

Joint Workshop of the EURLs/NRLs (FV-SRM)

Almeria, 27-28/09/18

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

Stephanos Kirkagaslis





✓ Organizational Overview

Residues Team

✓ Legislation work

MRL Setting and Review

Crops to which MRLs are applicable

EU Multi-Annual Control Programme (EU MACP)

√ Control aspects

2016 EU MACP/NCP Results

✓ Challenges

Cumulative Risk Assessment

Baby Food Report





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Organizational Overview



DIRECTORATE E: Food and Feed Safety,

Innovation

Unit E4: Pesticides and Biocides

Unit E4.001: Pesticide Residues

Unit E4.002: Pesticides – Placing on the market

Unit E4.003: Biocides

Standing Committee on Plants, Animals, Food and Feed – SECTION: Pesticide Residues

Standing Committee on Plants, Animals, Food and Feed – SECTION:
Legislation

Standing Committee on Biocidal Products

Health and Consumers

The Residues Team





Volker Wachtler



Roberto Manos



Christophe Didion



Almut Bitterhof



Marc Leguen de Lacroix



Stephanos Kirkagaslis



Sofie Hofkens





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Legislation work (1)



Regulation (EC) 396/2005

MRL setting (art.6)

- 2017 : ca. 50 a.s. -

- ✓ Routine (art.10), including ITs
- ✓ Temporary MRLs (art.16)
- ✓ Revocation of authorization (art.17)
- ✓ CXLs implementation (art. 14(2))

MRL Reviews (art.12)

- 2017 : ca. 20 a.s -

- > EFSA reasoned opinions
- Consultation of EURLs on analytical aspects in draft reasoned opinion (LOQs – residue definitions standards)
- LOQs are updated taking into account advice of EU RLs
- Footnote that standards should be made available



Legislation work (2)



Regulation (EC) 396/2005

Work at International Level

- ✓ Participation in CCPR
- ✓ Participation in e-WGs, e.g on the revision of the Guidelines on the use of mass spectrometry for the identification, confirmation and quantitative determination of residues (CXG 56-2005)

Crops to which MRLs are applicable

✓ Update of Annex I, e.g. Regulation (EU) 2018/62 for inter allia radish leaves...



Radish Leaves

European

Commission

Regulation (EU) 2018/62



E.g Chlorpyriphos 0.05*(243020) vs 0.2 (213080)->???



Radish Leaves

European

Commission

Regulation (EU) 2018/62



Regulation (EU) 2018/1049

- Voted on 22 March 2018
- 4yrs transition for Kales MRLs to apply on Radish Leaves



Legislation work (3)



Regulation (EC) 396/2005

EU Multi-Annual Coordinated Programme (MACP) (art.29-33)

- EU MACP 2020-2021-2022
 - WG Meeting of Experts on Monitoring 12/10/2018
 - Possible Re-Allocation of Sample number/country

Monitoring
Regulation
(02/2019)

- > **SANCO-12745-2013:** Working Document on pesticides to
 - be considered for inclusion in the national control
 - programmes (NCPs)
 - Current Revision endorsed 11/2017
 - Evaluation/Selection of Pesticides for Annex I,D of Monitoring Regulation

Survey on Labs' capabilities

Initiated 19/09/2018





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Control Aspects

Surveillance + enforcement

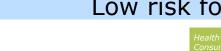


2016 EFSA Report on Pesticide Residues (July 2018) (art.32)

- Overall
 3.8% MRL exceedances (2015, 2.8%)
 2.2% non-compliant samples (2015, 1.6%)
 - MRL exceedances in Third Country samples Third Countries: 4.7% (2015, 3.4%) EEA-EFTA countries: 1.1% (2015, 0.9%)
 - Baby Foods: 1.9% (2015,3.3%)
 - Organic Products: 0.8% (2015, 0.7%)
 - Multiple Residues: 30% (2015, 28%)

Acute/Chronic Exposure Assessment:

Low risk for EU citizens





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Cumulative Risk Assessment (1)

>Legal basis - Regulation (EC) 396/2005

Recital (6): ...important [...] to develop a methodology to take into account cumulative and synergistic effects.

Art.14(2)(b): account shall be taken [...] their known cumulative and synergistic effects, when methods are available.

>Legal basis - Regulation (EC) 1107/2009

Art.4(2)(a): Residues of PPPs shall not have any harmful effects on human health tking into account known cumulative and synergistic effects...





Cumulative Risk Assessment (2)

EFSA

COM/MS

ACROPOLIS

WG Experts on CRA (15/06/2018)

WD on CRA, SANTE **±** 10216-2015, Rev7

Margin of Exposure?
Distribution Percentile?
Whole Population?
Handling NDs?
Tiered approach?

EFSA Guidance Document on the Use of Probabilistic Methodology for modelling dietary exposure to pesticides (2012)

EFSA Scientific Opinion on the identification of pesticides to be included in CAGs based on their toxicological profile (2013)

Report on CRA (2019)

Cumulative Assessment
Groups (e.g. CAG NAM, CAG
NAN – Public consultation,
May 2018)

Report on Verification Calculations (SAS)

RIVM

MCRA, v8.2

Retrospective calculations on acute/chronic exposure CAG NAN/NAM CAG TCP/TCF



Cumulative Risk Assessment (3)

> Do Laboratory results impact CRA?







Cumulative Risk Assessment (3)

> Do Laboratory results impact CRA?



- ✓ Good quality monitoring data are crucial for post-authorisation exposure assessment and for assessing the background exposure for MRL setting.
- ✓ Need for further refinement of NDs → reporting Limits of Detection (vs LOQs)





EFSA Opinion on Foods for Infants and Young Children (June 2018)

- ➤ For infants <16w.o., the default MRL is safe for pesticides with ADI>0.0026mg/kgbw
 - ✓ Discussed in the September PAFF
 - √ 66 pesticides ADI<0.0026mg/kgbw
 </p>
 - √ Request to EURLs (LOQs)
 - ✓ Very Low Findings 2012-2016 (IF, 3 findings)
 - > MSs to comment
 - Discussion during WG Monitoring







Project on Dithiocarbamates



- > EFSA Art.12 review on Dithiocarbamates (2019)
 - ✓ Background CS2 levels
 - ✓ Collection of organic samples (prioritised crops)
 - √ 59 samples per crop (as diverse as possible)
 - ✓ EURL-SRM → PestiPedia



- ✓ MSs to declare contact points for data entry (intention and existing): Authorities, CBs, etc.
 - Only 3 countries (DE,PT,GR) (06/2018)







Questions

stephanos.kirkagaslis@ec.europa.eu

