



# New Regulations in the European Union

Regulation 1107/2009 Placing of plant protection products on the market

Regulation 396/2005 Maximum Residue Limits

Presented by  
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# Regulation 1107/2009 – The new EU Regulation concerning the placing of plant protection products on the market

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# Purpose & timeline



1. To replace Council Directive 91/414/EEC
2. To repeal Council Directive 79/117/EEC (Prohibits the marketing and use of certain active substances)
3. Adopted October 2009 & comes into force 14 June 2011

# Basic measures of the Regulation



Active substances “approved” at Community level.

Plant protection products authorised at member state / zonal level (3 zones : North, Centre and South – Annex I)

Introduces rules for safeners, synergists, co-formulants and adjuvants

# Key changes: Hazard exclusion criteria (Article 4 & Annex II)

- No category 1 or 2 mutagens (3.6.2)
- No category 1 or 2 carcinogens, unless exposure is negligible (3.6.3);
- No category 1 or 2 reproductive toxins, unless exposure is negligible (3.6.4);
- No endocrine disruptors, unless exposure is negligible. Interim provisions will apply until the Commission develops definitive measures (3.6.5 for humans, 3.8.2 for non-target organisms);
- No POPs (3.7.1), PBTs (3.7.2) or VPVBs (3.7.3)
- Substances not complying may be approved for up to five years if no other means of control is available

# Key changes: Candidates for substitution

- They have toxicological endpoints which are significantly lower than those of most similar approved substances;
- They meet two of the criteria to be considered persistent, bioaccumulative and toxic substances;
- There are concerns about critical effects (such as developmental neurotoxic or immunotoxic effects) in use, even with very restrictive risk mitigation measures;
- They contain a significant proportion of non-active isomers;
- They are classified category 1 or 2 carcinogens or reproductive toxins, or endocrine disruptors, which are not excluded by the hazard criteria.

# Products containing candidates for substitution

Member States must perform a comparative assessment before authorising such a product.

- No authorised plant protection product, or non-chemical control or prevention method already exists, which is significantly safer for human or animal health or the environment.
- Substitution does not present significant economic or practical disadvantages.
- Chemical diversity of the active substances, or methods and practices of crop management and pest prevention are adequate to minimize the occurrence of resistance.
- Consequences on minor use authorisations are taken into account.

# Key changes: Zonal authorisations

- EC divided into three zones (Annex I)
  - Zone A (North): Denmark, Estonia, Latvia, Lithuania, Finland, Sweden
  - Zone B (Centre): Belgium, Czech Republic, Germany, Ireland, Luxembourg, Hungary, Netherlands, Austria, Poland, Romania, Slovenia, Slovakia, United Kingdom
  - Zone C (South): Bulgaria, Greece, Spain, France, Italy, Cyprus, Malta, Portugal
- Simultaneous applications for product authorisation may be made to several member States in a zone (Art. 33)
- Lead member State evaluates the dossier on behalf of the other member states.
- All member States grant or refuse authorisations with the same conditions unless specific national conditions justify alternative conditions of use or refusal of authorisation.

# Approval Procedure

- Process broadly the same in terms of the roles of RMS, EFSA and the Commission and the steps taken to achieve Annex 1 inclusion, but
  - Regulation states efficacy be demonstrated for one representative use before Annex 1 (implementation unclear)
- Actives placed into different categories
  - Standard' substances, for up to ten years (Art. 5)
  - Low-risk substances (i.e. those which comply with section 5 of Annex II), for up to 15 years
  - Candidates for substitution for up to seven years (Art. 24)
  - Basic substances (essentially commodity chemicals), without specific time limit.

NB: Active substances must be approved & MRLs set before product authorisations can be granted. (For MRLs see Regulation 396/2005/EC)

# Review of active substances & renewal of approval

- The Commission may develop a programme for reviewing approved substances (Art. 18), or review them ad hoc.
- Authorisation holders must notify all potential adverse data which suggest that approval or authorisation conditions may no longer be met (Art. 56).
- Approvals may be renewed:
  - Up to 15 years for 'standard' and low-risk substances,
  - Up to five years for substances needed to control serious dangers & no alternatives
  - Up to seven years for candidates for substitution (Art. 24)

# Mutual recognition

- Mutual recognition should be more workable due to Zonal Authorisations
  - Applications may be made to other member States in the zone for mutual recognition of authorisations (Art. 40).
  - Member States evaluate the dossier as appropriate to their national circumstances and grant authorisations on the same conditions of use, unless alternative conditions or refusal of authorisation is justified. (Voluntarily if product contains a candidate for substitution or substance approved under the Article 4 derogation (Art. 41).
  - Applications for authorisation and mutual recognition may be made regardless of zone for uses in greenhouses or storage facilities, or as post-harvest or seed treatments (Art. 33 and 40).

# Transitional arrangements

- Dir. 91/414/EEC continues to apply in the following cases:
  - new substances judged complete within 18 months of entry in force of the new Regulation (Mid 2012).
  - active substances under review for re-inclusion within the AIR project (Reg. 737/2007).
  - Resubmissions under Reg 33/2008 for which completeness has been established within 18 months of entry into force of the new Regulation.

# Other points of note

- Unacceptable co-formulants will be listed in Annex III.
- Adjuvants will be authorised in accordance with procedures to be established in a separate Commission Regulation.
- Data protection
  - Data required for product authorisations are protected for 10 years from 1st authorisation in that member State (extensions possible for low risk products and minor uses)
  - Sharing of vertebrate studies more strongly emphasised (Art. 61 & 62); not accepted if they could have been avoided.



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# HARMONISATION OF MAXIMUM RESIDUE LEVELS (MRLs) IN EUROPE – REGULATION 396/2005

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# EU MRL legislation in the past

900 a.s. not covered by  
EU MRL legislation

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graph TD; A[900 a.s. not covered by EU MRL legislation] --> B[Ca 650 a.s. no specific MRLs]; A --> C[Ca 250 a.s. MS MRLs established];
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**Ca 650 a.s.**  
**no specific**  
**MRLs**

**Ca 250 a.s.**  
**MS MRLs**  
**established**

# What's happened to MRLs in Europe (1)



- Four Directives to one Regulation
  - To facilitate trade within the EU
  - Ensure a consistent level of consumer protection
  - Automatically supersedes any national legislation i.e. pan-EU MRLs will supersede national MRLs
    - No need to write into national law
    - Differences between a Directive and a Regulation

# What's happened to MRLs in Europe (2)



- Split risk assessment and risk management
  - EFSA (risk assessment)
  - European Commission - SANCO (risk management) but will verify EFSA's assessment
  - No MRL – LoQ (0.01 mg/kg)
  - Prevents Member States setting their own MRLs
- New rules
  - Take account of Codex MRLs
  - Monitoring data (honey, spices, persistent OC compounds)

# Steps in the process for Regulation 396/2005



- Regulation 396/2005 – framework was agreed end of 2005
- All MRLs were harmonised after a transitional ‘phase-in’ period
- Six months after completion of the Annexes, the existing MRLs Directives were revoked and the Regulation and its Annexes become fully operational (publication of Annex II and Annex III in March 2008, fully operational from October 2008)

# Annexes of Regulation 396/2005 (Annex I)



- a listing of the commodities/crops to which harmonised MRLs will apply
- 315 commodities (10 main groups)
- 190 entries from previous Directives
- 125 new entries
  - Some “minor” crops such as cassava, thyme, lupins but also cocoa, coffee, sugar plants
  - Fish and animal feed items also listed but currently not progressed
- Europe is very active in crop grouping work at Codex Committee on Pesticide Residues (CCPR)

# Annexes of Regulation 396/2005 (Annex II)



- Annex II – permanent harmonised MRLs - all commodities/crops for which MRLs are already set in other Directives
  
- Ca. 45,000
  - Directive 76/895
    - Fruit and vegetables (mainly OCs)
  - Directive 86/362
    - Cereals
  - Directive 86/343
    - Foodstuffs of animal origin
  - Directive 90/642
    - Plant origin including fruit and vegetables
  - Plus many others!

# Annexes of Regulation 396/2005 (Annex II)



- Annex II – permanent harmonised MRLs - all commodities/crops for which MRLs are already set in other Directives
- Pesticide/commodity combinations where additional MRLs have been requested
- Active substances which have been reviewed under the MRL review program
- MRLs must be reviewed within 1 year of Annex I listing (Directive 91/414)

# Annexes of Regulation 396/2005 (Annex III)



- Annex III – harmonised temporary MRLs – includes essential uses
  - Based on highest national MRLs
- Annex IIIa - All MRLs for actives awaiting decisions under Directive 91/414
- Ca. 70,000
  - Existing actives still in the review programme
  - New actives not yet available in the EU
- Annex IIIb – for new commodities only and for actives in Annex II only
- Ca. 30,000

# Annexes of Regulation 396/2005 (Annex IV)



- Substances for which no MRLs required
  - 52 entries
  - 6 micro-organisms
  - 46 chemicals (including plant extracts and fatty acids)
  - Some temporarily included in Annex IV until 91/414 review finished
  - EFSA not keen on having compounds on this list!

# Annexes of Regulation 396/2005 (Annex V and VI)



- Annex V
  - Non-default LoQs
  - Usual default 0.01 mg/kg
- Annex VI
  - Processing factors
  - Will be published
  - Standard default values may be acceptable
  - First proposal to be discussed June 2011

## Annexes of Regulation 396/2005 (Annex VII - Fumigants)



- Annex VII is meant to allow for necessary fumigant use in, (for instance) long distance transport arrangements, without breaching the much lower MRLs that have been set in Annexes II or III to apply at the point of sale.
- Annex VII allows the use of the fumigants and the consequent high residue, on the basis that the residue decreases to the Annex II or III levels when the produce is marketed.
- Annex VII MRLs are meant to apply within a Member State's own territory.
- Annex VII can only refer to crops that are in Annex I.

# Procedures under Regulation 396/2005



1. Applicant makes a submission
2. MS produces an evaluation report (PROFile)
3. EFSA produces a reasoned opinion (3-6 months)
4. Proposals discussed at commission Working Group (proposal for a regulation/decision)
5. Vote by MSs at Standing Committee
6. Scrutiny by European Parliament (will only consider twice per year – takes ca. 2 months)
7. Back to Commission for adoption and publication

# Timeline for procedures under Regulation 396/2005



1. Quoted timeline 1 year
2. Most regulators say 2 years
3. Conflicts with product registration timelines!

## tMRLs (Annex III) to MRLs (Annex II)



- Maximum of 3 years for the process
- EFSA have 1 year to evaluate data/ask for support/ask for additional data
- In practice, expected to do this within one year of Annex I listing
- EFSA self tasking for some of these actives

# Residues in fish



- Guidelines now available with trigger points
  - BCF  $>100$  for whole fish
- On a practical basis, not yet clear how these will be established
- Possibly based on monitoring data only
- OECD guideline being developed
- Maybe will cover persistent compounds such as OCs only

# Residues in honey



- Guidelines now available with trigger points
- Focussing on compounds that used during flowering of plants/crops
- Crops that are used to produce blossom honey
- Test conditions
  - 3 studies at different geographic locations
  - Beehives placed before flowering in the relevant crop
  - Honey analysed just after the end of blossom

# European MRL database



- SANCO
  - [http://ec.europa.eu/sanco\\_pesticides/public/index.cfm](http://ec.europa.eu/sanco_pesticides/public/index.cfm)
- Includes review status and tox end points

# EU MRLs and Codex MRLs



- Many countries and companies working together to speed up process
- Time from JMPR to CAC acceptance less than 1 year
- In Europe, will be adopted straight into Regulation
  - Consumer exposure/risk assessment to be carried out using European models
  - Debates on variability factors

# Conclusions



- Significant changes to MRL legislation in EU
- Harmonised MRLs/import tolerances for the whole of the European Union
- Harmonised exposure assessment models
- No MRL, no approval
  - Significant time delays for new actives and new uses



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