


The Food and Environment Research Agency

Pesticide residues: The development and use of Maximum Residue Levels


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(Selected slides courtesy of Arne Andersson, NFA, Sweden)



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Scope of presentation

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



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What is a Maximum Residue level (MRL) ?

- The maximum concentration of a pesticide residue (expressed as mg/kg) legally permitted in or on food commodities and animal feed
- Indication of residues expected when crops treated in accordance with Good Agricultural Practice (GAP)
- Mechanism for regulating trade in agricultural produce
- Definition often includes metabolites etc.
- **NOT** a measure of consumer safety

Scope of MRLs



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

The old EC-MRL Directives



- 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
- Various MRLs
definitive, provisional, national, temporary, advisory

Lack of harmonisation across the EU

The new MRL legislation: Regulation (EC) 396/2005 of 23/02/2005



- On maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC
- Consolidates and replaces four existing Directives and many amendments
- Provides for full harmonisation of MRLs
- In force from September 1st 2008

Harmonisation of MRLs



	Old Directives	Regulation (EC) No 396/2005
EC MRLs	250 pesticides	530 pesticides
National MRLs or no specific MRLs established	950 pesticides	None except for feed and fish
Default MRLs	none	0.01 mg/kg

Regulation of 396/2005



- Consists of
- Annex I - List of commodities
- Annex II - EU MRLs
- Annex III - Temporary MRLs
- Annex IV - No MRL required
- Annex V - Higher LOQ than 0.01 mg/kg
- Annex VI - Specific concentration or dilution factors
- Annex VII - Post harvest treatment certain fumigants

Annex I: List of commodities Commission Regulation (EC No 17/2006)



- > 315 commodities (190 existing crops and 125 new crops) divided into 12 groups

1. Fruit, nuts	5. Cereals	9. Sugar plants
2. Vegetables	6. Tea, Coffee, Cocoa, Herbal infusions	10. Products of animal origin
3. Pulses, Dry	7. Hops	11. Fish and fish products
4. Oilseeds, Oil fruits	8. Spices	12. Crops used exclusively for animal feed

Annex II : Definitive EC MRLs
Commission Regulations (EC) No
149/2008, 839/2008 and 256/2009



- Contains 245 pesticides from the old MRL Directives
- Only for the crops in the old Directives

Annex III : Temporary EC MRLs
Commission Regulations (EC) No
149/2008, 839/2008 and 256/2009



Annex IIIA

- Contains 226 pesticides (previously not harmonised) from the old MRL Directives for all 315 commodities
- Approx. 70000 MRLs

Annex IIIB

- Contains 245 harmonised pesticides for 125 new crops (previously not harmonised)
- Approx. 30000 MRLs

Annex IV Substances for which an
MRL is not necessary



- Contains 6 microorganisms
- 46 chemicals' e.g. Fatty acids, plant extracts

Annex V Substances with default values different than 0.01 mg/kg



- This Annex is empty

Annex VI : Specific concentration or dilution factors



- MRLs applicable to processed and/or composite products (if not in Annex II and III)
- Taking into account changes in the concentration of pesticide residues as a result of processing and or mixing

This Annex is still empty

Annex VII :
Post harvest treatment with fumigant
Commission Regulation (EC) No 260/2008



- Contains 4 substances for certain commodities
 - hydrogen phosphide, aluminium phosphide,
 - magnesium phosphide and sulphuryl fluoride

Provided that

- Such products are not intended for immediate consumption
- Appropriate controls are in place to prevent products reaching the consumer/end user

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) The default EC MRL of **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.

EC MRL database



- A searchable database containing all EC-MRLs is available on the DG SANCO home page

http://ec.europa.eu/sanco_pesticides/public/index.cfm

Active substances

Directive 91/414/EEC

Active substance
Active substance updated on
28/10/2009



Directorate General for
Health & Consumers

Pesticide EU-MRLs

Regulation (EC) No
396/2005

Products Pesticides
MRLs updated on 06/11/2009

New MRLs setting process



- | | |
|----------------------|--------------------------------------|
| • Applicant | Application for MRL |
| • Member State | Evaluation report |
| • EFSA | Risk assessment and reasoned opinion |
| • Commission | Proposal for regulation |
| • Standing Committee | Opinion |
| • Parliament/Council | Right of Scrutiny |
| • Commission | Adoption/publication |

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

Import Tolerances



- An MRL set for imported products to meet the needs of international trade where the use of the active substance in a plant protection product is not authorised in the Community;
 - The use of the active substance in a plant protection product is not authorised in the Community (for environmental reasons) and the active poses no health concerns
 - A different level is appropriate because the existing Community MRL was set for reasons other than consumer health e.g. LOD MRLs for tea increased with supporting evidence

Consultation with Trading Partners



- EU trading partners are consulted via WTO regard MRLs proposed (SPS notifications)
- Their observations and data submitted are taken into account before MRLs are adopted
- MRLs are set at the international level by Codex are also considered
- Application for import tolerances should be submitted to the designated EU rapporteur Member State

Summary



- A new MRL setting procedure in place
- Harmonised MRLs for all pesticides in the EU
- Harmonised risk assessment (EFSA)
- A default 0.01 mg/kg EC-MRL for compliance
- Searchable MRLs database freely available

Further Information – MRLs 396/2005



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

Food Safety - From the Farm to the Fork

EUR/PA - European Commission - DG Health and Consumers - Overview - Plant Health

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

Plant Protection - Pesticide Residues

Pesticides are used to protect crops before and after harvest from infestation by pests and plant diseases. A possible consequence of their use may be the presence of pesticide residues in the traded products.

It is necessary to ensure that such residues should not be found in food or feed at levels presenting an unacceptable risk to humans. Maximum residue levels (MRLs) are therefore set by the European Commission to protect consumers from exposure to unacceptable levels of pesticides residues in food and feed.

In the EU, as from 1 September 2008, a new legislative framework (Regulation (EC) No 396/2005 of the European Parliament and of the Council) on pesticide residues is applicable. This Regulation completes the harmonisation and simplification of pesticide MRLs, whilst ensuring better consumer protection throughout the EU. With the new rules, MRLs undergo a common EU assessment to make sure that all citizens of consumers, including the vulnerable ones, the babies and children, are sufficiently protected.

Moreover, the new harmonised Community provisions also facilitate commerce, by eliminating inappropriate technical barriers to trade.

All decision-making in this area has to be science-based and a consumer intake assessment has to be carried out by the European Food Safety Authority before concluding on the safety of an MRL.

Press release: [New rules on pesticide residues to strengthen food safety in the European Union](#) (21/09/2008)

Important legal notice
English

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