European Pesticides Residues Workshop 24/05/16 – 27/05/16

Current activities of the European Commission in the area of pesticides residues

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Overview (1)

Legislation: implementation of Regulation (EC) No 396/2005

- **Routine MRL setting and review programme**
- **Crops to which MRLs apply**
- **Work at international level (CCPR) and EU legislation**

Control

- **EU coordinated programme (MACP) and EFSA report on the design of the MACP**
- **Working document on substances to be considered for inclusion in the national programmes**
- **Summing up of LOQs**

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Overview (2)

Enforcement

- **Art. 15(5) of Regulation 882/2004**

Future challenges

- **Cumulative risk assessment**
- **Revision of the IESTI equation**
- **Cut off criteria - endocrine disruptors**
- **Evaluation and possible review of Regulation (EC) No 396/2005**

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Legislation – routine MRL setting

- Evaluation of **new applications** to set or modify specific MRLs (Art. 6), including import tolerances
- **Specific measures/issues**: QUACs, phosphonates, chlorate

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Legislation – Review of existing MRLs - Reg. 396/2005 Art. 12

- Priority for DG SANTE: review of complete set of existing MRLs for more than 300 substances
- Scientific input:
  - EFSA reasoned opinions
  - Advice of EU Reference Laboratories on analytical aspects in stage of draft reasoned opinion and draft Regulation (LOQs – residue definitions – availability of standards)
- 2015: MRLs for about 40 substances were reviewed
- In total MRLs for 178 substances have been already reviewed.

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Lesgislation-crops to which MRLs apply

- New Annex I of Reg. 396/2005 entered into force on 1 January 2015 (Reg. (EU) No. 752/2014) and the Commission's database was adapted.
- Revision needed again when new crop groupings are decided in Codex (ongoing for several years)
- Extrapolation guidelines were updated in 2015 and some minor future amendments are planned.

Legislation - work at international level/ Codex Alimentarius

- Presenting EU positions in Codex Committee on pesticides residues (CCPR)
- Implementation of CXLs in EU legislation annually (specific Regulation in the second half of each year)
- Active participation in electronic working groups
  - o e.g. on performance criteria for methods of analysis for pesticides residues in food

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Control- EU coordinated programme and EFSA report on the design of the MACP

- **EU MACP 2017-2019**
  - Reg. (EU) 2016/662
- **EFSA 2015 Scientific report on the design assessment of the pesticide monitoring program**
  - Representativeness of the MACP commodities for the European diet
  - Number of samples needed to draw statistically significant conclusions on compliance
  - Allocation of the number of samples per Member State
- **Selection of the pesticides**
  - New substances: previously voluntary, need to be included because of frequent findings
  - 2,4-D, cyromazine, flonicamid, fluazifop-P-butyl, flubendiamide, haloxyfop including haloxyfop-P-butyl.

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Control- working document

- **Endorsed by MS 11/2014 and updated 11/2015**
- **Substances to be considered for inclusion in national control programs on a voluntary basis.**
  - 2015 and subsequent MACPs no longer contain substances to be analysed on a voluntary basis ↔ necessary to highlight in advance substances that could be considered for uptake in a future EU MACP on a mandatory basis
- **Candidate substances for future EU MACPs**
  - Criteria
    - Frequent detections, MRL exceedances, RASFF notifications
    - Recently approved
    - Art. 12 priority list
    - High toxicity
    - Voluntary in Reg. (EU) No 788/2012
  - Evaluation period 1-2 years
  - Decision criteria: monitoring data and analytical capability
  - Final decision (uptake in EU MACP/ deletion from WD/ prolonged evaluation period)
    - Discussion in expert group on pesticides residues monitoring
    - Final decision PAFF Committee pesticides residues

Control– summing up of LOQs in case of complex residue definitions

- Complex residue definitions: residue definitions consisting out of different components
- In case the different components are measured separately, Member States use different approaches for reporting the ResLOQ
- PAFF Committee 09/2015 agreement on a general approach:

Control– summing up of LOQs in case of complex residue definition

- **General approach**
  - MRL setting: EFSA follows OECD Guidelines → sum LOQs in case residues in trials < LOQ
  - Reporting LOQs and results
    - All individual components, as far as measured separately, should be reported
    - All individual component's LOQs as far as measured separately, should be reported
    - All quantified components (> indiv LOQ) are summed up for ResVal
    - For ResLOQ a reference code is selected that refers to the individual LOQs
  - Sensitivity check (to be performed by the labs):
    - Sum measured individual component's LOQs ≤ MRL-LOQ (0.06 mg/kg)
    - LOQ x1 = 0.015, x2 = 0.015*, x3 = 0.03
    - 0.015+0.015+0.03 = 0.06 = MRL LOQ : OK
    - Possible to report the result of the sensitivity check as ResLOQ instead of the reference code
  - Timelines
    - November 2015 approach was taken note of
    - Application date 1 January 2017: this means from 2017 data collection onwards

Enforcement – increased level of official controls

- Art. 15(5) of Regulation 882/2004 – updating the list of pesticides in food/feed of non-animal origin with increased level of official control at point of entry
- Annex I to Reg. (EC) No 669/2009
  - Commodity – country of origin
  - Pesticides residues
    - Previously FN listing all substances to be analysed
    - Now 'Footnote (2)': to be analysed for all pesticides listed in the EU MACP provided they can be analysed with multi-residue methods
    - Now 'Other footnotes (3) – (…)': to be analysed for specific additional pesticides
      - » Not EU MACP
      - » Single residue method needed

New challenges - cumulative risk assessment (CRA)

Legal basis for CRA:

- Art. 14 and 36 of Regulation (EC) No 396/2005 on maximum residue levels, Recital (6)
- Art. 4 of Reg. (EC) No 1107/2009 on the placing on the market of PPPs

→ cumulative risk assessment is to be used once methodology is available

New challenges – CRA: current status

- EFSA: opinions on the methodology
  - Grouping on the basis of a common effect
  - Probabilistic calculation methodology
- EFSA work on cumulative assessments groups (CAGs)
  - 2 CAGs established focusing on effects on thyroid and nervous system
  - EFSA work on other CAGs is ongoing
- ACROPOLIS on-line IT tool (RIVM- FP7)
- COM: working group currently discusses risk management questions

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New challenges: revision of the IESTI equation

- PAFF Committee identified the need to take up earlier discussions on the revision of the IESTI equation
- Close collaboration between risk assessors and risk managers needed
- Discussion should be held at international level first:
  - workshop by RIVM, JMPR and EFSA in September 2015
  - CCPR 2016: an e-WG has been set up for the preparation of discussions in the 2017 CCPR.

New challenges - cut-off criteria

- Approval of active substances: the cut-off criteria (carcinogens – reproductive toxicity – endocrine disruptors) ↔ decisions on definition negligible exposure and criteria for endocrine disruptors

- Application of the criteria may impact MRL and import tolerance setting for substances falling under the cut off criteria

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New challenges - cut-off criteria

- Criteria for endocrine disruptors
  - Significant impact on health, environment, trade and agriculture
  - Public consultation and stakeholder conference were held in 2015
  - Impact assessment to analyse different options for defining criteria is at its final stage

- COM will present a legislative proposal before summer.

New challenges – evaluation and possible review of Reg. (EC) No 396/2005

- Legal deadline in Reg. 396/2005 for a report on implementation to Council and Parliament: 10 years after entry into force → 2015
- Revision Reg. 396/2005 planned jointly with Reg. 1107/ 2009. Currently a road map for public consultation is being drafted.
- Evaluation study by an external contractor is planned for 2016/2017
- Reports to Council and Parliament: 2017/2018

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New challenges- Review of Reg. 396/2005

- Alignment with Reg. 1107/2009, e.g. cut-off criteria, procedural alignments
- Alignment with Treaty of Lisbon
- Biocides
- Clarifications and addressing legal gaps

  e.g. dual use substances, presence of residues from other sources than PPP use.

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Questions

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