Trusted science for safe food

TG IUCLID PESTICIDE meeting

17-18 June 2020

Pesticide MRL application submissions in IUCLID

Lucien Ferreira

Aija Kažocina

PRES Unit

European Food Safety Authority

Why a specific submission type is needed for MRL application?

- Specific Regulation (EC) No 396/2005 on maximum residue levels (MRLs) of pesticides in or on food and feed of plant an animal origin
- Specific MRL application dossiers and requirements for submission do not exist
- Administrative document MRL application form SANCO 4044/2008 (pdf)
- Particularities of MRL application submissions:
  - ✓ 9 different purposes (can contain more than 1 purpose per appl.)
  - ✓ From simple to extensive assessment
  - ✓ Specific information may be needed (e.g. for import tolerance cases…)
  - ✓ Evaluation of MRL applications done by EMS/RMS in an Evaluation Report (ER)
  - ✓ ER is the only place where a structure of MRL appl assessment is defined, equal to the Table of content of a.s. approval submission dossier, but simpler (in most cases no tox, no ecotox, no labelling)
  - ✓ Several applicants (and products) for different MRL dossiers for the same active substance
  - ✓ Often associated to a mixture/product but not 100% of the cases

Objectives and approach taken by the IUCLID WG on MRL submission type

- Objectives:

1) Development of a specific format for "MRL dossiers" in IUCLID

2) Adaptation of the Table of content (ToC) of "PPP active substance dossier" fit for the purpose of "MRL dossiers"

- What has been done? [3 online meetings]

✓ Identification of info/documents needed for MRL dossiers and finding them a place in IUCLID
  - ✓ Screening of the MRL application form
  - ✓ Screening the ToC of the a.s. dossier to identify the elements that are "relevant/not relevant/conditional/desirable" for MRL dossiers

✓ To reuse the existing formats as much as possible (new creation only if needed)

✓ Listing pros and cons of using "active substance" or "Mixture" dataset

✓ Discussion on the 2 options for the "MRL Dossier Header":
  - ✓ Simple (only administrative information)
  - ✓ Extensive ("surrogate" of MRL application form), noting duplication of information in ToC/GAP/LOEP

✓ Ensuring that all information required in the MRL application form is accounted for

✓ Ensuring harmonisation with other WG developing formats relevant for MRL dossiers (e.g. GAP table, Residues Endpoint summaries…)

✓ Ensuring that MRL applications submitted along with approval dossiers are linked/traced

Results: Key decisions taken

- All information needed for an MRL application could find a place in IUCLID

- "MRL dossier" to be created from:
  - **Active substance** dataset (with mixture document added in the a.s. dataset)?
  - **Mixture data** set (as for PPP dossier)?
- Decision to keep the MRL **dossier header simple** (acknowledging different opinions of the WG but following ECHA recommendation)
  - Creation of the Dossier header format
  - Possibility to upload the application form as an attachment (back-up option only)
  - If the MRL application is submitted with a PPP a.s. dossier, this is traced in the dossier header

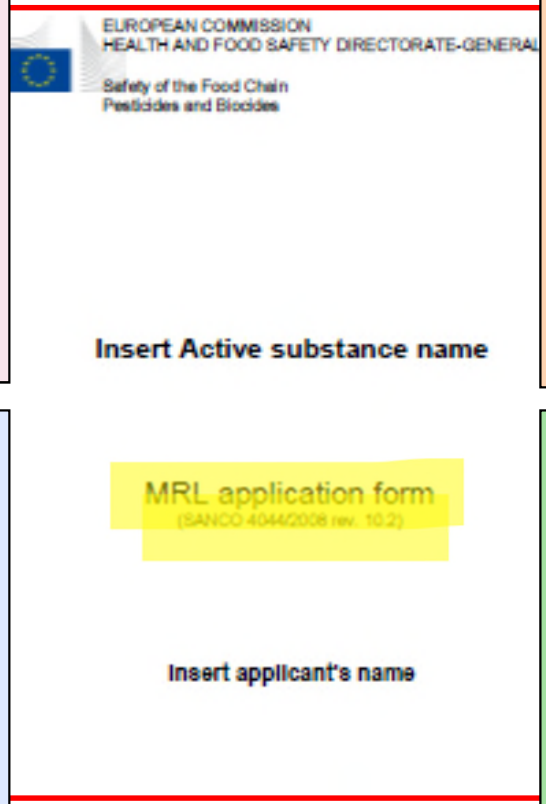
- The **ToC of active substance dossiers is fit** for the purpose of MRL dossiers
  - Simplified for MRL dossier: e.g. omitting fields on ecotoxicology and labelling
  - Elaborated endpoints summaries (e.g. MRL proposal, residue definitions)
  - Flexible GAP table (+Mixture composition document)
  - Places to upload docs (e.g. Evaluation report from applicants)

An MRL application contains…

Administrative data
- *Purpose of application*
- *Applicant's status*
- *EMS/RMS*
- *Data requirements*
- *…*

Scientific/regulatory data
- *GAP, product formulation…*
- *MRL (existing/proposed)*
- *Residue definitions (existing/proposed)*

Risk assessment data
- *Residue data (trials, metabolism…)*
- *(Tox data…)*
- *Exposure data (livestock, PRIMo…)*
- *Other calculations (OECD MRL…)*



Details concerning the applicant
- *Applicant name*
- *Applicant coordinates*
- *…*

Details on the active substance
- *IUPAC*
- *CAS number*
- *Status of the active substance at time of the application*
- *Further information on the active substance*
- *…*

How the information needed for an MRL application find a place in IUCLID?

Dossier header :

- *Administrative data*
- *EMS (RMS)*
- *Purpose of application*
- *Data requirements*
- *Applicant's status*
- *(admin attachments)*

Applicant login:

- *Applicant name*
- *Applicant coordinates*
- *…*

ToC (incl. endpoints summaries):

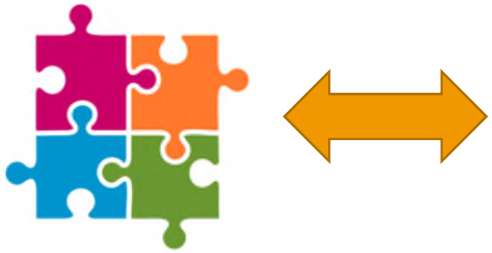
- *Risk assessment data*
  - *Simplified ToC of PPP dossier*
- *Proposed MRL*
- Proposed residue definition
- *Other assessments*
  - *Existing MRL and RD (in/out EU)*
  - *Is a.s. also biocide/veterinary drug?*
  - *Proof of authorisation in third countries?*
- *GAP table (Conditions of use)*
- *(Mixture Composition document)*

Active substance document/dataset:

- *Active substance identification*
- *IUPAC*
- *CAS number*
- *…*

Conclusion and perspectives

- **To follow-up during the developing phase (by October 2020):**
  - Connection/Linkage between the different pieces of the puzzle
  - Simple validation rules (e.g. mandatory fields in all cases)
  - Follow-up on endpoints summaries
  - Flexibility considering technical solutions
  - Report generator (what is possible?)



- **To follow-up during the implementing phase (by March 2021):**
  - Change of habits/ change of mindset
  - Training material to be developed for Applicants and MS, with specific attention to be given for the different types of Applicants (e.g. main authorisation holders, generic manufacturers, minor use growers associations…)

- **To follow-up for future update (October 2021…):**
  - Further validation rules to be developed with experience (e.g. flexible ToC depending on the purpose of MRL application)
  - Report generator (for application form, for evaluation report…)?