**IUCLID 6** 

# Webinar IUCLID 6 – Questions and Answers

IUCLID 6.3.16

29/04/2019



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# 1. INTRODUCTION

This IUCLID 6 webinar took place on the 29<sup>th</sup> of April 2019. It was intended for users of IUCLID 6. It presented the content of the IUCLID 6 update published on 24<sup>th</sup> of April 2019. The webinar built on feedback received from users after previous IUCLID 6 releases and addressed the most frequently asked questions and reported issues.

The webinar covered:

- Information on IUCLID version 6.3.16
- Web user interface: current status and future plans
- Poison Centres Notifications

The presentations were followed by a question and answer session. The content of this session is reported in this document.



#### 2. INSTALLATION AND UPDATE

**Q1**: We tried to install the new 3.16 version with the updater tool but I am not able to find the .exe to start the update.

**A1**: The Updater Tool is run using a script that has the file extension cmd. To run it, double-click on the file. This change was made to ensure that the Updater Tool has enough memory to run properly.

Q2: Is this version of IUCLID still compatible with Chesar 3.4.1?

**A2**: Yes, the new IUCLID 6 version 3.16 is compatible with the latest Chesar version. There is no planned release of Chesar before the end of the year.

Q3: Any changes in application server or will it be still GlassFish?

**A3**: GlassFish remains the application server for IUCLID. GlassFish is included in the installation package provided by ECHA.

**Q4**: We would like to know the migration procedure from version 6.2 to the new version.

**A4**: The migration and update procedure for the Desktop version is straightforward. Simply download the updater from the IUCLID website and follow the update steps. The migration will be performed as part of the update. For a Server installation, you will find more details in the document <u>installation manual</u> (section 9).

**Q5**: I did not fully understand the backwards compatibility with IUCLID 6.1 (there was a red arrow in the presentation). Is this version adding any incompatibility with the REACH module of past versions? In other words, will it affect people working in REACH reports?

**A5**: The latest major version of IUCLID is 6.3. Data can be exported from it in a format that is compatible with 6.2, but not with 6.1. Data can be imported into IUCLID 6.3 from any version of IUCLID, from version 5.6 or later. We recommend using either the latest version of IUCLID or the previous one. Using older versions of IUCLID 6 can create issues when exchanging data between users, although any IUCLID 6 versions can be used to submit data to ECHA now.

**Q6**: I have just installed the new IUCLID and I cannot see the substances in the web interface. Is it normal?

**A6**: If you have updated your existing IUCLID installation and you already had data, you should see the same information after the update, both in the classic or in the web interfaces. If this is not the case, please contact the ECHA Helpdesk.



#### 3. WEB INTERFACE

Q7: Why is ECHA phasing out the classic interface?

**A7**: The classic interface is based on technology that is becoming obsolete. In addition, the classic interface is not easily accessible to the users of the Server or the Cloud distributions as it is relying on the availability of the Java software locally.

**Q8**: The web interface still does not meet all the requirements of more complex dossiers. Will the classic IUCLID be maintained until this is fully ready?

**A8**: Yes, the classic interface will be maintained until all the features have been implemented in the web interface.

Q9: Is there a date when the web interface will be mandatory?

**A9**: By October 2019 the web interface should support the needs of the majority of users. The transition to the web interface will start then, possibly by removing progressively features in the classic interface. The transition period will last at least until the next IUCLID public release in April 2020.

**Q10**: When is it envisaged that the web interface will allow the full use of templates? This is the main reason we have not swapped to it yet.

**A10**: The next release planned to be published to all users is in October 2019 and Template management will be possible by that time. This feature will be made available beforehand for Cloud users, as updates are made to the Cloud more frequently.

Q11: Will there be a list of features that are available in the classic interface that remain to be implemented in the web interface? This will be helpful for frequent users in deciding when to switch.

**A11**: The high-level list of remaining features to be implemented in the web interface is available in the <u>webinar presentation</u>.

**Q12**: I understand that the choice between classic and new user interface is still available (desktop version). Is under the classic interface the PNEC and DNEL calculator still available?

A12: The functionalities for PNEC and DNEL are still available in the classic interface.

**Q13**: If we start using the web user interface as well as the original interface, will the changes be saved to the same database, are they synchronised?

**A13**: Yes, it is the same database in the background, which means that all changes will be saved in the same way when using the web and classic interfaces. So, if you use the new or the classic interface all data can be seen in both interfaces.

**Q14**: One practical question if we use the Desktop version not the Cloud Services, and select web interface all the data is inserted offline and saved in our Desktop version?

**A14**: Yes. The web user interface does not mean that you are using the ECHA Cloud Services. When you are using the Desktop version, and select new web user interface, it means that you are accessing your own local database from your own browser.

Q15: Can we switch from the IUCLID web interface to the classic interface during a dossier elaboration?

A15: Yes, you can switch from IUCLID web interface to Classic while working on your dossier.

**Q16**: Is it possible for the new user interface to manage users? Or do you recommend to manage as Admin (desktop version)?

**A16**: User management can only be performed in the classic interface. There are plans to add user management into the web interface. However, this might not be possible in the next major release of IUCLID at the end of 2019.

**Q17**: Regarding the IUCLID web interface: I am not sure whether this is a problem only at my side - the web interface seems to be quite slow when, for example, changing the endpoint record. Are you aware of this issue and can improvements be expected?

**A17**: ECHA is aware of some performance issues in some features and is working on improvements. The new table of content shown when a document is open is one of these actions already available in the recent release. Together with inline editing, it should speed up the navigation and edition of a dataset. Do not hesitate to report such issues to the ECHA Helpdesk.

**Q18**: Is there any detailed training for the web user interface?

**A18**: There are <u>video-tutorials</u> available for the web interface. We are also starting to publish our <u>training materials</u> using the web UI (e.g. 'Biocides Stakeholders Day, ECHA, Helsinki (25/10/2018)'). There is also an updated <u>user manual</u> for the web interface. Additionally we offer a trial service in our ECHA Cloud service for anyone who needs a testing / training installation.

Q19: Why is in the web interface an "assessment approach" included in every dossier by default?

**A19**: This is a change made since IUCLID 6.3 last year, for the classic and web interfaces. Due to migration needs, a record was created for the assessment approach for all IUCLID files created before 6.3.



# 4. ECHA CLOUD SERVICES

Q20: When do ECHA expect to update to allow more than 1 GB of information for companies?

**A20**: The initial service was defined to support smaller companies or companies that deal with a small numbers of substances. The provided service level will need to be assessed at a later stage in the future. At the moment the storage cost is the limiting factor.

Q21: Is there a clear procedure on how to migrate current data to the Cloud solution?

**A21**: It is possible to import all your data exported from any IUCLID 5.6 or newer version into IUCLID Cloud easily. For this, you simply need to use the export functionality in your previous installation and then import the data into IUCLID Cloud. If you have an older version than 5.6, you first need to upgrade to version 5.6, and then you will be able to import into IUCLID Cloud (follow this link to see how to do it or watch this video tutorial on how to exchange data between different versions of IUCLID 6).

Q22: Does the IUCLID Cloud Trial Version still exist? I can only see the IUCLID Cloud.

**A22**: Yes, this service is still available. Please refresh your browser cache in case it is not visible to you.

Q23: What is the difference between IUCLID Cloud and the Web interface of IUCLID?

**A23**: The web interface is now available on all distributions of IUCLID and available to all users. The Cloud option gives you the possibility to have ECHA manage the installation for you. This service is currently only available to REACH and CLP users.

**Q24**: How can I work as a consultant of a SME (for example for preparing Poison Centres Notifications)?

**A24**: Please see the <u>ECHA account manual</u> on how to work on somebody's behalf using ECHA Cloud Services.

# 5. POISON CENTRES NOTIFICATIONS

#### 5.1. Poison Centres wizard in IUCLID

**Q25**: I prefer to use the classic IUCLID. I noticed there is already a manual with guidance to prepare Poison Centres Notifications using the Web User interface. Will the same guidance be provided for the classic interface?

**A25**: The classic user interface cannot be fully used to create PCN dossiers, as it does not support multilingual fields. Only the web interface supports fully the preparation of this new dossier type. The classic user interface can be used but no guidance is, or will be, available.

**Q26**: In the pilot project we sent feedback that the default section names like 'name 001' when inserting data in the PCN guided approach is confusing. What is the plan to improve this?

**A26**: Improvements are going to be made to the PCN editor. They will be available for Cloud users first, in July, then to all IUCLID users in the October version. The PCN preview report already offers a way to have an overview of all data contained in a PCN dossier.

**Q27**: Can substance dataset (chemical name, hazard profile, CAS/EC no., etc.) be automatically reused from ECHA's databases (e.g.: C&L Inventory)?

**A27**: There is no possibility to automatically retrieve information from other locations, for example the C&L inventory, into IUCLID. The information will have to be entered manually.

Q28: Can you please show more from the functionalities of Mixture in Mixture (MiM) in IUCLID?

**A28**: Please visit our <u>webpage</u>, under key documents, to find 'Poison Centre Notifications: Guide to dossier preparation and submission'.

**Q29**: What is the best solution for preparing dossiers for SME companies, with many customers and many hazardous mixtures to notify - Cloud or Download IUCLID?

**A29**: Both IUCLIDs have the same functionalities and then you can choose if you would like to manage the installation yourself or use it directly from the ECHA Cloud. If you prepare data for others, you might be asked to use the Cloud instances by your clients. If you then want to reuse the same data for several clients, it would be better to use a local IUCLID installation for preparation and then upload the data into your clients' databases.

**Q30**: Once we save the file with PCN notification, can we in the future edit it and add additional countries? If yes, do we also need to delete the countries that we notified initially?

**A30**: The data for the mixture is available and stored in your IUCLID database. You will be able to change target countries and start another process re-using the existing data. At the moment the system will not accept updated notifications that contain additional countries. If you want to send the same data for the same mixture/product to another country you will need to submit an initial notification.



Q31: Can you please describe the differences in the tool between full and limited submissions?

**A31**: There are no differences in the tool. The difference is in the information required to be able to prepare a successful dossier. In case of limited submission, the compositional information can be limited to what is available in the SDS. In this case you have to provide 24/7 contact information.

Q32: Can you please provide a link to the guidance on the poison centre website for managing PCN when you do not know all substances in a mixture as it is confidential and your suppliers' proprietary information?

**A32**: The link to the Guidance can be found <u>here</u>: section 5 is of particular relevance in your case.

Q33: If a company manufactures for a third party, how can you present the PCN of a mixture without your client seeing the composition of that mixture?

**A33**: The company formulating the mixture is the one requested to submit the notification i.e. the duty holder). There is no need to share the compositional information with the customer. Please find the link to the Guidance, where more detailed information can be found on this topic: <a href="https://poisoncentres.echa.europa.eu/guidance">https://poisoncentres.echa.europa.eu/guidance</a>

Q34: Is it possible to transfer information from a BPR IUCLID File to the PCN dossier without retyping the information

**A34**: Yes, in the preparation of a PCN notification you can refer to existing substances and mixtures in your IUCLID instance. For the time being there is no possibility to reuse an existing mixture as starting point but this will be made available to Cloud users in July.

Q35: If I work for several legal entities (LE), do I need several accounts in order to change from a dossier with a LE1 to another dossier with LE2?

**A35**: For every LE you need a separate account. Please see the <u>ECHA account manual</u> on how to work with several accounts and switch from one account to the other using ECHA Cloud Services. If you work with a local IUCLID installation, you can manage all you legal entities in the same database and will have to switch to the relevant one when creating a dossier. This feature is available only in the classic interface though. This is explained in the <u>IUCLID functionalities manual</u>, under section 8.

Q36: Can you clarify for the free text fields if the notifier has to provide the translations?

**A36**: Yes. For the relevant free-text fields, the user has to provide the translation. For more information please consult the document <u>In which language(s) can I submit my PCN dossier to each Member State?</u> available at the Poison Centres <u>website</u>.

Q37: How do I insert substance names in multiple languages?

**A37**: Data entry in multiple languages is supported only to relevant fields of PCN dossiers. If you have different variations of the substance name, you can insert them as synonyms.

**Q38**: Will the free text translation boxes appear in the same order as countries selected at the beginning?

A38: Yes.

# 5.2. Unique Formula Identifiers (UFI)

**Q39**: Must we change the UFI when we make an updated submission? When can we use Generic product identifier?

**A39**: The UFI needs to be updated in certain conditions (e.g. when composition changes beyond certain limits) - you can check the <u>Guidance on Annex VIII</u> for full details (sections 4 and 7). You can use a Generic Product Identifier to identify components which are used exclusively to add perfume, fragrance or colour when they meet certain conditions (i.e. related to hazard classification and concentration) - please check the Guidance on Annex VIII for full details (section 5.3).

Q40: Shall the UFI be shown in the label from 2020 for hazardous consumer mixtures?

**A40**: The UFI needs to be part of the notification and label from 01/01/2020 onwards. Please, note that in general the placement of the UFI on the label and the submission should be carefully planned as they should ideally coincide.

**Q41**: Why do we have to repeat the UFI code of the mixture notified: once in 'mixture information' and another time in 'product information'?

**A41**: You need to indicate the UFI (or UFIs) first, and then you need to link them to the various products if relevant. One tip, you can also do this in one-step in the product level directly. The UFI is assigned to a mixture composition when the UFI is notified with the mixture information and placed on the label of the product containing that mixture. The UFI acts as a link to the information submitted on that mixture. The poison centre operator will be able to retrieve the notified information when provided with the UFI.

**Q42**: We are a private label manufacturer of aerosols. How should we manage all UFI codes? We have our Mixture UFI code and those from our customers. Where do we manage (connect) the UFI codes.

**A42**: The use of UFI is flexible. In principle, you can use one single UFI along the supply chain as long as the composition remains the same. Please consult our <u>Guidance on Annex VIII</u> for details (section 4.2 in particular).



**Q43**: We are Downstream Users and contract filler for various EU customers. Can we create UFI on behalf of our customers, with their VAT numbers, and notify to the PCN portal on behalf of our customer as well?

**A43**: Re-fillers are downstream users under CLP (and REACH), therefore are duty holders with respect to Article 45 and Annex VIII. A submission can nevertheless be physically prepared and submitted by a third party, but the responsibility remains on the duty holder. We recommend agreeing with your business partners about how practically to fulfil the obligations. Please see also the <u>Guidance on Annex VIII</u> for additional information on this topic.

Q44: Can we show the UFI on the label even if the mixture dossier has not been submitted yet?

**A44**: The Guidance recommends 'The inclusion of the UFI on the label should ideally be followed by the submission within a short period of time'. See <a href="here">here</a> for full details. Please check with your national authority to confirm, if needed.

#### 5.3. IUCLID format

Q45: Regarding the PCN IUCLID dossier: is this format accepted by all Member States?

**A45**: The harmonised submission format is a IUCLID-based XML format and shall be accepted by all Member States according to the transition phases stated in the legislation.

**Q46**: In Picklist GHS17 - v1.0 and GHS63 - v3.0 there are different Phraselds used for Hazard category Acute Tox. 1 to Acute Tox. 5. Which Picklist should I use in FLEXIBLE RECORD.Ghs?

**A46**: The phrase identifiers from GHS63 should be used when populating the 'Hazard categories' field for Specific concentration limits. For the rest of the relevant fields use the identifiers from GHS17. For more information, please consult the <u>format manual</u>.

Q47: Do we have to use IUCLID to create the Poison Centre Notification report?

**A47**: You have to use the IUCLID format to prepare the notification. The easiest way, if you plan to prepare the notifications manually is to use IUCLID. Large companies with many mixtures might want to implement system-to-system solutions at some stage

**Q48**: We are a software provider and we are implementing the PCN format, but we have some specific technical questions about the format. Do you maybe know a contact/email address to which we can send those technical questions?

**A48**: Please contact the <u>ECHA helpdesk</u> with any of your questions. We will make sure they are assigned to an expert here internally.

**Q49**: Documents published for this version differ from the respective XSD files. As an example the LEGAL\_ENTITY should be mentioned here. The Fax and Website fields are not listed in the documents. However, according to the XSD file, these are mandatory fields.

A49: Part A – Preparing a PCN dossier specifications mention only those IUCLID fields that are relevant for a PCN dossier while the XSD files specify all possible fields of the relevant IUCLID documents. The address field type specified in platform-fields.xsd and used by the LEGAL\_ENTITY document XSD is a special case and, indeed, due to the way it has been defined a number of XML elements are supposed to be present but their value is expected to be empty in a PCN dossier. E.g.: <i6:fax/>, <i6:website/> etc.

**Q50**: The latest dossier guide refers to an Excel file containing the picklists to be used for PCN, but I have not been able to find them. Where are they?

**A50**: The Excel is available from the Poison centre website under the PCN format section.

Q51: What is the PCN number in the IUCLID dossier?

**A51**: It is a dossier identifier that has the same UUID format. It is used by poison centres to keep track of related notifications (initial, first update, second update, etc.). You can automatically generate it in the dossier header and keep it for a standard update or generate a new one for a significant change of composition.

**Q52**: Is there a way to generate the PCN dossier Number in an external way (Web Services, API,) and not having to generate it via IUCLID?

**A52**: The PCN number is a unique identifier used for the initial notification and kept for the subsequent updates. Its format follows the UUID definition. You can find more information in the format documentation. There is no need to use IUCLID for the UUID generation.

**Q53**: For PCN notification for multiple countries, do we need to provide contact details for each of the country separately? In addition, which details are required for that information?

**A53**: Only for limited submissions, the emergency contact(s) needs to be provided for each country. Please check the support material in the <u>Poison Centres website</u> for more information.

#### 5.4. PCN Portal

**Q54**: The validation report that Appointed Body will receive from the portal when downloading notifications - is that the same as a validation report from IUCLID? Can we produce the same report from IUCLID?

**A54**: It is the same, but the ECHA Submission Portal will show you some additional information, for example, the outcome of business rules that can only be checked by the Portal itself.



**Q55**: What is the difference between the submitting legal entity of the dossier and the legal entity owner of the notified mixture?

**A55**: You will find more information in the <u>format</u> and <u>validation rules</u> manuals.

**Q56**: What are the differences between PCN submission online via ECHA submission tool & offline using IUCLID 6? Meaning: advantages/disadvantages of both methods. This is to assess which approach would be best for our organisation.

**A56**: The PCN notifications can be prepared online via the ECHA Submission portal/ECHA Cloud or offline using IUCLID 6. Please see this <u>webpage</u> as well as the videos which are available on our <u>YouTube Channel</u>. The submission is taking place online, via the ECHA Submission portal, or via the submission systems established locally by Member States. In the future, the submission of notifications prepared online to the ECHA submission portal will be made easier.

Q57: What is exactly the goal of the PCN Number?

**A57**: The PCN number is used in order to track and link initial and updated notifications, including updates where a significant change in the composition of the mixture takes place.

**Q58**: If the dossier lead submits the PCN for all countries in Europe, is it then necessary for all members of the same consortium to submit the same PCN?

**A58**: There is no concept of lead registrant for PCN. Each company qualifying as importer or downstream user and placing hazardous mixtures (falling under the scope of Article 45 and Annex VIII) on the market, have submission obligations. You can check the <u>Guidance on Annex VIII</u> for more details.

**Q59**: From when will it be possible to notify to ECHA's portal?

**A59**: Technically, you can already submit. However, to see if Member States where you want to place your product is ready to receive your notification, you have to consult the information material available on the PCN website at <a href="https://poisoncentres.echa.europa.eu/echa-submission-portal">https://poisoncentres.echa.europa.eu/echa-submission-portal</a> and look at the key document Member States decisions on implementing Annex VIII of the CLP for more information per Member State. This document will be updated but you could also directly contact the relevant appointed body or national CLP Helpdesk (contact information are provided in the Poison Centres website).

**Q60**: The manual mentions 'The submitted information has to be consistent with the SDS and the SDS itself may be part of the submission to the appointed body'. If we are a toll formulator, who does not own the formulation but duty holder, which Legal Entity should we use?

**A60**: Please consult the section 3.1 of the <u>Guidance document</u> to know more about Duty holders and the possibility to use third parties to submit the information. Please also see the <u>ECHA</u> account <u>manual</u> on how to work on somebody's behalf.

Q61: How can we do the PCN as an external consultant of a SME?

**A61**: please see the ECHA account manual on how to work on somebody's behalf.

**Q62**: Mixture in Mixture (MiM): if a company has two suppliers for the same MiM, used a raw material in a mixture notified, can we provide, in the same submission, the information for these two MiMs (SDS for example and UFI code)?

**A62**: In the situation where the component purchased from different suppliers is the same (i.e. same composition and hazard profile), you do not need to provide all the UFIs (the one that has been notified in your country would be enough). In case the MiM is identified via the SDS (i.e. no UFI available), the contact details of one supplier suffices. Please check the Poison Centres Guidance document and/or contact the ECHA Helpdesk in case further clarification is needed.

Q63: Can we have only one dossier for all Member States (MS) that accept English as submission language?

A63: In one dossier, you can include more than one member state and more than one language. If all the MS where you want to submit accept English as submission language, then you can indicate only English and fill in the information in English in the free text fields. If additionally to the before mentioned MS you want to include a MS that accepts the information in their local language, you can include that as well in the same dossier. The dossier will reach all the relevant MS at once. For more information please consult the document 'In which language(s) can I submit my PCN dossier to each Member State?' and the 'Poison centre notifications: Guide to dossier preparation and submission' available at the Poison Centres website.

**Q64**: Can you confirm that it is possible to manually submit to the ECHA portal also PCN files (format .i6z) created with IT systems different from IUCLID (without using the system-to-system integration)?

**A64**: It is possible to upload and submit via the ECHA Submission Portal files created with any system as long as they have an .i6z extension and are in the (IUCLID) format defined by ECHA.

**Q65**: If national systems are not yet ready for accepting notifications, do we have to wait for starting submitting notification?

**A65**: Yes, you can check with your national appointed body – more details are available <a href="here">here</a>. The ECHA poison centre website also contains an overview of Member State readiness to accept notifications via the ECHA Submission portal – see <a href="here">here</a> for more.

**Q66**: our company notified all mixtures in 2012 to the German National Federal Institute for Risk Assessment Unit Poison and Product Documentation Centre Department Scientific Services. Does this fulfil the requirement for sending data to PCN?

**A66**: Yes, you may benefit from the transition period up until January 2025, unless you make a change to the notified mixtures. Please see the <u>Guidance</u> for which cases you will need to make an update in the new format.



Q67: Poison centre notification: when will the system-to-system notification be ready?

**A67**: The current plan is that ECHA will be able to receive requests for system-to-system connectivity with companies by July (to be confirmed; information will be communicated via the <u>Poison Centres</u> website). We are currently working in implementing the solution and will start testing it as soon as feasible.

# 5.5. PCN guidance

Q68: PCN: when will there be a clarification for repackaging, relabelling?

**A68**: The clarification about duty holders and the role of certain operators is under preparation and the Guidance is planned to be updated (tentatively before summer). Please contact the regulatory team via the <u>ECHA Helpdesk</u> contact form for further information.

Q69: Could you, please inform if we will have a transition period after 1 January of 2020?

**A69**: You can benefit from the transition period if you have already submitted your notification at national level and as long as no changes to the mixture occur. If the mixture had never been notified and the mixture is for consumer use, you have to start notifying from first of January 2020.

### 5.6. PCN and Member States

**Q70**: Is it compulsory nowadays to notify to national poison centres in each member state for mixtures or substances used only in industrial sites and for professionals (not at consumer level?

**A70**: From January 2020, it will be required to notify mixtures for consumer use (professional use from 2021, and industrial use from 2024) in all Member States. Note that the obligation refers to mixtures.

**Q71**: Poison centre notification in Member States: it seems that many regulations are still unclear at member states side. Cf. this <u>document</u>. When will we get additional clarity?

**A71**: That depends on each Member State. As soon as they make clear how and when they are ready to receive notifications, ECHA will update that Table on the PCN website.

**Q72**: How does the new system compare to the current national PCN notifications. Are there more data needed for this portal?

**A72**: Even if the current requirements differ from a Member State to another, in general the information required by Annex VIII, which is now harmonised in the European Union, will possibly be more detailed than what was required nationally until now. Please, note that from the date of applicability of Annex VIII, the same information requirements will apply, regardless of which system is used (i.e. ECHA central system or national system).

**Q73**: If I well understood, a PCN dossier has to be created to each Member State where the product to be declared is commercialised unless the language accepted by the Members States is the same (e.g. English)?

**A73**: A submission has to be made in each member state where the mixture is placed on the market. This is true regardless if the language of the MSs is the same or different. The ECHA Submission Portal facilitates the submission in one dossier/notification in case of multiple countries and languages. This dossier will reach all the relevant MSs at once.

**Q74**: Will there a possibility to transfer the PCN submitted from the current Member State web site, which in Italy is like a database, to the IUCLID database?

**A74**: Currently there is no plan to facilitate the transfer of information already submitted via the current national system to the ECHA Submission Portal. Please, note that if you have notified a mixture to the national system, you may benefit from the transitional period until 2025 (unless a change to the mixture occurs).

**Q75**: Will we still have to pay when notifying to those Poison Centres like Spain or France? Will we be informed prior to notify?

**A75**: Please check the <u>ECHA poison centre website</u> for more details for each Member State e.g. concerning fees. We plan to update this document when new information is available to us.

**Q76**: If a notification was made in at least one member state, does that mean that a PCN is not necessary before 2025 for any of the member states?

**A76**: No, the existing notifications can benefit from the transition period only for the Member State where you had already notified. For the others, you have to submit an initial notification, using the new format, in due time.

**Q77**: What about pay of fees? When we submit the dossier, depending of the Member State, will we receive the payment notice?

**A77**: In case the member state requires a fee for a PCN notification, the payment notice will be communicated outside of the system by the Member State directly to the submitter. It is also advisable to directly contact the relevant appointed body or national CLP Helpdesk (contact information are provided in the <a href="Poison Centres website">Poison Centres website</a>).

**Q78**: Regarding Poison centre notification: does this procedure substitute the equivalent procedure for biocidal product registration according to the transitional regulation, as it is handled in some European countries (France for example).

**A78**: The poison centres notification procedure does not substitute any other regulatory obligations. Please check with the local national authorities in case of any transitional measures.



## 6. MISCELLANEOUS

Q79: Has the CSR report format been modified in any way?

**A79**: No, the CSR report has not been updated in this new release.

**Q80**: Could you provide more details about the XML import new feature? Does it follows a new format?

**A80**: This new version of IUCLID accepts XML files generated with the ECHA SPC editor.

**Q81**: Is there any search functionality in IUCLID?

**A81**: The IUCLID web interface offers basic searches for substances and mixtures. You can search by substance names and identifiers and by submission type (for dossiers). The search options will be further extended in the October version.

**Q82**: When we create Biocides Dossiers they pass the validation assistant check but do not always upload on the R4BP website i.e. they fail the upload process.

**A82**: The validation assistant in IUCLID currently does not cover all verifications performed by R4BP. This is going to be addressed in a next IUCLID release. The R4BP system should inform you about the reasons for a failed upload. You can also contact the <u>ECHA Helpdesk</u> if the error is unclear.