POINTS FOR DISCUSSION DOSSIERS UNDER TR, FEEDBACK ANSES

3rd PSN IUCLID subgroup meeting 4 May 2022

1. NoS check and documents available in IUCLID

Extraction of studies available in IUCLID

EFSA provides an extraction of studies available in the IUCLID dossier in pdf format on EFSA DMS.
This list is different from the list that RMS can extract by itself by using the report generator in IUCLID

$\Rightarrow$ Why are there differences in these 2 lists ? => confusing

$\Rightarrow$ The report generator allows an excel format whitch is very useful, BUT: as the list is not correct RMS cannot use it.

Requests from RMS FR to EFSA:

$\Rightarrow$ EFSA adapts the report generator so that RMS can use the excel list extracted directly from IUCLID

$\Rightarrow$ Or: EFSA provides an excel format in addition to the pdf format already provided on EFSA DMS as the excel format will allow to make selections easily, not possible with the pdf format

Also: in the extraction of studies available in the IUCLID dossier provided to the RMS by EFSA:

Please include annex points or at least section numbers as proposed in document L or in the validation assistant report

Extraction of studies available in IUCLID (ctd)

Warning from RMS FR to EFSA:

Extractions are filtered by the business operator :

It can happen that the business operator is identified by different ways although it is the same applicant (e.g.: XXX Agro vs XXX SA) with applicant XXX Agro:

$\Rightarrow$ Studies from XXX SA need also to be extracted - easily identifiable. Otherwise, number of studies from XXX will not be extracted although they should be.

2. Validation assistant report

Warnings in validation assistant report

Warnings are often difficult to understand for the RMS

$\Rightarrow$ how to handle them? In some cases there are >1000 warnings

In most of cases: the dossier seems to be complete from a scientific point of view to RMS

$\Rightarrow$ Often the warnings do not seem to be problematic to RMS

So, what is the way forward?

$\Rightarrow$ According to EFSA, what kind of warnings should not be accepted by the RMS if according to RMS the dossiers seems to be complete?

$\Rightarrow$ What would be blocking for EFSA?

$\Rightarrow$ What does EFSA with the validation assistant report provided by the RMS in the frame of the admissibility check?

3. Documents necessary to RMS
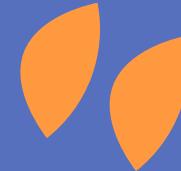
Documents A to O in particular doc D, J, L, <u>M</u> and N according to GD for applicants on preparing AS dossiers_SANCO-10181-2013

These documents are not available in IUCLID with the correct OECD format but are however necessary to start the assessment.

Currently, the non submission of these documents in IUCLID **is not a basis for non admissibility as it is not anymore a regulatory requirement** (argument of some applicants)**.**

However, these **documents are absolutely needed for the assessment**, and, if not submitted, or submitted at a later stage, the evaluation will be highly impacted, especially regarding the delay.

Automatic extractions are not acceptable at this stage.

The point has already been highlighted several times before, but is still a reality that RMS is confronted with.

4. Confidentiality check

Light check on confidentiality

Thanks EFSA for providing a procedure for RMSs

On how to handle this light check and what is expected.

Issue from the industry: with regular updates of IUCLID, applicants are afraid that their confidentiality claims do not follow as confidentiality rules are updated also

⇒ RMS cannot answer this point

⇒ What is EFSA's point of view?

⇒ **Does the applicant need to update his dossiers related to confidentiality claims?** This would be a very big task

5. AOB
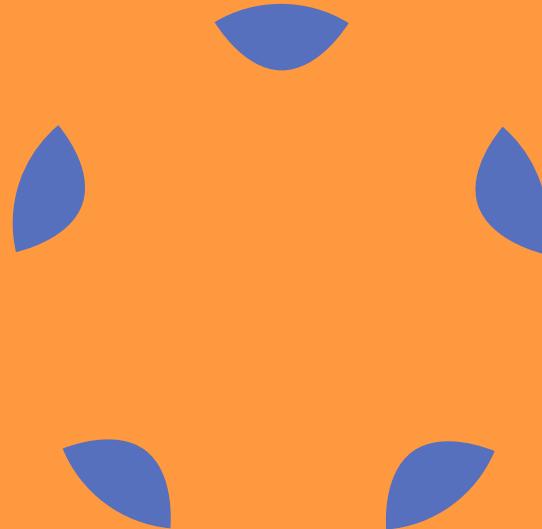
Question related to the applicant's dossier

It may happen that some studies are still ongoing when the applicant submits his dossier

This is not obviously a reason for non admissibility

But: as the studies are not available, <u>they are not in IUCLID</u>

⇒ **Is it possible in IUCLID that the applicant 'saves' a location in the IUCLID dossier and indicates at that place that a specific study is ongoing?**

⇒ **This would highly easy the scientific admissibility** of the dossier and give insight on what will come later to complete the dossier

⇒ **This would also easy the NoS check** and understand a justification for non submission (because the study is not available yet), whereas there is a notification in the NoS database.

Question to EFSA

EFSA sent an email on 12th of April with new guidance in case of questions for RMSs:

- Use of Efsa portal 'ask a question service'

- Teams Hypercare channel will be deleted

=> Will it still be possible to ask questions via the Teams PSN subgroup IUCLID channel?