



European MRLs:

- Status on Regulatory Framework
- New Initiatives in the EU

2010 Maximum Residue Level (MRL) Workshop – Global Regulations
San Francisco





- **Background**
- **MRL Application**
- **Procedures and timelines**
- **Impact of new legislation**



- **Background**
- MRL Application
- Procedures and timelines
- Impact of new legislation

Short history

- **MRL setting in Europe started in 1976.**
- **In the beginning changing of MRLs were proposed by “acclamation”.**
- **In the 1990th a more formal procedure started.**
- **Today the procedure is completely formalised.**

Aims

- **Public health**
 - ✓ **High level of consumer protection**
 - ✓ **Taking into account good agricultural practice**
- **Functioning of the internal market**
 - ✓ **Differences in national MRLs for pesticides can pose barriers to trade**
 - **Between Member States**
 - **Between third countries and the Community**

Internal Market

- ✓ Put together different (four) Directives
 - ✓ Add additional commodities
 - ✓ Add additional active substances
 - ✓ Add additional rules (e. g. default MRL of 0.01 mg/kg)
- ➔ Complete harmonization of all active substances and all commodities

But

➤ **Complete harmonization of commodities not yet fulfilled**

✘ **Missing commodities:**

✘ **Fish, fish products, shell fish, molluscs and other marine and freshwater food products**

✘ **Crops, exclusively used for animal feed**

✘ **Missing active substances:**

✘ **Safener and synergist**

Requirements for functioning

- **Not to put on the market products that are not in compliance with the MRLs set**
 - ✓ **No authorisation of a plant protection product without an established MRL**
 - ✓ **No import without a sufficient MRL**
- **Participation of Member States, European Commission and EFSA in MRL setting process**



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Before applying for a MRL

- Check EU database
http://ec.europa.eu/sanco_pesticides/public/index.cfm
- ✘ BUT: Publication in the official journal is legally binding
- Keep in mind the rules of Annex I to Regulation (EC) No. 396/2005



- Applicants according to Directive 91/414/EEC
- Parties demonstrating, through adequate evidence, a legitimate interest in health, including civil society organisations
- Commercially interested parties such as manufacturers, growers, importers and producers
- Member States of the EC

- **To set a MRL**
- **To amend a MRL**
- **To delete a MRL**
- **To include an active substance in Annex IV
(MRL setting is not necessary)**
- **To evaluate the influence of a proposal to
change the residue definition on the levels set**

- **Member States granting an authorisation**
- **For import tolerance:**
Rapporteur Member State responsible for the evaluation of the active substance
- **Possibilities to re-arrange the work between MS**

Use the application form available on the internet

http://ec.europa.eu/food/plant/protection/resources/publications_en.htm#residues





- Background
- MRL Application
- **Procedures and timelines**
- Impact of Regulation (EC) No. 1107/2009

Applicant

- **Applicant to apply for MRL using the application form**
- **Applicant to provide the necessary information**

Member State (1)

- **Receives application form submitted by applicant**
- **May request missing information**
- **Forwards copies of the application to EFSA and Commission **immediately****

European Commission (1)

Without undue delay

- Inform MS about application made
- Forward information to EFSA, i. e. the application form

In reality

- ☑ Information of EFSA is done by MS
- ☑ Information of MS is done by electronic notification through EFSA

Member State (2)

- Evaluates the information **without undue delay**
- Makes use of publicly available data (e.g. **CODEX**)
- Sends evaluation report to Commission

- ☑ Format of evaluation report agreed between EFSA, MS and Commission
- ☒ It does not mean that CODEX MRLs will be automatically used

European Commission (2)

Without undue delay

- **Inform MS**
- **Forward information with formal request to EFSA:**
 - ✓ **Application form**
 - ✓ **Evaluation report**
 - ✓ **Supporting dossier**

European Commission (3)

In reality

- **Commission request for reasoned opinion**
- **Evaluating MS send to EFSA**
 - ✓ **Evaluation report**
 - ✓ **Supporting dossier**
- **Information of other MS is done by electronic notification through EFSA**

EFSA (1)

Within 3 months

- **Acknowledge the receipt of the evaluation report to the applicant, European Commission and the evaluating MS**
- **Draft a reasoned opinion especially concerning the risk for consumers and animal health**
- **Request for supplementary information (optional)**

EFSA (2)

Within 6 months

- **Prolonged period of time where more detailed evaluations need to be carried out, e. g. in case of**
 - ✓ **Additional/new toxicological data**
 - ✓ **Additional/new metabolism data**
 - ✓ **(Additional methods of analysis)**
- **Consultation of expert in a meeting possible**

EFSA (3)

- **Send the reasoned opinion to MSs, applicant, and European Commission**
- **Reasoned opinion are published in the EFSA Journal**
<http://www.efsa.europa.eu/en/efsajournal.htm>
- ☒ **Decisions may be subject to an administrative review**

European Commission (4)

Within 3 months

- **Draft a Regulation after submission of the reasoned opinion**
- **Request for supplementary information (optional)**
 - ✓ **To be made available to EFSA and MS**

European Commission (5)

- **Draft Regulation has to be voted in Standing Committee**
- **Text to send out**
 - ✓ **for SPS notification**
 - ✓ **to the European Parliament and the Council**
- ☑ **In case of revocation of MRLs no need to involve EFSA the process**

European Parliament and Council Regulatory procedure with scrutiny

Two month

- **European Parliament and Council may oppose the adoption**
 - ✓ **Opposition expected on political not technical reasons**

European Commission (6)

➤ Adoption by Commission

➤ Publication in the OJ

[http://eur-](http://eur-lex.europa.eu/JOIndex.do?ihmlang=en)

[lex.europa.eu/JOIndex.do?ihmlang=en](http://eur-lex.europa.eu/JOIndex.do?ihmlang=en)



Summary of timelines





- Background
- MRL Application
- Procedures and timelines
- **Impact of Regulation (EC) No. 1107/2009**

Package of two Directives and two Regulations

- Regulation (EC) No 1185/2009 of the European Parliament and of the Council of 25 November 2009 concerning statistics on pesticides
 - Directive 2009/127/EC of the European Parliament and of the Council of 21 October 2009 amending Directive 2006/42/EC with regard to machinery for pesticide application
 - Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides
- ➡ Only of interest for the European market

Package of two Directives and two Regulations

- **Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC**

May influence imports

Cut-off criteria

- ADI, ARfD, (AOEL)
- Mutagen category 1A and 1B
- Carcinogen, reproductive toxicity category 1A and 1B or have endocrine disrupting properties that may cause adverse effect in humans
 - ✓ Unless the **exposure** of humans, under realistic proposed conditions of use, **is negligible**,
 - ✗ The product is used in closed systems or in other conditions excluding contact with humans
 - ✗ Where residues on food and feed do not exceed the default value

Cut-off criteria

- In parts based on science
- Other parts really risk management based
- Negligible exposure of humans is discussed controversially

- ☑ Use of these criteria for authorization of plant protection is without any discussion
- ☒ Use of these criteria for import tolerances not yet clear

Loosing compounds in EU - different reasons

- ✓ Fate
- ✓ Ecotoxicology
- ✓ Toxicology
- ✓ Residues

In case of the first two points means that a complete data set for

- ✗ Toxicology and
 - ✗ Residue behaviour (including methods of analysis)
- has to be provided for an import tolerance.

In the other two cases the reason has to be checked first (cut-offs, consumer protection, ...?)



Thank you for your attention!



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