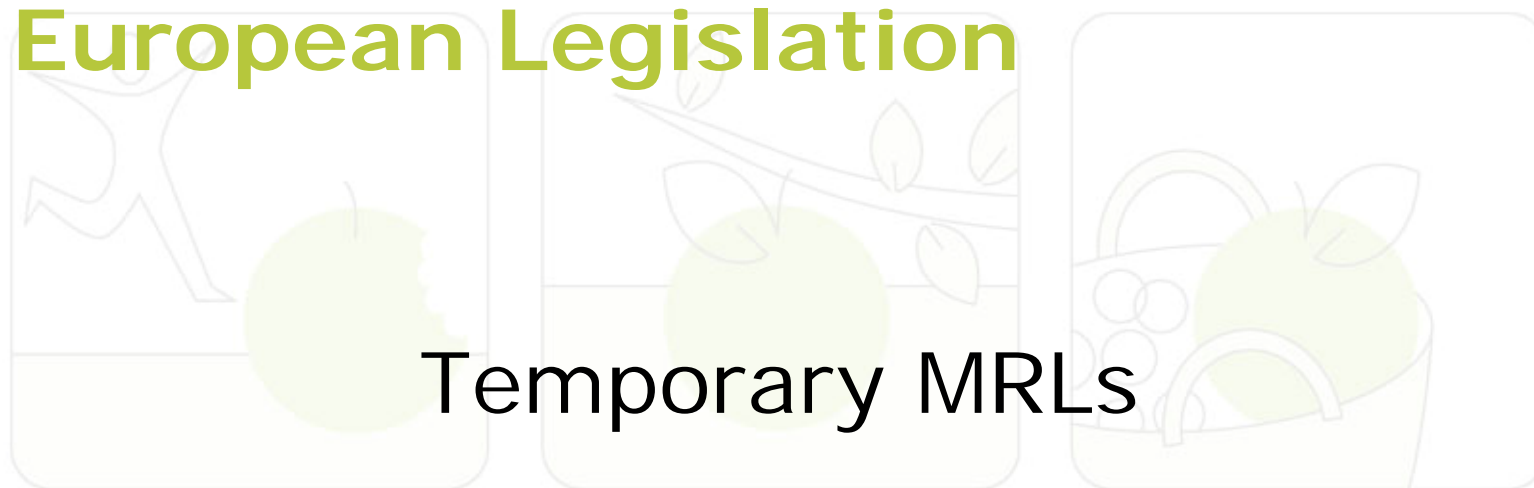




Regulation 396/2005 on MRLs for Pesticide Residues and other European Legislation



Temporary MRLs

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Regulation (EC) N. 396/2005 adopted by European Parliament and the Council but **not yet implemented**

-will **apply** 6 months after adoption by Commission of annex I, II, III and IV

-**application date** foreseen: June 2008 at the earliest

Until then: existing MRL Directives and national legislation of the EU Member States still apply

Contents rest of this presentation:

Why we change legal framework; what are the differences in the new Regulation; timelines for the implementation of the Regulation;

Directive 91/414/EEC. On the authorisation and use of ppps

- Review programme for pesticides on the European market since 1993
- Only pesticides on the positive list (Annex I) may be marketed in EU
- Withdrawal of 470 of the 830 pesticides (many because of data gaps)
- No direct bearing on use outside EU
- Import tolerances possible

Why change legal framework?

Complexity of present legislation

- 4 parent Council Directives (*86/362/EEC, 86/363/EEC, 76/895/EEC, 90/642/EEC*)
- each with different provisions for the same problems
- complicated lists of MRLs, both at national and at Community level
- National MRLs: problems for the internal market and for the importers

Why change legal framework?

Lack of harmonisation

- No complete overview of MRLs
- No provisions for pesticides and commodities not mentioned in legislation
- Incomplete information exchange on national MRLs for substances not fully evaluated

Why change legal framework?

- Avoid duplicating work (mss to copy and paste EU MRLs in national legislation)
- Role of EFSA defined (required by reg 178/2002)
- Under 91/414/EEC a simplified approach needed for all 470 unsupported active substances



Reg. (EC) 396/2005

Improvements and simplifications

- Regulation: directly applicable
- Clear and transparent: list of all EU MRLs, if not explicitly mentioned: Default residue level <0.01 mg/kg
- Responsibilities divided between Commission, EFSA and Member States



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Improvements and simplifications

- Clear procedure for application
- Accessible database with information
- Shelf life taken into account
- Complete harmonisation: no more trade problems



Annexes in Bold: Conditions for Applicability of the Regulation

- Annex I** → **List of commodities**
- Annex II** → **EU MRLs**
- Annex III** → **Temporary MRLs**
- Annex IV** → **List of active substances for which no MRLs are required**
- Annex V** → **Substances for which a default MRL applies**
- Annex VI** → **Processing factors**
- Annex VII** → **Fumigants**



ANNEX I: List of commodities

■ Published as Regulation (EC) n° 178/2006

- Total: 380 entries
- Existing commodities from the 4 MRL Directives (230 entries)
- Commodities for which Member States have set national MRLs (150 entries)
Mainly very minor crops (loquat, spices, lupins), but also cocoa, coffee, sugar plants
- Fish and animal feed plants mentioned, but for the time being exempted from MRL setting (Not enough information)



Annex II: Existing MRLs

- Copy the MRLs from the MRL Directives (in progress)
- Add MRLs for new commodities collected from the Member States (done)
- Develop a database (in progress)
- Adoption and publication simultaneous with Annex III and IV
- EFSA opinion on risk: within one year after Regulation is applicable



Annex III: Harmonise the national MRLs as Temporary EU MRLs

- Step 1: develop a database to collect national MRLs and assess the highest MRLs (December 2004)
- Step 2: Member States to submit information on national MRLs (31 March 2005)
- Step 3: Commission to elaborate draft Temporary MRLs (June 2005)
- Step 4: Commission requests EFSA for opinion on draft TMRLs (4 July 2005)



Annex III: Harmonise the national MRLs as Temporary EU MRLs

- Step 5: Commission to collect ADIs and ARfDs used by the Member States when setting national MRLs (December 2005)
- Step 6: EFSA and Commission discuss workplan, additional data needed and division of tasks (March 2006) and agree that EFSA will develop EU exposure assessment models (June 2006) and that Commission will update the TMRL database (September 2006)



Annex III: Harmonise the national MRLs as Temporary EU MRLs

- Step 7: EFSA to give opinion on TMRLs and identify MRLs which are not safe (March 2007)
- Step 8: Commission proposal for discussion with Member States
- Step 9: Commission adopts TMRL Regulation
- Regulation 396 will be applicable 6 months later

Annex IV: Active substances for which no MRLs are needed

- Member States have sent proposals to Commission
- The list contains pesticides with low toxicity and pesticides that are not expected to be present
- The latter do not need to be in Annex IV because the 0.01 mg/kg would apply – discussions ongoing
- To be published together with Annex II and III



Reg. (EC) 396/2005

Documents on the Internet

Legislation:

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

Draft Temporary MRLs for the first establishment of Annex III to Reg. (EC) N. 396/2005. [SANCO 1825-2007 - rev. 0](#) Updated 25-07-2007

http://ec.europa.eu/food/plant/protection/resources/draft_list_high_estnmrls.xls



Thanks for your attention !!!

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