



BfR Workshop on MRL-Setting for biocides

Legal aspects of relevant EU legislation related to pesticides

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Overview

- *Basic legislation on pesticides*
- *Regulation (EC) No 396/2005 on MRLs*
- *MRL setting procedures*
- *International dimension – Codex Alimentarius*
- *DG SANCO MRL database*
- *Control and Enforcement*
- *Coordinated EU multiannual programme*
- *Future review of Regulation (EC) No 396/2005*

Basic legislation on pesticides

Regulation (EC) No. 1107/2009:

- Placing of plant protection products on the market
- Authorisation of active substances and plant protection products (PPPs)

Regulation (EC) No. 396/2005:

- Maximum residue levels of pesticides in and on food and feed of plant and animal origin

Regulation (EC) No. 396/2005

Scope: Regulation applies

- to products of plant and animal origin or parts thereof covered by Annex 1 to be used as fresh, processed and/or composite food or feed in or on which pesticides residues may be present
- and without prejudice to
 - Directive 98/8/EC → Reg. 528/2012 (biocidal products),
 - Directive 2002/32 /EC (undesirable substances in animal feed) and
 - Reg. (EEC) No. 2377/90 (veterinary medicinal products)

Regulation (EC) No. 396/2005

Definition of "pesticides residues":

Residues incl. active substances, metabolites and/or breakdown or reaction products of active substances currently or formerly used in PPPs (...), which are present in/on the products covered by Annex 1 to this Regulation, incl. in particular those which may arise as a result of use in PPPs, in veterinary medicine and as a biocide

Regulation (EC) No. 396/2005

Maximum residue level (MRL)

- Upper legal level of a concentration for a pesticide residue in or on food or feed..., based on Good Agricultural Practice (GAP) and the lowest consumer exposure necessary to protect vulnerable consumers.
- Where there is more than one GAP for an active substance/product combination the critical GAP is the basis for establishing the MRL (critical GAP gives rise to the highest acceptable level of pesticide residues in a treated crop).

Regulation (EC) No. 396/2005

General principle: For any substance not covered by the Annexes of Regulation No. 396/2005 that falls under the definition of "pesticides residues" a default MRL of 0.01 mg/kg applies

Annexes of Reg.(EC) No 396/2005



Not covered by the Annexes

→ **Default MRL 0.01 mg/kg**

Annex I



List of commodities



315 commodities

Annex II



Existing EU MRLs



228 substances

Annex III A



Temporary MRLs



225 substances

Annex IV



No MRLs required



59 substances

Annex V



Default value other than 0.01 mg/kg



17 substances

Annex VI



Processing factors



Not yet established

Annex VII



Fumigants



4 substances

Regulation (EC) No 396/2005

Setting, modifying or deletion of MRLs: 2 main procedures

- Routine MRL setting: Evaluation of new applications to set or modify specific MRLs, including import tolerances (Art. 10 of Reg. 396/2005)
- Review of existing MRLs (Art. 12 of Reg. 396/2005)

Routine MRL Setting (1)

- Application to the MS in which authorisation is sought
- Clear data requirements
- MS draws up an Evaluation Report and makes it available to COM, MS and EFSA
- EFSA opinion within 3 months or in exceptional cases 6 months

Routine MRL Setting (2)

- SPS notification, if appropriate (60 days commenting period)
- Legislative proposal of COM (within 3 months)
- Discussion with the MS in the Standing Committee and vote
- Adoption after scrutiny (2 months) by Council and Parliament
- Estimated time: 12 months

Import tolerances

- An import tolerance is an MRL for imported products to meet the needs of international trade where
 - The use of the active substance on a given product is not authorised in the EU for reasons other than public health reasons for the specific product and specific use; or
 - A different level is appropriate because the existing EU MRL was set for reasons other than public health reasons for the specific products and specific use
- Basically same procedure as routine MRL setting.
- Registration in country of origin must be proven.
- Supporting data need to be submitted → EFSA assesses the safety of proposed MRLs

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

- Review of complete set of existing MRLs for more than 300 substances (Art.12 review)
- For substances approved before 1 September 2008: within 1 year
- For substances approved or non-approved after 1 September 2008: within a period of 12 months from the date of approval or non-approval of an active substance
- Exercise much delayed, also due to deficiencies in Reg. 396/2005

International dimension

Codex Alimentarius

- Codex Committee on pesticides residues (CCPR) → EU coordinated positions on CXLs prepared, based on EFSA scientific report
- Implementation of acceptable CXLs in EU legislation annually (second half of each year)



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EU Pesticides database - Windows Internet Explorer
http://ec.europa.eu/sanco_pesticides/public/?event=homepage

EU Pesticides database

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Active substances

Regulation (EC) No 1107/2009

[Active substance](#)

Active substance updated on 06/01/2014

Directorate General for
Health & Consumers

Pesticide EU-MRLs

Regulation (EC) No 396/2005

[Products](#)

[Pesticides](#)

MRLs updated on 20/01/2014

Disclaimer
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EU Pesticides database - Windows Internet Explorer
 http://ec.europa.eu/sanco_pesticides/public/?event= substance.historic
 Favorites: EURL: Residues of Pesticid... CIRCABC - Welcome (2) CIRCABC - Welcome Web Slice Gallery
 EU Pesticides database

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Fluazinam (F)

Reports

back to search

Pages: 1 2 3 4 5 6 7 8 9 10		Products as in Reg. (EU) No 212/2012	
Code number	Groups and examples of individual products to which the MRLs apply (a)	Pesticide residues and maximum residue levels (mg/kg)	
		Reg. (EU) No 251/2013	Reg. (EC) No 149/2008
0100000	1. FRUIT FRESH OR FROZEN/NUTS		
0100000	(i) Citrus fruit	0,05*	0,05*
0100030	Grapefruit (Shaddocks, poncifs, sweeties, tangelo (except minicola), ugl) and other hybrids	0,05*	0,05*
0100020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,05*	0,05*
0100030	Lemons (Citron, lemon, Buddha's hand (Citrus medica var. sarcodactyla))	0,05*	0,05*
0100040	Limes	0,05*	0,05*
0100050	Mandarins (Clementine, tangerine, minicola and other hybrids tanger (Citrus reticulata x sinensis))	0,05*	0,05*
0100990	Others	0,05*	0,05*
0120000	(ii) Tree nuts	0,05*	0,05*
0120010	Almonds	0,05*	0,05*
0120020	Brazil nuts	0,05*	0,05*
0120030	Cashew nuts	0,05*	0,05*
0120040	Chestnuts	0,05*	0,05*
0120050	Coconuts	0,05*	0,05*
0120060	Hazelnuts (Fiber!)	0,05*	0,05*
0120070	Macadamia	0,05*	0,05*
0120080	Pecans	0,05*	0,05*
0120090	Pine nuts	0,05*	0,05*
0120100	Pistachios	0,05*	0,05*
0120110	Walnuts	0,05*	0,05*
0100990	Others	0,05*	0,05*
0130000	(iii) Pome fruit		
0130010	Apples (Crab apple)	0,3	0,05*
0130020	Pears (Oriental pear)	0,05*	0,05*
0130030	Quinces	0,05*	0,05*
0130040	Medlar	0,05*	0,05*
0130050	Loquat	0,05*	0,05*
0100990	Others	0,05*	0,05*
0140000	(iv) Stone fruit	0,05*	0,05*
0140010	Apricots	0,05*	0,05*
0140020	Cherries (Sweet cherries, sour cherries)	0,05*	0,05*
0140030	Peaches (Nectarines and similar hybrids)	0,05*	0,05*
0140040	Plums (Dawson, greengage, mirabelle, sloe, red date/Chinese date/Chinese jujube (Ziziphus zizyphus))	0,05*	0,05*

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Control and Enforcement

- Compliance against MRLs is checked by MS authorities
- Unauthorised uses can be controlled through the setting of MRLs at LOD where no authorised uses exist
- Coordinated EU multiannual programme
- Rapid Alert System on Food and Feed
- Art. 15(5) of Regulation 882/2004 – pesticides in food/feed of non-animal origin with increased level of official control at import
- FVO audits in Member States and Third Countries

Coordinated EU multiannual programme

- Dual purpose: a) Check for compliance with MRLs and b) dietary exposure assessment
- Rolling programme with 3 year cycles covering major dietary contributors (3x17 commodities)
- Basis for national monitoring programmes of the MS
- 2015 – 2017 programme voted in February 2014 (166 pesticides)

Review of Reg. 396/2005

- Evaluation study for Reg. 396/2005 planned for 2015. Background: Report to EP and Council on the implementation of Reg. 396/2005 by 2015 (Art. 47 of Reg. 396/2005)
- Review should run parallel to planned review of Reg. 1107/2009
- Alignment to Lisbon Treaty
- Addressing legal gaps and clarifications (procedural aspects, dual use substances, etc.)
- Biocides?

Useful links

- DG SANCO webpage, pesticides:

http://ec.europa.eu/food/plant/pesticides/index_en.htm

- MRL database:

http://ec.europa.eu/food/plant/pesticides/pesticides_database/index_en.htm

Questions?

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