European Food Safety Authority

Consumer Risk Assessment with regards to Pesticides in Food

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Overview

- European legislation on pesticides
- **EFSA's role in the MRL setting process:**
- Risk assessment
  - First establishment of temporary MRLs
  - MRL review programme
  - Routine MRL applications
- Data collection activities related with pesticide residues
  - Scientific database
  - Monitoring data, Monitoring Report
- Risk communication

European legislation on pesticides

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Residues in food/feed

Regulation 396/2005



Use of pesticides
Directive on
sustainable use
(under preparation)



Pre-marketing approval
Directive 91/414/EEC
(will be replaced by Regulation)



Regulation 396/2005

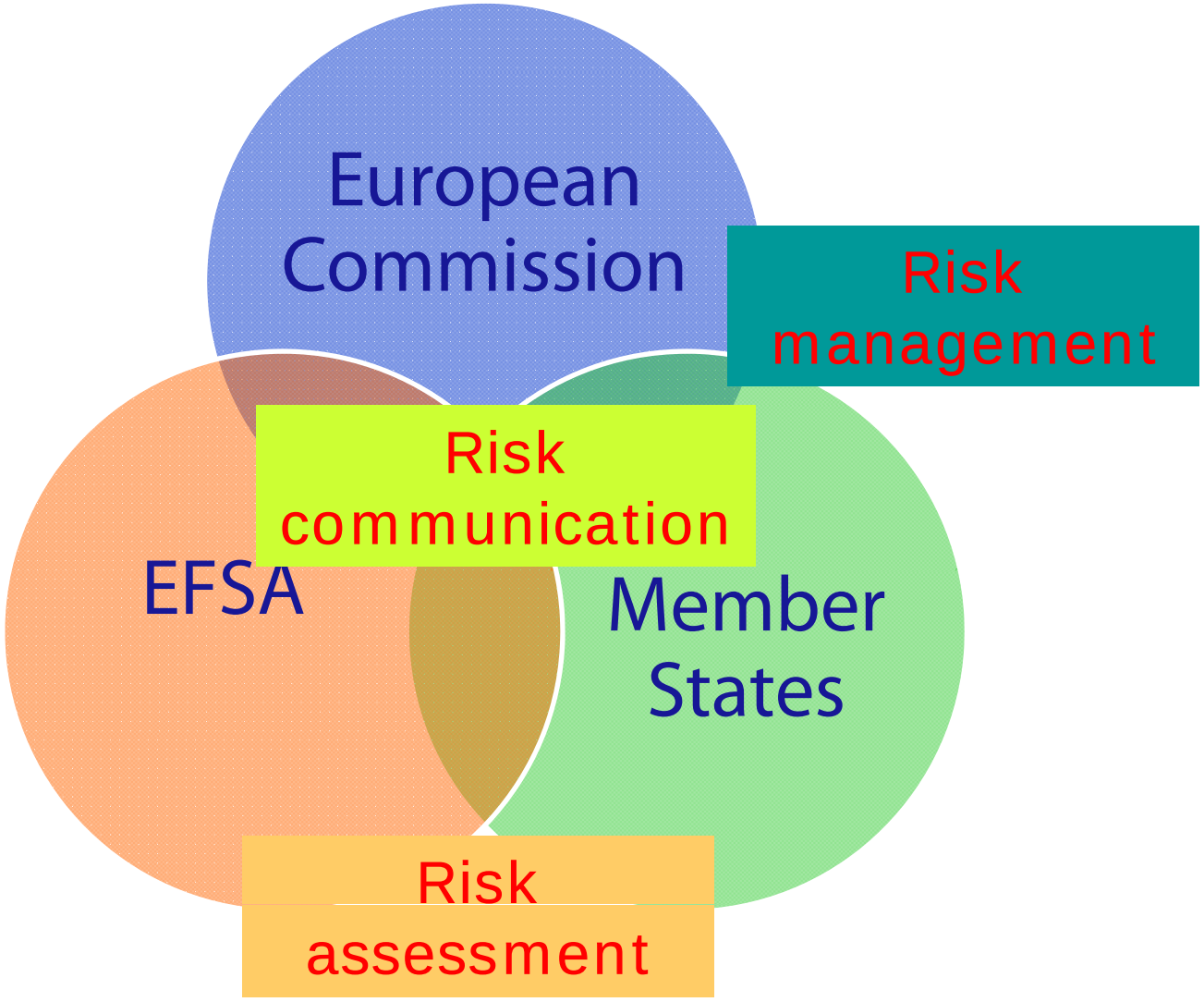
Main purpose of the Regulation

- Ensure a high level of consumer protection and establish harmonised Community provisions relating to maximum levels of pesticide residues in or on food and feed of plant and animal origin

- Separation of risk assessment and risk management

- Defining the role of Member States, EFSA and the European Commission in the MRL setting procedure

Regulation 396/2005



Regulation 396/2005

Outline of the content of the Regulation



- Establishing harmonised MRLs for all active substances
- MRL review programme
- Procedures for setting/amending MRLs
- Development and maintenance of a scientific MRL database
- Monitoring of pesticide residues

Establishment of harmonised MRLs

European Commission
collected national MRLs

88 000 proposed MRLs

for 280 active substances

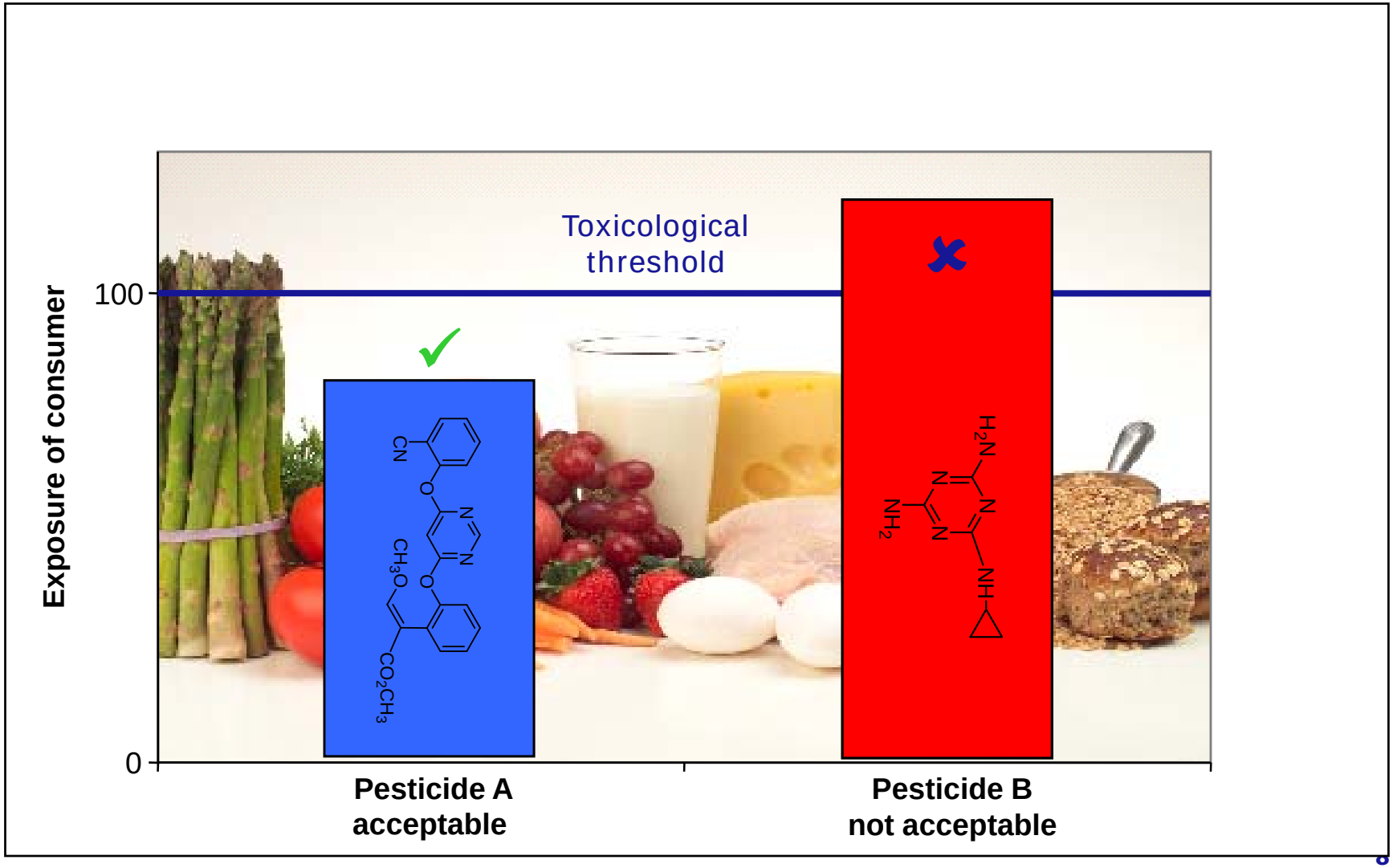
Risk assessment

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Unacceptable risk

No consumer risk

Risk assessment



Regulation 396/2005

Establishing of harmonised EU MRLs for all active substances

- Based on the results of EFSA's risk assessment, risk managers decided which national MRLs could be included in **Annex III** of Regulation as temporary EU MRLs
  - MRLs published in Regulation (EC) No 149/2008 and 839/2008
  - Temporary MRLs entered into force on **1 September 2008**
- MRLs established under the previous MRL legislation (consolidated list) compiled in **Annex II** of Regulation 396/2005

Regulation 396/2005

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MRL review programme
(linked with Directive 91/414/EEC)

167 active substances:
inclusion in Annex I of
Directive 91/414 entered into force
before 1 September 2008

+ 216 active substances:
inclusion or non-inclusion in Annex I of
Directive 91/414 enters into force
after 1 September 2008

MRL review programme: What is requested from EFSA?

EFSA is required to give:

"… a reasoned opinion based in particular on the relevant assessment report prepared under Directive 91/414/EEC … on:

*(a) **Existing MRLs** set out in Annex II or III to Regulation 396/2005;*

*(b) the **necessity of setting new MRLs** for that active substance, or its inclusion in annex IV to this Regulation;*

*(c) **Specific processing factors** as referred to in Article 20(2) of this Regulation that may be needed for that active substance;*

*(d) **MRLs** which the Commission may consider **including in Annex II and/or III** and those MRLs **which may be deleted***

MRL review programme

- Collection and compilation of scientific data provided during the last 30 years to Member States and European Commission in support of MRL applications at national or EU level.
- Re-evaluation of data according to current scientific standards.
- Establishment of a well structured data base accessible to all Member States and the European Commission.

MRL review programme

Close collaboration between Member States, EFSA and the European Commission is necessary!



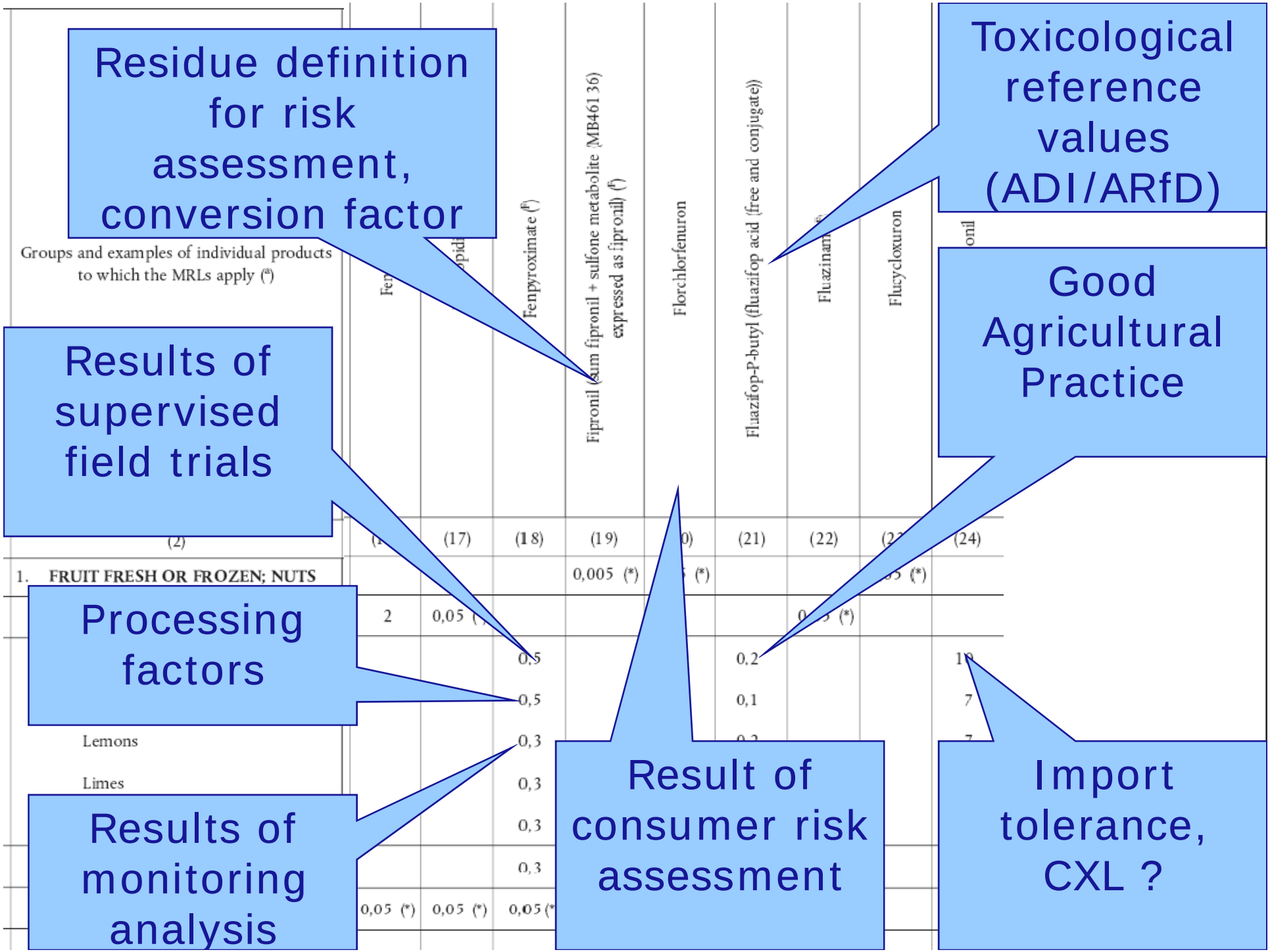
Routine MRL applications for setting/amending MRLs

- If a Member State intends to authorise a pesticide and the existing MRL is not sufficient
- Member States prepare evaluation report in support of the MRL application
  - Ca 100 applications per year are expected
- EFSA is asked to give a reasoned opinion regarding the consumer safety of the proposed MRL within 3 months (in exceptional cases 6 months)

Regulation 396/2005

Development and maintenance of a scientific MRL database

- European Commission has established a MRL database covering the legal aspects
- EFSA has to establish a database covering the technical and scientific aspects of MRLs
- Link between these databases

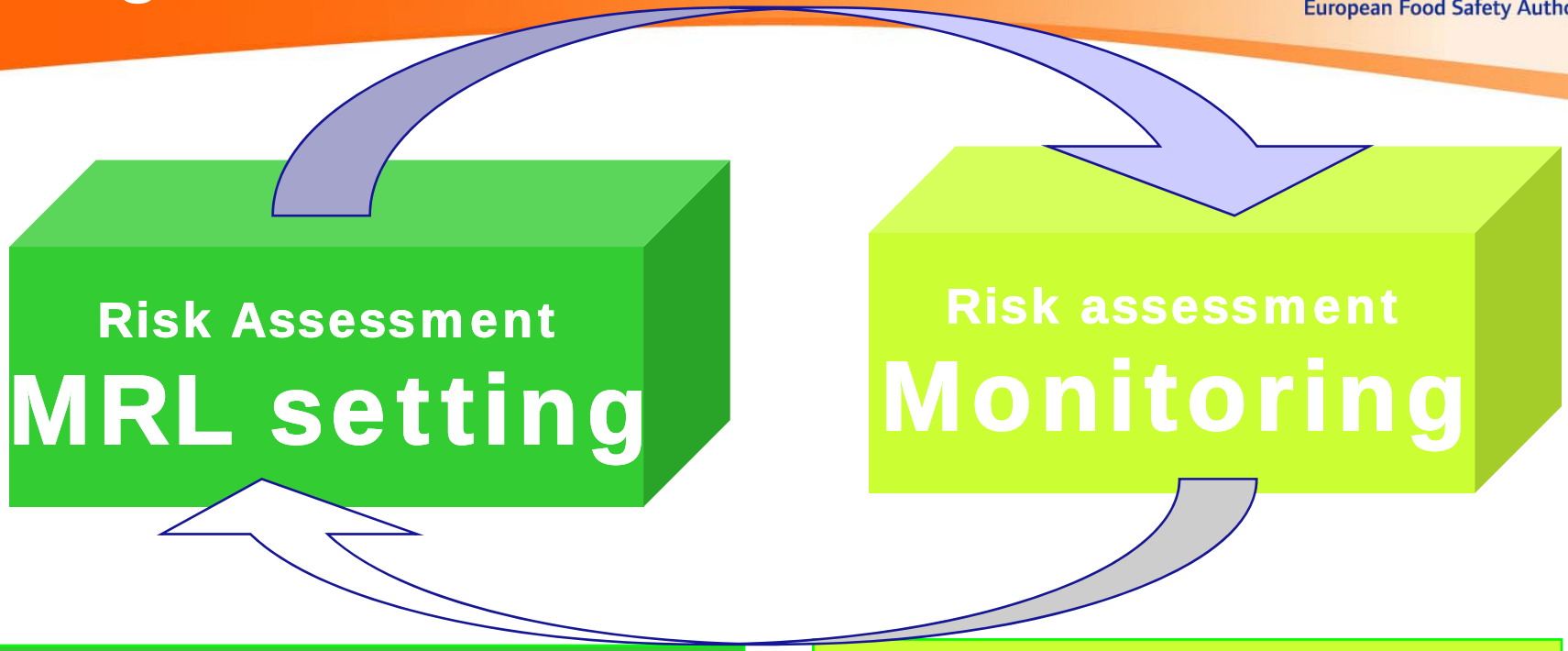

Residue definition for risk assessment, conversion factor
Toxicological reference values (ADI/ARfD)
Good Agricultural Practice
Results of supervised field trials
Processing factors
Result of consumer risk assessment
Import tolerance, CXL ?
Results of monitoring analysis
Groups and examples of individual products to which the MRLs apply (a)
Fenpyroximate (f)
Fipronil (sum fipronil + sulfone metabolite (MB46136) expressed as fipronil) (f)
Florchlorfenuron
Fluazifop-P-butyl (fluazifop acid (free and conjugate))
Fluazinam
Flucycloxuron
(2)
(17)
(18)
(19)
(21)
(22)
(24)
1. FRUIT FRESH OR FROZEN; NUTS
0,005 (*)
0,05 (*)
0,5
0,5
0,2
0,1
Lemons
Limes
0,3
0,3
0,3
0,05 (*)
0,05 (*)
0,05 (*)

Regulation 396/2005

Monitoring of pesticide residues

- By end of August, results of previous year's control activities have to be submitted to EFSA
- EFSA prepares the Annual Report on Pesticide Residues, in particular on the following aspects:
  - Analysis of the results
  - **Actual consumer exposure assessment**
  - Recommendations for future monitoring programmes
- Report has to be submitted to COM by 6 months (end of February)
- Publication of Report (including comments from MS and COM)

Regulation 396/2005



Worst case assumptions

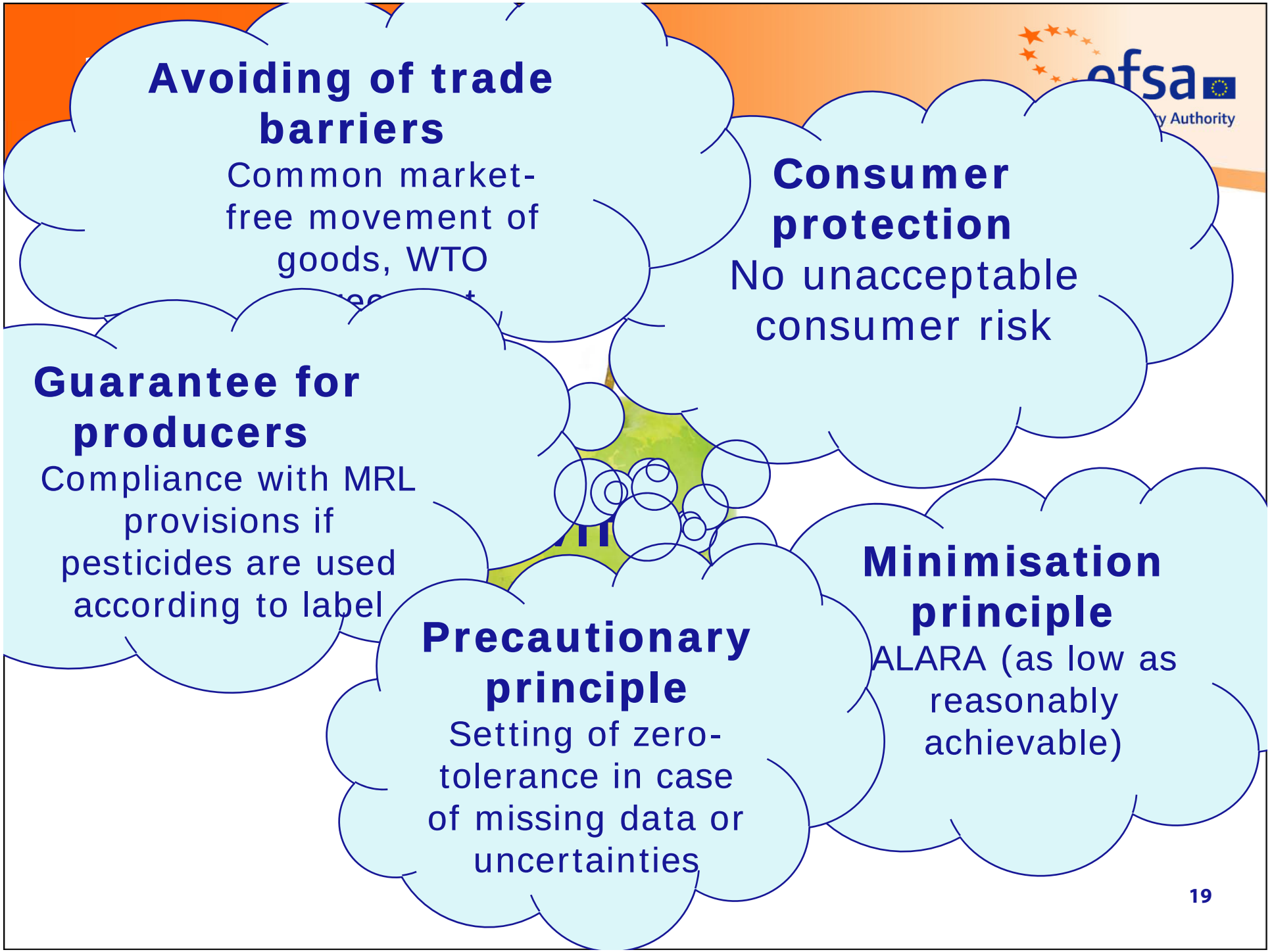
Risk assessment based on data generated by applicants

Supervised field trials

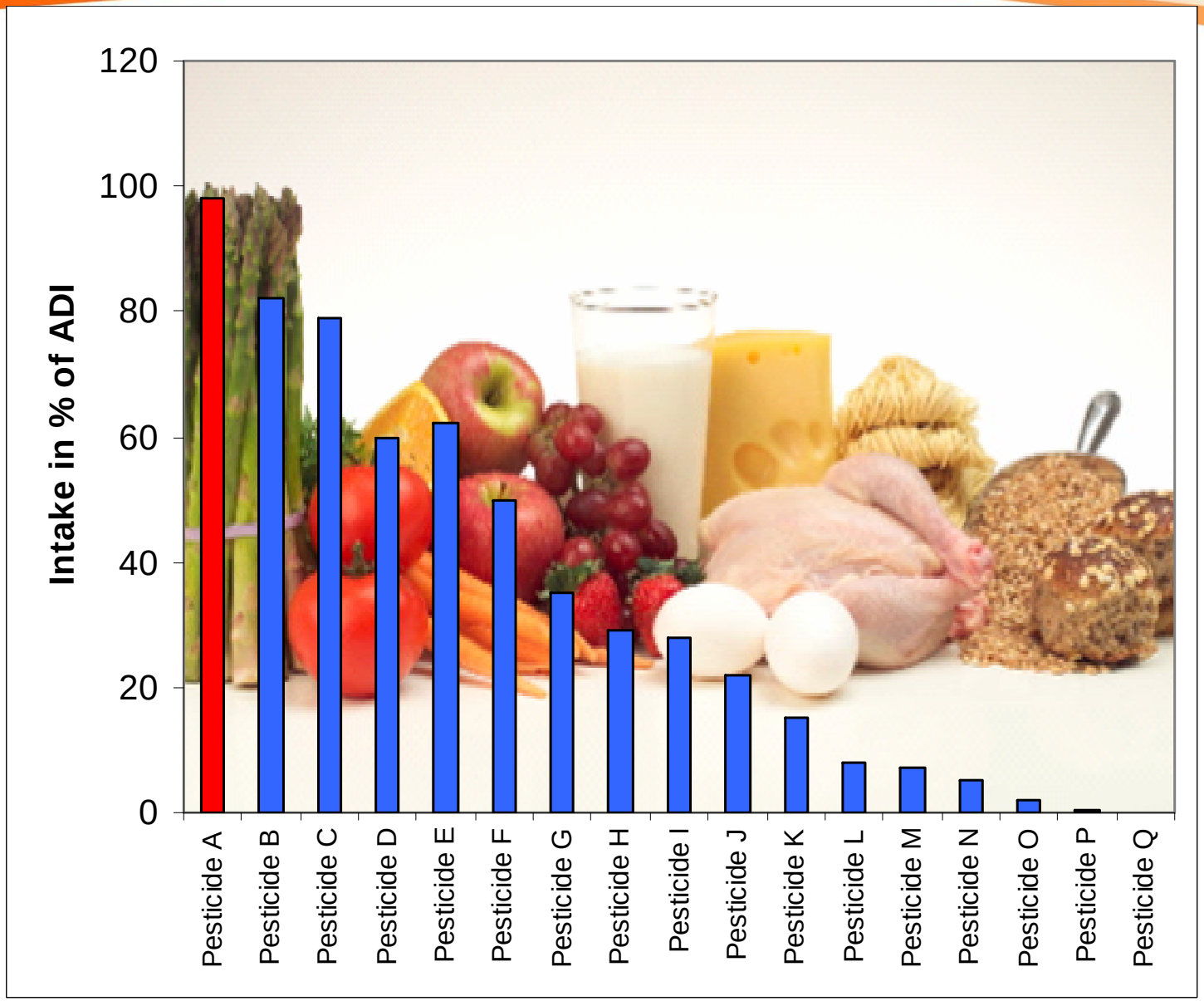
Real occurrence data
Better estimate of consumer exposure

Limitations regarding current reporting format

Change of reporting format and data model/XML schema under preparation


Avoiding of trade barriers
Common market-free movement of goods, WTO
Consumer protection
No unacceptable consumer risk
Guarantee for producers
Compliance with MRL provisions if pesticides are used according to label
Precautionary principle
Setting of zero-tolerance in case of missing data or uncertainties
Minimisation principle
ALARA (as low as reasonably achievable)

Safety margins in MRL setting



MRL is not borderline

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between acceptable residue concentration on food and

immediate consumer health risk

