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Applications to modify, set or delete MRL (Article 10 MRL applications)

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Legal background

Umbrella regulation on substance approval Reg. (EC) No 1107/2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

Procedures for MRL applications: Reg. (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin (Articles 6-10 and Article 18)
Data requirements (new data requirements): Reg. (EU) No 283/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market
Data requirements (old data requirements): Reg.(EU) No 544/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances

Basis for MRL applications:

- Set specific maximum residue level(s) (new active substance not mentioned in Annex II/III/IV of Regulation (EC) No 396/2005) not evaluated a.s.
- Set specific maximum residue level(s) (changing current EU MRL listed in Annex II or III of Regulation (EC) No 396/2005 approved a.s.
- Set import tolerance(s) (new active substance not mentioned in Annex II/III/IV of Regulation (EC) No 396/2005) not evaluated a.s./not approved a.s.
- Set import tolerance(s) (changing current EU MRL listed in Annex II or III of Regulation (EC) No 396/2005) approved a.s.
- Delete maximum residue level(s) consumer risk

Basis for MRL applications (contd):

- Include an active substance in Annex IV no MRLs needed
- Amend existing residue definition could trigger new tox. assessment
- Include active substance/product combinations into Annex VII as referred to in Article 18 (3) of Regulation (EC) No 396/2005
- Evaluation of confirmatory data following review according to Article 12 of Regulation (EC) No 396/2005

Procedure for applications for MRLs:

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_mrl-setting-proc.pdf

Done before authorisation can be granted/before import of commodity/Currently no dossier format

- Step1: Applicant (any party, including MS) prepares MRL application, dossier and non-confidential version of dossier and submits to EMS (evaluating MS) where authorisation is sought/to RMS for import tolerances. Pre-submission advice provided by EMS, EFSA (new requirement Transparency Regulation).
- Step 2: Verification of application by EMS, check of dossier vs Register of Studies (new requirement Transparency Regulation)
- Step 3: EMS informs COM and EFSA on receipt of application. Confidentiality decision on dossier, publication and launch of public consultation on dossier (new requirement Transparency Regulation)

Procedure for applications for MRLs (contd):

- Step 4: EMS carries out assessment in a form of Evaluation Report (ER) and has the possibility to stop-the-clock in which case an updated dossier needs to be submitted
- Step 5: Uploading of ER and informing COM and EFSA on finalisation of ER
- Step 6: COM mandates EFSA to start assessment
- Step 7: EFSA performs assessment in a form of Reasoned Opinion (risk assessment, MRL proposals), EFSA has possibility to stop-the-clock in which case an updated dossier needs to be submitted.
- Step 8: Voting of MRL proposals by PAFF "Pesticide residues"

Content/format of APPL/dossier

- **Good Agricultural Practice (GAP) excel table** (details on the use patterns, to be verified by MS; basis for overall assessment) (1)

- **MRL application form: SANCO 4044/2008 Rev. 10.2 of 16 June 2016** (information on applicant and the type of request) (2) https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_mrl-appl-form.pdf

- **Regulations (EU) No 283/2013 and (EU) No 544/2011 on data requirements** (Describes/defines content of dossier/assessment) (3)

GAP TABLE (1) IUCLID backlog 1687

- Reference (Application)
- Use number
- Crop EPPO code
- Crop common name (EN)
- Crop scientific name
- Food code (Reg. 396/2005)
- Commodity name (MRL request)
- Country full name
- Country ISO code
- Zone (for ppp authorisation)
- Region for MRL setting
- Growing crops
- Outdoor / Indoor
- Pest/harmful organism/diseases- EPPO code
- Pest/harmful organism/disease scientific name
- Pests/harmful organism/diseases controlled common name (EN)
- Comments pest/harmful organism/diseases
- Formulation name
- Formulation type
- Number of a.s. present in the formulation
- active substance 1 (a.s. 1) - basic substance
- variant of a.s. 1
- a.s. 1- conc. in formulation .. (up to 3)
- Unit (concentration of a.s. in formulation)
- Method / kind of application
- Growth stage from BBCH
- Growth stage until BBCH
- Season
- Min. number -Max. number
- Interval (days) Min. - Interval (days) Max
- Min. water amount -Max. water amount
- Unit for water amount
- Min. application rate (expressed as a.s.)
- Max. application rate per application (expressed as a.s.)
- Maximum seasonal application rate
- Unit for application rate
- PHI or waiting period (days)
- Re-entry period (Unit for re-entry period)
- Seed density (kg of seeds per ha)
- Label
- NOT completed yet! Excel format/drop down lists

MRL application form (2)
DOSSIER HEADER INFORMATION?

- Purpose of the application (slide 3)
- Details on the status of evaluation (date of receipt of APPL to MS)
- Applicability of GD (new or old data requirements) and justification
- Evaluating Member State (EMS)/Rapporteur Member State (RMS)
- Applicant (which party)
- Details on the status of evaluation (pending/scheduled)
- Details Concerning Applicant (code, contact person, address)
- Information on the PPP Used (trade name/formulation)
- Active substance (a.s.) for which the MRL Application is to be Submitted (ISO, IUPAC, use, biocide, vet.d.)
- Content of that a.s. in the Formulation (variant, code name)
- Name and content of other a. s. (n…)
- Residue definitions for RA, Monitoring (plant/animal)
- Product(s) of Plant or Animal Origin as listed in Annex I of regulation (EC) No 396/2005 (code, name, existing MRL, proposed MRL)
- Enclosed Documents According to Regulation (EC) No. 396/2005
- Further information requested by MS to cover requirements on national procedures
- GAP table

- + subsections

Assessment/dossier content (3)
ACTIVE SUBSTANCE DATASET ?

- **Identity and use of a.s.** (part covered by MRL APPL and GAP table; structures, molar mass; log Pow; mode of action)
- **Mammalian toxicology** (min.metabolism study in rats – max. full tox package)
- **Methods of analysis for enforcement in plant and animal commodities** (study reports method validation data, confirmatory methods, ILV)
- **Residues in plants**
- - Metabolism studies in primary crops and rotational crops (number of crops; study reports)
- - Storage stability studies (number of matrices; study reports)
- - Processing: nature and magnitude of residues (number of commodities; study reports)
- - Magnitude of residues in primary crops (residue trials)(from 1-XX crops, study reports; method validation; storage stability; OECD calculator)
- - Magnitude of residues in rotational crops (many crops, study reports; method validation; storage stability studies)
  - + information on fate and behaviour in soil (relevant metabolites; degradation rate)
  - + soil plateau conc. calculation
- **Residues in livestock**
- - Metabolism studies in livestock (number of animals; study reports)
- - Livestock dietary burden calculation (DB calculator)
- - Magnitude of residues in livestock (feeding studies) (number of animals, method validation, storage stability)
- **Dietary exposure**
- PRIMo model (consumption data)+ from other sources
- **Proposed MRLs**
- **GAP table**

Points for discussion (1)

- One application can contain more than 1 request (i.e., for change of MRL + for change of residue definition)= option of multiple fields
- MRL application: from relatively simple to full assessment (full data set, normally except ecotoxicology and fate and behaviour)

Q: Two dossiers in one Evaluation Report?

- Application receipt date in the Member State shall be recorded (relevant for the choice of applicable data requirements)
- Application can be based on monitoring data

Q: Join application with dossier: does the MRL dossier submission type for MRL applications would also cover the needs for an MRL application submitted as part of the peer review?

Points for discussion (2)

Ability/platform where to upload models and/or forms:

- Good Agricultural Practice (GAP) table (IUCLID backlog 1687)
- Pesticides Residue Intake Model (PRIMo) (IUCLID backlog 1748)
- Livestock Dietary Burden (DB) calculator (IUCLID backlog 1776)
- Evidences of a.s. registrations in third countries/label registration (IUCLID backlog 1757)
- Evidence of the MRL in place in the third country (IUCLID backlog 1757)
- Monitoring data – how to upload? EMS or applicant?
- OECD MRL calculator
- to link with Residue trial database (IUCLID backlog 1903) and MetaPath (metabolism data)

Points for discussion (3)
Proposals for Dossier Headers

- Application type (according to Regulation 396/2005):
  - Setting of specific maximum residue level
  - Modification of specific maximum residue
  - Deletion of maximum residue level
  - Inclusion of active substance in Annex IV
  - Amendment of existing residue definition
  - Evaluation of Article 12 confirmatory data
- Justification for amendment (intended EU use/Import tolerance/Consumer intake concerns/Change of RD/Emergency authorisation…)
- Status of active substance in EU (approved/not approved/not evaluated)
- Date of receipt of APPL to MS
- Applicability of GD (new or old data requirements) and justification
- More….?

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