



Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit



Recent Developments in MRL Estimations in the EU

**2014 MRL Harmonization Workshop
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About the presentation

- ⦿ **Revision of Annex I to Regulation (EC) No 396/2005**
- ⦿ **MRL setting for non-agricultural pesticides**
- ⦿ **Cumulative risk assessment**

Revision of Annex I (1)

In February 2014 MS took note on a new Annex I.

- ☑ Annex I will be divided into two parts:**
- ☑ Part A will consist of crop groups and example of crops**
- ☑ Part B will consist of other products to which the same MRLs apply (the related crops)**

Publication expected in early summer 2014.

Revision of Annex I (2)

Part A

- ☒ **The existing crop groups will not be changed!**
- ☒ **Scientific names of the crops were checked and amended, where necessary.**
 - ☒ This was especially the case for products of animal origin.
- ☒ **"Part of the product to which MRLs apply" was checked and where necessary amended.**
- ☒ **An empty group 13 will be added to cover "Processed Food Products".**
 - ☒ Footnote added: "MRLs are not applicable until individual products are identified and listed within the category."

Revision of Annex I (3)

Part B




The related crop form no a separate Part of Annex I.

- ☒ **Number of related crops changed, in some cases dramatically.
In many cases crops from Codex classification were added.**
- ☒ **For all related crops scientific names were added.**
- ☒ **Reference to Part A is made by naming category, code and
crop to which the crop in part A relates.**

Revision of Annex I (4)

Part B

A some related crop changed their relation. These are:

-  **cloudberries, cowberries, arbutus berry, black choke berry, sea buckthorn, service berries, kiwi berries, pomerac, rose apple, pulasan, rambutan, mangosteen, langsat, mammey sapote, dragon fruit, angelica roots, lovage roots, tree tomato (tamarillos), turnip greens, mizuna, choi sum, kohlrabi leaves, sorrel, summer and winter savory, wild betel leaves, curry leaves, lemmon grass, canary grass seed, elder flowers, ginkgo leaves, kangaroo**
-  **Codex classification was taken into account.**
-  **No transitional period for checking the applicability of the new MRLs was granted.**

Revision of Annex I (5)

Part B

Exemptions:

- ✓ **Kiwi berries**
- ✓ **Choi sum/tsoi sum**
- ✓ **Mizuna**
- ✓ **Turnip greens/turnip tops**
 - ✓ For all four commodities a transitional period is granted.
- ✓ **Kohlrabi leaves**
 - ✓ The existing transitional period still remains.

MRL setting for non-agricultural pesticides (1)

- ☑ **Non agricultural pesticides, called biocides in the EU**
- ☑ **Covered by Regulation (EU) No 528/2012 (OJ L 167, 27.6.2012, p. 1)**
- ☑ **Includes uses that are internationally covered by the definition of pesticides**
 - ☑ Uses in animal housing
 - ☑ Direct animal treatments

MRL setting for non-agricultural pesticides (2)

- ☑ **Active substances are grouped into 4 main groups with overall 22 product-types**
- ☑ **Main group 1: disinfectants**
- ☑ **Main group 2: preservatives**
- ☑ **Main group 3: pest control**
- ☑ **Main group 4: other biocidal products**

MRL setting for non-agricultural pesticides (3)

- ☑ **A short comparison showed that about 40% of active substances used in plant protection products will also be used in biocidal products.**
- ☑ **They do not only belong to main group 3 (pest control substances) but also to other groups, especially disinfectants.**

MRL setting for non-agricultural pesticides (4)

☑ Main group 3: pest control

- Product-type 14: Rodenticides
- Product-type 15: Avicides
- Product-type 16: Molluscicides, vermicides and products to control other invertebrates
- Product-type 17: Piscicides
- Product-type 18: Insecticides, acaricides and products to control other arthropods
- Product-type 19: Repellents and attractants
- Product-type 20: Control of other vertebrates

MRL setting for non-agricultural pesticides (5)

☑ Main group 1: disinfectants

- Product-type 1: Human hygiene
- Product-type 2: Disinfectants and algaecides not intended for direct application to humans or animals
- Product-type 3: Veterinary hygiene
- Product-type 4: Food and feed area
- Product-type 5: Drinking water

MRL setting for non-agricultural pesticides (6)

- ☑ **Article 19 of Regulation (EU) No 528/2012 requires, where appropriate MRL setting in one of the following legal acts, before authorisation:**
- Council Regulation (EEC) No 315/93: contaminants in food
 - Regulation (EC) No 1935/2004: materials and articles intended to come into contact with food
 - Regulation (EC) No 396/2005: pesticides in or on food and feed of plant and animal origin
 - Regulation (EC) No 470/2009: pharmacologically active substances in foodstuffs of animal origin
 - Directive 2002/32/EC: undesirable substances in animal feed

MRL setting for non-agricultural pesticides (7)

- ☑ Independent of the interpretation of the phrase "where appropriate" and
- ☑ independent of the question of the MRL legislation mentioned the following applies:
 - ☞ Any active substances mentioned in the pesticide data base of the European Commission is covered by a MRL based on the rules of Regulation (EC) 396/2005.
http://ec.europa.eu/sanco_pesticides/public/?event=activesubstance.selection
 - ☞ These MRLs also apply to the same active substance when used as biocide.

MRL setting for non-agricultural pesticides (9)

Some of the problems so far known (use as disinfectants)

- ✓ **DDAC (didecyldimethylammoniumchlorid):** old as mentioned in the database, approval from 1st January 2010 to 20th June 2013.
- ✓ **BAC (benzalkonium chloride):** old as mentioned in the database; as not approved.
- ✓ **For both substances default MRL of 0.01 mg/kg legally applies.**
- ✓ **For DDAC and BAC Member States agreed to apply Guideline Levels at 0.5 mg/kg**
- ✓ **The Levels will be replaced by temporary MRLs at 0.1 mg/kg (Regulation voted last week). MRLs will be reassessed in 2019.**
- ✓ **Guideline levels will be in place for a transitional period of 9 months after entry into force of the above mentioned Regulation.**

MRL setting for non-agricultural pesticides (8)

Some of the problems so far known (use as disinfectants)

- ☒ **Sodium chlorate: old as mentioned in the database; use in Germany as an herbicide terminates end of 1988; active substance not approved.**
- ☒ **Default MRL of 0.01 mg/kg legally applies.**
- ☒ **European Commission failed to set Guideline Levels last week as some Member States did not agree.**

MRL setting for non-agricultural pesticides (10)

- ☑ **Some of the problems arise from transitional measures in biocide regulations**
- ☑ **Old substances not yet approved remain on the market until approval of the active substance.**
- ☞ **Approval of active substance is based on product types; active substance may be used in different product types.**
- ☞ **After approval of the active substance authorisation of products starts.**
 - ☑ **Only then uses are known.**
 - ☑ **Only then MRL setting is obligatory ("where appropriate") for authorisation.**

Cumulative risk assessment (1)

Starting Point

- ☑ **EFSA 7th Scientific Colloquium – Cumulative Risk Assessment of Pesticides to Human Health: The Way Forward**
November 2006 to discuss the problems with stakeholders and to prepare the opinion
[<http://www.efsa.europa.eu/en/supporting/pub/117e.htm>]

Cumulative risk assessment (2)

EFSA publications

- ☑ **Scientific Opinion to evaluate the suitability of existing methodologies and, if appropriate, the identification of new approaches to assess cumulative and synergistic risks from pesticides to human health with a view to set MRLs for those pesticides in the frame of Regulation (EC) 396/2005 (EFSA Journal (2008) 704, 1-85), [<http://www.efsa.europa.eu/en/efsajournal/doc/705.pdf>]**
- ☑ **Scientific Opinion on Risk Assessment for a Selected Group of Pesticides from the Triazole Group to Test Possible Methodologies to Assess Cumulative Effects from Exposure through Food from these Pesticides on Human Health (EFSA Journal 2009; 7 (9); 1167), [<http://www.efsa.europa.eu/en/efsajournal/doc/1167.pdf>]**

Cumulative risk assessment (3)

EFSA publications

- ☑ **Guidance on the Use of Probabilistic Methodology for Modelling Dietary Exposure to Pesticide Residue** (EFSA Journal 2012; 10 (10); 2839), [<http://www.efsa.europa.eu/en/efsajournal/pub/2839.htm>]

Still not discussed in detail with risk managers.

Cumulative risk assessment (4)

EFSA publications

- ☑ **Scientific Opinion on the identification of pesticides to be included in cumulative assessment groups on the basis of their toxicological profile** (EFSA Journal 2013;11(7):3293 [131 pp.]), [<http://www.efsa.europa.eu/en/efsajournal/doc/3293.pdf>]
- ☑ **Scientific Opinion on the relevance of dissimilar mode of action and its appropriate application for cumulative risk assessment of pesticides residues in food** (EFSA Journal 2013;11(12): 3472, 40 pp.), [<http://www.efsa.europa.eu/en/efsajournal/doc/3472.pdf>]

Cumulative risk assessment (5)

For the moment

- ✓ (Only) Two cumulative assessment groups (CAG) available
- ✓ Nervous system (65 substances)
 - ✓ Chronic effects with five subgroups
 - ✓ Acute effects with four subgroups
- ✓ Throid system (101 substances)
 - ✓ Chronic effects with two subgroups
- ☹ The substances mentioned above may occur in several of its subgroups
- ☹ Any active substance is expected to occurs in more then one CAG

Cumulative risk assessment (6)

Next steps

- ☑ **Include non-approved and pending substances into the two existing CAGs.**
- ☑ **Set up further CAGS**
 - ☑ Liver effects
 - ☑ Adrenal effects
 - ☑ Effects on eyes
 - ☑ Reproduction and development system
 - ☑

Cumulative risk assessment (7)

Next steps

- ☑ **Calculation of the overall exposure based on monitoring data**
- ☑ **Some questions need to be answered first:**
 - ☑ How to handle results exceeding the MRL?
 - ☑ How to handle results from illegal uses?
 - ☑ How to handle non-detectable residues and zero values?
 - ☑ How to fill the gaps for pesticides not sufficiently covered by the monitoring data?
 - ☑ How to keep informed on authorised uses and changes in authorised uses per MS at EU level?

Cumulative risk assessment (8)

Additional data needed

- ☑ **Market share information: if available, a couple of details are missing**
- ☑ **Information of approval at Member State level: comprehensive authorisation data base not yet available.**
- ☑ **Processing data**

Cumulative risk assessment (9)

Last step

- ☑ **Use for MRL setting**
- ☑ **Further problems and data needs expected**

Cumulative risk assessment (10)

Upcoming activities

- ☑ **Set-up of an electronic working group from European Commission, risk manager and risk assessors**
- ☑ **Discussion of strategies to implement cumulative risk assessment in routine MRL setting process**
- ☑ **Routine calculation of background exposure for the different CAGs on an annual basis**
- ☑ **Explore combination of probabilistic models (background exposure) and deterministic models for MRL setting**

Cumulative risk assessment (11)

Last but not least

- ☑ **Collection and assessment of data relevant for non-dietary cumulative exposure to pesticides and proposal for conceptual approaches for non-dietary cumulative exposure assessment – External Scientific Report (Supporting Publications 2012: EN-346) [<http://www.efsa.europa.eu/en/supporting/pub/346e.htm>]**

Thank you for your attention!

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