5th Joint Workshop of the European Union Reference Laboratories – 30/09/15 – 02/10/15

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

- **Results of the 2013 monitoring**
- **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**

Overview (2)

Enforcement

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

Future challenges

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

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

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

- Priority for DG SANTE to speed up the review
- Review of complete set of existing MRLs for more than 300 substances (Art.12 review)
- Scientific input:
  - EFSA reasoned opinions
  - Advice of EU Reference Laboratories on analytical aspects in stage of draft reasoned opinion (LOQs – residue definitions - standards)
  - LOQs are updated taking into account advice of EU RLs
  - Footnote that standards should be made available
- 2013: MRLs for about 50 substances were reviewed
- 2014: MRLs for about 60 substances were reviewed

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 currently under discussion with the Member States

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
  - e.g. on performance criteria for methods of analysis for pesticides residues in food

Control– Results of the 2013 monitoring exercise (1)

Surveillance + enforcement samples

- **2.6% MRL exceedances**
- **1.5% non-compliant samples (taking into account the uncertainty of measurement)**

Declining trend since 2005 (surveillance samples)

2005	2006	2007	2008	2009	2010	2011	2012	2013
5%	5%	4%	3.5%	2.6%	2.8%	2.5%	2.2%	2.0%

More MRL exceedances in Third Country samples

- **EU and EFTA countries: 1.4%**
- **Third Countries: 5.7%**

Control– Results of the 2013 monitoring exercise (2)

Babyfood: 0.7 % MRL exceedances

Organic products: 0.8% MRL exceedances

Multiple residues: 27.3% of the samples

No chronic health concerns identified.

Probability of acute health concerns very low:

- **Mostly due to non-compliant samples**
  →Enforcement actions taken
- **All MRLs currently under review**

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

- **EU MACP 2017-2019**
  - Expert Group on Monitoring 25 Oct 2015
  - Vote February 2016
- **EFSA 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
  - Because of analytical challenges the 2014 Working group agreed to postpone their uptake in the MACP until 2017
  - 2,4-D, cyromazine, flonicamid, fluazifop-P-butyl, flubendiamide, haloxyfop including haloxyfop-P-butyl.

Control- working document

- **Endorsed by MS 11/2014**
- **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**
  - Listed in chapter 4
    - 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 - working document

- **Evaluation procedure**
  - Substances with priority 1: evaluation period 1 year
    - Analysis in 2015
    - Evaluation by Oct 2016
      - » EURLs: analytical capability - % of labs analysing full residue definition
      - » EFSA (results reported under national programs-08/2016): % findings, % MRL exceedances, No RASFF norifications
      - » Discussion in WG Oct 2016
    - Vote EU MACP 2018 in Feb 2017
  - Substances with priority 2: evaluation period 2 years
    - Analysis in 2015 and 2016
    - Evaluation +discussion in WG by Oct 2017
    - Vote EU MACP 2019 in Feb 2018

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

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

- **Requirements for implementation:**
  - Assigning specific ParamCodes to all individual components that can be measured separately
  - Data model reflecting hierarchical link between individual components and the residue definition
  - Algorithm for calculating ResLOQ
- **Timelines**
  - Sept 2015 PAFF: general approach agreed
  - Nov 2015 PAFF: final version working document presented for Note Taking
  - EFSA spring 2016 networking group: establishing code list (input EURLs and labs needed)
  - EFSA autumn 2016 networking group: SSD Guidance on 2017 data collection
  - Approach will be applicable 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 (1)

- 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)

New challenges – CRA: current status (2)

- COM: working group currently discusses risk management questions
- DG SANTE and EFSA drew up projects on cumulative risk assessment for RIVM to continue the work of the FP 7 ACROPOLIS project during 2015 and 2016

New challenges – CRA: subjects under discussion in WG

- Regulatory actions to be undertaken when a cumulative risk is identified
- Threshold for regulatory concern
- Probabilistic versus deterministic methodology
- Tiered approaches
- Different procedures
  - Acute ↔ chronic
  - Exposure assessment post approval ↔ MRL setting
- Other international systems
- Communication

New challenges – CRA: importance of monitoring data

- Good quality monitoring data are crucial for post-authorisation exposure assessment and for assessing the background exposure for MRL setting.
- Reporting on all individual substances that are measured separately → refined calculations.
- Reporting residues as 'detected, non-quantified'

  → Needed for refinements on the non-detects

  → To be added to SSD format

New challenges – CRA: future implementation of CRA in risk management

When?

- Once all the Cumulative risk assessment groups have been established by EFSA

How?

- Define detailed procedures
- Evaluate impact of change of methodology
- Consideration of international trade
- Define communication strategy

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

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
- COM is developing criteria to identify endocrine disruptors, as required by Reg. 1107/2009 on plant protection products and by Reg. 528/2012 on biocides
- Criteria may impact MRL and import tolerance setting for substances falling under the cut off criteria

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 ongoing until mid-2016
- Legislative proposal will only be submitted after finalisation of impact assessment.

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

- Legal deadline in Reg. 396/2005 for 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 drafting road map for public consultation.
- Evaluation study by external contractor planned for 2016/2017
- Reports to Council and Parliament: 2017/2018

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 from other sources than PPP use, Art. 12 procedures.

European Commission

Questions

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