2nd PSN IUCLID subgroup meeting – 31 Jan 2022

Admissibility

Trusted science for safe food

efsa
European Food Safety Authority

Admissibility check for pesticide applications

In the context of the admissibility check, the relevant regulatory body must ensure the compliance of the application with the requirements of the applicable regulations. The admissibility check includes:

1. the **completeness check** against the **data requirements**
2. the **check** on the **Notification of Studies**
3. a **light check** on the presence of key elements in **confidentiality requests** submitted by the applicant
    a. sanitised personal data
    b. for confidentiality requests submitted, background documents and justification

1. Completeness check

- The required **supporting documents** listed by TOC section must be provided as attachments to the dossier:

Table of Content	Attachment
MIXTURE DATASET	
4.4 Packaging, compatibility of the plant protection product with proposed packaging materials	Picture of label of pack
5. Analytical methods	Template 4.1. Template risk assessment" (https: to the endpoint summar
7.2 Data on exposure	Excel calculator from E summary)
11.1 Literature data	Bibliographic results of
13. Summary and evaluation	• **Document B:** of dossiers (att information" fie • **Document C:** "Reports and a

Active substance DATASET	Endpoint summary
1.8 Method of manufacture (synthesis pathway) of the active substance	Document J including assessment for the ec https://zenodo.org/re
4. Analytical methods	Template 4.1 - Templa for risk assessment" (h (attached to the endpo
5.1 Studies on absorption, distribution, metabolism and excretion in mammals	DER composer xml file study record)
5.4 Genotoxicity testing	Template 5.3 - Templa evidence on genotoxici http://doi.org/10.5281/

1. Completeness check

Mapping of EU table of Contents document into IUCLID:

- The mapping of **documents A-J** is reported in detail in the crosswalks
  - **Document A** (APPLICATION FORM) is dismissed.
  - **Documents D** can be created in IUCLID using the report generator.
  - The report generator should be used to create **documents M**, **N** and **L** when the appropriate report (ftl file) is available
  - **Document F** is dismissed and **Document O** is dismissed by the validation assistant.
  - **Document N-4** corresponds to the newly developed document "Relevance of metabolites in groundwater" (Section 11.3 in the Metabolites dataset)

- **Active Substance application Manual**: https://zenodo.org/record/5864849#.YeZ2XP7MJII
- **Cross-walks IUCLID 6.5**: a.s. https://zenodo.org/record/5749819#.YfKv0urMKUk m.o. https://zenodo.org/record/5751887#.YfKv5upKjD4

2. NoS extraction procedure

- To avoid unintentional disclosure of confidential information pertaining to applicants not part of the submission, a **filter on BO** is applied on all NoS extractions from the DB.
- Creation of an Excel file with the **list of BO retrieved** in the DB and the **list of BO selected**/BO present in the application (individual/joint submission).

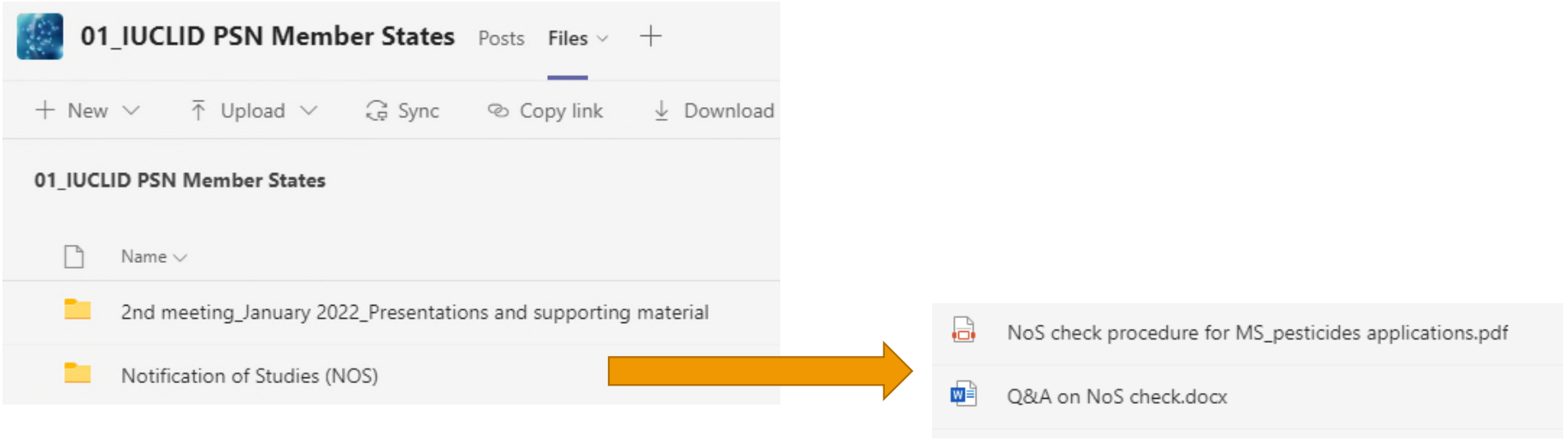
Business Operators	Business Operators selected
ATRC Aurigon Toxicologiai Kutatokozpont Korlatolt Felelossegu Tarsasay	0
Oy Medfiles Ltd	0
AR Toxicology Inc	0
TOA Biopharma Co., Ltd, Japan	1
EIHA projects GmbH	0
Hanfama Pflanzen Produktions GmbH	1
Leveret GmbH	0
罗盖特生物营养品（武汉）有限公司	0
Nutraveris	1
AOM	0
CBDepot, s.r.o.	0

2. NoS check

- There will be new tab called BO in the excel files in which a list of Business Operators is present.
- The **names** that are signed with the **number 1** are the applicant/s **selected** for that extraction.
- If during your NoS check, you detect that also other Business Operators included in the list with number 0 (and thus excluded from the extraction) might be relevant for the application you are checking, please inform us and we can provide an updated extraction.

Questions and Answers on NoS

- IUCLID PSN Member State team channel: **Q&A on NoS check**.
- This is kept constantly updated with the most common questions received on the NoS check and EFSA's approach to address them.



3. Light confidentiality check

The relevant regulatory body should also consider that the non-confidential version of the **dossier**, as submitted by the applicant, will be **published** via the OpenEFSA Portal **immediately after the declaration of admissibility**.

Dossier filtering is an automated process.

During admissibility, it is important to check the **sanitisation of personal data**, the presence of **sanitised version of attached document** (e.g. study reports).

3. Light confidentiality check

- Despite extensive communication on the topic, there are still severe issues in relation to unsanitised personal data in IUCLID dossiers
- **Every** IUCLID dossier published until now has been taken offline within a couple of hours due to the inclusion of personal data
  - As per Article 39b(1)(a) of Reg. 178/2002, upon admissibility of validity of an application, EFSA *"shall make public the non-confidential version of the application as submitted by the applicant"*
  - Even though EFSA identifies the personal data there is no legal basis for contacting the applicant, requesting a re-submission or publishing a version of the dossier other than the one which was declared admissible by the RMS/EMS

3. Light confidentiality check

- EFSA has taken measures to improve personal data management within IUCLID itself (e.g. contact person details are now **not published** by default) however, the "sanitised" study reports typically still include names of physical persons, signatures, etc
- Under the current situation if EFSA publishes IUCLID dossiers we are typically in breach of the GDPR/EUDPR and if we do not publish, we are in breach of our obligations under the TR
- **EFSA has currently suspended IUCLID dossier publication** if personal data is detected and will currently publish only after the confidentiality assessment process has been finalised
- A better process is needed and clear responsibilities must be defined (involving the applicant, the MS and EFSA)

Admissibility check for pesticide applications

For each of the checked points, the relevant regulatory body may ask the applicant to **provide additional information**.

It is important to highlight that the **relevant regulatory body should judge the importance of the missing data and whether this will have an impact on their admissibility decision** (e.g in case of missing studies), leading to a decision of non-admissibility.

Admissibility check for pesticide applications

Applications should be prepared in accordance with the relevant legal provisions in place and **all data** should be provided **as complete as possible already in the initial dossier**.

Resubmission of IUCLID dossiers:

1. **Following request from RELEVANT REGULATORY BODY** (RMS/EMS/EC/EFSA)
2. **Spontaneus re-submissions**

Declaration of Admissibility

In line with the EFSA Administrative Guidance, upon declaration of admissibility, the RMS/EMS should include in the notification the following information:

- Dossier UUID
- Dossier URL
- European Reference number
- Dossier subject/Substance name
- Pre-application ID(s)
- Purpose of application

Declaration of Admissibility

Ensure to **notify the decision on admissibility** to the relevant parties in accordance with:

- Art. 9 (2) of REGULATION (EC) No 1107/2009 for New Active Substance submissions;
- Article 8 of Commission Implementing Regulation (EU) 2020/1740 for Renewal of approval submissions;
- Regulation (EC) No 396/2005 and EC TECHNICAL GUIDELINES SANTE/2015/10595 Rev. 6.1 for MRL submissions.

EFSA contacts. **FDP: fdp@efsa.europa.eu**

Peer review: pesticides.peerreview@efsa.europa.eu

MRL: pesticides.mrl@efsa.europa.eu.

Declaration of Admissibility

When sending the notification, the RMS/EMS is expected to make available to EFSA:

- **validation assistant report,**
- **notification of studies report,**
- **confidentiality assessment report** (only for NAS/Amend)

These documents shall be generated on the **version (submission) of the dossier** which is declared **admissible** and can be automatically generated by IUCLID.

Validation report: where **rules cannot be resolved** the excel file should also include the **justification by the applicant.**

Concluding remarks

- Do you currently use a checklist to perfom the admissibility check of pesticide submission?
- Could we develop something together?