

The new EU-Regulation on Maximum Residue Levels (MRLs) of Pesticides in Food *- An Overview*

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- *The life cycle of pesticides and the legal framework*
- *How Maximum Residue Levels (MRL) were set?*
- *The new MRL Regulation*
 - *key questions of implementation*

Pesticide Life Cycle

Legal Framework

Authorisation



Directive 91/414/EEC concerning the placing of plant protection products on the market (Revision, expected 2007)



Use



“Use Directive” concerning establishing a framework for Community action to achieve a sustainable use of pesticides (new, expected 2007)

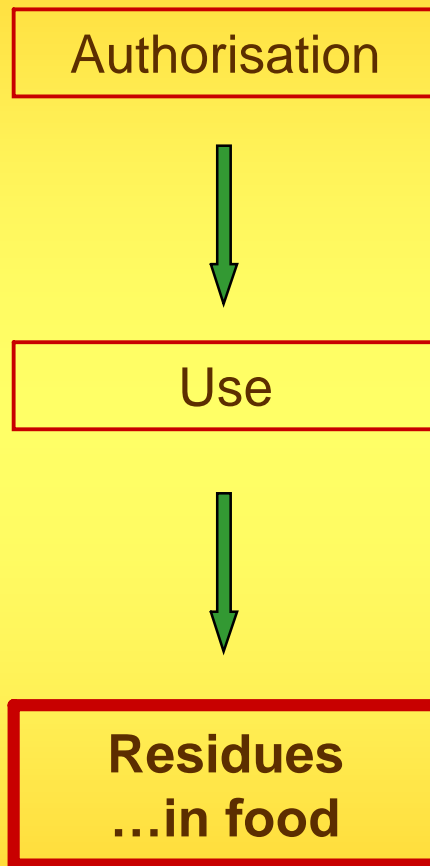


**Residues
...in Food**



Regulation 396/2005/EC on maximum residue levels of pesticides in or on food and feed of plant and animal origin (23 February 2005)

Pesticide Life Cycle



1. Pesticides are applied in the growing season and rests of the applied amounts remain in or on the treated crop. Pesticides may also drift to nearby areas and contaminate crops, which have not been treated.
2. Pesticides occur as contaminants in soils and sediments - and animals such as fish accumulate these pesticides via the food chain over time in their body. Usually such pesticides have been used in the past and have a very long half life- they are also known as *persistent organic pollutants* or POPs (e.g. DDT).

How EU MRLs were set?

(1)

Estimation of the residue level in or on an agricultural crop treated with the pesticide under conditions of the Good Agricultural Practice (GAP) in a supervised trial.

(2)

Estimation of the total daily intake of the specific pesticide using appropriate consumer intake models and the established residue level.

How EU MRLS were set?

(3)

Estimation of an 'acceptable daily intake' (ADI) using data from toxicological tests. This involves finding the highest dose that would produce no adverse effects over a lifetime (chronic) exposure period and then applying appropriate safety factors.

(4)

Setting the Maximum Residue Level (MRL) from (1)

under the condition that:

Daily Consumer Intake (2) < Acceptable Daily Intake (3)

The new MRL Regulation (396/2005/EC)

- **ensure free trade throughout the EU and the European Free Trade Area (EFTA) because of harmonisation;**
- **will replace the variety of national MRLs with an unique MRL setting on the EU-level, and**
- **give a chance of a great progress towards more protection of consumers, especially of children.**

The major improvements of the MRL Regulation:

- **NO pesticide authorisation without an established MRL**
- **All pesticide/commodity combinations without an established MRL = 0,01 mg/kg (⇒ „zero limit“ a priori)**
- **Children and the unborn are planned to be protected (⇒ *protection of vulnerable groups*)**
- **Member States are required to publish annual reports about the situation in the country (⇒ *improved transparency*) .**

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MRL Regulation

Recital 5:

„.....public health should be given priority over the interests of crop protection, thus it is necessary to ensure that such residues should not be present at levels presenting an unacceptable risk to humans and, where relevant, to animals“.

MRL Regulation

Recital 5:

„.... MRLs should be set at the lowest achievable level consistent with good agricultural practice for each pesticide with a view to protecting vulnerable groups such as children and the unborn“.

Consequence for MRL-setting:

- *The safety limit (**ADI**) must take into account the sensitive groups such as children.*
- *The MRL setting must take into account a second safety limit – **The Acute Reference Dose (ARfD)**
 - *the pesticide dose that can be ingested over a short period of time, usually during one day, without appreciable health risks (taking into account sensitive groups within the population).**

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MRL Regulation

Recital 6:

„It is also important to take into account cumulative and synergistic effects“

Consequence for MRL-setting

- *Development of guidelines on cumulative risk assessment of pesticides that have a common mechanism of toxicity:*
Organophosphates, Carbamates
- *Laying down summative MRLs for such pesticide groups*

MRL Regulation

Recital 34:

„To ensure that consumers are kept adequately informed, Member States should,...., publish the results of national monitoring residues annually on the Internet, providing all individual data, including the place of collection and the names of retailers, traders and/or producers“. („name & shame“)

New EU Authority:

European Food Safety Authority (EFSA)

- *laying down procedures in matters of food safety*
- *responsible body in the MRL harmonisation process*

<http://www.efsa.eu.int>

Key Questions of Implementation

- Whose diet will be considered as THE European diet?
- What´s about already harmonised „old“ EU MRLs which do not consider the vulnerability of certain groups?
- How the EU will taken into account unknown combination effects?
- How the EU will avoid potential trade conflicts in the WTO? (*international MRLs do not consider vulnerable groups*)
- How the MS will avoid non-coherence with other national laws regarding the „name & shame reporting“?

Conclusion:

The new MRL Regulation on pesticide residues in food could be a great progress towards better protection of children and consumer in general....but

... there are a number of open questions how the EU and the Member States will implement this Regulation.

Therefore, civivil society must actively watch the development in the next years.

Thank you for your attention