

Pesticide residues: The development and use of Maximum Residue Levels

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20 minutes

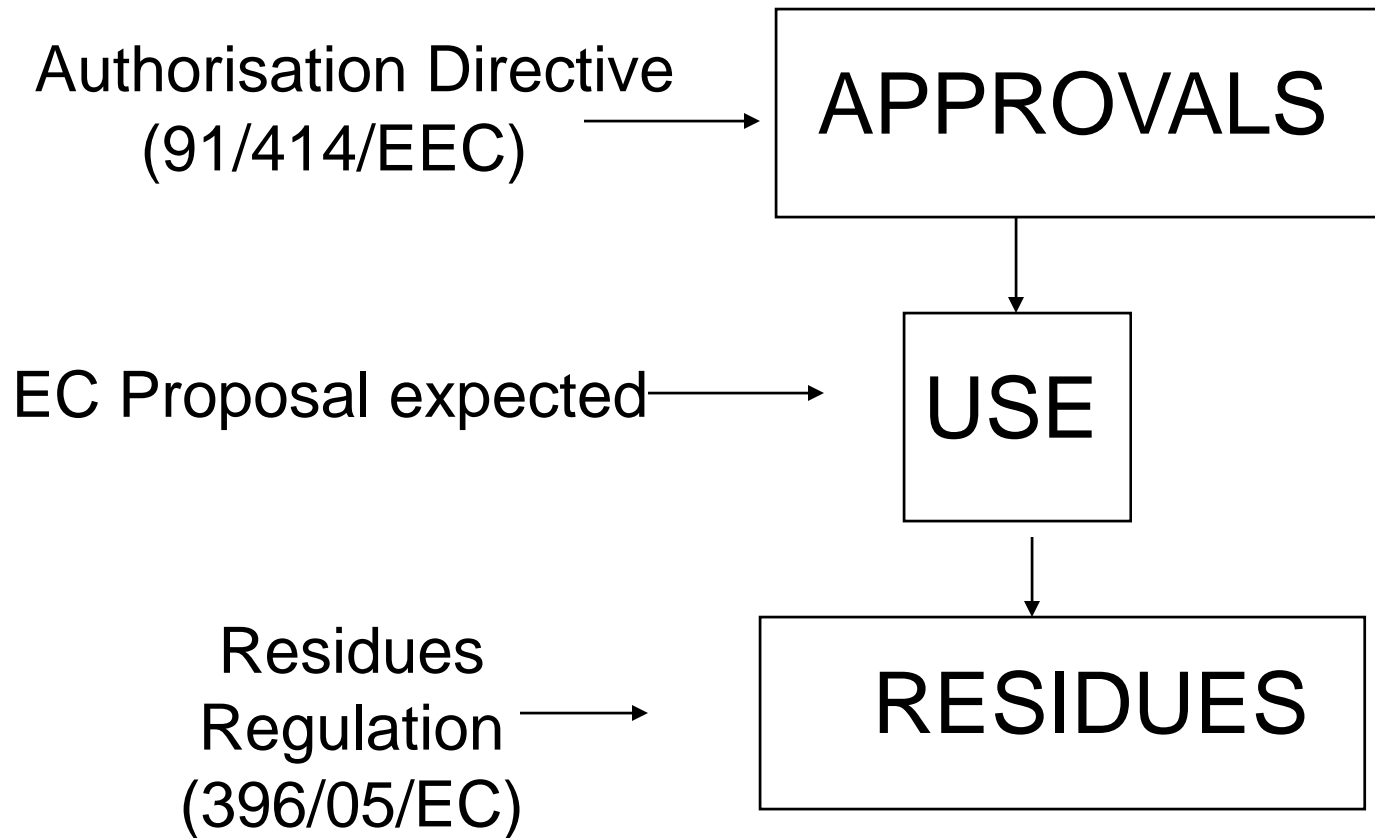


Scope of presentation

- What is an MRL?
- Previous arrangements
- New legislation
- Further sources of information



Regulatory Framework



EU Thematic Strategy for Pesticides

Comprised four elements including

- a proposed Regulation to replace the pesticide authorisation Directive 91/414/EEC
- a proposed new Sustainable Use Directive;

<http://ec.europa.eu/environment/ppps/strategy.htm>



What is an MRL? (1)

- Maximum Residue Level

The maximum concentration of a pesticide residue (expressed as mg/kg) legally permitted in or on food commodities and animal feeds

Typical concentrations of interest:

**0.01 mg/Kg = 10 µg/Kg
= 10 parts per billion**



What is an MRL ? (2)

- Mechanism for regulating trade in agricultural produce.
- Indication of residues expected when crops treated in accordance with Good Agricultural Practice (GAP).
- Definition often includes metabolites etc.
- **NOT** a measure of consumer safety.



Scope of MRLs (1)

- Fruits & Vegetables
 - *apply to specified parts*
- Cereals
- Products of animal origin
 - *variable depending on fat content*



Scope of MRLs (2)

- Dried, processed and composite products.
- Baby-food and infant formulae (separate arrangements)
- MRLs apply when listed commodities are:
 - *placed on the market*
 - *fed to animals*



Previous arrangements – in brief

- EC MRLs
 - definitive and provisional
- National (e.g. UK) temporary MRLs
- Advisory MRLs
 - import tolerances and Codex levels
- Different ranges of produce covered by each regime
- Lack of harmonisation across the EU



Previous EC MRL Directives

- 76/895/EEC fruit and vegetables
- 86/362/EEC cereals
- 86/363/EEC animal origin
- 90/642/EEC plant origin including fruit and vegetables
- All these Directives have been amended and updated many times



Codex Maximum Residue Levels (MRLs)

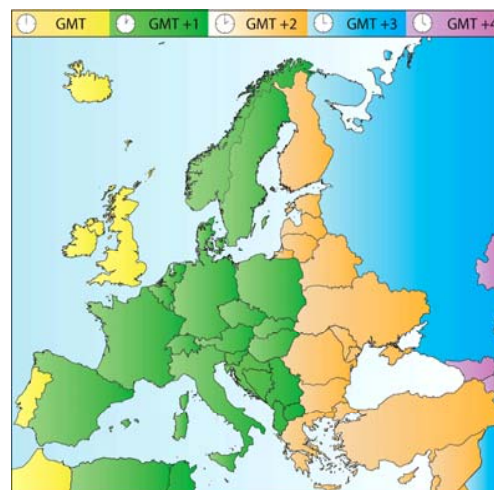
- **MRLs** set by Codex are indicative and not statutory. They are used as guidance on acceptable levels when there are no other MRLs in place.



Problems with the previous system (1)

- Too many types of MRL

Codex



EU,



National



Further problems with the previous system

- Statutory levels only set for a limited number of active substance/food combinations
- Inconsistent regulatory framework = general confusion for those wishing to trade goods within the EU



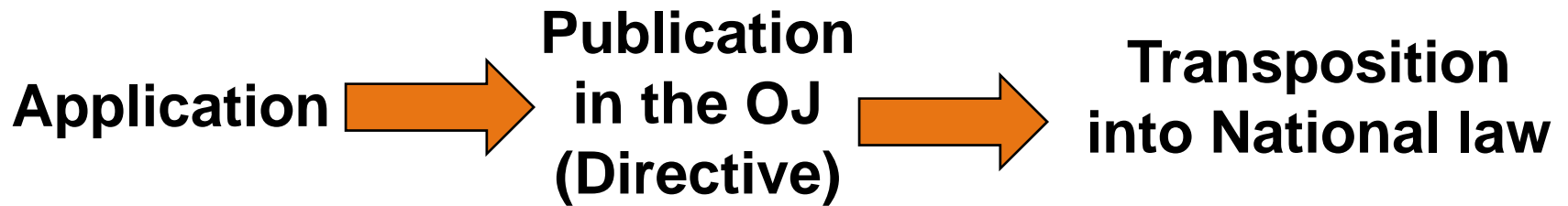
Harmonisation - EC Regulation 396/2005

- Regulation (EC) No. 396/2005
- Consolidates and replaces four existing Directives and many amendments
- Provides for full harmonisation of MRLs
- In force from September 2008
- Previous Directives revoked



EC MRLs : overview of old versus new system

Previous regime



New regime



Objective



- To set MRLs for all major commodity and pesticide combinations
- Will eventually cover around 400 pesticides and over 200 commodities
- > 100,000 MRLs set to date
- Default value if no specific MRL set (effectively zero)
- Harmonised arrangements for import tolerances

EC Regulation 396/2005 – main points

- Annex I published February 2006
 - all significant food and feed commodities
 - new inclusions e.g. spices, cocoa, coffee and sugar beet
 - fish and animal feeds expected later
 - >300 commodities

Annexes II-IV published January 2008

- **Commission Regulation (EC) No 149/2008**

- Definitive or substantive MRLs (Annex II) for 245 pesticides



EC Regulation 396/2005 – main points

- EU temporary MRLs (Annex III)
 - Harmonisation of national MRLs for >450 pesticides
- Pesticides for which MRLs **not** required (Annex IV)
 - 52 low risk pesticides
 - 6 micro-organisms & 46 plant extracts, pheromones etc.
- Annex V
 - 52 low risk pesticides
 - Default values other than 0.01 mg/kg
 - Not yet published



Other Annexes

- Annex VI
 - Conversion factors of MRLs for processed commodities
 - Not yet published
- Annex VII
 - Post-harvest treatments (stored commodities e.g. grain and seeds) which exceed MRLs

See Commission Regulation (EC) No 260/2008 establishing Annex VII listing active substance/product combinations covered by a derogation as regards post harvest treatments with a fumigant



Compliance with MRLs - 396/2005

- The products covered by Annex I shall not contain, from the time they are placed on the market as food or feed, or fed to animals, any pesticide residue exceeding:
 - (a) the MRLs for those products set out in Annexes II and III;
 - (b) **0,01 mg/kg** for those products for which **no specific MRL is set** out in Annexes II or III, or for active **substances not listed in Annex IV** unless different default values are fixed for an active substance in accordance with the procedure referred to in Article 45(2) while taking into account the routine analytical methods available. Such default values shall be listed in Annex V.



New MRLs setting process

- Member State
 - evaluates applications
 - refers dossier to EFSA if MRL changes needed
- European Food Safety Authority (EFSA)
 - risk assessment
 - recommendations to Commission
- Commission
 - risk management
 - regulatory proposals for consideration and vote



Some issues/implications arising (1)

- Member States no longer set MRLs for commodities in Annex I.
- EFSA risk assessment needed for all MRLs.
- End to system of temporary national MRLs and immediate setting of import tolerances.



Some issues/implications arising (2)

- Significant expansion to number of EC MRLs
- Many default values set at the LoD of the methods
- Possibility of more MRL breaches; enforcement consequences for those responsible

Impact on monitoring requirements

- Member States are required to carry out official controls with greater scope to determine compliance
- The Commission has prepared a co-ordinated multi-annual community control plan (2008/103/EC) with specified pesticide-commodity combinations



Further Information – MRLs 396/2005

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

The screenshot shows a web browser window displaying the European Commission website. The page title is "Food Safety - From the Farm to the Fork". The main navigation bar includes "EUROPA > European Commission > DG Health and Consumers > Overview > Plant Health". The page content is titled "Plant Protection - Pesticide Residues" and "Maximum pesticide levels for food products for human consumption and animal feedingsuffs". The text describes the Regulation (EC) No 396/2005, its purpose, and the maximum residue levels (MRLs) for various food products. The page also includes a sidebar with "Resources" and "International Affairs" sections. The browser's taskbar at the bottom shows several open applications, including Firefox, Microsoft Word, and Outlook.

Food Safety - From the Farm to the Fork

EUROPA > European Commission > DG Health and Consumers > Overview > Plant Health

Site Map | What's New | A to Z Index | Contact

Plant Protection | Harmful Organisms | Property Rights | Genetic Resources | Seeds and Plant Propagating Material | GM Plants & Seeds

Plant Protection - Pesticide Residues

Maximum pesticide levels for food products for human consumption and animal feedingsuffs

All foodstuffs intended for human or animal consumption in the European Union (EU) are now subject to a maximum residue level (MRL) of pesticides in their composition in order to protect animal and human health. The Regulation brings together and harmonises in one text the levels that apply to different human or animal food products and, in addition, it establishes a maximum level applicable by default.

Act

[Regulation \(EC\) No 396/2005](#) of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in products of plant and animal origin [[See amending acts](#)]

The Regulation shall be fully applicable on the 2 September 2008. Until that day, chapters II, III and V to the Regulation are not applicable; and the national MRL of each Member State for each pesticide/crop combination remains in force and operators/stakeholders should comply with the relevant national legislation.

Summary

The Regulation establishes the maximum residue levels (MRLs) of pesticides permitted in products of animal or vegetable origin that are intended for human or animal consumption. These MRLs include, on the one hand, MRLs that are specific to particular foodstuffs that are intended for human or animal consumption and, on the other, a general level that applies where no specific MRL has been set. The use of active substances in plant protection products is one of the best methods of protecting vegetables from harmful organisms. This use can, however, cause residues to be present in treated products, in animals fed with those products and in honey produced by bees exposed to these substances. The objective is to ensure that pesticide residues in foodstuffs do not constitute an unacceptable risk for consumer and animal health.

Context

Prior to this Regulation, each Member State applied its own maximum residue levels for pesticides. Previous European legislation set different levels for different kinds of product: some fruit and vegetables ([Directive 76/395/EEC](#)), cereals ([Directive 86/362/EEC](#)), foodstuffs of animal origin ([Directive 86/363/EEC](#)) and plant products, including fruit and vegetables ([Directive 90/642/EEC](#)). This Regulation repealed all these Directives, proposing harmonised maximum levels for all foodstuffs instead. It includes the same level of protection for animal feedingsuffs.

Foodstuffs concerned

The Regulation covers all products intended for human or animal consumption. These products are listed in [Annex I](#) drawn up by Regulation (EC) No 178/2006. These products are not subject to the set levels if they are intended for sowing or planting, authorised tests on active substances, manufacture of non-food products, or export outside the European Union.

Specific levels

Specific MRLs are listed in [Annex II](#) it contains MRLs already established by Directive 86/362/EEC (MRLs on cereals), Directive 86/363/EEC (MRLs for foodstuffs of animal origin) and Directive 90/642/EEC MRLs for foodstuffs of plant origin). They may be higher than the default limit.

In some cases, Temporary MRLs may be set and should then be listed in [Annex III part A and B](#). Temporary MRLs should in particular be set in the following cases:

- for national MRLs which have not yet been harmonised
- for honey and herbal infusions;
- in exceptional circumstances where contamination by plant protection products has taken place;
- where new products are listed in Annex I and a Member State requests it, in order to have enough time for a comprehensive scientific assessment and provided that no risk to the consumer has been detected.

[Annex III: part A](#) [EXCEL](#), it encloses all draft Temporary MRLs that were thus far not harmonised at EU level

[Annex III: part B](#) [EXCEL](#), it encloses all draft Temporary MRLs of active substances harmonised at EU level in and on new commodities

Default level and exceptions to the levels

The maximum pesticide residue level in foodstuffs is **0.01 mg/kg**. This general level is applicable 'by default', i.e. in all cases where an MRL has not been specifically set for a product or product type.

printable version

Resources

- Press Releases
- Consumer Voice
- Newsletter
- Publications

International Affairs

- Organisations
- Codex
- OIE
- Import Conditions
- Pets and Animal Welfare
- Enlargement
- Agreements

FOOD AND FEED SAFETY

ANIMAL HEALTH AND WELFARE

PLANT HEALTH

FVO INSPECTIONS

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