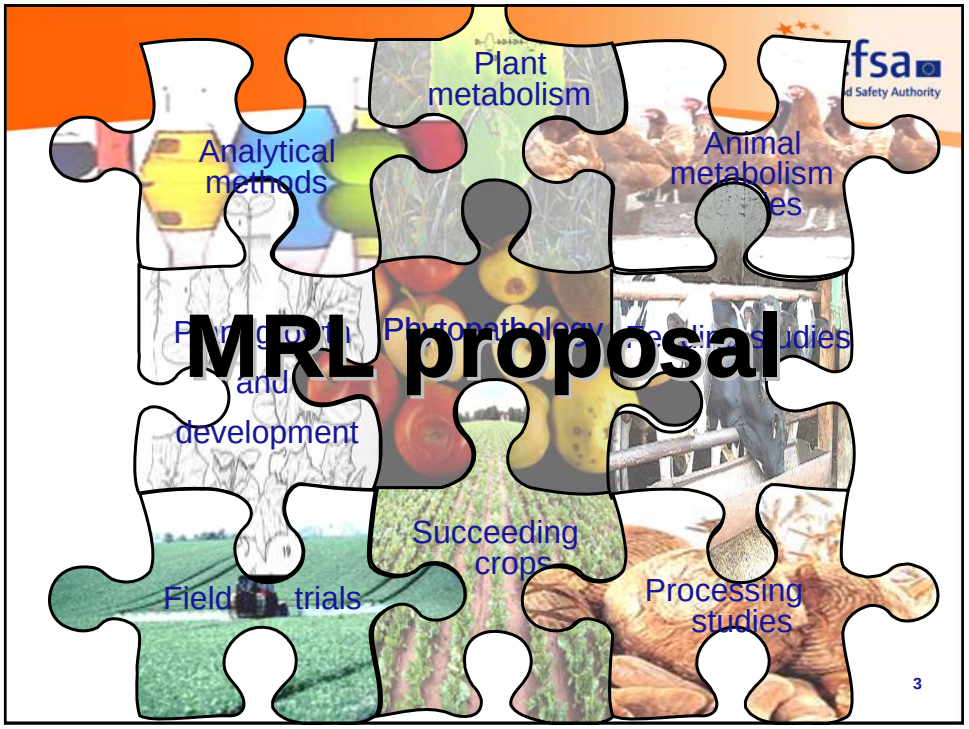
EFSA's role in the risk assessment of pesticide residues Regulation 396/2005

Hermine Reich
Pesticide **R**isk **A**ssessment **Pe**er **R**eview (PRAPeR)

Outline

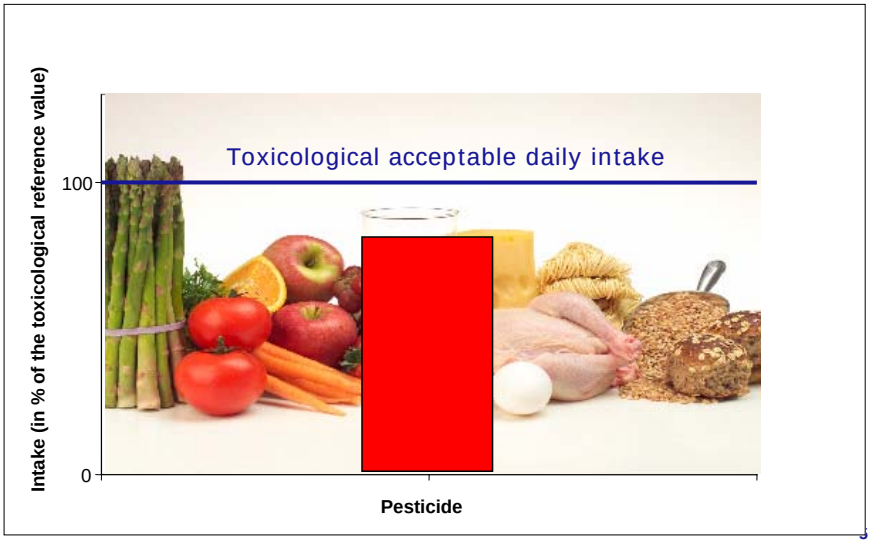
- What means "consumer risk assessment of pesticide residues"
- European legislation on MRLs (maximum residue levels)
- EFSA's tasks in the MRL setting process



Exposure assessment



Risk assessment



Model for exposure assessment

EFSA Pesticide Residue Intake Model EFSA
EFSA PRIMo

EFSA developed a model to calculate the expected short and long term intake of pesticide residues via food,

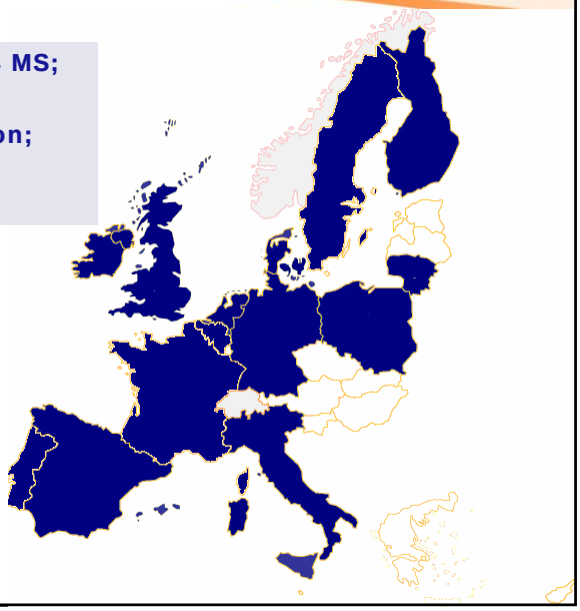
considering the different food consumption habits in Europe.

EFSA PRIMo

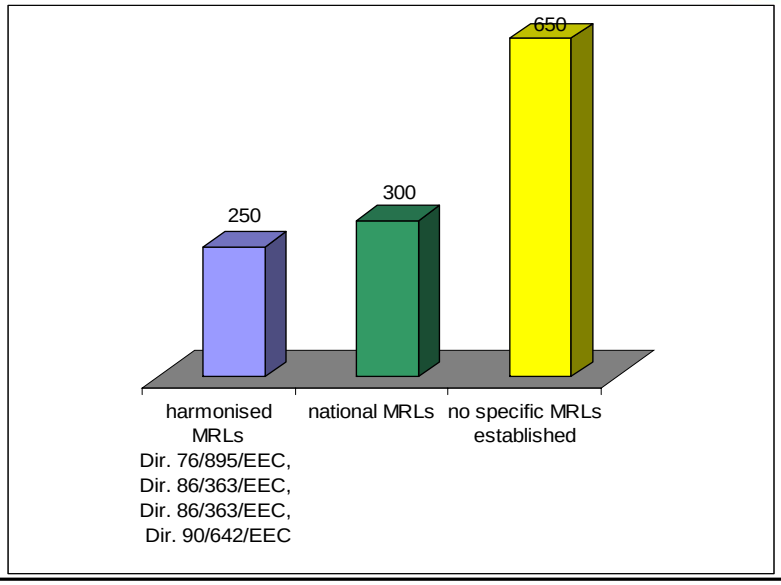
Consumption data from 14 MS;

41 diet sets for different subgroups of the population;

short term and long term consumption data



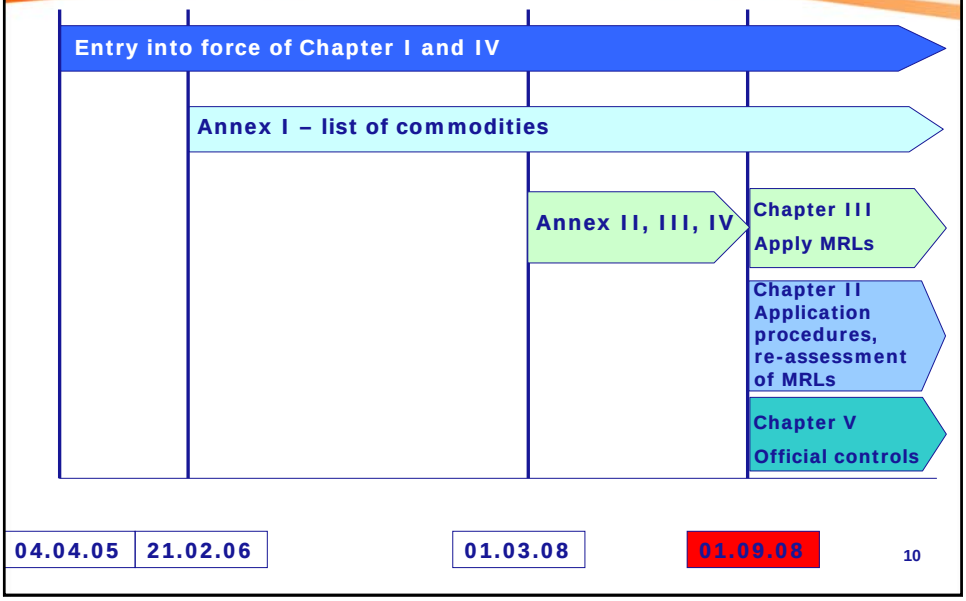
"Old" MRL legislation



Regulation 396/2005

- Defining the role of EFSA in the MRL setting procedure
- Establishing of harmonised MRLs for all active substances – Chapter IV
- Review programme for all MRLs established – Chapter III
- Procedures for setting/amending MRLs – Chapter II
- Monitoring of pesticide residues – Chapter V

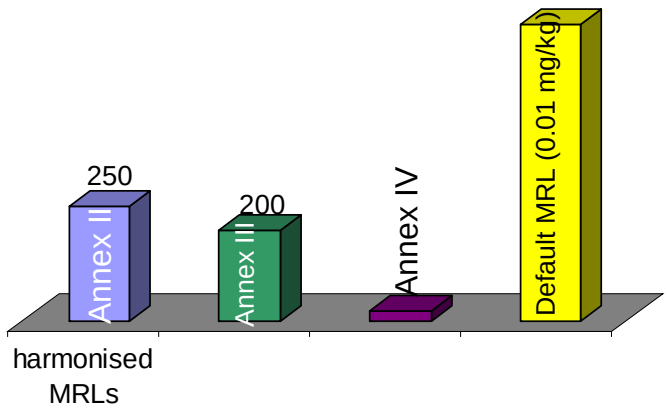
Entry into force of Reg. 396/2005



Regulation 396/2005

- **Annex I –** list of commodities to which MRLs apply
- **Annex II** – MRLs established under old MRL legislation
- **Annex III** – temporary MRLs derived from national MRLs
- **Annex IV** – active substances for which no MRLs are necessary
- **Default MRLs** of 0,01 mg/kg for all active substances not explicitly mentioned

"New" MRL legislation



EFSA tasks under Reg. 396/2005

Assessment of proposed temporary MRLs - Article 24

Assessment of existing MRLs - Article 12

- Article 12 (2): for substances **included** in Annex I to Dir. 91/414/EEC **before** the entry into force of Regulation (EC) N°396/2005
- Article 12 (1): for substances **included or not included** in Annex I to Dir. 91/414/EEC **after** the entry into force of Regulation (EC) N°396/2005

Assessment of MRL applications for amending MRLs - Articles 10 & 11:

Database of the Authority on MRLs - Article 41

Annual Monitoring Report – Article 32

Article 24 - Temporary MRLs What was EFSAs task ?

- **EFSA to provide risk assessment for all active substances for which temporary MRLs were proposed**
- **More than 200 active substances had to be assessed**
- **Reasoned opinion on:**
  - Retention, modification or deletion of existing MRLs
- **Finalisation: March 2007**
  - **Addenda in April 2007 and February 2008**

Article 12(2) – What is expected?

- **MRLs for all active substances included in Annex I of Dir. 91/414 before 01/09/2008 to be assessed within one year**
- **About 170 active substances to be assessed**
- **Reasoned opinion on:**
  - Retention, modification or deletion of existing MRLs
  - Necessity of setting new MRLs
  - No MRLs necessary ?
- **Deadline: 01/09/2009**

Article 12(1) – What is expected?

- **Each active substances included or not included in Annex I to Dir. 91/414 after 01/09/2008:**
  - to be assessed individually
- **Reasoned opinion on:**
  - Retention, modification or deletion of existing MRLs
  - Necessity of setting new MRLs
  - No MRLs necessary ?
- **Deadline: 1 year following the inclusion or non-inclusion**
- **Problems with accelerated procedure for Annex I inclusion or non-inclusion**

Article 10 & 11 – What is expected?

MRL applications

- **Assessment of applications:**
  - For setting, modifying or deleting MRLs
  - For inclusion of active substance in Annex IV to the Regulation
  - Submitted by the Evaluating Member State (EMS is not necessarily RMS)
  - Based on the Evaluation Report (ER) of the EMS
- **Reasoned opinion including:**
  - Assessment on the analytical method for the routine monitoring
  - Assessment of the risk of the ADI or ARfD being exceeded
  - Any other element relevant to the risk assessment
- **Time limits**
  - 3 months
  - 6 months in exceptional cases (more detailed evaluation)
  - Suspension of time limits when further information is requested

Article 41 – What is expected?

Database

- **Develop and maintain a database on:**
  - All relevant scientific information relating to the MRLs set out in Regulation 396/2005
  - Good Agricultural Practices (GAPs) relating to the MRLs set out in annex II and III, the active substances set out in Annex IV and processing factors set out in Annex VII
  - Dietary intake assessments
  - Toxicological reference values
- **Accessible to:**
  - Commission
  - Competent authorities of Member States
- **Not to be confused with Commission database on MRL legislation**

Article 32 – What is expected?

Annual Report on the control of pesticide residues in food

- **Summarise the results of control activities**
  - Ca 80.000 samples
  - On average 190 active substances
- **Assessment of actual exposure of European consumers**
- **Accessible to:**
  - Public

Conclusion

EFSA is involved in different areas related to risk assessment of pesticide residues

- MRL setting activities
- Data Management - Databases
- Monitoring / control activities

Thank you for your attention!