

FIRST SUBMISSIONS UNDER TR FEEDBACK FROM FRANCE - ANSES

PSN meeting 1st october 2021

1. Transparency regulation and new EU procedures to be implemented at MS level

IUCLID : a new tool to be used by coordinators and evaluators

- Many meetings organised by EFSA (Anses involved in TG since 2019), HC programme (FR RMS for 2 AS), specific RMS meetings,...
=> Progressive comprehension of the tool, adapted step by step to the needs of both industry and MSs
- RMS was looking forward the publication of user manuals promised by EFSA ; 27/03/2021 approached dangerously!
- First submission deadline 31st of July ; RMS wanted to be prepared, but without the dossier and concrete answers it was not easy to anticipate and estimate needs of additional resources

=>Bit stressful period ; administrative guidance led to a number of unanswered questions, especially related to the admissibility check

When 1st dossier arrived for admissibility check: *IUCLID is perhaps the most easy part of the new procedures and tools to be implemented at MS level !*

RPSA & GPSA ; messages to EFSA

- The **short deadlines** foreseen in Efsa's AG do not allow RMS to take the lead on GPSA and RPSA => EFSA will be asked to take the lead systematically – *EFSA still kindly requested to accept functional mailboxes in the automatic system*
 - **RPSA** : even though needed for more transparency, lack of interest on this task - no valuable input for RMS as no context explaining the submission of the studies, often addressed during bilateral exchanges RMS / applicant.
 - Lots of questions araised (how to reply to EFSA? What is exactly expected? What is acceptable, what is not?...)
- ⇒ **high availability of EFSA** to help RMS by individual reply and/or addressing the questions during HC meetings
- Request of RMS to be informed by EFSA when RPSA is finished i.e. available on Open EFSA and sent to the applicant

Notification of the dossier ; message to industry

- The notifications of the availability of a dossier on IUCID arrive automatically to RMS **BUT**
- **This is not sufficient to submit a dossier** : The IUCLID submission is the 'scientific' part of the dossier ; the administrative submission has still to be done at RMS level i.e. in France (same procedure as before TR):
 - Need of a cover letter and
 - Proof of payment of the fees

Otherwise the dossier cannot be accepted and the evaluation cannot start; the dossier is not admissible if this part of the submission has not been addressed.

Admissibility check: thoughts and proposals for improvements, related to IUCLID

- **Deadline of 30 days extremely short:** same timeline as before TR **but** more things to do; no more resources available
=> RMS needs to organise differently
- EFSA needs 10 days (more for MRLs) among these 30 days to provide the NoS list; RMS cannot start the NoS check before
=> **Proposal for improvement:** deadline should start when RMS has all the documents to allow the admissibility check

EFSA is kindly asked to **include data points in all documents provided to RMS** (List of Intended Studies (LIS/RPSA), extraction from NoS-DB; ...): this will allow RMS to filter section by section which will ease a lot our work.

- **Validation assistant:**
 - **Warnings should be addressed by the applicant before the submission of the dossier.** France in favor of blocking rules in case too low quality of the dossier submitted
 - **Proposal for improvement:** If warnings remain and cannot be removed by the applicant, justifications could be sent to RMS at the submission of the dossier, avoiding unnecessary exchanges and helping RMS to understand
 - **Proposal for improvement:** include justifications in IUCLID

Other requests and proposals for improvements of IUCLID

Proposal to include equivalents of documents A to O in IUCLID:

in accordance with GD SANCO/10181/2013 (GD for applicants on preparing dossiers for the approval of a chemical new active substance and for the renewal of approval of a chemical active substance according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013)

=> *rev.6: 24 March 2021 states:*

“This guidance document **is not applicable for applications (including dossiers) submitted on or after 27 March 2021**”. as “applications must be submitted electronically through a central submission system using the IUCLID (International Uniform Chemical Information Database) software package “

=> This does not mean that RMS does not need equivalents of documents A to O

However: views of RMS are different (according to applicants) ; discussions needed

- RMS (FR) needs at least equivalents of documents D, M and L, facilitating the generation of the DAR/RAR.
- Doc L is also needed to prepare the list of studies according to SANCO/12580/2012– rev. 4 GD on preparing lists of test and study reports according to article 60 of regulation (EC) No 1107/2009

2. Conclusions and way forward



Conclusions on first IUCLID submissions

- Admissibility check is **much more time consuming** as before 27th march 2021 and **needs more ressources**, whereas not more available at RMS level
- **New procedures** related to implementation of the Transparency regulation **raise new questions**
- For the time being meetings were more turned to the dossier submitters;
RMS meetings are in progress since september, allowing to solve problems and answer concrete questions on the dossiers submitted during the summer (Q&A sessions).
- **Availability of EFSA** to help answering, find solutions and improve the tools **is very appreciated**

Way forward

- For the time being, **admissibility checks are still in progress** – need to verify that all the new requests have been correctly addressed
- **How to fulfill specific requests**, e.g. an Evaluation report in an MRL application (requested in France) – should be submitted in IUCLID and not submitted separately. If not submitted in IUCLID, there is no warning from the validation assistant
- **Need to experience** the submission of an **updated IUCLID dossier** in the frame of the admissibility phase
- Need to experience the **comparaison tool**
- We will come back with new questions once the evaluation has been started!