The implementation of the EU legislation on pesticide residues
- Regulation (EC) 396/2005-

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Joint Regional Symposium on Regulation of Pesticide Residues in Food
Hong Kong
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Regional Symposium on Regulation of Pesticide Residues in Food

Regulation (EC) No 396/2005

on maximum residue levels of pesticides in or on food and feed of plant and animal origin

**Main objective**: high and consistent level of consumer protection across Europe

Setting of harmonised EU-MRLs

It replaces 4 previous Directives

Applicable since 1 September 2008
Food can circulate freely on the EU market

Guarantee a high level of protection for all EU consumers

Pesticide Maximum Residue Levels (MRLs) established at EU level

Regional Symposium on Regulation of Pesticide Residues in Food
### Harmonisation of pesticide MRLs

<table>
<thead>
<tr>
<th></th>
<th>Old Directives</th>
<th>Reg. No 396/2005</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EU-MRLs</strong></td>
<td>± 250 pesticides</td>
<td>± 530 pesticides</td>
</tr>
<tr>
<td><strong>National MRLs</strong></td>
<td>± 850 pesticides</td>
<td>None, except for feed/fish</td>
</tr>
<tr>
<td><strong>Default MRLs</strong></td>
<td>None</td>
<td>0,01 mg/kg</td>
</tr>
</tbody>
</table>
Harmonisation = Simplification

**National MRLs**: 500,000

**EU-harmonised MRLs**: 100,000
Implementation of Reg. (EC) 396/2005


Annex II → Existing EU MRLs

Reg. (EC) No 149/2008 published on 1 March ‘08

+ Up-date: Reg. (EC) No 839/2008 published on 30 August ‘08

Annex III → Temporary MRLs

Reg. (EC) No 260/2008 published on 19 March ‘08

Annex IV → Substances for which no MRLs are required

Annex VII → Fumigants
ANNEX I: List of commodities

Regulation (EC) N. 178/2006

- 315 commodities – 10 main groups.
- 190 existing entries from current Directives.
- 125 new entries.
  - Mainly minor crops (e.g. cassava, thyme, lupins), but also cocoa, coffee, sugar plants.
- Fish and plants used in animal feed listed, but for the time being exempted from EU-MRL setting.
# ANNEX I: List of commodities

Regulation (EC) N. 178/2006

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
</table>
Overview harmonisation exercise

- Old CROPS (190)
- New CROPS (125)
- Pesticides MRLs Directives (245)
- Pesticides previously not harmonised (226)
Annexes II: EU definitive MRLs

± 45,000 MRLs

Old CROPS (190)

Pesticides MRLs Directives (245)
ANNEX II: Definitive EU-MRLs

- Covering 245 pesticides from old MRLs Directives.
  - ± 45000 MRLs for 229 entries
  - only existing crops under old Directives
  - combinations new crops/245 pesticides in Annex III B
Annex III part A - temporary MRLs

± 70,000 MRLs

Old CROPS
(190)

New CROPS
(125)

Pesticides previously not harmonised
(226)
Annex III Part B - temporary MRLs

± 30,000 MRLs

New CROPS (125)

Pesticides MRLs Directives (245)
ANNEX III: temporary EU-MRLs

- Part A
  - MRLs Harmonisation for 226 pesticides
  - ± 70000 MRLs for 217 entries

- Part B
  - combinations new crops/245 pesticides in Annex II
  - ± 30000 MRLs for 229 entries
ANNEX III: temporary EU-MRLs
Implementation procedure

- Creation of a **database of National MRLs**
- **EFSA reasoned opinion** on the proposed temporary EU-MRLs.
- **COM-EFSA-MS: refinement risk assessment.**
- **Opinion** Standing Committee on the Food Chain and Animal Health (SCoFCAH).
- Adoption and **Publication**

Regional Symposium on Regulation of Pesticide Residues in Food
ANNEX IV: substances for which an MRL is not necessary

- 52 entries
  - 6 micro-organisms
  - 46 chemicals (incl. plant extracts, fatty acids)

- Many substances recently evaluated or still under evaluation under Dir. 91/414/EEC. They are temporarily included in Annex IV, pending finalisation of their review under Dir. 91/414/EEC.
Compliance with MRLs

Pesticides not covered by any of the Annexes

Default MRL
0,01 mg/kg
Reg. (EC) No 396/2005

What has changed in practice

- Harmonised risk assessment (EFSA’s role)
- EU -MRLs= Pre-condition for national authorisations
- New MRLs setting procedure
- Public database on EU-MRLs
- New provisions for monitoring of pesticide residues
Reg. (EC) 396/2005

MRLs setting procedure

Applicant → Application for MRL (Annex II, III or IV)

Member State → Evaluation report

EFSA → Reasoned opinion

Commission → Proposal for a Regulation/Decision + SPS notification

Standing Committee → Opinion

Parliament and Council → Right of scrutiny

Commission → Adoption and publication

\[ \Delta t = 1 \text{ year} \]

\[ \Delta t = 2 \text{ months} \]
Consultation with trading partners and import tolerances

- EU trading partners are consulted about MRLs proposed (SPS notification)
- Their observations and data submitted are taken into account before MRLs are adopted
- MRLs set at the international level by the Codex Alimentarius Commission are also considered
- Import tolerances can be set provided that data are submitted and that the risk to EU consumers is acceptable
DATABASE on EU-MRLs

Pesticide EU-MRLs Database

Regulation (EC) No 396/2005

Disclaimer

This database is made available solely for the purpose of information. It has no legal value. It lists MRLs according to the Annexes of Regulation (EC) No 396/2005. The official MRLs are those published in the Official Journal of the European Union (Plant Protection - Pesticide Residues - Community Legislation). The Commission declines all responsibility or liability whatsoever for errors or deficiencies in this list. Neither the Commission nor any person acting on behalf of the Commission is responsible with regard to the improper use of the document and its contents.

http://ec.europa.eu/sanco_pesticides/public/index.cfm
DATABASE on EU-MRLs

Search by pesticide name
### DATABASE on EU-MRLs

**Search by pesticide name**

- **Navigation bar**
- **Export to Excel file**

<table>
<thead>
<tr>
<th>Code number</th>
<th>Groups and examples of individual products to which the MRLs apply (a)</th>
<th>Dithiocarbamates (dithiocarbamates expressed as CS₂, including maneb, mancozeb, metiram, propineb, thiram and ziram)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0100000</td>
<td>1. FRUIT FRESH OR FROZEN NUTS</td>
<td>Dithiocarbamates (dithiocarbamates expressed as CS₂, including maneb, mancozeb, metiram, propineb, thiram and ziram)</td>
</tr>
<tr>
<td>0110000</td>
<td>1) Citrus fruit (Shaddock, pomegranate, sweet almonds, tangelos, tangerines, and other hybrids)</td>
<td>5</td>
</tr>
<tr>
<td>0110010</td>
<td>2) Oranges (Bergamot, bitter orange, tangerine and other hybrids)</td>
<td>5</td>
</tr>
<tr>
<td>0120000</td>
<td>3) Limes</td>
<td>5</td>
</tr>
<tr>
<td>0130000</td>
<td>4) Mandarins (Clementine, tangerine and other hybrids)</td>
<td>5</td>
</tr>
<tr>
<td>0130500</td>
<td>5) Others</td>
<td>5</td>
</tr>
<tr>
<td>0130900</td>
<td>6) Peanuts (shelled or unshelled)</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130910</td>
<td>7) Almonds</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130920</td>
<td>8) Brazils</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130930</td>
<td>9) Cashews</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130940</td>
<td>10) Chestnuts</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130950</td>
<td>11) Coconuts</td>
<td>0.08*</td>
</tr>
<tr>
<td>0130960</td>
<td>12) Hazelnuts (Filbert)</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130970</td>
<td>13) Macadamia</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130980</td>
<td>14) Peaches</td>
<td>0.05*</td>
</tr>
<tr>
<td>0130990</td>
<td>15) Pecans</td>
<td>0.05*</td>
</tr>
<tr>
<td>0131000</td>
<td>16) Patachos</td>
<td>0.05*</td>
</tr>
<tr>
<td>0131000</td>
<td>17) Walnuts</td>
<td>0.05*</td>
</tr>
<tr>
<td>0131990</td>
<td>18) Others</td>
<td>0.05*</td>
</tr>
<tr>
<td>0132000</td>
<td>19) Figs</td>
<td>0.05*</td>
</tr>
<tr>
<td>0132010</td>
<td>20) Apricots (Cherry apple)</td>
<td>0.05*</td>
</tr>
<tr>
<td>0132020</td>
<td>21) Peaches (Cherries)</td>
<td>0.05*</td>
</tr>
<tr>
<td>0132030</td>
<td>22) Quinces</td>
<td>0.05*</td>
</tr>
<tr>
<td>0132040</td>
<td>23) Medlar</td>
<td>0.05*</td>
</tr>
<tr>
<td>0132050</td>
<td>24) Loquat</td>
<td>0.05*</td>
</tr>
<tr>
<td>0132990</td>
<td>25) Others</td>
<td>0.05*</td>
</tr>
<tr>
<td>0134000</td>
<td>26) Stone fruit</td>
<td>0.05*</td>
</tr>
<tr>
<td>0134010</td>
<td>27) Apricots</td>
<td>0.05*</td>
</tr>
<tr>
<td>0134020</td>
<td>28) Cherries (sweet cherries, sour cherries)</td>
<td>0.05*</td>
</tr>
<tr>
<td>0134030</td>
<td>29) Peaches (more cherry and similar hybrids)</td>
<td>0.05*</td>
</tr>
<tr>
<td>0134040</td>
<td>30) Plums (Grenadine, greengage, mirabelle)</td>
<td>0.05*</td>
</tr>
<tr>
<td>0134990</td>
<td>31) Others</td>
<td>0.05*</td>
</tr>
</tbody>
</table>
DATABASE on EU-MRLs

Search by product (crop)

<table>
<thead>
<tr>
<th>Product</th>
<th>MRL (mg/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apples</td>
<td>0.08</td>
</tr>
<tr>
<td>Arab apples</td>
<td>0.05</td>
</tr>
<tr>
<td>Carrots</td>
<td>0.02</td>
</tr>
<tr>
<td>Asparagus</td>
<td>0.02</td>
</tr>
<tr>
<td>Celery</td>
<td>0.06</td>
</tr>
<tr>
<td>Fruits</td>
<td>0.04</td>
</tr>
<tr>
<td>Vegetables</td>
<td>0.02</td>
</tr>
<tr>
<td>Grapes</td>
<td>0.05</td>
</tr>
<tr>
<td>Oranges</td>
<td>0.04</td>
</tr>
<tr>
<td>Potatoes</td>
<td>0.03</td>
</tr>
<tr>
<td>Tomatoes</td>
<td>0.04</td>
</tr>
</tbody>
</table>

Note: MRLs (Maximum Residue Levels) are the highest levels of pesticide that are allowed in food.
Reg. (EC) No 396/2005
What is still to be implemented ....

- Complete Annex I (Fish/feed)
- Annex VI (Processing factors)
- Article 12 (revision of MRLs)
- Cumulative risk assessment
- IESTI equation (MRL instead of HR)
Documents on the Internet

DG SANCO webpage
http://ec.europa.eu/dgs/health_consumer/index_en.htm

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

Approval of active substances
Factsheet on pesticide residues

New rules on pesticide residues in food

September 2008

Consumers are exposed to pesticides because small amounts can be found on harvested crops. These amounts are called pesticide residues. In the EU, from September 2008 onwards, a new Regulation comes into force which lays down revised rules for pesticide residues.

WHAT ARE PESTICIDES AND WHY ARE THEY USED?

The yield of agricultural and horticultural crops can be seriously reduced as a result of infestations by pests and diseases. In order to protect crops against and after harvest, plant protection products are used.

In some cases these products act by confusing insects or making crops less palatable for pests. But more commonly, the targeting chemicals, residues and later crops killed by chemical, affect pesticides result from severe undesirable effects if they are not strictly regulated.

WHAT ARE THE MAXIMUM RESIDUE LEVELS (MRLs)?

The amounts of residues found in food must be safe for consumers and must be as low as possible.

A maximum residue level (MRL) is the highest level of a pesticide residue that is legally tolerated in or on food or feed.

The European Commission has MRLs for all food and animal feed.

The MRLs for all crops and all pesticides can be found in the MRL database on the Commission website.


WHY ARE MRLS LIMITED?

In the European Union, plant protection products can be used, and it has been scientifically established that:

- They have no harmful effects on consumers, forests, or biodiversity.
- They do not prevent unacceptable effects on the environment.
- They are sufficiently effective.

HOW ARE MRLS FIXED?

In order to ensure that MRLs are as low as practically possible, in relation to the overall benefits of using plant protection products, the Commission, in consultation with the Standing Committee on the Food Chain and Animal Health, determines the MRLs for each pesticide.

These are based on the scientific advice of the European Food Safety Authority (EFSA), taking into account:

- The toxicological properties of each pesticide.
- The dietary intake of any group of consumers who may be at particular risk, such as pregnant women, infants, and young children.
- The environmental impact of the use of each pesticide.

The following table provides a list of the MRLs that are currently in force in the European Union.

HOW ARE MRLS CONTROLLED AND ENFORCED?

- General, regular, and targeted inspections are performed for all food and feed samples. Dietary and environmental studies are carried out to check if the Member States are complying with the MRLs. National authorities can carry out these inspections.
- The Commission monitors the implementation of MRLs by checking samples from food and feed sold in the EU.

WHAT IS THE EUROPEAN UNION DOING TO REDUCE THE USE OF PESTICIDES?

In addition to relying on its own research, the European Commission has also worked closely with national authorities and industry to identify new methods to reduce the use of pesticides.

THE MRL DATABASE

The Commission website contains a database which allows users to search for information on pesticides, including MRLs. The database is regularly updated to reflect the latest scientific and regulatory changes.

THE NATIONAL DATABASES AND INFORMATION SYSTEMS FOR PESTICIDES

In many countries, national databases and information systems for pesticides are available to help users find the latest information on MRLs and other relevant data.

FOR FURTHER INFORMATION

- EU database on plant protection products:
  http://ec.europa.eu/agriculture/pesticides/products/
- Food and Agriculture Organization of the United Nations:
  <http://www.fao.org/3/a-i4039e.htm>
- Publications:
  <http://publications.europa.eu/resource.htm>
- The European Chemicals Agency:
  <http://echa.europa.eu>
- The European Commission’s website:
  <http://ec.europa.eu}
Thank you for your attention