

**Update of EU pesticides legisla-  
tion, Regulation (EC) 396/2005,  
import tolerances and moni-  
toring results for Latin American  
products**

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# The old EC-MRL Directives

- Dir. 76/895/EEC: certain fruits & vegetables
  - Dir. 86/362/EEC: cereals
  - Dir. 86/363/EEC: animal products
  - Dir. 90/642/EEC: fruits & vegetables
- about 250 pesticides were included in these directives**

# **The new MRL legislation: Regulation (EC) No 396/2005 of 23 February 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

**Applicable since 1 September 2008**

[http://ec.europa.eu/sanco\\_pesticides/public/index.cfm](http://ec.europa.eu/sanco_pesticides/public/index.cfm)

# Harmonisation of MRLs for pesticides

	<b>Old Directives</b>	<b>Regulation (EC) No 396/2005</b>
EC MRLs	250 pesticides	<b>530 pesticides</b>
National MRLs or no specific MRLs estab- lished	950 pesticides	<b>None, except for feed and fish</b>
Default MRLs	none	<b>0.01 mg/kg</b>

# Regulation 396/2005

- **Contents**

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

# **Annex I: List of commodities**

Commission Regulation (EC) No 178/2006

- **315 commodities divided in 12 groups**
  - **125 new crops**
  - **190 already existing crops**

# Annex I: List of commodities

Commission Regulation (EC) No 178/2006

<b>1.</b> Fruits, nuts	<b>2.</b> Vegetables	<b>3.</b> Pulses, dry
<b>4.</b> Oilseeds, oilfruits	<b>5.</b> Cereals	<b>6.</b> Tea, coffee, herbal infusions, cocoa
<b>7.</b> Hops	<b>8.</b> Spices	<b>9.</b> Sugar plants
<b>10.</b> Products of animal origin	<b>11.</b> Fish, fish products	<b>12.</b> Crops exclusively used for animal feed

# Annex II: Definitive EC MRLs

Commission Regulations (EC) No  
**149/2008, 839/2008 and 256/2009**

## Contains:

245 **pesticides** from old MRL  
directives

Only for the **crops** in the old  
directives

# **Annex III A: Temporary EC MRLs** **- previously not harmonized** **pesticides**

Commission Regulations (EC) No:  
149/2008, 839/2008 and 256/2009

## **Contains:**

226 pesticides **previously not**  
**harmonized**

for 315 crops: 190 old + 125 new

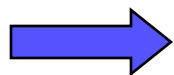
Corresponds to about 70 000 MRLs

# Annex III B: Temporary EC MRLs -previously not harmonized crops

Commission Regulations (EC) No:  
149/2008, 839/2008 and 256/2009

## Contains:

- the harmonized 245 pesticides **for the 125 new crops** (previously not harmonized)



corresponds to 30 000 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 different default values than 0.01 mg/kg**

**This Annex is still empty**

# **Annex VI: Specific concentration or dilution factors**

**MRLs applicable to processed and/or composite products (if not set out in Annex II and III)**

- taking into account changes in the levels of pesticide residues caused by processing and/or mixing**

**This Annex is still empty**

# **Annex VII: Post-harvest treatment with a fumigant**

Commission Regulation (EC) No 260/2008

## **Contains:**

- **4 substances for certain commodities:**
  - Hydrogen phosphide, aluminiumphosphide, magnesiumphosphide and sulfurylfluoride

## **Provided that:**

- **Such products are not intended for immediate consumption**
- **Appropriate controls are in place to ensure that such products can not be made available for the end user or consumer.....**

# A Default EC-MRL

- In general a default EC-MRL of **0.01 mg/kg** is applicable for those crops for which no specific MRL is set out in Annex II or III, or for active substances not listed in Annex IV

# EC-MRL database

- A simple to search database containing all EC-MRLs is available on DG SANCO home page

[http://ec.europa.eu/sanco\\_pesticides/public/index.cfm](http://ec.europa.eu/sanco_pesticides/public/index.cfm)

You can choose between **Active substances** and **Pesticide/products combinations**

# Regulation (EC) 396/2005 MRLs setting procedure

- |                           |                                      |
|---------------------------|--------------------------------------|
| • Applicant:              | Application for an MRL               |
| • Member State:           | Evaluation report                    |
| • EFSA:                   | Risk assessment and reasoned opinion |
| • Commission:             | Proposal for a Regulation            |
| • Standing Committee:     | Opinion                              |
| • Parliament and Council: | Right of scrutiny                    |
| • Commission:             | Adoption and publication             |

# Import tolerances

- Means an MRL set for imported products to meet the needs of international trade where:
- The use of the active substance in a plant protection products on a given product is not authorised in the Community for reasons other than public health reasons for the specific product and specific use
- A different level is appropriate because the existing Community MRL was set for reasons other than public public reasons for the specific product and specific use

# Consultation with trading partners, SPS-Notifications and import tolerances

- Through the World Trade Organisation (WTO), EU trading partners are consulted about MRLs proposed (SPS-Notifications)
- 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
- Application for import tolerances shall be submitted to designated EU rapporteur Member State

# SUMMARY

- Harmonized MRLs for all pesticides within the European Union
- Public database on EC-MRLs
- A new MRL setting procedure
- Harmonized risk assessment (EFSA)
- EC-MRLs are a precondition for national authorization within EC
- A default 0.01 mg/kg EC-MRL for compliance

# **Results from the Swedish Monitoring of Pesticide Residues in products from Latin America**

## **Samples of fresh fruits and vegetables 2008**

# Sampling and analysis of fruits and vegetables

- **Sampling**

The surveillance sampling is not directed to any specific grower or supplier but is partly based on prior residue findings

- **Analysis**

Both multi- and single residue methods are used. The multi method is based on an ethyl acetate extraction after addition of  $\text{NaHCO}_3$ . The determinations are carried out using LC-MS/MS and GC-MS/MS.

## **Pesticide coverage**

In all 350 pesticides and metabolites are covered

# Enforcement sampling

- When surveillance samples contained residues above an MRL
- NFA prescribes condition for sale of the lot to which the food belongs
- **As a follow-up**
  - next coming lot will be detained for enforcement sampling
  - released if the residue is in compliance with the MRLs

# The "Black List"

- **List with:**  
**commodity/producer/exporter/country/importer**  
where enforcement sampling has to be done  
**before** offering for sale
- Distributed to wholesalers, sampling officers, local health authorities
- **Published** at National Food Administration (NFA)  
website:  
**[www.slv.se/black\\_list](http://www.slv.se/black_list)**

# Commodities with at least 10 samples

<b>Commodity</b>	<b>No of countries</b>	<b>No of samples</b>
Bananas	5	60
Apples	3	35
Table grapes	4	28
Pears	2	24
Mandarins	3	19
Papaya	2	15
Pineapples	4	13
<b>Sum</b>		<b>194</b>

# Sampling in 2008

<b>Country</b>	<b>No of commodities</b>	<b>No of samples</b>	<b>No of samples above MRLs</b>
<b>Argentina</b>	<b>9</b>	<b>60</b>	<b>1 mandarins</b>
<b>Brazil</b>	<b>8</b>	<b>54</b>	<b>4 apples, oranges, papayas</b>
<b>Chile</b>	<b>7</b>	<b>34</b>	<b>0</b>
<b>Colombia</b>	<b>3</b>	<b>23</b>	<b>3 passion fruits</b>
<b>Costa Rica</b>	<b>2</b>	<b>19</b>	<b>0</b>

# Sampling in 2008

<b>Country</b>	<b>No of commodities</b>	<b>No of samples</b>	<b>No of samples above MRLs</b>
<b>Ecuador</b>	<b>3</b>	<b>10</b>	<b>1 pineapple</b>
<b>Honduras</b>	<b>2</b>	<b>4</b>	<b>0</b>
<b>Panama</b>	<b>3</b>	<b>21</b>	<b>0</b>
<b>Peru</b>	<b>5</b>	<b>10</b>	<b>0</b>
<b>Uruguay</b>	<b>3</b>	<b>11</b>	<b>3 apples</b>

# Sampling in 2008

<b>Country</b>	<b>No of commodities</b>	<b>No of samples</b>	<b>No of samples above MRLs</b>
<b>Latin American countries</b>	<b>19</b>	<b>246</b>	<b>12 (4.9 %)</b>
<b>All countries</b>	<b>64</b>	<b>1 096</b>	<b>76 (6.9 %)</b>

# Residue problems with apples from Argentina in May – June 2009

- Azinphos-methyl was recently found above the EU MRL in several samples of apples from Argentina on the Swedish market
- As the calculated acute intake exceeds the ARfD a Notification has been sent to the EU Commission

# Azinphos-methyl

## assessment in EU and Codex

- **EU**

- MRL: 0.05 mg/kg
- ARfD: 0.01 mg/kg bw
- ADI: 0,005 mg/kg bw
- Variability factor: 5/7

- **CODEX**

- MRL: 2 mg/kg
- ARfD: 0.1 mg/kg bw
- ADI: 0.03 mg/kg bw
- Variability factor: 3

More information concerning the Swedish residue monitoring: [www.slv.se](http://www.slv.se)

**Black list:** [www.slv.se/black\\_list](http://www.slv.se/black_list)

**Thank you for your  
attention**

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