Regional Symposium on Regulation of Pesticide Residues in Food

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Hermine Reich,
European Food Safety Authority
Dietary risk assessment of pesticide residues in food
Overview

- EFSA’s mandate and tasks
- Concept of Risk Analysis
- Risk Assessment in the process of setting maximum residue levels (MRLs) for pesticides on food
What EFSA does

Mandate

• **Provide scientific advice** and support for EU legislation/policies in all fields that impact food and feed safety

• **Provide independent information** on all relevant matters

• **Communicate the risks**
What EFSA does

Mission

EFSA is the keystone of EU risk assessment regarding food and feed safety. In close cooperation with national authorities and in open consultation with its stakeholders, EFSA provides independent scientific advice and clear communication on existing and emerging risks.
Scientific Panels

- Animal health and welfare (AHAW)
- Food additives and nutrient sources (ANS)
- Biological hazards (BIOHAZ)
- Food contact materials, enzymes, flavourings (CEF)
- Contaminants (CONTAM)
- Feed additives (FEEDAP)
- Genetically modified organisms (GMO)
- Nutrition (NDA)
- Plant health (PLH)
- Plant protection products (PPR)
Grazie per la vostra attenzione!
EFSA in Parma/Italy

EFSA’s Official seat: Palazzo Ducale

EFSA’s operational seat: “DUS” building
Risk analysis concept

Need for close cooperation between risk assessor and risk manager

Source: WHO/FAO 1997
Risk Assessment

Scientifically based process consisting of four steps

1. Hazard identification
2. Hazard characterisation
3. Exposure assessment
4. Risk characterisation
MRL setting procedure

GAP

Good Agricultural practice
Which active substance is used on which crop, against which pest or disease, with which application rate, what timing of application, number of applications, which application technique, which interval between treatments, field or glasshouse, what is the pre-harvest interval (PHI)
MRL setting procedure

GAP

Good Agricultural practice

Hazard identification and characterisation
Hazard quantification

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A factor of at least 100 is applied between NOAEL and ADI/ARfD.

Explanations:
- ADI: Acceptable Daily Intake
- ARfD: Acute Reference Dose
- NOAEL: No Observable Adverse Effect Level
- LOAEL: Lowest Observable Adverse Effect Level

What is the NOAEL for the most sensitive animal species?

Lowest LOAEL derived for most sensitive animal species

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Extrapolation from most sensitive animal species to humans

Sensitivity of different subgroups of the population

SF: Safety factors
Toxicological reference values

Acceptable daily intake (ADI)
is the estimate of the amount of substances in food, expressed on a body weight basis, that can be ingested daily over a lifetime, without appreciable risk to consumers.
Expressed in mg/kg body weight/day

Acute Reference Dose (ARfD)
is the estimate of the amount of substance in food, expressed on a body weight basis, that can be ingested over a short period of time, usually during one day, without appreciable risk to the consumer.
Expressed in mg/kg body weight
MRL setting procedure

- Hazard characterisation
- Exposure assessment

GAP

Good Agricultural practice
Exposure assessment

- Occurrence of chemical on food
- Food consumption
- Exposure
Occurrence of residues in food

- Analytical methods
- Plant growth and development
- Field trials
- Succeeding crops
- Processing studies
- Animal metabolism studies
- Phytopathology
- Processing studies
- Field trials
- Plant growth and development
- Analytical methods

Information required for establishing an MRL
EFSA Model for pesticide consumer risk assessment

Long term dietary intake data (average consumption data)

Short term dietary intake data (97.5th percentile consumption data)

PRIMo Pesticide Residues Intake Model
Average consumption data from different European sub-populations
Representing consumption habits of children, adults, vegetarians etc.
Chronic exposure

GEMS/food cluster diets

- Cluster F – Nordic/Baltic region
- Cluster E – Central EU region
- Cluster B – Mediterranean region
- Cluster D – Eastern European region
Consumption data for “extreme” consumer (97.5 percentile of distribution of food consumption)

In general, children are most critical group
Model for exposure assessment

**Acute model**
Identification of critical European consumer for each commodity

**Chronic model**
Calculation for all diet sets
Chronic exposure

Assumptions:

• All food consumed is treated with the pesticide

• Lifetime exposure
How to calculate chronic exposure

According to agreed international methodology developed by JMPR (FAO/WHO)/ Codex Alimentarius

Theoretical maximum daily intake

$$\text{TMDI} = \sum \text{residue}(i) \times \text{average food intake}(i)$$
Chronic exposure

Intake (mg/kg body weight /day)

Pesticide A

Pesticide B
Chronic risk assessment

Refined intake calculation:
Reduction or concentration after processing
Distribution of residues between edible and inedible part of the crops
Acute exposure

Assumptions:

• Single meal / daily consumption
• Extreme consumer (97.5th percentile)
• Critical consumer group (children)
• Inhomogeneous distribution of residues on individual units
• Highest residue found in trials
National estimated short term intake

**NESTI = HR *97.5th percentile food intake*VF**

**HR:** highest residue (edible part of the crop) observed in supervised field trials

**VF:** variability factor, inhomogeneous distribution
Acute exposure

Calculations are performed for each individual commodity since it is not very likely that you are an extreme consumer for more than one commodity and that this extreme consumer finds extreme residues on more than one commodity.
Acute exposure

Calculation performed for critical European consumer

Intake (in mg/kg body weight/day)

Pesticide A

Pesticide B
Acute risk assessment

Refined intake calculations
Reduction or concentration after processing
MRL setting procedure

- Good Agricultural Practice (GAP)
- Hazard characterisation
- Exposure assessment
- Risk assessment

Good Agricultural practice
Risk characterisation

Exposure

Compare with toxicological reference values
Chronic risk assessment

Intake (in % of the ADI)

- **Pesticide A**: acceptable
- **Pesticide B**: not acceptable

ADI
Chronic risk assessment

% of ADI

DE child
NL child
WHO Cluster diet B
FR toddler
IE adult
UK toddler
ES child
FR infant
UK infant
SE general population
IT toddler
PT general population
FR all population
IT adult
DK child
WHO European diet
FR adult
WHO cluster diet E
UK vegetarian
FI adult
UK adult
DK adult
PL general population
LT adult
Acute risk assessment

Intake (in % of ARfD)

- Pesticide A acceptable
- Pesticide B not acceptable

ARfD
Based on the recommendations given in the reasoned opinions issued by EFSA, the European Commission will prepare the Regulations regarding the setting, modification or deletion of MRLs.

Member States vote on the Regulation in the Standing Committee on Food Chain and Animal Health.

Other legitimate factors.

Publication of the Regulation in the Official Journal.
Avoiding of trade barriers
Common market-free movement of goods, WTO

Certainty for producers
Compliance with MRL provisions if pesticides are used according to label

Consumer protection
No unacceptable consumer risk

Precautionary principle
Setting of zero-tolerance in case of missing data or uncertainties

Minimisation principle
ALARA (as low as reasonably achievable)
MRL setting policy

Minimisation principle
ALARA (as low as reasonably achievable)

No MRL
Default value
0,01 mg/kg
No GAP
MRL setting policy

Precautionary principle
Setting of zero-tolerance in case of missing data or uncertainties

Good agricultural Practice (GAP)

Default value
0,01 mg/kg

Insufficient data

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MRL is not borderline

between acceptable residue concentration on food and immediate consumer health risk
THANK YOU

Hermine Reich
Tel: +39 0521 036 662
Email: hermine.reich@efsaeuropa.eu