using the ECHA submission portal. Each MS can also decides how many bodies to appoint to receive the PCN notifications.
Can you repeat the name of profile on LinkedIn?	ECHA's poison centre notification group - Annex VIII to CLP
The company A is a toll manufacturer for many companies. The company A is the duty holder but the mixtures are placed on the market directly with the private label of the costumers. Should the Company A made all the notifications for all the mixtures	Either the duty holder, company A, can make the submissions for all these mixtures, or company A can make a contractual agreement with the distributor-relabeller/s and the latter can make the submission for those Member States they are placing on the market
What are the penalties/enforcements of non-compliance?	Enforcement is a responsibility of the Member states. You need to contact the relevant one for more information.

How ECHA will handle cases of non-hazardours mixture components for which we are not given EINECS or CAS numbers, e. g. polymers?	Even if numerical identifiers are the best option, the legal text allows you to identify the components also with other elements (e.g. international chemical name). Please refer to section B.3.2 of Annex VIII
Can the range of colours be extended with e.g. "cream"?	For 2020, changes to the PCN format picklists, including colour, are not foreseen. Please continue to provide your feedback for improvements!!
How to assign a reference substance from the registration dossier in the IUCLID Cloud?	For this you need to have the dataset (the editable version) corresponding to your registration dossier.
Germany has access to the portal but do the hospitals which are contracted for the emergency calls have this access too?	For ways of working in specific Member states, please contact the relevant one.
Are any member state which can already take the information from the submission portal?	Germany and Estonia accept notifications made through the ECHA Submission portal. Most of the rest of the countries will accept from 1 Jan 2021. We compile the information we receive from EU Member States in our website.
What are the proposed actions by ECHA if Annex VIII no longer applies to the UK after the end of the transition period (12/2020)?	Given the time constraints, we have limited our responses to questions within the scope of today's presentations. We kindly ask you to resubmit your question to our Helpdesk using the link below: https://echa.europa.eu/contact
slide 10,three options are listed. Kindly indicate the option that describes us, as we have subsidiary company based in EU(the duty holder). The UFI generation and notification in PCN format will be done by us-the headquarters(physically not in EU-same com	Good morning! The situation in which you describe would fit the first option.
When making a notification MiM and when pit all the compositionsdatas in the systemwhy does the system not uses all the ECHA database for each substances. Almost each substance with a CAS number is listed with all updated information.	I am not sure if I get your questions, nevertheless we are currently working on a solution to integrate the PCN IT tools with the ECHA substance list. The planned date to have the solution implemented is October 2020.
Mixture classified only as hazardous to the environment (does not need to be notified and does not have a UFI number) is a component of another mixture that must be notified. Do we have to list it as an ingredient? How can we do it?	Ideally, all components of a hazardous mixture need to be reported. The dossier preparation tools allows you to do this
During production most companies make mixtures of ingredients (and eventually keep them in stock for some time) which later on they use for making e.g. articles. Do such mixtures are require poison centre notification?	If any such mixture is marketed for consumer, professional or industry use. such hazardous mixture do require notification

Does cosmetics and medical devices in aerosol need to have the UFI code?	If these mixtures are in scope of Article 45/Annex VIII, yes, if they are not, then no.
For currently-sold hazardous mixtures, shall we do the notification to the member states or shall we wait so that we can make one notification to multiple member states?	If they are currently on the market, you may benefit from the transition period.
Did you receive my question? I've some problem with the app	If you do not receive an answer by the end of the webinar, please resend them through our contact form.
Can we mention more than one UFI in a single notification? (in the case we want to have 1 UFI/commercial reference) thank you	If you have created multiple UFIs for the same mixture, you can include all of them in one submission for this mixture.
If a multiple UFIs are used for the same mixture, do I need to create multiple dossiers and make multiple submission?	If you have created multiple UFIs for the same mixture, you can include all of them in one submission for this mixture.
If I'm doing the notification to the Spain Poison Centre, do I have until 2025 to do the submission to the ECHA? Or we don't have to?	If you have not placed on the market then it depends on the compliance date. Before the compliance date, follow national rules. After the compliance date, you can use the submission portal. Our understanding is that Spain will continue to operate their
If I'm doing the notification to the Spain Poison Centre, do I have until 2025 to do the submission to the ECHA?	If you have notified your mixture to the Spanish authorities before the Annex VIII compliance date, and there are no significant changes to your mixture, you can benefit from the transition period until 2025.
If I notify now by the ECHA portal, do I oblige to label with the UFI ? I must or I can ? you respons is not clear enough for me (sorry for that)	If you notify by ECHA portal, you must label with UFI as to compliance with Annex VIII.
What do you mean by dissenting view by 4 MS? What are the different interpretations?	If you refer to the relabellers/rebranders issue, the MSs listed in the note to the guidance do not share the majority's view. You will have to verify with them the obligations for these operators
If our mixture is used in an industrial setting by another company to create consumer use product, should our mixture follow the consumer use or industrial use compliance date?	If your mixture ends up in a consumer or professional use product, then you need to comply with the consumer/professional use compliance date
1- which adress should we inquire ? Our client's which is also on the label or ours ? 2- what VAT number should we use to generate the UFI code ? Our client's or ours ?	In addition, it is allowed to use the VAT of your distributor but arrangements and careful UFI management practices must be in place.

I was said that is sufficient to put the UFI on the outer-layer in case of multi-layer-packaging. Does is mean that the UFI can be on a folding box and it does not to be on the inner packaging?	In all cases it is required to have the UFI on the label or it is now possible to have it on the inner packaging. Only in cases where the size or shape is so that it is impossible to affix the UFI with the other label elements on an outer packaging.
Mixtures for consumer and professional use requires the UFI also in SDS? In which section?	In case of hazardous mixtures and the UFI in the SDS, the obligation lies only with mixtures that are unpackaged. The section would be 1.1 in the SDS.
How to assign a reference substance from the registration dossier in the IUCLID Cloud?	In case you have a reference substance in your inventory in your IUCLID database, you can select it in order to reuse it while preparing a PCN dossier. In the same way you can also reuse existing substances and mixtures.
If you formulate the same product in two different manufacturing locations in two different countries. Do you need to request two UFI codes with the two VAT numbers? And do you need to submit two Notifications for the different production locations?	In principle the same UFI can be used in different notifications as long as the composition is the same. The VAT is a mere element to create the UFI and assure te uniqueness. Notifications have to be submitted in each relevant MS
If I make a notification in the PCN for two Member States (Germany and Spain for example), is this notification valid in the future for Spain (knowing that they don't accept notification from PCN yet)?	In your example, the notification will not be considered fulfilling Spanish requirements as of today. However, the notification will be waiting in the system ready to be received by Spain once they connect and start accepting.
MIM: if the MIM is a perfume, the SDS contains more than 30 known substances. The work is huge to re-copy all the substances! Could you forsee a simplification?	Indeed according to the legal text the composition contained in the SDS has to be provided, unless you can use the UFI (previously notified). Simplifications can be discussed in other fora
For a notification for the same formulation in multiple countries can we enter our 'master' classification only? Sometimes the classification may differ in some member states. Would we need to to a separate notification in that case?	Indeed, you would need to make separate notifications
Is it possible to notify under the new process (Annex VIII) the mixtures addressed to industrial and professional workers? or only the mixtures for consumers are being accepted?	It all depends on the member state and their readiness to accept harmonised notifications before (and after) the compliance dates start
If a substance is dissolved in water to make a solution then this should not be considered to be a mixture. Please can you confirm this understanding.	It is considered as a mixture

Since the compliance date is Jan 1st, 2021 for Professional Use, will all MS be connected to receive the information via ECHA submission portal before Jan 1st, 2021?	It is hard to say at this point in time if all member states will be connected as we do not have info for each- please check the overview of member states document that was shown in the presentation for more. We update it as soon as we get learn more
Do I need to obbligatory update a notification if I market the same mixture with no changes but with a different volume?	It is ideal that a notification is kept up to date with all relevant information regardless of whether it is obligatory to update or not.
If a product is registered with same recipoe in EU countryA and EU coubtry " but obatined different classification, how can we notify them together?	It is not possible to do so in a single notification. You would need to make separate notifications.
when the same product is produced in different sites (with different legal entitities) can be covered by the same UFI and notifications?	It is possible to use the same UFI but each duty holder must make their own submission
Can a toll formulator use the VAT of the brand owner to generate the UFI?	It is possible, but arrangements need to be in place to ensure correct UFI management (no nuplication of UFI)
1- which adress should we inquire? Our client's which is also on the label or ours? 2- what VAT number should we use to generate the UFI code? Our client's or ours?	It is the duty holder's responsibility to provide all the relevent information. This includes also the generation of the UFI - of course the use of your own VAT number is preferable.
If a flavouring is sold for food use, and the purchaser decides to use it in a non-food application, who is responsible for notification - the purchaser or supplier?	It is the responsibility of the duty holder to gather as much as possible information on the mixture's uses. But also the distributor is responsible to be compliant with CLP (art 4(10)) and should provide the information or notify themselves
For a multiple country notification can we enter a representative pack size & type to cover all those countries or is it mandatory to enter the packaging specific to each country?	It is up to you. The format gives you the possibility to pursue both options. Poison Centres will receive the information both ways.
In case ONLY the trade name changes but composition- classification remain the same and notification is already done to various EU countries according to their current system, is it still possible to benefit from the transition period or we have to resubmit	It would not be possible to continue benefitting from the transition period. You can refer to Part B, section 4, Submission Update.
Thank you for your answer, so if I understand correcly, we need to notify the product because we are manufacturing the product BUT our client will also need to notify its product even if he doesn't make a change on it?	Mixtures for research and development are exempt

For flavourings, we have to check flavouring by flavouring if it is used in other application that in foodstuffs ? And If the flavouring is only used in foodstuffs, the flavouring is out of scope and no submission is required ?	Mixtures in the form of food and feeding stuffs, which are in the finished state, intended for the final user as indicated in Article 1(5) are exempted. If the mixture is used for different uses, it has to notified.
For organic mixtures, a pH is often not determined, because it's in comparison a negligible hazard. What are sufficient justifications besides "not applicable"?	More information will be available in the guidance soon
How does the submission of our notification get to the member states, that are not ready to receive the notification via the ECHA submission portal?	MS that have decided to accept notifications via the ECHA portal but are not connected yet, they still have time to do so until the first compliance date.
If a national Poiscon Center according to national law in a member state (MS) can require information on substances sold as such and not in mixtures, can this Poison Center ask for such data outside the scope of Annex VIII from a company in another MS?	National law is the competence of the different Member states. For further information, you should contact the relevant Member state.
Thank you for your answer, so if I understand correcly, we need to notify the product because we are manufacturing the product BUT our client will also need to notify its product even if he doesn't make a change on it?	No it will not be necessary for your client to make a notification - as long as the UFI refers to the correct composition.
Are you aware of on-going discussion for new change on compliance dates?	No, we are not aware of such discussions. The message from the European Commission is that the compliance dates will not change.
Are you going to be providing the picklists (phrases) in all applicable languages? Or just in English?	No immediate plans to translate them.
If notification is done in 4 countries, and we also want to sell in a fifth country, is it possible to include this fifth country in the notification? Or is a new one needed to include this fifth country?	Not yes but we are working on that
Is it possible to notify a non hazardous substance to benefit from using the UFI (not disclose the true id of this substance ) when a downstream user uses this substance in his hazardous mixture?	Note that notification is per mixture and the UFI should apply to a Mixture. Eventually it is technically possible but it would render the emergency response more difficult
if the formultor of mixture has a contract with his distributor saying that the distributor takes over the resposibility for the notification, is the formulator realy no longer responsible for the notification, sice the formul is technically a duty holder	Notification can be taken by other actors, upon agreement. However, every actor remains responsible to comply with all obligations under Article 45.
If the UFI is already displayed on the label but the MS is not yet ready to receive notification, is that compliant?	Our recommendation is to align as much as possible the UFI in the label with the notification in terms of timing.
If I'm doing the notification to the Spain Poison Centre, do I have until 2025 to do the submission to the ECHA? Or we don't have to?	own system in parallel with the Echa system

a formulator and a rebrander, who must send the transmission and put UFI on the label? only formulator or also rebrander?	Please consult Annex VIII guidance on overview of duty holder roles and notification obligation table.
What are the proposed actions by ECHA if Annex VIII no longer applies to the UK after the end of the transition period (12/2020)?	Please follow our dedicated webpage UK withdrawal from the EU, available on the ECHA website
is there any progress regarding notification language obligation update on Finland; seem to be only country where 2 languages are obligatory	Please get in touch with the Finnish authorities
Do I need to update a notification if the mixture classification does not change but the classification of one of the components changes?	Please refer to section 4 of Annex VIII, in result of new toxicological information on mixture or substance, an update would be necessary.
Is the webinar stopped? Idon't hear and see something	Presentations have finished. Now we are replying to the questions received.
If you have a PPORD mixture, is it exempt from notification to poison centers?	R&D and PPORD mixtures are out scope
What is the difference between the column Readiness of member state to accept notifications via ECHA sumbission system and Submission portal?	Readiness indicates when MS are connected to the ECHA portal. Submission portal refers to whether a MS will accept notifications via the ECHA portal or via the national submission systems or both.
Do we have to notify when we fill a product in smaller containers but use the same UFI and label components as the manufacturer?	Refilling is considered as downstream use. Therefore notification obligations apply
Which are the specific differences between an notification update and new 'notification record'? when I do need to prepare an update and when a new notification?	section 4 of Annex VIII
Please can you explain what you mean by Mixture In a Mixture or provide link to a source to explains this much better?	Several MiMs (Mixture in mixture) can be incorporated into a final mixture. A MiM is therefore one of the components of a mixture. Please refer to the Guidance, as well as the Steps for industry section on the ECHA poison centre website
Will the June 2020 IUCLID cloud updates include the second amendment changes?	Some of the changes introduced by the second amendment might require format changes which can be introduced only in the October release of IUCLID.
where can we find guidance to distinguish between professional and industrial use	Indeed there is no guidance available, other than a mixture for consumer use is intended to be used by consumers, similarly for professional use mixtures. A mixture for industrial use means a mixture intended to be

At first, Thank you for your work! could you please made a timetable avaiable, where one can easyl find when, which change is to be expected, e.g. IUCLD, LEGAL, Business rules, Gudiance, PCN format,	Thank you for your feedback. Please consult our support material and the poison centre website where we post news on current regulatory and IT developments. You can also join ECHA's groups in LinkedIn, for poison centres and IUCLID for current updates.
What is the reason behind choosing the Marketing Placement on Mixture info level as well as on the Product Information level? If a country is "forgotten", the message only appears during the validation. One field for Market Placement should be sufficient.	Thank you for your observation, we take that in to account for the next development phase.
Practically I am using the VAT and company ID and UUID of our subsidiary EU based company, correct? Also I can add as contact point my ID(NOT in EU) to the submitter(in EU)?	Thank you for your question, ECHA would need to conduct further analysis on your request. We kindly ask you to resubmit this question to our Helpdesk using the link below so that a proper evaluation can take place: https://echa.europa.eu/contact
Hello, thanks! Will there be a Webinar on how to make a notification step by step on the PCN system. That would be helpful!	Thank you for your suggestion! We are planning and hands-on training as part of the ECHA Conference in June. We will see how to make it available online as well. Stay tuned!
substances to mixtures? Without the need to connect it to reference substances? It would be useful if a user could simply type in CAS/EC number and the system would automatically match names and other relevant data that ar already availabl at ECHA web.	Thanks for the suggestion. We are currently working on a solution to address your requirement. The planned date to have the solution implemented is October 2020.
Is it possible that the portal would enable easier adding substances to mixtures? Without the need to connect it to reference substances? It would be useful if a user could simply type in CAS/EC number and the system would automatically match names etc	Thanks for the suggestion. We are currently working on a solution to address your requirement. The planned date to have the solution implemented is October 2020.
Can you please add in your picklist of packaging ? Cartrige, sausage. thank you	Thanks for the suggestion. We will consider your requirement and prioritise it accordingly with the other requirements on the scope.
In my previous Q you said that the documentation updated in October 2019 is live in the current IT implementation. If that's the case, why are the H360 and H361 D/F/d/f variants in the picklist on the ECHA website but not in the ECHA tool?	Thanks for your comment. We'll check the documentation and investigate further.
In case that a MIM only has in the MSDS the trade name as information shall this MSDS be attached to the PCN dossier, since no information of the components are available?	The attachment of the SDS does not replace the obligations with regards of the MiM's identification

are there any simplifications for small containers e.g. < 125 ml (concerning UFI)?	The CLP provides the specifications for small containers, please refer to the Guidance on labelling and packaging
It is to late to provide the new version in October 2020 considering the second amendmend of Annexe XIII because the software providers will change its software only after this new version. When shall duty holder notify big numbers of products?	The compliance dates will not change. The IT tools have been in place since April 2019. The current version doesn't prevent you from complying, although future versions might ease the task by implementing the latest amendment (still under discussion).
a formulator and a rebrander, who must send the transmission and put UFI on the label? only formulator or also rebrander?	The duty holder is the rebrander that places the product on the market. The notification has to be made by the rebrander. If the formulator wants to keep the mixture information confidential, it can submit a voluntary notification.and provide UFI to the rebrander
Will there also be a public consultation as for the 1st amendment?	The European Commission has consulted stakeholders for the second amendment, as it did for the first one. They are now compiling the feedback. The proposal will then be discussed with Member States.
if a formulator and a distributor agree that in a member state the PCN is submitted by the distributor, is the formulator compliant with CLP Annex VIII obligations ?	The formulator is the duty holder, but if they have a contractual agreement with the distributor that the latter will make a submission in a certain Member state, the formulator has complied with their CLP Annex VIII obligation.
I apologize, but I had to leave the call and enter again for a technical trouble, and I guess I lost the answers to my questions	The formulator is the duty holder, but if they have a contractual agreement with the distributor that the latter will make a submission in a certain Member state, the formulator has complied with their CLP Annex VIII obligation.
If you change the branding of a product but do not change its composition. Would this involve a new notification, notification update, or no implications?	The information should be ideally included in the notification of the supplier (duty holder). Rebrander is a distributor and not a duty holder under art45, but has to make sure this information is submitted (possibly by himself)
Concerning colours of mixtures, how will we have to give them for differently coloured mixtures in a group submission? Is there a possibility to indicate "coloured" instead of giving all possible colours?	The legal text includes the possibility to use the Generic Product Identifier Colouring agents" for components used exclusively to add colour (if Annex VIII, B.3.2.3 conditions apply)"
If a MIM is not classified and does not contain a hazardous component, can this MIM then just notified as "NON HAZARDOUS" ingredient, because it has no impact on the classification of the finished product?	The MiM will have to be identified with product identifier and supplier's details (if the full composition is not available)

Morning Team. October 2019 saw the various ECHA documentation on the PCN format updated (Part A, Picklists, structure etc). When will v2.0 of the phrases/picklists be live in ECHA's systems? Thanks in advance.	The most up to date documentation about the format can be found on the Poison Centres website (https://poisoncentres.echa.europa.eu/poisoncentres-notification-format). Furthermore, the documentation available reflects the current IT implementation.
Morning Team. October 2019 saw the various ECHA documentation on the PCN format updated (Part A, Picklists, structure etc). When will v2.0 of the phrases/picklists be live in ECHA's systems? Thanks in advance.	The most up to date documentation about the format can be found on the Poison Centres website (https://poisoncentres.echa.europa.eu/poisoncentres-notification-format). Furthermore, the documentation available reflects the current IT implementation.
We produce hazardous mixtures in Belgium, which are stored in a third party warehouse in the Netherlands, before it is exported out of the EU. The mixtures themselves are not used in the EU. Do we have to notify, and if yes: In which countries?	The notification obligation are made in EU countries, where you place your mixture for marketing to consumers, professionals or to industry. If You dont market in EU, then you are not obliged to notify in EU.
If Company A sells their mixture only to Company B (second formulator) who then sells final product to all member states, does Company A need to submit their notification in all member states, or is it enough to submit in Company B country?	The notification obligations are for duty holders, it could be a contractual agreement between companies on notification but its the always duty holders, who are responsible for notification in relevant MS.
If building our own XML generator, how can we test that our format is correct - is there a dummy QA ECHA account to which we can submit the files generated to test the structure/content?	The recommend approach to, initially, test i6z files created on your own is to import them into a IUCLID local installation or import the i6z file on your own ECHA Cloud IUCLID instance.
Whom we need to mention as the supplier, the manufacturer of the MIM as mentioned in the MSDS or ths company which is selling us the MIM?	The regulation requires the MiM's supplier's details
IUCLID Format update: When the technical documentation about updated PCN format (v3?) will be available on ECHA website (i.e. the update reflecting 1 amendment of Annex VIII, including for example the field for reasons for pH not available)?	The relevant changes will be introduced in the release of IUCLID scheduled for the end of October 2020. We expect to be able to share a draft v3 of the format in June and a final version in September.
If we need to change the SDS due to a new ghs classification of a ingredient but the classification of our product doesn't change. do we need to submit the updated SDS?	The SDS is not an information requirement. But if new toxicological information becomes available on the mixture or its components, then you would need to update a notification
If we need to change the SDS due to a new ghs classification of a ingredient but the classification of our product doesn't change. do we need to submit the updated SDS?	The SDS is not an information requirement. But if new toxicological information becomes available on the mixture or its components, then you would need to update a notification

If we need to change the SDS due to a new ghs classification of a ingredient but the classification of our product doesn't change. do we need to submit the updated SDS?	The SDS is not an information requirement. But if new toxicological information becomes available on the mixture or its components, then you would need to update a notification
Supplier details is included in MiM SDS, why we have to copy also the addres etc details?	The SDS itesIf is not part of the information required.
Question about IUCLID cloud data limitation: do you mean data size of 1 notification dossier or all dossiers together?	The size limit of a IUCLID Cloud instance is 1GB for all notifications. Usually, a single notification takes less than 1MB.
if we see changes in summer, the time left to comply is very short	The timeline for the second amendment was set by the Commission.
QLT506 in ECHA validation rules-there is the limited flexibility of reporting mixture ingredient sum of no less than 91% correct?	The total concentration of the mixture must be > 90%. If the reported concentration is lower than 90 %, the notifier is warned that the full composition is currently not included.
Repeating my questions send on 10:01: If a notification has been submitted in a member state by a distributor, will the transitional time apply to the formulator in such member state? thank you	The transition period applies for the mixture, if no significant changes occur during this time. Please note that the contact point details for further information on emergency health response must be valid at all times.
Does the UFI need to go on the MSDS for consumer and professional use products?	The UFI has to be included in the SDS only in case of unpackaged mixtures or as an alternative to the label in case of mixtures used at industrial sites. In other cases is voluntary
So UFi of a Professional7consumer product has not to be included in Section 1 of SDS, right?	The UFI has to be included in the SDS only in case of unpackaged mixtures or as an alternative to the label in case of mixtures used at industrial sites. In other cases is voluntary
Which places on the label/package are not allowed to print or affix UFI? Is allowed to affix or print UFI on the bottom of the can?	The UFI should be normally included in the label. The legal text allows some flexibility and the UFI could be placed outside, but always in proximity to the other label elements
Is it required the VAT numberto create UFI or it is optional?	The use of VAT number is not mandatory. As you can see on the UFI generator, you can choose to generate a UFI without VAT.
Is it required the VAT number to create UFI or it is optional?	The use of VAT number is not mandatory. As you can see on the UFI generator, you can choose to generate a UFI without VAT.
The UFI can only be generated by the online ECHA tool? Or it can be generated differently?	There are two ways of generating UFIs: using the UFI generator or encoding the UFI algorithm on a third party tool. The UFI alghoritm is free and available on Poison Centres website (https://poisoncentres.echa.europa.eu/ufi-generator).

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Is there a system in place to make sure that no duplicated UFI codes can exist for mixtures of different composition in the Poision centre database? If by accident duplicated UFI codes are submitted for different mixtures, what is the process to solve it.	There are validation rules checking what you are describing. Please refer to the list of PCN rules published here: //poisoncentres.echa.europa.eu/documents/22284544/28470089/PCN+F ormat+-+Annex+-+Validation+rules_v2.pdf/7eb924bd-234c-4bfd-4079-6f8be198b0d7
Do all downstream users/importers of a non-EU supplier have to submit a PCN? (no OR system in place?)	There is no OR system in place in Annex VIII. Under this legislation they are the duty holder. There are work around solutions in place though - check our Guidance on Annex VIII for more details.
My question on Animal Premix sector. Would 2nd Ammendment cover a creation of a new GPI for non-hazardous premixture components (which could make up 50% of the product).	There is no plan to create new Generic Product Identifiers in addition to the existing two
Can I notify on behalf of my private label customers on my notification or do they need to do it on their own?	They are duty holders so the notification has to be done by them. You cannot include them in your notification. Alternatively, you can do a voluntary submission, notify a UFI and then provide that UFI to your customer who will be able to submit itself.
where are the 23 guidance translations?	They are published in our poison centre website, along with the English version.
When will the recording be available?	They will be available as soon as the event ends.
UFI positioning, would it possible to place the UFI on the lid of say for instance a paint can?	This issue is related to the CLP Annex VIII second amendment and is under discussion
EU importer to another MS and completes a notification according to Annex VIII, in the event that the UK will no longer follow Annex VIII post 12/2020, will the notification remain compliant? Or will it need to be updated to change the submitter details?	This question is rather for the UK authorities, as it depends on their legislation after the transition period.
What happens if compliance date is not followed?	This woud be a matter of enforcement. Enforcement actions are carried out by the authorities of each EU Member State.
The toll manufatcurer can't include the name written on the label (in a case of private label): this is not a relevant information, that's right? Is it enough to include the trade name?	Trade name(s) has to be provided as they appear on the label. This is relevant infromation for the identification of the product in case of accident.

Hi, if we have made PCN notification in one country but we now want to sell it to another country within EMEA, do we benefit from the 1 Jan 2025 date instead of 2021?	transition period applies to all notification done before compliance date
a rebrander, on his product label, must insert his Ufi or that of the supplier?	UFI is linked to certain chemical composition, same UFI could be used in supply chain, if chemical composition does not change. However different UFI could also be used in different characters in supply chain.
We have a palett with 40 cement bags. The palett is covered by a shrinkage foile as outer packaging. Is it sufficient to plave the UFI only on the foile than on every bag?	UFI is part of the supplemental labelling information. Normal labelling rules apply. Annex VIII allows including the UFI on the inner packaging only and not n every layer. For question on specific cases, please submit the question via the contact form
ation of the final mixture is always the same. Can we do the same thing with the notification on PCN? Can we have a single UFI for a product which it contains, alternately, different components with the same CAS, composition and different classification?	Unfortunately we didn't get the whole sentence, thus could you please get in touch with us via the ECHA contact form
When will we have news about the member state that are not agree with relabeller treatement (letter in the guidance version 2)	Unfortunately you will have to inquiry with the dissenting MSs. ECHA will continue striving for agreement and consensus in relevant fora (e.g. Guidance update).
Good morning, Are UK company allowed to notify their products? Will the existing notifications remain valid after the Brexit transitional period?	Until the end of the year, CLP applies in UK. After the end of the transitional period you will have to comply with UK rules
Germany only accepts the notification (Annex VIII) through ECHA's submission portal and France is not connected yet. If product containing the UFI on the label is sold in both Germany and France, would France be okay seeing the UFI on the label?	We advise you to submit this question to the French authorities.
Often, same recipe is clasified differently between EU countries. So this oblies to prepare separate notifications. Does ECHA knows this no armonized situation that implies more burden work to notify please?	We are aware of your concerns and extra burdens
Will there be a workshop organised as in 2018?	We are planning a hands-on training during the ECHA Conference in June. Details will be announced in our website soon.
Are aqueous solutions of (for example NaCl fully dissolved in water) a solution or a mixture?	We believe that definitons of substance and mixture remain the same. A solution is a mixture
Standard Formulas, if implemented for specific sectors, must be $100\%$ of the submitted formula or, e.g. a composition could include a SF $+$ % of other components? Thank you.	We believe the full compositon will have to comply with the Standard, but it cannot be confirmed at the moment since the solution is still under discussion

We can not promise but we hope so for training on such
We compile information on whether national fees apply or not in a document in our website (https://poisoncentres.echa.europa.eu/documents/22284544/27487986/msd_en.pdf/982d9115-58cb-75c8-80ae-8eb16f5c0009).
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When all Member state decisions will be taken? When is expected to publish the final version of the document in which the decisions of all member states are indicated?	We compile this information from EU countries in our website as soon as we receive it from them. If you need further information from a specific country, we advise you to contact them directly.
Do all downstream users/importers of a non-EU supplier have to submit a PCN? (no OR system in place?)	We confirm there is no OR in CLP
How do we know that our submission/notification in PCN is accepted by the member states?	We encourage you to make contact with the relevant Member States if you have any doubt.
Are already valid notifications in current version of PCN portal?	We encourage you to make contact with the relevant Member States if you have any doubt.
Dear, thanks for this webinar. Will "BR556 Total concentration of the mixture is too low (below 70 %). If the reported concentration is lower than 70 %, the dossier cannot be accepted." be kept as Business Rule failure?	We have currently no plans to change BR556.
Slide 22-MiM:If we know all components, than we dont need to demand the UFI code from the MiM supplier?(some suppliers may not plan on generating UFI).	We kindly ask you to wait for the presentation. Later we can answer the questions, which are not clarified in presentation. Thanks you for patience.
Slide 22- kindly clarify 'Fragrances as a GPI is removed'.	We kindly ask you to wait for the presentation. Later we can answer the questions, which are not clarified in presentation. Thanks you for patience.
Is it allowed to print the UFI in SDS already from now on before a notification has done ?	We recommend to include the UFI (in particular on labels) when a Annex VIII notification is done to avoid confusion and misleading customer. If this has to be done, it shuld be done as close as possible to the time of the notification
Is it foreseen to getting more apointed bodies from the member states into the online submision?	We register the available information on the PCN website and on the following table: https://poisoncentres.echa.europa.eu/documents/22284544/27487986/msd_en.pdf/982d9115-58cb-75c8-80ae-8eb16f5c0009
I missed the answer: refill pouche (UFI 1) is sold for use in original bottle (UFI 1dilute) after dilution with 3 parts of water. Refill formula change will require new UFI2. How consumers could be made aware of new of in-use concentration UFI 2dilute?	We requested to submit the question via the contact form as it is not fully clear
If a substance is manufactured in an aqueous medium and remains in solution as the product placed on the market, then this would not be a mixture. Please confirm this understanding.	We understand it is a mixture and should be notified

If a substance is manufactured (and completely dissolved) as in an aqueous solution (and sold as an aqueous solution) is this a susbtance or a mxiture	We understand that a solution is a mixture.
When will there be an update in the member state overview, because there are still 7 countries that didn't provide any feedback yet?	We update the overview table as soon as we receive information from the national Authorities
What if my question is not answered by the end of the webinar?	We will answer as many as possible until 13. There are currently so many questions and so little time left that many will be left unanswered. If you dont get a reply, send your question to https://echa.europa.eu/contact.
Is there any backward compatibility support with regards to the PCN formst or should we always use the latest available PCN format to validate and submit a dossier?	We would recommend to always use the latest version of (IUCLID) PCN format to validate the dossier in order to have the up to date validation requirements. However ECHA Submission Portal accepts also dossiers made with all i6z formats.
You said that notification obligations apply, if we place mixtures on the market to consumers, professionals or industry. A warehouse is non of these three options. So how can we be obligated to notify, then?	Well there is possibility of exposure/ accident as you are storing in some others ware house, so you have to notify. If you store in your own ware house, then you do not need to notify.
if the formultor of mixture has a contract with his distributor saying that the distributor takes over the resposibility for the notification, is the formulator realy no longer responsible for the notification, sice the formul is technically a duty holder	Well, formulator being the duty holder is responsible and must assure that notification is submitted in relevant MS, where the mixture is placed in market.
We are a non-EU manufacturer. As there is no OR, we would do voluntary notifications via third party to 27 member states. However, each member state importer would need to notify again themselves even though we have done voluntary notification. Correct?	Well, if you are some other company could do notification on behalf of your importers, then they do not have to notify again. But they are sole responsible for the correctness of information.
There are a limit of submissions that can be made online and saved on IUCLID cloudl?	When you use the IUCLID Cloud services provided by ECHA, there is a limit of 1 GB for the database. This corresponds to hundreds of PCN notifications. You can monitor the Cloud usage from the top bar of your IUCLID Cloud instance.
What is the definition of a 'bespoke' paint colour? Does this simply mean a colour which is mixed on demand at the request of the consumer?	Yes indeed, this is the intended meaning.
MIM identification question: will it be possible to notify BOTH the UFI of the MIM and known components+supplier info together?	Yes the dossier preparation tools will allow you to add the supplier details along with the UFI and the known components

Can a toll formulator use the VAT of the brand owner to generate the UFI?	Yes this is possible, however it should be arranged with both parties to ensure that correct UFI management (i.e. to avoid UFI duplication) occurs.
So mixture that have been already notified according to article 45 to National appointed bodies does not need an harmonised notification until 2025 ?	Yes until any change happens to mixture
Undertood that as VAT is not intended to identity the submitter but to avoid UFIs duplications, a mather company can use its VAT to create UFIs for all its affiliated companies. Can you kindly confirm?	Yes, a mother company can use its VAT to create UFIs for all its affiliated companies.
• If the pH of my product changes, should I update or make a new notification?	Yes, as composition is changing
Is it possible to have two products on the market on the same time, with same name, different UFI because of different item numbers and same classification?	Yes, as long as each product bears the correct UFI i.e. that corresponds to the right mixture composition.
Hi, if we have made PCN notification in one country but we now want to sell it to another country within EMEA, do we benefit from the 1 Jan 2025 date instead of 2021?	Yes, but you have also to made notification in that another country tooo
Can I notify with Annex VIII for Estonia and Germany and the rest of member states with MS requirements? I will benefit from the transitional period for the rest of member states, right?	Yes, correct. But for the rest of the countries you cannot use the ECHA Submission portal, but the national systems.
Will more information become available on how to use the interchangeable components?	Yes, currently the Commission is working on the solutions and we will provide guidance when we have the finalised amendment
Would you confirm for a mixture commercialized on certain EU markets, and notified there nationally, if it is introduced after Jan 2021 to additional EU markets, this will require a notification through ECHA portal?	Yes, for more information, you can consult overview of Member States decision table. The table is available on poison center website and is updated as new information arrives.
Hi, It was presented that adaptations to IUCLID cloud are expected in Oct 2020 due to 2nd amendment to Annex VIII. Will there also be adaptations to system-to-system at that time?	Yes, if needed we will do adapations to S2S. Of course we will update the documentation if needed
But currently the Guidance says that notification obligations would apply, if a hazardous mixture is stored in a third party warehouse, before it is being exported outside of the EU.	Yes, if you store in 3rd party warehouse, then you have to notify in that country such as Netherlands in your case.
Is the System-to-systme service still aviable for testing purposes (dummy submissions) ? in this this case until which date ?	Yes, testing is part of the S2S service. You will always be able to test S2S API call's before using them with real data.
If the S2S tool is working, does the user still have to link (manually) with the reference substances of the ECHA database?	Yes, the S2S user still has to provide the reference substance information manually.
any plan to provide translations for EuPCS product categories for the intended use?	Yes, there are - more information will be made available in the near future

Private labels: in case 2 notifications need to be done, for each UFI, can we duplicate the file and modify only the fields trade name, UFI,?	Yes, this is possible
aving a EU common format for submission, the Member States that keep their national submission system will have also to consider/accommodate in their notification forms UFIs, EuPCS and further new requirements of Annex VIII?	Yes, this is the main aim of Annex VIII of CLP: harmonising the information to be notified across the EU.
If we are notifying a hazardous mixture now, we do not need to have the UFI in labels and/or SDS until 2025 providing there is no change, is this correct?	Yes, until there is no change in mixture composition
will there be a live training again on IT tools like last year ?	Yes, we are planning a hands-on training during the ECHA Conference in June. Details will be announced in our website soon :)
In mixtures that are colored, and the colorant is not hazardous below 1% or hazardous below 0.1%(irrelevant for emergency) I can prepare a dossier without indicating the colorant at all correct?	Yes, we confirm (as per Annex VIII, B.3.3)
how and when we can test S2S service? we have already recevied the ok from ECHA and have access to S2S button. it there any manual for the testing?	Yes, we do offer a document which explains the S2S API, https://poisoncentres.echa.europa.eu/documents/22284544/22284907/s 2s-submission-swagger.json/f1480df2-4b8d-c1a8-d0fa-6abf25663077
Thank you for the answer, please be aware that for implementation in external software system (and subsequent S2S integration) it is necessary to have the updated PCN format documentation as soon as available.	Yes, we understand. We will update the documentation on time.
Nowadays only Germany and Estonian are accepting notifications via ECHA Portal?	Yes, you are correct. We compile this information from each EU country in our website . Most of them indicated they will accept only from 1 Jan 2021 (first compliance date)
Is the VAT number just useful to create the UFI number ? (for exemple if we produce the same mixture for 2 differents brands (2 compagnies), can we use the VAT number of each compagny (even if they are not the responsible person) ?	Yes, you can use the VAT number of each company. Please cfr the UFI user guide on https://poisoncentres.echa.europa.eu/documents/22284544/22295820/u fi_user_guide_en.pdf/71d273a7-0bae-4a46-96bc-639e8fd23b0e
• If the UFI of a product changes, when do I need to prepare a new notification?	Yes. As the UFI change and before placing in market.
If I notify now by the ECHA portal, do I oblige to label with the UFI ?	Yes. In this case as you notify by ECHA portal. You can label with UFI

If we intend to submit a notifiaction to the ECHA portal to a Member state not ready to accet notificiation to ECHA, will this member state be able to consult this notification later (once it will be ready?)	Yes. notifications done via the ECHA portal are already made available to MS. They will be accessible to MS once they are ready to connect. However, check with the national HD if those notifications will be considered as accepted" by the MS."
We want to import a mixture containing only confidential ingredients, so we don't disclose any of the CAS# nor the EC#. How can those ingredients enter in the ECHA Portal without refer to CAS# nor the EC#?	You can contact our helpdesk and we will answer you in details by consulting our experts on this.
where can we fin	You can find all available guidance documents on ECHA webpage at: https://echa.europa.eu/guidance-documents/guidance-on-clp
Where can we get information about the fees of member states?	You can get them from the relevant Member state.
Toll manufacturing: some clients may want their own UFI, so as not to be traced by the UFI decryptor. Does that mean that we will have to make 2 declarations?	You can include multiple UFIs in the same submission
I intend to roll out a product across EU markets in a 6 month period. Am I allowed to notify all EU MS with the submssion due to the first ciuntry of launch?	You can notify, in all MS , where you want to place your mixture in market.
Are these interesting Q&A questions ans answered being available after this event finalises. Thanks a lot.	You can save the Q&A from the file, save as menu in Webex. We will also publish a cleaned up version on the webinar page at a later stage.
When will the Q&A be available?	You can save the Q&A from the file, save as menu in Webex. We will also publish a cleaned up version on the webinar page at a later stage.
Yesterday I notified at national letter a product indicating the UFI. When I am oblied to put UFI in the lable? IN jannuary 2021 or now? It is a professional insecticide	You have to follow national requirments and follow national legislation before date of compliance.
In case of a two components product. Each part need a UFI code. But if a part is not classified and other part is classified. I need one or two UFI ? Thank you in advance	You need to assign a UFI (and fulfil all Annex VIII obligations) only to mixture classified for phsical and health hazards (and placed on the market)
regarding pH and solution conc. for viscous liquids is there one cocn. required or it varies?	You should indicate the concentration of the solution tested, to which the measurement was done
In case of trade product bought from a supplier outside Europe. What about if he does not give us the formula and his EU legal representative does not want to do a voluntary submission. We can not do our submission.	You will have to obtain some information. Eventually at least the SDS. Other REACH and CLP obligations apply

After the transition period, do we have to completely re-submit mixtures that were registered through the national system? Or will there be a way to import data?	You will need to notify according to the new requirements before the transition period ends.
If a multiple UFIs are used for the same mixture, we can realise one submission for the mixture. But if precautions statement are different (professional / general public), can we realise only one submission?	You would need to make separate submissions