

Webinar: Poison centres: closing in on the first compliance date Questions and answers

ECHA organised a webinar on 4 November 2020 on <u>Poison centres: closing on the first compliance date</u>. It explained the scope and main requirements of second amendment of Annex VIII to the CLP Regulation.

This document compiles the questions and answers from the webinar. Minor editorial changes have been made to correct spelling mistakes and similar questions have been combined into one. The document will not be updated.

For the most up-to-date advice on Article 45 and Annex VIII to the CLP Regulation, refer to our <u>support material</u>, or if in doubt about any of the answers covered in the webinar contact us.

Question	Answer
Some countries do not accept English in the PCN but we do not have the requested language. What do you recommend?	Some Member States accept the PCN notification in English language. For more details please see: https://poisoncentres.echa.europa.eu/documents/22284544/27487986/msd_en.pdf. If the Member State does not accept English the information provided in the notification has to be translated to the national(s) languages of the receiving Member State.
What level of detail must be achieved to identify the name of the non-hazardous polymers to be notified?	The legal text states the requirement, which is quite flexible: "The product identifier for the substances identified according to Section 3.3 shall be provided in accordance with Article 18(2). However, an INCI name, a colour index name or another international chemical name may be used, provided the chemical name is well-known and unambiguously defines the substance identity. The chemical name of substances for which an alternative chemical name has been allowed in accordance with Article 24 shall be provided as well".
We have some products on the markets in some EU countries. They all have UFI numbers on their labels,	The UFI should be included on the label only when a notification is submitted (and the MS is accepting it). A notification should at least shortly follow the inclusion of the UFI on the label

but are NOT submitted to national registers of the appointed bodies. How does this 01.01.2021.deadline refer to those products? 'Empty' UFI of MiM from supplier. How I can check if my supplier of MiM really made a submission and if included the markets where my finally mixture is placed on markets/ countries? "Duty holder can start placing the mixture on the market only after confirmation in the submission There is no check you can do as such. However, when you make a submission in the ECHA portal, you will receive a warning if the UFI used to identify the MiM is not in the database - this could mean that indeed the UFI has not been notified in the portal but it is possible that it could have been notified using the national systems. You will need to check with the supplier. Your understanding is correct. The fact that the dossier has been submitted does not necessarily imply that it has been accepted.
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market only after confirmation in the submission has been accepted.
report that the dossier has been received by the MS
appointed body": does it means that I still have to
check directly with that Member state that the
dossier is "ACCEPTED" (not only received), right?
A company has a mixture in 6 different countries, We understand this can be the case for biocidal and plant protection products. As these different classifications
however the classification of the mixture is different are based on the national authorisations for the products, you need to include in each notification only those
in each country (sometimes the H and P phrases relevant for the specific Member State. In conclusion: yes, you need to make one notification per Member State.
differ, depending on evaluation). Can this company
make only one notification for this mix or does it have
to do the notification for each country?
A producer of e.g. detergents are selling to private The toll formulator is the duty holder. This is addressed in the Guidance on Annex VIII.
label companies who will put them on the market. Is
the producer or the private label supplier the LE?
a UK legal entity can submit to ECHA portal for UK is not an exception. From 1 January UK account holders will not be allowed to submit Annex VIII notifications
example a notification for France?(you said that non-
EU legal entities cannot submit but I didn't
understand if UK is an exception or not). Is Northern
Ireland different than the rest of UK?
About SF: If a MIM contained in my formula conforms In case your mixture contains a MiM that is a SF, only the MiM component has to be flagged as SF component.
with a SF: I must flag as "standard formula The SF name must be inserted in the final mixture.
component" both the MIM itself and also all the MIM
components, correct? In this case, the standard
formula name (cement) must be inserted only at
MIM level , not at final mixture level, correct? Thanks
After IUCLID OCT improvement we are having error Your question requires some further analysis. Could you send it to the ECHA Contact form please? As the rule
on disclosure part for main hazardous components. refers to concentration ranges, you could provide more information on the way you have assembled your
BR518 and we don't understand the reason for composition.
that.validated in IUCLID 6.4 standalone but failed in

submission. RMH554601-22 trial submission.if needed	
we'll send also via echa format question	
An industrial company sells bespoke paints in small	The exemption applies to bespoke paints formulated at the point of sales on demand for an individual consumer
amounts via online shop to consumers and	or professional user. Online sales do not fulfil these conditions. The issue is under discussion with the expert
professional users. Can the company benefit from	group working on the Guidance update and will be clarified in the next version.
exemption for PCN notification for bespoke paints?	
Are feed included in this Regulation and this topic?	Article 1 clarifies which mixtures are outside the scope of the CLP Regulation as a whole. It includes food and
	feeding stuff mixtures in the finished state, intended for the final user.
Are importers and formulators who use mixtures in	If the end use is outside the scope of Article 45 or Annex VIII, this use does not need to be taken into
industrial settings only and (further down the supply	consideration.
chain) are intended for final use in food, exempt from	
Annex XIII?	
Are the existing UFI expiring by end of the year?	If you have already notified a UFI, that same UFI remains valid. UFI have no expiration date.
Are the validation rules also implemented in the TEST	Yes, they are.
submission portal?	
Are these interesting Q&A questions and answered	There will be a summary of today's Q&A published on the webinar's page - https://echa.europa.eu/-/poison-
being available after this event finalises. Thanks a lot.	centres-closing-in-on-the-first-compliance-date. Follow our newsletter and social media channels to get notified
	when the document will be online.
As a head quarter function we will submit dossiers on	A Legal Entity has to be associated to each substance for technical (IUCLID related) reasons. But the information
behalf of all our subsidiaries. When creating	is not checked and it can be the same.
substance in IUCLID Cloud, must the substances be	
created in each legal entity? If you need the same	
substances in another legal entity they get the first	
legal entity name in the substance dossier after	
copying. Do we need to change that legal entity?	
As a third party or service provider, we send the PCN	Yes, each customer/company would need their own ECHA account. You would have to create for each of your
by S2S for our customers. Do we have to create a	customers an account or ask your customer to create an ECHA account themselves. The S2S access request - you
login for each customer/company or is it sufficient to	can bundle and send us a list with all ECHA accounts you would like to have access to. Please also explain who
use the customers UUID or S2S Key if the customer	you are and how you validate that the company is legitimate on your side.
has already an account.	
As the deadline is around the holiday period and we	ECHA Submission portal will be open for submissions during the end-of-year period.
have noticed that sometimes around that time the	
ECHA portals are down for maintenance. Is there	
already known if this will be also the case for this	
year? will this affect the notifications and deadline?	
Atm not all MS accept ECHA PCN. But 2021 it is	You have to contact the MS of your interest to understand their specific approach. You can find their contact
mandatory. Is it sure that all MS will accept ECHA PCN	details collected in our website at: https://poisoncentres.echa.europa.eu/appointed-bodies

or do we have to notify nationally again?	
·	We confirm that the Member States! Appointed Dedies are in verticus states of the authorities are asset that
Is it known which MSs will be ready on time? Contacting all MSs not ready will be a lot of work. If	We confirm that the Member States' Appointed Bodies are in various stages of the onboarding process and that they aim to be ready by January 1 2021. Please remember that this date is not a deadline - before this date
,	
every individual company has to do this it will be an	national obligations apply, and after this date, harmonised reporting is required.
overload for these MSs, while they can better use the	We also see the defendant of the latest and the Member Control Constraints and the latest and see the
time to get ready rather than answering why they are	We also confirm the information contained in the Member States' Overview document is the latest and most up
not ready.	to date information as provided by the Member States themselves. ECHA only collects and organises this
	information, regarding the intentions of which submission systems will be in place (i.e. Portal and/or national
	systems). The information does not cover Bulgaria, Czech Republic, Liechtenstein, Luxembourg and Romania, of
Com on Ell outiture stift, on hoholf of all outsidiaries in	which we have no knowledge at this stage.
Can an EU entity notify on behalf of all subsidiaries in	Yes, this can be done in practice. You can use the "foreign user" functionality to do so. You will still have to do
the MS?	one submission per subsidiary (if each subsidiary is a separate LE). Please refer to the ECHA accounts manual for
We are Ell optitus and we are grown of comparies. Com	further information.
We are EU entity and we are group of companies. Can	Each legal entity/subsidiary needs their own account. The mother company will have theirs and use the "foreign
we have only 1 account for doing notification for all EU countries?	user" functionality to submit notifications through the accounts of the subsidiaries.
	From 1st January 2021, the harmonised DCN format will be the required one for consumer and professional use
Can a Member State require notification by the	From 1st January 2021, the harmonised PCN format will be the required one for consumer and professional use
national rules as well as PCN after 1.1.2021?	types. Industrial use types may be required to follow the national systems.
Can I notify private label products with my UUID even on the label the address of my partner company is	It depends on your role in the supply chain. I recommend that you consult Section 3.1 Who is required to submit information? from the Guidance document, to get a comprehensive explanation of your possible duties.
written?	information: from the duidance document, to get a comprehensive explanation of your possible duties.
So, if I am the formulator, I am allowed to notify the	UFI can be reused as long as the composition remains exactly the same.
different trade names in one UFI and my partner can	of teat be reused as long as the composition remains exactly the same.
use the UFI for their labels	
Can I still do test submissions?	Yes, you can.
Can the UFI be included on the label if the notification	Companies can start generating their UFIs and perform internal preparations such as the mapping with
to the PCN has not been sent yet?	formulation numbers used to generate the UFI. However, placing the UFI on the product label should coincide
, , , , , , , , , , , , , , , , , , , ,	with the submission of information to the Appointed Body of the relevant Member State. It is not recommended
	to place the UFI on the product if it has not been included in a prior submission, as this would lead to 'empty
	UFIs' on the market with no relevance for emergency health response.
Can UFIs, which have been prepared for e.g. cements,	Yes, different legal entities can use the same UFI if the formulation is the same. If the different legal entities use
following standard formulas, be used by several legal	the same UFI in their own notifications they will get warning [BR571], 'UFI(s) which have been notified by
entities without violating validation rules?	another legal entity unless there is a valid reason (e.g. you are successor of that legal entity, you are toll
	formulators customer and you act with an agreement on the re-use of the UFI, same UFI is used by different
	subsidiaries companies)'. In other words, if you have valid reason to use the same UFI, you can ignore the
	warning. (If dossiers have just 'warnings' they are accepted for processing and dispatched for member states).
Can we submit a biocide tradename to a country	Yes, you can as any other trade name. Its inclusion does not trigger other regulations. It is up to you to make

where it is not yet approved for use as biocide? If it can be submitted, does the PCN notification always force other regulatory actions, such as biocide authorization or is it only necessary if it is finally placed on the market?	sure you are complying with them, such as BPR.
Can you explain in more detail ``extension of derogation of the obligation to notify only components which are present?''	The 2nd amendment to Annex VIII includes a number of derogations (workability solutions) from the obligation to notify only components which are present. Both Standard Formulas and ICGs could contain components which are not necessarily always present. Please watch the whole webinar to understand the concept.
Could you better specify the concept of standard formula and if one of the three options for each mixture component has to be indicated.	The amended Annex VIII includes a list of Standard Formulas which specify components' identity and concentration. These concentration ranges are generally broader than the allowed ranges specified in Annex VIII. Mixtures conforming to one of these Standard Formulas do not need to comply with these standard requirements with regards to the information on composition. The information can be instead provided as listed in the Standard Formula itself. The list of Standard Formulas is exhaustive, and is limited to cement, gypsum and concrete products. PCN: a practical guide section 4.3.7 p.39 à explains how you can report standard formulas when 100% of the formula conforms to SF, only part of the composition conforms SF or SF as MiM including other components (https://poisoncentres.echa.europa.eu/documents/22284544/22295820/pcn_practical_guide_en.pdf/4f01baa5-40f1-3103-66e7-25e9584b738e)
Could you please clarify if a 'Mother company' based in the EU can submit a PCN including a link to their 10 other legal entities (subsidiaries) based in the EU? How we can ensure that by submitting a PCN as a 'Mother company' all 10 subsidiaries are also covered by this notification?	In brief, the mother company has to submit a notification per subsidiary. To that end, they can use the "foreign user" functionality in the ECHA submission portal. You can find the practicalities in the ECHA accounts manual.
Dear all, If I'm the manufacturer of a substance as such, classified according to CLP Regulation, should I have to notified my substance? According to Annex II of REACH Regulation, the emergency telephone number must be included in the SDS. So, should the poison centre be informed about it?	Article 45 and Annex VIII apply only to mixtures, not to substances.
If I have to include the emergency number in section 1.4 of the SDS, isn't it necessary to inform the Poison Centre about it, even If I commercialize this substance as such (e.g Fuels)?	You need to contact the Member State of your concern to get a definite answer, following the details of the table "Emergency telephone numbers" available at: https://echa.europa.eu/support/helpdesks
Did I understand correctly: if you perform a submission using the portal you do not need to put the UFI on the label until your relevant deadline (in	The transitional period applies if a notification is made before the compliance date with the current national system. Some MSs decided to accept the harmonized format already now, allowing this by amending the national legislation. The transitional period still applies. Note that you can submit notification via the

most of our cases 2025 because of the transition period). Many customers + ABs will want to see a UFI on the label if it is submitted via the portal	Submissions portal to all the MSs but only few of them are actually accepting them. National systems still have to be used in many MSs.
	The UFI has to be included on the label when Annex VIII start applying. If a notification is made before the compliance date, there is no need to include the UFI on the label until a change occurs and Annex VIII kicks in. The user of a MiM has different options to identify it in their own submission
Do biocidal products and PMC (Italy) have to be notified to the PCN? Does the UFI have to be reported on the label?	Biocidal products are covered by the PCN obligations. These obligations cover the need to include the UFI on the label.
Do single substance also needs to be notified to the poison centres or only MiM's and mixtures needs to be notified?	A single substance does not need to be notified as such, but of course, the substance components in a mixture must be reported.
Do we have a submission report (or other type of evidence) when we make a System-to-System	Yes, you do get a submission report when submitting via S2S as well. It is described in chapter 2.3 in the S2S documentation: https://echa.europa.eu/documents/10162/29996051/s2s_integration_for_industry_en.pdf/ae221934-d00e-c4a4-bdcb-ff88829ad90d
Do you confirm that UFI is not mandatory on label or SDS for a PPP that is NOT classified according to CLP?	In such a case, there are no obligations for a UFI or a poison centre notification.
Does a member state have access to the PCN portal in case of emergency, if a UFI number is available, but the product has not been notified in that country	Each MS can only see the dossiers related to products notified in each specific MS. If a product is notified in Finland and Spain, only Finland and Spain can see them.
Does ECHA plan to allow certain data to be "retrieved" from the registration dossier of a reference substance (for a specific registration number) for PCN notification purposes? I am thinking in particular of the classification and labelling of substances.	Currently there is not such an option. We are investigating the possibility to include the classification and labelling information based on the provided substance. We cannot say if and when that will be available yet.
Does the change of toxicological data triggers the change of the UFI?	No, but if the composition changes however, then yes, this triggers a change in the UFI.
Does the compositional info submitted to the PCN portal just remain on the central EU database, for MS poison centres to access when required, or are there also 27 MS national databases on which the compositional info is duplicated?	Some MS prefer to use their own systems to view the dossiers. They will receive the dossiers from the portal and import them in their own systems. The PCN database will be available to all MSs, regardless if they want to use it or not.
Is there any information on what security measures are in place to protect the confidential compositional information stored in ECHA's PCN database, and in	Standard Security requirements are detailed and shared with Appointed Bodies receiving PCN dossiers. For further details about the list of SSR, please contact ECHA Contact form.

the MS's national databases?	
For ca. 10 countries, we found no information, if they will require fees (Belgium, Bulgaria, Croatia, Czech Republic, Iceland, Luxembourg, Rumania, Spain, UK) and what/how much that fee will be (Italy, Hungary). Can you please provide that information?	To get that information, you need to contact the relevant Member State appointed body, as they are responsible for these. You can find their contact details at: https://poisoncentres.echa.europa.eu/appointed-bodies
For fragrance's supplier, the product is not on the market for consumer. Product's packaging depends on the quantity ordered which may vary. Do we need to fill in all possible packaging? Or could we fill in only one or two packaging? We have 25 different packaging.	In principles all the relevant packaging effectively placed on the market should be notified. You can include all in the same product record or create different product records in the same notification
For non-hazardous mixtures, how much effort do we need to do to obtain the composition? If our supplier does not provide UFI and is not planning to do a voluntary notification. Can a general identifier, like non-hazardous polymer be sufficient for notifications, or does it need to be more specific	If you mean non-hazardous MiMs, eventually a product identifier plus the supplier's details suffice. You should make sure the name allows a clear identification
for S2S for a LE, how many people can be assigned to use the Key?	One S2S key per legal entity at the moment. Basically you have one "system account" which holds the S2S key so the S2S key is not managed like a "human account".
Understand that only one S2S key to a LE. But can a few persons in a LE use this S2S key at different computers (not at the same time of course)?	Yes. The S2S key is an API key. I believe it would also be possible to use it on multiple computers at the same time.
For the ICG group if you have say three substances with the same health and physical hazards but one substance has a minor environmental hazard, can the substance with the environmental hazard be included in the group	Environmental classification is not information required. The legal text requires same classification for health and physical hazards
From 01 January 2021 only PCN dossiers according to Annex VIII will be acceptable by Member states authorities or can they request the national requirements?	National requirements apply to industrial mixtures which have a later deadline. It's up to each MS to decide whether to make use of the Portal for those mixture or keep open national systems. Furthermore, some MSs may decide to continue requesting notifications via their own system in addition to the harmonised one. This because they want to request different/additional information but under national legal framework (e.g. Nordic Countries)
Given a product notified to the national portal by 31 December 2020, if after 1 January 2021 it is modified but the changes would not trigger any update of the notification to the PCN, the product must still be	If a mixture has been already notified before the compliance date, the transitional period applies until a change listed in Part B.4.1 applies. In that case, a notification in accordance with Annex VIII is needed

notified at PCN or we can still take advantage of the	
transitional period?	
I am working for a multinational company with	Yes, they can do so on behalf of each of the individual companies. In practice this is done with the "foreign user"
headquarters (and also the production) in Germany.	functionality. You can find more information about it in the ECHA submissions manual.
Could It be possible that the headquarter can make	
the PCN notification for all the responsible country in	
Europe? Thank you very much	
Is my understanding correct that if our company	Without further details of your specific scenario, the answer is yes. From 1 January 2021 the notifications
(Hungary) imports from the UK, we need to submit	submitted by UK-based companies are no longer valid, and therefore the EU-based importer needs to make
the UFI code to ECHA once again although they have	their own notification.
already submitted it via ECHA page? Thank you!	
Guide for PCN: "specify the upper and lower limits	The upper/lower input fields are to report the concentration of a specific component. In case the mixture has
percentages for each of the component using	more than one component, for each component it is necessary to report its concentration.
following qualifiers:">" or ">=" for the lower value;	
and "<" or "<=" for the upper value. What means	
"lower"/"upper" value for mixture with more	
components? Doesn't work for 3 and more	
components!	
Hello if my product contains 4% of a classified	If you are trying to benefit from a GCI flag, such components must not be classified for any health hazards.
perfume, can I only indicate "perfume" ? Thank you	
Could you give us some info regarding stocks? Do we	You do not need to relabel your mixtures if they were notified under national schemes as the notification
need to re-label those? To tell the truth it is almost	remains valid until 1 January 2025, unless you need to make an update. When you are required to submit
impossible if yes. Thank you!	information according to Annex VIII (i.e. in case of changes to existing mixtures or new mixtures), you are also
	required to relabel your mixtures with the UFI code.
Hi, I have a product we sell, it only has one ingredient	You will need to obtain the full composition. Concerning the fuel question, could you submit a helpdesk question
in SDS, which is 25-50%. I get error that must be 70%.	and include screenshots with the error message etc.? We can look more closely at it.
How do I do? I also have another that is a fuel and can	
use the exemption, but I can't figure out how to not	
get the 70% error on this, even if I mark the substance	
as fuel.	
Hi,once the PCN dossier is submitted to a particular	The submitted dossier can still be viewed in your IUCLID instance, if you have that. From the IUCLID instance you
Member State through ECHA submission portal,one	can also generate a PDF report of the dossier and store it. There is no possibility to print a copy of the submitted
can view generated submission report but is there a	dossiers via the ECHA submission portal.
provision to view copy of submitted dossier(this	
would be helpful to check the submitted information	
even after few months/years' post submission)	
Hi, when making multi-market submission, based on	Updates must always be sent to the same MS where you have sent the initial notification. You can eventually

information authorized by each Member States if there is 20% information variation,like pack-size approved data,CLP phrases.In such case,can we still submit a single dossier to multi-markets by mentioning MS's name besides the variable information?	add MS in the update but you cannot remove them. One single updated submission can still reach multiple MS.
How can I download the not submitted PCN before a dossier is created?	You can download the datasets (not finished dossier) by clicking on the "" on the top right corner and select export to i6z option.
How can i edit a PCN notification in the platform that has been made using a S2S interface.	You would have to get the dataset (so the editable version of the file which has been submitted via S2S) and edit it in IUCLID (either ECHA Cloud service or standalone). In other words, you would have to export the i6z file (IUCLID dataset) from the S2S system and edit it in IUCLID
How come only 7 or 8 EU Countries are accepting ECHA? If its a European regulation and institution, we should have all 27 countries accepting it.	Appointed bodies and poison centres are under the remits of each Member State. You are encouraged to contact those of your interest to get a clear answer on how they will handle the notifications after 1 January 2021.
How do we fill a non-dangerous substance or mixture, where only the trade name is available and we do not get more information from our supplier. No CAS-, EC-or IUPAC name is available?	One possibility is to ask your supplier to do a voluntary submission for the mixture. They can provide you the UFI and product identifier, along with the MS where they have made the notification. You can include then this information in your notification. You can find more information in Section 5.3.3 Information required on components of the Guidance document.
How should the UFIs of the components of an IGC be managed?	If you mean ICG, no UFI is required. The ICG has to be identified with a meaningful name only.
How the ICG are management by the S2S?	S2S is just the way of submitting data to us, you would have to look at the PCN format - https://poisoncentres.echa.europa.eu/poison-centres-notification-format We have published some examples as well
How to differentiate products with same composition but having different UFI codes for different countries in the same PCN submission? E.g. Product A in Greece & Product B in France have same compositions but different UFI codes in resp. countries.	You can do this by creating two different packaging documents. Take a look at the PCN: a practical guide for more information https://poisoncentres.echa.europa.eu/documents/22284544/22295820/pcn_practical_guide_en.pdf/4f01baa5-40f1-3103-66e7-25e9584b738e
How to do when the total concentration of substances is under 90% because any substance have a specific concentration less than 100%, due to impurities or water or so on?	In case the total concentration of the mixture is between 70-90%, the system warns the submitter that the full composition is not included (the dossier can be submitted but Appointed Bodies receiving the notification can question the submission and ask for further information)(QLT506).
How to notify a component of a mixture where I do not know the chemical identity. E.g. polymer in solvent: fluorocarbon resin without CAS / EC / inventory in SDS of raw material supplier? The validator does not accept a substance only called	The Guidance on Annex VIII states that in case the substance does not have EC number, CAS number or IUPAC name then; An INCI name, a colour index name or another international chemical name may also be used, provided the chemical name is well known and unambiguously defines the substance identity. As a minimum information for substance identification you have to provide at least one of the below identifiers:

"fluorocarbon resin" without any other identificators. In SDS is the only information "fluorocarbon resin" and is non-hazardous. Any CAS, EC, IUPAC, INCI, INN. We asked him and he replied that identity of fluorocarbon resin is "trade secret." and is not willing to tell us any identity. How to solve this problem with	1) EC number 2) CAS number 3) IUPAC name 4) International chemical name (can be reported in 'IUPAC name' field.) 5) Colour index 6) INCI name
validation of "unknown" substance.	The second part of your question requires some further analysis, could you please submit this to the ECHA Helpdesk. Thanks
How to understand phrase from Paragraph 3.3 Annex VIII: "unless the submitter can demonstrate that those components are irrelevant for the purposes of emergency health response and preventative measures". When hazardous component below 0,1 % is irrelevant or when is relevant for the above phrase?	This is up to the submitter to decide whether the component is relevant for emergency reasons (e.g. according to the classification). A justification is not required in the submission
I am a non-EU manufacturer and does not intend to do the notification by an EU LE. We agreed Our clients in EU will do it. Can we generate the UFI for each mixture and provide it for them to use in the notification?	Yes, you can generate the UFI. However, if the EU-based importer is the one doing the whole notification, it may be easier for them to generate their own UFI.
I am an EU company in need to notify my mixture. For a MIM I do have an SDS from Extra-EU (China). Is it a problem to include the Chinese references as the MIM supplier?	If you are importing the MiM, then you need to make a notification for this mixture as well as for the final product. It would not be acceptable to include the supplier details from a non-EU supplier in the notification.
I am an importer of a mixture. My supplier does not want to give me the full composition of the mixture. He states that the entire composition relevant to health hazards is given in the safety data sheet. What should I do?	We acknowledge the issue. One suggestion is to explain to your supplier why you need the full composition. Other alternatives would be that the supplier makes a notification via en EU based legal entity, to protect the confidential information. You could then link to their UFI in your notification.
I assume it is reasonable to assume that until all 27 member states are ready to receive data via PCN, no submissions via ECHA are required. When does ECHA expect all member states to be ready.	In the document "Overview of Member states decisions on implementing Annex VIII to the CLP" you can see that already now some Member States are accepting, or a committed to accept notifications, by 1 January 2021. For those for which there is no information, you need to contact them directly, as it is in their remits to decide how and when to accept these submissions. You can find their contact details at: https://poisoncentres.echa.europa.eu/appointed-bodies
I have a Submission Status as Succeeded in the Submission report for my product. In the Submission	Each Member State has a different approach, please consult the table: https://poisoncentres.echa.europa.eu/documents/22284544/27487986/msd_en.pdf/982d9115-58cb-75c8-

Events the Dossier received by RO. Do I still have to notify to the appointed body in Romania although the	80ae-8eb16f5c0009 and identify the Romanian case.
submission event says that the Dossier received by	
RO?	
I have had connection errors using system to system PCN notification and now I have 2 initial submissions with different PCN number. Will that be problematic in the future or should I submit updated submission?	It depends, did you have the connection error in the "production" environment (no test flag active)? Are both dossiers containing the same information? It might be easier to handle this questions via a helpdesk ticket - https://comments.echa.europa.eu/comments_cms/Contact_CLP.aspx
I have multilingual labels. Some countries have already been notified so you will benefit from the transition period, others will be notified according to Annex VIII in 2021. Can I put UFI on the label? Do I have to specify for which countries is UFI valid?	UFI should be included on the label only where they are notified in the relevant Member State. If for practical reasons the label has to be prepared in advance, we recommend submitting an Annex VIII notification as soon as possible
I heard, UFI implementation timeline of 1st January 2021 is expected to shift further. Please confirm.	No, it is not going to be postponed. The publication of the 2nd amendment to Annex VIII is expected in the near future, and it will legally confirm this.
I missed the Webinar, will it be Online to rewatch it?	Recording of the webinar is already available here - https://www.youtube.com/watch?v=DK9ptph5Olc
I'm updating some mixtures to the National Poison	It depends on the scope of the update, your supply chain and the Member State you are placing on the market.
Centre. Can I do that after January 1st, 2021 or do I have to update until December 31st, 2020?	You may need to update already now to continue to be legally on the market.
I'm a non EU supplier to EU (distributor) importer. I	Yes, you can use an EU-based legal entity to do a voluntary submission. Your EU-based importer can refer to that
market industrial use only products while the EU	voluntary submission to do their own submission.
importers market some of them also for professional use . my full composition is CBI. Can I notify now even the date for industrial use is 2024?	
If a company is introducing today a mixture on the	Today, this company has to comply with the applicable national legislation. As seen in the document "Overview
market, can they just use the EU-wide system or do	of Member States decisions on implementing Annex VIII to the CLP", Denmark, Estonia, Germany, Lithuania,
they still have to notify the individual member states?	Norway, Poland and Slovenia already accept notifications through the system. This means that for those
(for the period today – end 2020).	countries, if you use the ECHA submission portal you are already complying with their national legislation.
If a mixture contains substances which react during the production process, should the PCN notification contain the substances going into the formula or the end reaction products?	It is usual to notify the mixture that is placed on the market
If a MS is not connected to the ECHA submission system (red in the first column of the overview table), how is it possible that this MS can accept a notification via the ECHA system (green or yellow in the second column)?	MSs may not be connected yet, but they normally plan to accept them once the connection is open

If a MS requires fees for PCN how is the process if I submit only ECHA PCN?	You need to contact the specific MS to get further explanations of their process before submitting the notification. You can find all their contact details at: https://poisoncentres.echa.europa.eu/appointed-bodies .
If a poison centre notification has been made using the ECHA online portal which has currently only been accepted by a few Member States, will the remaining Member States automatically receive the notification once they go live or will a notification need to be	The remaining Member States will have access to the notification once they go live. No need to resubmit the notification again.
made again? If a UK company has made a PCN submission before Jan 1st do these submissions have to be made again	Submissions made by UK suppliers before 1 January do not exempt the EU customers from fulfilling their obligation (once they become importers and therefore duty holders).
by a new EU duty holder after Jan 1st If a UK company make a submission before 31st Dec 2020, can this UFI be used to supply EU distributors to	The UFI itself can be used by several companies and in different market, as long as the composition is the same. The way how the UFI is generated does not matter
make their own submission as the duty holder (without providing them with formulations) If after notification a Member State requires further clarification, will this be communicated through the	How to communicate with the submitter is up to the Member States. ECHA is building a tool for Appointed Bodies to communicate with industry via the portal but then it's up to each MS if using that.
portal by that Member State? If all our products are registered in the poison centre of the countries where these are sold, do we have to	You are recommended to still contact them, to have a clear understanding of how they are going to handle them after 1 January 2021.
do anything when these countries start to accept the harmonized PCN notifications? If currently ABs are asking more information than	From 1st January 2021, the harmonised PCN format will be the required one so in principle no additional
what is foreseen in the portal because of their own national legislation but they will use the portal in the future. What do companies need to do handle this?	information needs to be requested. If additional information is requested, that does not hinder your compliance to the requested legal requirements. Note: There can be other regulatory obligations than the poison centre notification. In many cases national product registers, for example, will still be in place also because they provide
Will we receive a request after submission for additional info from the AB? If I have different legal entities within a company and	data to other authorities than Poison Centres. In principle, both legal entities are placing on the market, so both should notify. Please refer to Section 3.1 Who
LE1 manufactures the mixture that is put on market only by LE2, who needs to do the notification? If I have industrial mixtures who are notified today,	is required to submit information? of the Guidance document for a more comprehensive reply. If the composition of your industrial mixture remains the same, you can keep the same UFI and you do not need
but my customers will use it as a MiM in a new consumer product after 2021, do I have I have to	to generate a new one.
generate the UFI still or can I continue benefit from the transition period?	In case the industrial mixture has already been notified under national regimes and a UFI has not been assigned to it, it can benefit from the transition period. Note though that your customers will still require information about your mixture for their own notification.

if I submit a PCN notification through the ECHA portal for a country which currently accepts notifications through the ECHA portal before the compliance date of my product, can I benefit of the transition period for that country? so I could not affix the UFI on my label.	Yes you can
If I understand correctly, from April 2021 it will no longer be possible to use the "Guided dossier preparations" box on IUCLID?	Your understanding is correct. The de-commissioning of the Guided Dossier Preparation tool is scheduled for April 2021.
If I'm a company with different sites in Europe that operate under the same legal entity, who has to submit the notification: the single site or just one legal entity?	In principle, it is per legal entity. However, it is anticipated that if the sites are in different MS, they may need to submit their notifications individually.
If my company is the importer of a MiM, do we have to do the PCN instead of the NON-EU manufacturer?	You are the duty holder under Article 45 and Annex VIII. CLP is an EU regulation, so it does not apply to actors based outside the EU. Please, also refer to Section 4.2.5 UFI and non-EU suppliers of the Guidance document, to find hints on how to get their support to comply with your duties.
If using the ECHA Cloud, can one automatically access a library of reference substances or?	Not automatically, no, you would need to create them or import them from the IUCLID website
If we are a company who sells fragrances (mixture of ingredients) to companies in order to manufacture detergents and air fresheners, we understand that we have to indicate the UFI on the SDS and not on the label.	There are several aspects to consider. Please refer to Section 4.2.8 Display, position and placement of UFI of the Guidance document to understand them.
If we are notifying the countries (giving the country and language information) in our current PCN notifications, which do not accept it yet, will the data be submitted later (when the MS is ready) or do we do the notification again?	The remaining Member States will have access to the notification once they go live. No need to resubmit the notification again.
If we have a common substance to several mixtures/notification, is there a way to save the 'PCN-profile' of this substance for reusing it foreach mixture?	When you create a substance dataset in IUCLID, you can re-use that same dataset in as many notifications as you wish.
If we have artwork left over in stock after December 31st 2020 with no UFI number on, will be still be able to use these? I.e. can we run out current stock?	No. There is no need to relabel mixtures in stock, that were notified under the current national system.
If we have submitted a PCN notification through the ECHA submission cloud and it shows as successful, can	You can use the relevant UFI on the labels immediately.

we use the relevant UFI on the labels immediately or	
do we need to wait for their confirmation receipt in	
order to be able to indicate it on the labels?	
If we notify an unclassified detergent, does the	If you decide to make a voluntary submission by notifying a mixture that is not classified, it is voluntary to
generated UFI have to be placed on the label or may it	include the UFI on the label.
not be present?	
If we produce chemical products for industrial use our	Yes, the use of a mixture downstream is relevant. An industrial mixture is defined as used for industrial uses
compliance date is 2024, right? But, if we have	only.
distributors which sell our products directly to	
professional sector or consumer users, do we need to	
generate UFI and notify our products and provide the	
information to distributors?	
If you submit to the ECHA portal before the	First notification to the ECHA Submission portal are always considered "new notifications", even if the
compliance date (e.g. you benefit from transition	notification information is know by the Member State at national level system.
period but customer needs UFI for MiM). Do you need	
to select "new notification" in the ECHA portal - as it is	
a known notification but in the national system?	
If you work with tollers, product info is completely	Toll formulators, in their role of formulators, are the first duty holders for PCN obligations. In the Guidance
decided by you as company (e.g. composition, C&L,	document, Section 4.2.4 Toll formulator and UFIs, you can find more information about this scenario.
markets). It doesn't make sense that a toller does the	
notification as they not have all the information	
needed. Can you, as company contracting the toller,	
do the poison centre notification?	
If your mixture is a solid. Is it now a legal requirement	You can choose a justification for why pH is not available.
to test pH for those mixtures?	
In our SDS concertation range of the component of	For the composition of the final mixture, max concentration ranges have to be those indicated in Tables 1 or 2.
mixture is 0-15% and meets the classification as in	Normally an SDS does contain the information required by Annex VIII
hazard class and category paragraph 3.4.2, part B,	
Annex VIII). In table 2, part B for this concentration	
range maximum width is 10% units. So, what	
concentration I should provide in my submission?	
In today's webinar it was mentioned that PCN	Mixtures can be placed on the market not only as such, but in combination with articles. This is explained in the
obligations apply to combinations of mixtures and	Guidance on substances in articles. Also the Guidance on Annex VIII addresses this
articles. I cannot detect this clearly in the Regulation's	
text. Can you please explain where I can find this	
information in the Regulation or in any guidance	
document?	

Is it mandatory to create a substance or we can directly add or connect reference substance if available?	When you start your dossier, you need to create the link to a reference substance. After that, you can update the reference substance.
Is it not possible to use the guided dossier preparation if we do not have created an account on ECHA cloud?	No. You always need to create an account in our IT tools to be able to use them.
Is it possible to increase IUCLID CLOUD working space to more than 1 GB. 1 GB seems very low for the huge number of dossiers that need to be created.	Currently there are no plans to increase the storage. If you need additional storage, please send a motivated request via the ECHA Contact form.
Is it possible to manage substances with different classifications in the system? That is, substances that have the same identifiers (CAS, EC) but different classifications (for example, different grades of ZnO)	Different grades would imply the presence or absence of impurities I understand. So no, this would require different notifications.
Is it useful that every company should now contact the appointed bodies to get to know if they will accepted the notifications via ECHA submission portal on 1.1.2020? I think it will better that ECHA will do this and publish this information on the pcn website	It is up to each Member State to decide how and when to accept notifications submitted through the ECHA submission portal. ECHA keeps the "Overview of Member States decisions on implementing Annex VIII to the CLP" up to date based on the information provided by them, as a means to help notifiers getting a first impression of the situation.
Is possible to copy several substances added in IUCLID cloud from one LE to another so we don't need to add them manually for each legal entity?	It is possible to export substance datasets and reimport them in the Cloud instance of a different LE.
Is possible to do the notification by a non-EU establishment (our "mother" HQ located outside EU)? or does it always have to be EU establishment that does the notification?	A non Eu company can prepare the submissions but the submission itself must be made by an EU company.
Is there a minimum number of characters/information required for the toxicological section	Validation rule BR538 checks that the provided toxicological information is at least 200 characters for each relevant language. (The provided toxicological information should be according section 11 of the SDS.)
Is there inside the system the possibility to duplicate a PCN notification and change the trade name and the UFI?	In IUCLID Cloud you can use the option "Clone" from the Mixture/Substance datasets list. You can find that by clicking on "" on the dataset record. In the Cloned dataset you can change what you need without loosing the original dataset.
Isn't there going to be a presentation like in the previous webinar?	You can find the presentation here: https://www.youtube.com/watch?v=DK9ptph5Olc&feature=emb_logo
Justification for no pH. What to choose if your solvent does not contain water (e.g. propylene glycol, glycerol etc.)? pH has no meaning if there is no water. The justification options do not include this scenario	Thanks for your feedback on this! The justifications were discussed with Appointed Bodies and industry stakeholders. I would suggest you submit feedback and proposal to our Helpdesk so that it can be handled accordingly.
Make lubricants. Interchangeable base oils used (> 70%): different suppliers with CAS/EC n° different and	You can use the ICG if the criteria are met. If the classification for health and physical hazards is the same, the technical function is the same, the tox properties are the same and the information on the final mixture does

some different physical characteristics . Tech. function & subst. classif. are the same (NC or Asp. tox 1) . Change related to the market, C&L of mixtures remains the same. Can I use ICG?	not change, you can group the components in an ICG
Most of our products we sell to industrial end users. If our customer is re packaging and/or relabelling and selling to other customers do we have to make PCN?	You have to submit a notification if you are placing on the market, regardless the use. In case the mixture is used for industrial uses only, Annex VIII obligations will start applying only later (2024). At the moment current national obligations apply
My company produces mixtures for further formulation. We chose consumer end-use as worst case scenario? Does this mean that the mixture can used be used as professional and industrial?	It is possible to select all use types if needed.
My German supplier announced the notification of a product to all EU countries. I market the product in the Czech Republic and Poland. How can I verify that my supplier has notified a product for the CR and Poland? Is his confirmation enough? Am I responsible for the insufficient notification?	I understand your supplier is providing you with the UFI and the product identifier. You are then using this information in your notification. You may want to ask your supplier for a written confirmation. It is understood that this is a shared responsibility, so your supplier's compliance implies your own compliance, and the other way round.
My supplier communicate a new UFI for his MIM/Mixture. Do I have to update my notification also changing the UFI associated to my mixture?	You have to update your notification including the new MiM UFI. if the composition of the MiM has changed in a way that defines a change in the composition of your mixture, then also the UFI of your mixture has to be modified.
If I notify the MIM as the importer. When I notify my Mixture containing the MIM, who do I need to put as the supplier? Me or the Original non-EU?	A non-EU supplier has no obligations within the EU and no obligations to provide information to the EU authorities. The responsible legal entity remains the importer. We would like to remind you that the Guidance on Annex VIII (available at https://echa.europa.eu/guidance-documents/guidance-on-clp) suggests a work around in case it is not possible to obtain information about mixtures supplied by non-EU supplier. A non-EU supplier may be asked to submit a voluntary submission via a EU-based legal entity and provide the importer with the UFI (hence maintaining the confidentiality of the compositional information).
Non-EU-Manufacturers (without legal EU based) selling on EU Market are not subject of Annex VIII of CLP and Article 45 of CLP?	Non EU companies do not have obligations. EU importers do. The Non-EU supplier is expected to support as only compliant products should be placed on the EU market
Normally we can use the EU / ECHA system for European-wide PCN as from January next year. But can we already do PCN notifications right now, ahead of the deadline? (assuming those notification will remain valid next year)	Yes, the portal is open and ready to accept notifications following Annex VIII format. You can check the document "Overview of Member states decisions on implementing Annex VIII to the CLP" to have a first understanding about which Member States will accept them. In case of doubt, you have to contact the individual Member State to get a conclusive answer.
Notification for industrial uses in Spain may be	The compliance dates are established in the legal text. National provisions are the competence of the Member

compulsory already from 01/01/2021 instead of 01/01/2024 as stated in the ECHA. Could you comment on this?	States. You are invited to contact the Spanish competent authority for more information. You can find their contact details at: https://poisoncentres.echa.europa.eu/appointed-bodies
On slide 27, you mentioned 'pyrotechnic products", could you confirm that declaration of a mixture with Expl. 1.4 classification is not mandatory?	Mixtures classified as explosives only are outside the scope of Annex VIII
Our products are used in all fields (end user, professional and industrial). Do we have to include the UFI number on the label of the products used in all three areas?	No. From 1 January 2021 the new obligations under Annex VIII apply to consumer and professional use types. Only from 1 January 2024 they apply to industrial use types.
PCN are compulsory in the EU-wide system for formulations sold to consumer and professional. Is it possible to make PCN notification for the industrial use already now or just after new year, without waiting for 2024 and without having to notify each relevant member state?	At the moment national obligations applies. In general you don't have to wait until the end of the transitional period. You can submit a harmonised notification any time, but it has to be verified with each appointed body when they start accepting them. Notifications have to submitted in each MS where you place the mixture on the market.
What are the criteria to decide if a use is for the professional or industrial sector?	There are no precise criteria. This is up to the submitter and possibly to be discussed with the national authorities if they see the need to verify. But the main driver should be the settings where the use takes place (an industrial settings requires certain risk management measures)
PCN Submission in multiple language/countries are possible in one dossier. Can we send updates to selected countries and not to all countries?	Currently the updated dossier will be sent to all countries included in the dossier.
Please explain what how non-EU companies can do UFI's when an OR is not needed in REACH. Providing the full formula to all our EU clients is not a viable solution.	If you do not want to share the full composition of your mixture to your EU- based importers, and you already have appointed an OR under REACH, you can rely on them to make voluntary submissions. You can find further explanations in the Guidance document, in Section 4.2.5 UFI and non-EU suppliers.
please show the difference between reference substance and substance in the mixture clearly	The substance and reference substance document are clearly labelled in IUCLID. All substance datasets need to be linked to a reference substance document which defines it's identity. You can read more about it in the functionalities of IUCLID manual (web user interface) https://iuclid6.echa.europa.eu/documentation
Portugal one of the countries which are not currently accepting notifications by pcn. do you have news regarding this issue? When it is expected to accept this format?	ECHA has prepared the table below with the information collected by all the Member States: Some Member States accept the PCN notification in English language. For more details please see: https://poisoncentres.echa.europa.eu/documents/22284544/27487986/msd_en.pdf/982d9115-58cb-75c8-80ae-8eb16f5c0009. This table gets updated as soon we receive information from the Member States.
Questions about ICG: 1) Why pH and toxicological info data input are present at ICG level? Can you confirm that they are not mandatory? 2) can you confirm that	For the second set of criteria, the pH has to be the same (similar enough), but it is not an information required. You can still provide it. The classification can be provided either at ICG or each component level.

for ICG it is sufficient to provide classification only at	
ICG level (instead of repeating it for all Interchangeable component)? thank you	
Regarding the new concept of end-use. If we place a	If the professional uses, for example, are in scope, then no the mixture would not be exempt from a notification.
mixture on the market where the final end use is out	The professional ases, for example, are in scope, then no the mixture would not see exempt from a nothing are in
of scope, are we exempt from notifying even if there	
are uses in between the end use that are professional	
or industrial uses?	
Regarding the new concept of end-use. If we place a	You need to notify according to the use type that lies in scope, therefore if the end use is consumer and is out of
mixture on the market where the final end use is out	scope, but the mixture is used professionally and in the scope, then you need to notify accordingly.
of scope, are we then exempt from notifying?	
S2S services: if we notify as foreign users for an EU	You can only do a submission with a legal entity which is within the EU, so you would have to ask the S2S key for
legal entity, do we need to ask ECHA to use the S2S	the EU company
services for both the EU and non-EU company?	
S2S services: Version 3.0 of the PCN format has been	Yes, the S2S endpoints support the latest IUCLID format - S2S v2 is compatible with PCN format v3.0
released. There does not seem to be a /v3 endpoint	
yet for submitting via S2S when using version 3.0 of	
the format. Does S2S endpoints support the newest	
version of the format?	
S2S services: We develop a SAAS cloud solution where	each legal entity would need their own S2S key so they would have to request the access from us. However, you
multiple companies (Legal Entities) will be making	can also collect all your customers (legal entities) and send us a list with them (so you make one S2S access
their submissions to ECHA from. Do the companies	requests with all of the legal entities). Please also describe in that request who you are and how you validated
need to request S2S access and give us API keys or can	the companies (e.g they purchased the product from you and you are sure this is a legit company because). I
they appoint our S2S user so we make submissions on	hope I could answer your question
their LE behalf using our own API key?	
Safety data sheets of MIMs must be in the language of	Safety data sheets are not an info requirement (for the final product or the MiM). Voluntary inclusion of the SDS
the notification?	can be made in the notification and should be then included in the relevant language – noting that some
	Member States accept the PCN notification in English language
	(https://poisoncentres.echa.europa.eu/documents/22284544/27487986/msd_en.pdf/982d9115-58cb-75c8-
Several PCN dossiers have been created with the	80ae-8eb16f5c0009). If the information is available the recommendation is to resubmit the notifications. This way the most accurate
earlier IUCLID cloud version (no pH-justification	information is available to the emergency health response professionals.
needed), and were already submitted through the	Innormation is available to the emergency health response professionals.
ECHA portal. With the update now, do these	
notifications have to be resubmitted using the new	
format in order to include the pH justification?	
Should the substance name be provided always in	Regarding the "Substance name", that is a free-text field and in the same field you can include the substance
Should the substance name be provided always in	negaraning the Sabstance name, that is a free text field and in the same field you can include the substance

English?	name e.g. in Italian, Polish and Greek. Moreover, when you add the Reference substance, you can include the names in Italian, Polish and Greek in the field "Synonyms". Note also, some Member States accept the PCN notification in English language. For more details please see: https://poisoncentres.echa.europa.eu/documents/22284544/27487986/msd_en.pdf/982d9115-58cb-75c8-80ae-8eb16f5c0009 .
	In case the Member State does not accept English the information provided in the notification has to be translated to the national(s) languages of the receiving Member State.
Should the UFI requestor and PCN duty holder be the same entity?	The UFI can be generated by any entity. The duty holder information shall be included in the dossier.
Should we attach a SDS for the mixture we are making a submission for? And if so - given a submission can span multiple countries and languages, should we then attach an SDS for each country/language?	The SDS is an optional information requirement. The information requirements should be reported in the different sections of the PCN format. In case you want to provide the SDS, as additional information requirement, please take into account the country languages.
Since guidance with new information will only be available in 2021, video tutorials are also not ready at the moment, and not all member states are ready, why weren't the deadlines postponed by a few months?	Draft Guidance is available on the ECHA website, even if not final. Existing mixtures should be already notified via national systems and benefit from transitional period. In any case postponement of legal deadlines are under Commission's remit
Since only a few MSs accept submission via ECHA portal, process of notification to some other MS is on national language and sometimes is difficult to get in touch with national appointed body. What are the options to notify since deadline is close?	This reply depends on the MS in which you are placing on the market. You are recommended to contact them to get a clear answer.
Some countries have additional requirements in their own national legislation. They may require an obliged notification for hazardous substances, mixtures only environmentally hazardous, etc. How do you handle this in the portal? Would you select voluntary submission as it is not CLP art 45 obliged?	The portal is designed to allow Article 45/Annex VIII notification. Certain Member States do require additional information and possibly on other products (e.g. substances) but under different legal frameworks. You can submit voluntary submissions for products outside the scope of Annex VIII.
some customers don't want to use MIM and they ask as for full composition. Can we provide generic names for non-hazardous components, for example polymers. These are CBI protected	The components must be able to be identified in an unambiguous manner by the poison centres. 'Polymer' would not suffice as a component identifier.
Sometimes customers do not disclose in which countries they sell their products. If our customer sells	There is a shared responsibility between all actors in the supply chain to ensure the information reaches the poison centres - Duty holders under Article 45 are clearly EU importers and downstream users. Distributors also

a product in a country and the appropriate translation of legal texts is not on the packaging, can we (as the manufacturer) held liable for not registering this product in the Poison Centre?	have the obligation to ensure their mixture is compliant with CLP as a whole according to Article 4(10)).
The concept of reference substance is very unclear. Could you please clarify when and how to use it?	This information is well covered in the IUCLID functionalities manual for web user interface (https://iuclid6.echa.europa.eu/documentation) as well as the PCN: a practical guide (https://poisoncentres.echa.europa.eu/documents/22284544/22295820/pcn_practical_guide_en.pdf/4f01baa5-40f1-3103-66e7-25e9584b738e).
The PCN notification has to been done before to put the product in the market. How it would be possible to manage this poin If we put a new product in the market? Nowdays with ISS we have 30 days to notificate dangerous products	The legal text says that mixtures cannot be placed on the market if they do not comply with the regulation (Article 4.10). It is therefore understood that the notification, and inclusion of the UFI on the label, has to be done before placing on the market.
Could we put the UFI code only on the SDS? Or it has to be shown also on the label?	The UFI must be placed on the label either in the section for 'supplemental information' or be placed in proximity of the product name or trade name. Note that it is possible to place outside the label on the inner packaging, but, must be located with obligatory CLP label elements such as the product identifiers or hazard information
	Also note there are some derogations - For mixtures used on industrial sites the UFI can be <u>alternatively</u> included in the Safety Data Sheet (SDS; Section 1.1). For unpackaged mixtures the UFI is an information requirement in Section 1.1 SDS. You can find further information in Section 4.2.8 Display, position and placement of UFI of the Guidance document.
The PCN portal does not allow any choice of product colour. Our products are colourless to yellowish. This cannot be specified in the PCN with default selections	The pick list in the format does include "colourless". The list of options was discussed and agreed and you should select the most suitable one. Note that you can add several product records.
Why is not possible "free field" for the description of exact colour range I need to describe?	That's the way the format is designed. The decisions were taken with the dedicated Working Group. The principle is to limit as much as possible free text fields which would need to be manually translated. The format can be modified if need arises
The PCN portal does not allow you to enter both volume of the packaging and volume of the product in aerosol container for aerosol products. The product volume in aerosol can is significantly smaller than volume of the package. What value to include in the PCN - contents of the package or product?	The aerosol issue is under discussion at the CARACAL. Please resend your question through the contact form at: https://comments.echa.europa.eu/comments_cms/Contact_CLP.aspx
The post submission activities – like some MS requires acceptance. Will that be monitored in the Submission	There will be an event in the ECHA Submission portal to inform you that the notification has reached the Member States. Regarding Member State acceptance, please refer to:

Portal or where? We could not see that from Test	https://poisoncentres.echa.europa.eu/documents/22284544/27487986/msd_en.pdf/982d9115-58cb-75c8-80ae-8eb16f5c0009. Each Member State has a different approach so please consult the document.
Will invoices come in the submission portal too from those MS that requires that?	That part of the submission, and the matter of the fees, lie on the remits of the Member States. You have to contact the relevant ones to get a definite reply. You can find their contact details at: https://poisoncentres.echa.europa.eu/appointed-bodies
There are some countries which want fees for the submission of products (e.g. Belgium, Italy, Spain,) how can I find out what the submission costs per products are in this countries?	You would need to contact the Appointed Bodies - you can check our poison centre website here https://poisoncentres.echa.europa.eu/appointed-bodies
There was a lot of new information in the webinar. It would be good to arrange another live Q&A session after companies have been able to test themselves the tools and guidance. Many would benefit from answers.	Thank you for your suggestion, we'll discuss it with the team and plan accordingly. Meanwhile follow our newsletter and social media channels for updated information on the PCN process.
There was a recommendation to contact AB in specific countries to check if the submission is accepted. Does this already work before 1.1.2021? Are the AB contact details available in Echa webpages? Is this the only way to check, if the notification is accepted by specific MS?	The contact details of the appointed bodies are in our website, at: https://poisoncentres.echa.europa.eu/appointed-bodies
There will be a lot of companies contacting some MS not accepting the submissions when submitted in the beginning of Jan 2021. Are those MS really prepared for this?	This is exclusively in the remits of the MS. You are invited to contact them to get the definite reply.
Today, the usual way is to proceed with PCN notifications in all relevant Member State (i.e. in various languages). Tomorrow, with the EU-wide system: what about translation needs?	The dossier made available to Appointed Bodies is a combination of codes and free-text. The codes are independent from the language used in the user interface to prepare the notification. The free-text is populated with the information you have provided in the free-text fields. Therefore, if in the dossier you have included the information in e.g. Slovenian, Slovenian is the language used to populate the free-text and will be available to the Appointed Body.
UK supplier with an office in the EU, currently sending goods from UK to EU customers. We want EU office to take responsibility of importer, including PCN. For our EU office to be considered the importer, must the goods physically be sent to our EU office, before they are sent on to the customer?	This is outside the scope of this webinar. We cannot advise on the organization and structure of a company and the status of each entity. You should inquiry the competent authorities
Using system to system PCN notification I found some	I'm afraid I don't get your question. If you are using S2S, you should add the justification when you prepare the

products where pH is not available because they are insoluble. How can I add the justification in the portal?	dossier in your system, following PCN format 3.0 (Justification provided in the pH document). Could you send your question to the ECHA Contact form and elaborate on the case please? thanks
Voluntary submission is to be flagged by non duty holdersthis means if I am a distributor (es. relabeller) and I must/want to notify, I have to flag it in my submission?Thanks	If you are making a voluntary submission, you can flag that in your submission. You can find more details in the document PCN: a practical guide.
We are a NON-EU supplier of MIM's, an EU LE will notify for us, UFI will be sent to our EU customers for their notification. Some customers are asking indeed to receive full disclosure of our product instead of UFI, do we have any obligation on that? We are not in favour to provide full disclosure.	No, non-EU companies do not have any obligation - you can find more information in the presentation on this topic
We are a SME we work on IUCLID cloud. Will ECHA increase capacity storage? The dataset, REACH dossiers, CLP notifications and PCN dossiers take a lot of space. We don't want to install IUCLID on our server it will be expensive for us and we don't have the IT support for.	Currently there are no plans to increase the storage. If you need additional storage, please send a motivated request via the ECHA Contact form.
We are producing mixtures in Austria and send our final products to our "sister company" in Hungary, which is selling them to the Hungarian customers. Who is the duty holder for PCN? Austrian company which produces or Hungarian Company which sells it?	It would seem Austria (without knowing the full scenario). The duty holder under Article 45 is the formulator who has to notify where he places on the market. It seems they are placing only on the Hungarian market, therefore a notification is needed there. If this not the case and the sister is a different LE which distribute in a different country, the notification can be done by either the supplier or the distributor
We are the formulator of products sold under different brand names. We are also delivering the goods directly to the end user, so we are manufacturing and placing on the market, but the distributors name is on the label. Can we notify the product under our UUID?	The duty holder must notify in all cases, using their legal entity UUID. It is possible to include information from the distributor e.g. other trade names, UFI, or their market areas, into the duty holder's notification.
We are using "Guided dossier preparations" approach: If we set up substances in a Mixture in Mixture (MiM), we found no possibility to add the hazard classification for the substances which are included the MiM. During the validation check we always get a corresponding error message at the end.	The GDP will be decommissioned in April 2021 as mentioned in the presentation today - as it does not support the latest developments you are advised to switch to the dataset view. You can check here in the practical guide for more details: https://poisoncentres.echa.europa.eu/documents/22284544/22295820/pcn_practical_guide_en.pdf/4f01baa5-40f1-3103-66e7-25e9584b738e

We distribute a product for special professional use, whereas the manufacturer is only notifying to industrial uses. Is there any legal terms we could convince the manufacturer to notify their product to professional use already now and give the UFI to us? The use is safe in this case.	The UFI is for a mixture composition, not a use. Therefor you can select multiple use types in the notification
We have a sister company and we sell the same	Notifications have to be done per legal entity.
product under our brand name and under their brand	
name. Is it possible to do the submission only under	
our legal entity, implementing the other names in this	
submission, or is it necessary that they also do a	
second submission under their legal entity?	
We have a UK company in our group. Can we submit notification for them even if they sell directly to other UE company? or in this case only importer have to notify the mixture?	UK companies will not have any obligation from 1 January. The EU importer will have to submit (and include the UFI on the label) before placing on the market after 31 December. One notification cannot cover several duty holders. Please note that mixtures already on the market now should comply with current national obligations
We have one SDS for six trade names. We going to	The main point is that different compositions require different UFIs. You should not include on the same SDS UFI
make a two group submission:	referring to two different compositions. In particular if the mixture is used as MiM downstream
a) SF + MinM + substance -> UFI 1 for four trade	
names	
b) SF+ MinM + substance + MinM2 -> UFI 2 for the	
other two trade names	
These products are not packaged. Can we include both UFI (UFI 1 and UFI 2) in our SDS?	
We produce a hazardous mixture in France and sell it	Each company has to notify in each country where the mixture is placed on the market. You can do that from
in France, Belgium and Germany. Do we need an	one single account (your own) and submit a multi-country notification. Please be aware that at the moment
ECHA Submission Portal Login for each country of	national obligations apply
sale, or can the manufacturing legal entity also notify	
the product for the selling countries Belgium and	
Germany?	
We produce the same construction product in 3	Indeed, you can copy the information from one dataset to the other. IUCLID tool has features that support you
different countries with 3 different legal entities (we	on this task. Please keep in mind to change/adapt e.g. LE information, contact information and UFI. The best
have 3 different echa accounts for notification). Can	guide to help you with this is the 'PCN: a practical guide'
we copy the notification dossier from one legal entity	https://poisoncentres.echa.europa.eu/documents/22284544/22295820/pcn_practical_guide_en.pdf/4f01baa5-
to the other two, changing UFI numbers and other	<u>40f1-3103-66e7-25e9584b738e</u>
infos which refers to legal entity? is there a guide	
about this?	

We sell a product to a company which uses it in sewage treatment plants. Is this plant considered as an industrial site, so is it industrial use? Do you have examples for professional use? Our customer thinks it is not industrial use but professional.	This question requires further clarification. Please send it again through our contact form at: https://comments.echa.europa.eu/comments_cms/Contact_CLP.aspx
We sell formulations to industrial end users but also some distributors. Do we have to ask the distributor if they are selling to professional end users? we sell our product on the market and will notify accordingly, but we have distributors selling the same mixture under a different brand name, can we do the notification with one Legal entity (ours) and include their brand names in our submission?	You are recommended to do so. In the context of CLP and REACH, information both up and down the supply chain in strongly encourage to help all actor comply with their duties and allow the safe use of chemicals. More specifically in your case, this information will help you determine which is your compliance date. In principle, each actor in the supply chain that is placing on the market has to notify.
We sell to industrial use and our deadline is 2024. If in meantime our customers asks the UFI, which we do not have yet, what info are we obliged to share?	You are invited to check with your customer if your mixture does end in a consumer or professional mixture. This may move your compliance date to January 2021. Otherwise, other duties under CLP, and potentially under REACH apply. This means you may already have to provide them with a SDS. If your customer formulate a mixture intended for consumer/professional uses, than your compliance date is 1/1/2021. Otherwise, your customer can identify the MiM with SDS composition and your (i.e. supplier) details.
We sell to the distributor and they proceed with their notification: we are obligated to give them information regarding the country in which we have notified?	You are not legally obligated to share that information. However, if you are only providing only the UFI and product identifier of your mixture, and your customer is relying on that information for notification, it is in your interest that they now in which countries you have notified.
We supply fragrances for Cosmetic, Perfumery. We have already declared on SYNAPSE. We don't have details of market countries. But, if our customer gives us details of countries, do we have to make the declaration on PCN even if the SYNAPSE declaration is still valid until 2025?	This question requires an elaborated answer. Please submit that via the ECHA contact form and add further details to the case description. Thanks
We use MIM and the manufacturer closed its plant at the end of October. We still have quantities in stock that we will sell in 2021. Since the manufacturer does not exist, I do not get any information on the composition (the concentration ranges are too large). How can I report the mixture anyway?	The MiM can be identified by indicating SDS composition and supplier's details. If the latter does not exist, you will be responsible before the authorities. Companies are responsible for what they place on the market. Knowledge of the mixture is needed not only to fill in a notification.
We're a UK company and have created many reference substances. We are now about to notify using an EU legal entity, as foreign users. How can we	Anyone (even a non-EU LE) can work as foreign user on behalf of EU companies (the EU company has to assign you the role). In any case data sets can be exported and shared with other account' holders

use the reference substances when notifying with the EU legal entity?	
We're downstream users that buy cement from several suppliers and use it in our own formulations: what's the legal entity we've to add when we create the component for cement that is used in our formulation since we have several suppliers for the same kind of cement?	The supplier's details are relevant only in case of MiMs when you don't have a UFI. In case of substances, it is indeed mandatory to link the record to a LE but it is not checked. If the MiM components purchased from different suppliers are exactly the same, you can indicate one supplier only. If you cannot say that the components are the same, you should consider different notification (or apply the ICG solution).
What are Standard Formulas?	The amended Annex VIII (Part D) includes a list of Standard Formulas which specify components' identity and concentration. These concentration ranges are generally broader than the allowed ranges specified in Annex VIII. Mixtures conforming to one of these Standard Formulas do not need to comply with these standard requirements with regards to the information on composition. The information can be instead provided as listed in the Standard Formula itself. The list of Standard Formulas is exhaustive, and is limited to cement, gypsum and concrete products.
What are the Standard Formula datasets?	The amended Annex VIII includes a list of Standard Formulas which specify components' identity and concentration. These concentration ranges are generally broader than the allowed ranges specified in Annex VIII. Mixtures conforming to one of these Standard Formulas do not need to comply with these standard requirements with regards to the information on composition. The information can be instead provided as listed in the Standard Formula itself. The list of Standard Formulas is exhaustive, and is limited to cement, gypsum and concrete products.
What if we submit our dossiers with MIM-UFI before supplier "activates" their UFI, it is assumed we get a warning. Will those disappear once MIM ufi is notified? And what if the ufi has not been submitted to all our market placements?	It is not recommended to do the submission before-hand, and yes you will get a warning which will not disappear. You would need to provide other information on the MiM to support its identification.
What information are needed for MiM in case no UFI is available? Would a SDS be sufficient? If yes, what are requirements on the SDSs (maximum age, EU-REACH or similar GHS system like US-OSHA)?	Just to clarify, the SDS itself is not an information requirement. A MiM can be identified with the UFI only if this is known to the relevant appointed body(ies). This means that a notification including this UFI must have been previously made by a supplier in the Member State(s) where this MiM is used. If this did not happen, the MiM cannot be identified with the UFI. Annex VIII provides for alternative options. If the composition cannot be fully provided, a MiM can be identified with its product identifier and the components from the SDS (in addition to others if known) plus the supplier's details.
What is the smallest number of characters that should be used in the "Toxicological Information" field "so that the invalidator does not show an mistake?	Validation rule BR538 checks that the provided toxicological information is at least 200 characters for each relevant language. (The provided toxicological information should be according section 11 of the SDS.)
When an eu entity makes a voluntary submission for a non eu company after jan1st.ls it the eu entities vat no which is used	The UFI generator allows both to use the VAT and avoid it. Non-EU based companies are not expected to have a VAT, therefore you can use the second option, and generate the UFI without a VAT.

When creating a new substance can the name used be a code eg BOO100	Yes. You can use the name you wish. The real identity of the substance is given by the Reference substance.
When is the update guidance in German available	After the update is finalised (early 2021). We translate only final versions.
When products are used in scientific research &	The question is not clear. If a mixture is exempted from Annex VIII/Article 45 obligations, this does not mean
development, they would be exempted from Annex	that other obligations would not apply. SDS requirements and notification requirements are not necessarily
VIII. There is still the requirement from REACH to	linked
include national emergency phone numbers in SDS.	
Does that mean if you're exempted from PCN you still	
have to notify products in each MS individually?	
When renaming and re-labelling a product from a EU	Yes it must be notified in the your/other countries, otherwise the Appointed Body you would be sending the
company , we will make a PCN/UFI code for the new	notification to would not be able to link to the MiM composition.
Product name. But in cases where we want to use the	
pre-manufacturer UFI code as the composition in our	
PCN, does the manufacturer PCN needed to be	
registered for our country/countries as well?	
When the dossier is validated and ready for	It is possible but it is a browser dependent feature. Some working better than others.
downloading. Is it possible to change the name of file	
to something more logical than the row of letters and	
numbers? And is it also possible to save to another	
folder than "Downloads"?	the first control of the control of
When will the IUCLID reference substance dataset be	Unfortunately, the message on the website has not been updated (it will soon) and the reference substance
updated? It is stated on the website that it should be	datasets will not be updated in 2020. That is still in ECHA plans but a new timeline will be soon provided on the IUCLID website.
updated during 2020. When you choose IGC in PCN, then it is not possible	The validation is meant to be run for the whole mixture, not for single components. We cannot replicate the
mixture or product with IGC to validate!! Validator	issue. Please, try with a different browser or please use the contact form so we can investigate further.
button is not available for IGC!!	issue. Please, try with a unferent browser or please use the contact form so we can investigate further.
Where can these video tutorials be found to prepare	We are working on these at the moment. Please subscribe to our YouTube channel and follow us on social media
notification?	to get notified when these are online -
notification:	https://www.youtube.com/watch?v=DK9ptph5Olc&list=PLOPGDACSd6qy-pVbXvKkxsIukZ3XAKOMy
which mixtures are actually exempt from notification?	Section 3.3.1 Which mixtures require information to be submitted? of the Guidance document will help you
	identifying them.
Why are you decommission the Guided Dossier tool?	That is needed because maintaining both the guided dossier tool AND the dataset view is not possible anymore:
Please keep it, it is a very great help.	it requires double time, money and effort and the double-implementation and maintenance it is too error-
, , , , , , ,	prone. The support material, training events and video-tutorials are meant to support users in the transition.
Why do you have to contact the appointed body to	Member States are in different stages of on-boarding process to accept notifications from the ECHA submission
ask if dossier has been accepted? This is an additional	portal. Appointed bodies and poison centres are under their remits, therefore it is up to them how they
task for the notifier, which could have been	proceed.

automated through the portal	
Why does it take so long time to Access the PCN and Submission Portals?	Please use our contact forms, selecting "Technical support". Specify your web browser and time of the event, so we can investigate the case. The contact form can be found at: https://comments.echa.europa.eu/comments_cms/Contact_CLP.aspx
Why has the justification of pH been integrated in the system-to-system solution but not in the manual submission portal?	The update of the online tools to prepare was indeed on 26th October - you should see the new features. If you are working offline, then you need to download the latest version of UICLID from the IUCLID website.
Why the guided dossier preparation will be removed in April 2021?	Yes, the guided dossier preparation tool will be decommissioned in April 2021. You will still have the possibility to prepare your PCN notifications from the dataset view.
Will a UK based company have the possibility to access the luclid cloud on ECHA portal to fill in the information on the mixture in order to lower the burden of the EU legal entity that will then take the lead to end the notification to each MS of market areas? If yes how to do it?	UK LE will be able to work as foreign user in the duty holder account (if assigned with that role). Alternatively, you can always create mixture/substance data sets and share them
Will all member states be ready to accept notifications at 01/01/2021?	It is up to the MS to decide how and when to accept notifications through the ECHA submission portal. You are recommended to contact those of your interest to obtain the definite answer. You can find their contact details at: https://poisoncentres.echa.europa.eu/appointed-bodies
Will countries require additional notification through their national system when you do the notification through the ECHA portal?	National requirements are in the remits of Member States. You will need to contact the Member State of your concern to get a definite answer. You can find their contact details at: https://poisoncentres.echa.europa.eu/appointed-bodies
Will it be possible to choose (form example dropdown list) in IUCLID the components with concentrations covered by Standard Formula for fuels? Currently, I can choose only type of Standard Formula	In IUCLID you can select the different fuels (based on table 3 of Annex VIII) in section 'Mixture identity and legal submitter' in 'Other identifiers' part from the 'Name' drop down list. Other information such as concentrations and components are not defined in the legal text, so there are no premade information regarding that.
Will MS invoices come in the submission portal from those MS that requires that?	In principle, the ECHA submission portal is not build to support this functionality. You need to contact the MS of your concern to get a definite reply on how they will handle fees. You can find their contact details at: https://poisoncentres.echa.europa.eu/appointed-bodies
Will there be a moratorium on further significant updates to the validation rules heading to the deadline?	We are not planning to have more Validation rules before the January applicability date requiring to provide more information. We aim to have few rules implemented in late November/December which check that some of the already previously required information is not incomplete BR630, BR634 and BR635. (these rules were indicated already in the validation rules list) https://poisoncentres.echa.europa.eu/documents/22284544/27425404/PCN+Validation+rules.pdf/6f7c90ce-dc2e-d937-e084-b8f58fa71314 However, we reserve the possibility to fix bugs in Validation rules if those are found and improve the Validation rule error messages.
Will there be examples on ICG in the guidance? How	The draft updated guidance (available on the consultation page) does include examples. Practical information is

will these have to be reported in notification?	provided in the Manual
Will there be pre-evaluation phase for submissions	There is no pre-evaluation phase as such once your dossier has passed the automated checks. You still need to
within the notification portal to wait for a positive	check the Overview of Member States table to see when the Appointed Body accepts notifications (if you submit
respond in order complete submission (If it would be	via the Portal before a Member State is accepting, the notification is not considered as fulfilling the legal
case how long does it take to complete a	requirements).
notification)? This may create pressure on the supply	
for urgent customer orders.	
Will UK company data already input be deleted	Notifications already submitted via the Portal before 1/1/21 will not be deleted. These will be accessible to
1/1/21? Are there any agreed or anticipated	appointed bodies and PCs only
grandfathering rights for data?	
Will you publish the picklist values of the new IUCLID	Thanks for your request. We'll take that into account.
phrases? Thank you	
You stated, if we notify before the compliance date in	You can benefit from the transition period with respect to the labelling in some Member States. This is also
some member states via the ECHA portal, we can	explained in the Guidance on Annex VIII
benefit with respect to timing for placing the UFI on	
the label. Does this mean that in this case we can	
exhaust the transition period, before we have to place	
the UFI on the label?	
You've mentioned right now that it's not possible to	You can select and submit to all the EU MS. But many of them are not receiving the harmonised notification yet
select UK for doing the submission. However, could	(national obligations still apply). Nevertheless, submissions made via the portal will remain and not deleted
we select any country which is not accepting PCN	
notifications at the moment? What happens in that	
case?	