

Regional Symposium on Regulation of Pesticide Residues in Food

Hong Kong, 27-28 March 2009

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European Food Safety Authority



Dietary risk assessment of pesticide residues in food

Pesticide Risk Assessment Peer Review (PRAPeR) – MRLs

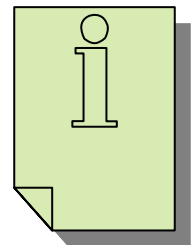
- ❖ EFSA's mandate and tasks
- ❖ Concept of Risk Analysis
- ❖ Risk Assessment in the process of setting maximum residue levels (MRLs) for pesticides on food

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**



Mission

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

- 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

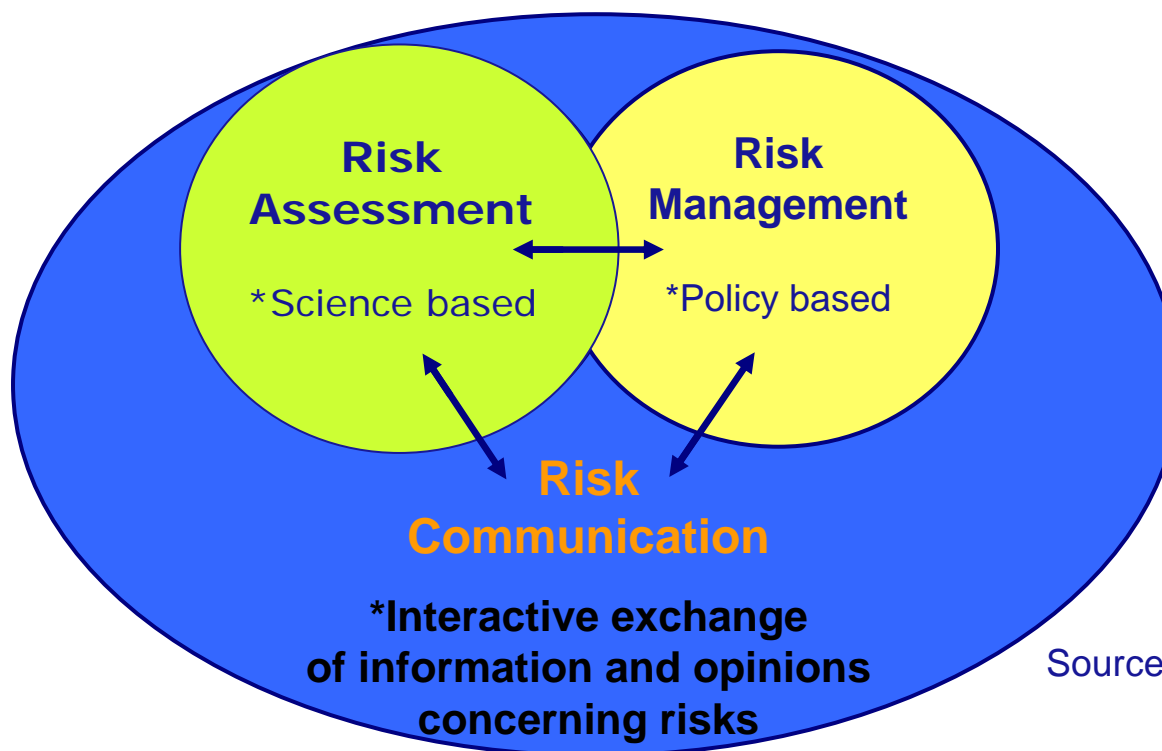


EFSA's Official seat:
Palazzo Ducale



EFSA's operational seat:
"DUS" building

Risk analysis concept



Source: WHO/FAO 1997



Need for close cooperation between risk assessor and risk manager

Scientifically based process consisting of four steps

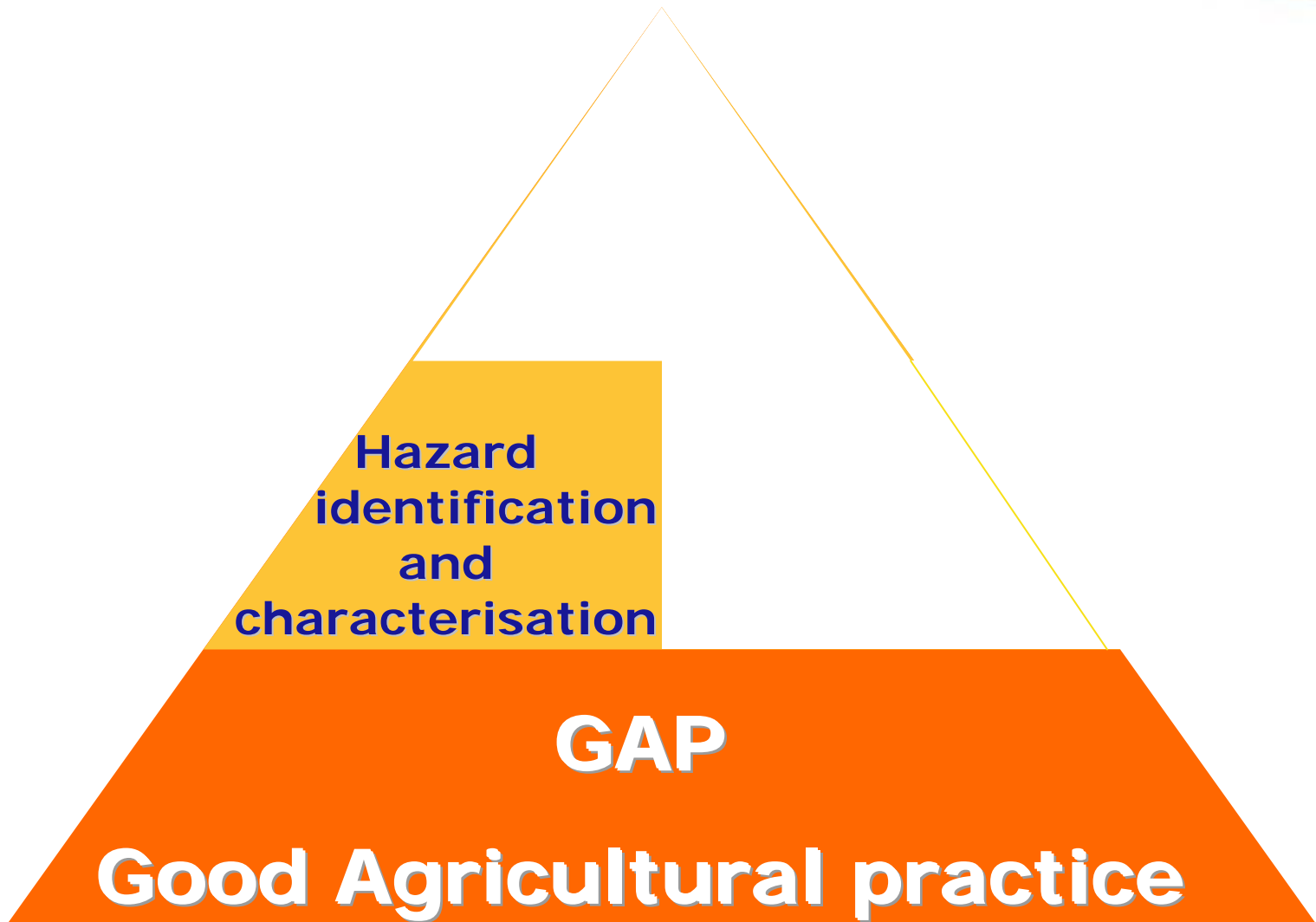
1. Hazard identification
2. Hazard characterisation
3. Exposure assessment
4. Risk characterisation

MRL setting procedure

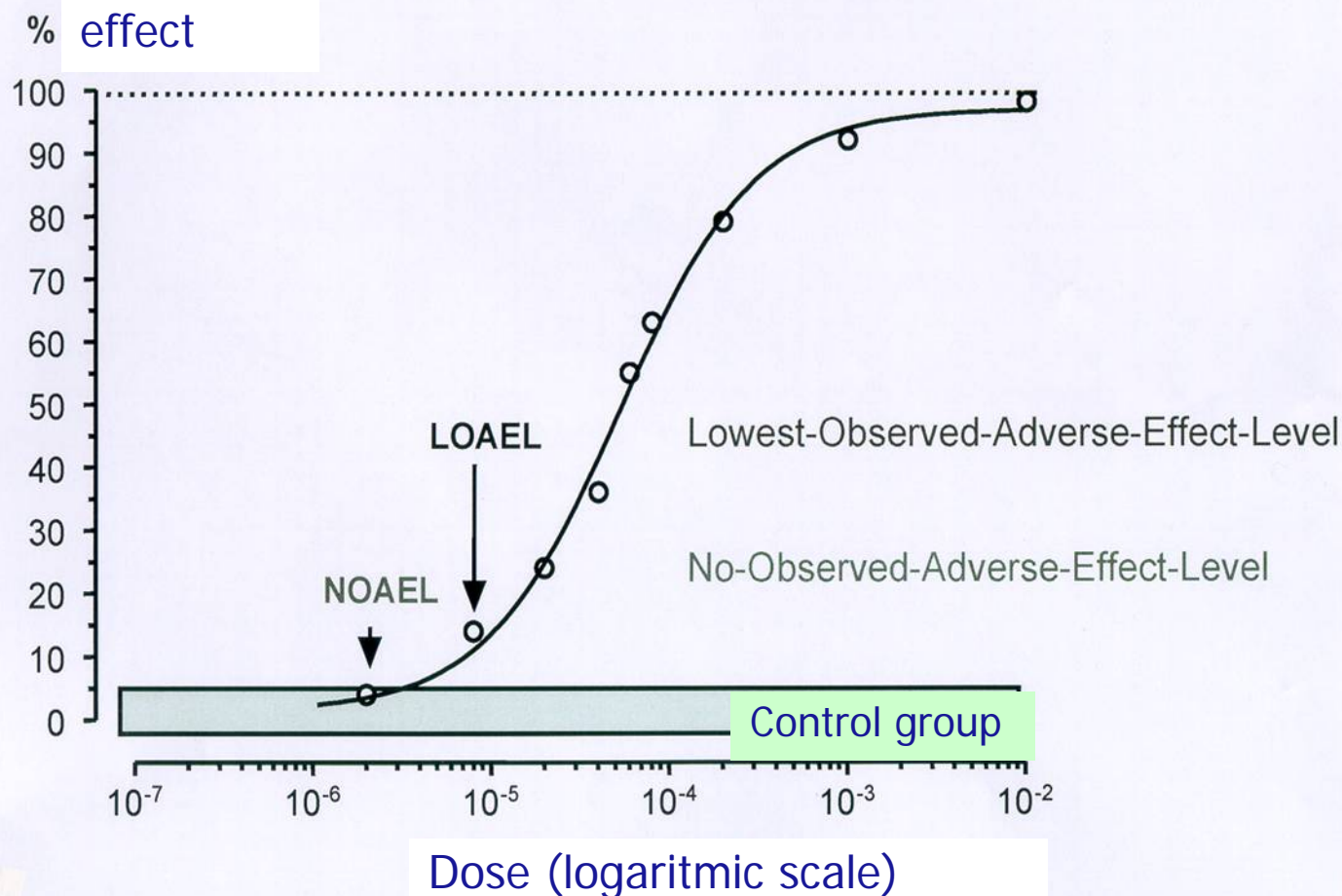


Which active substance is used on
which **crop**,
against which **pest** or **disease**,
with which **application rate**,
what **timing of application**,
number of applications,
which **application technique**,
which **interval** between treatments,
field or **glasshouse**,
what is the **pre-harvest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

MRL setting procedure



Hazard quantification



Explanations:

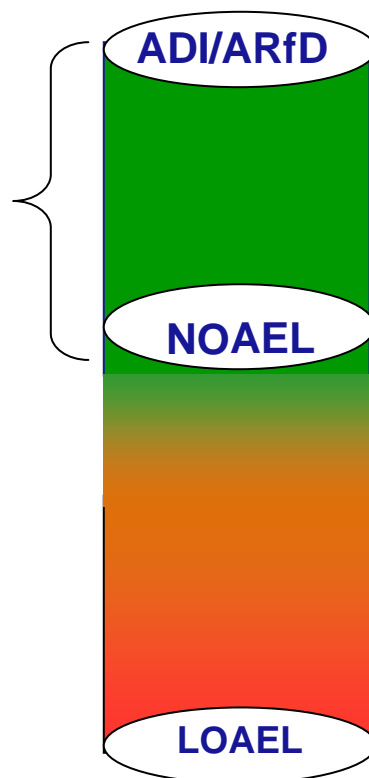
ADI: Acceptable Daily Intake

ARfD: Acute Reference Dose

NOAEL: No Observable Adverse Effect Level

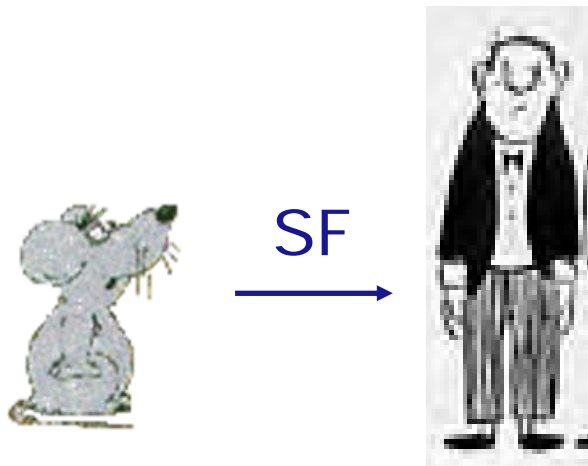
LOAEL: Lowest Observable Adverse Effect Level

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



**What is the NOAEL for the
most sensitive animal species ?**

Lowest LOAEL derived for most sensitive animal species



Extrapolation from
most sensitive animal
species to humans



Sensitivity of different
subgroups of the population

SF: Safety factors

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.

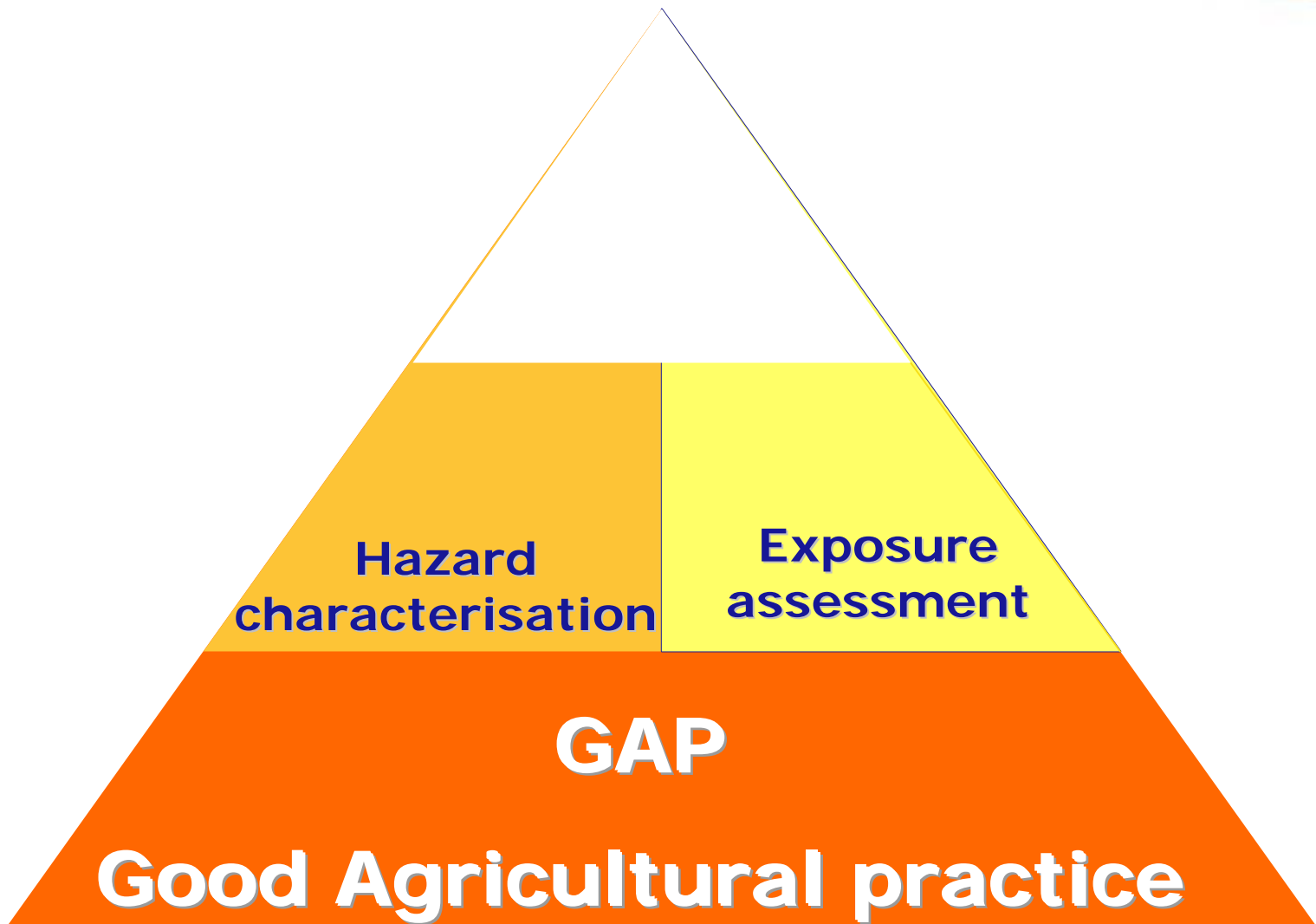
Expressed in
mg/kg body weight/day

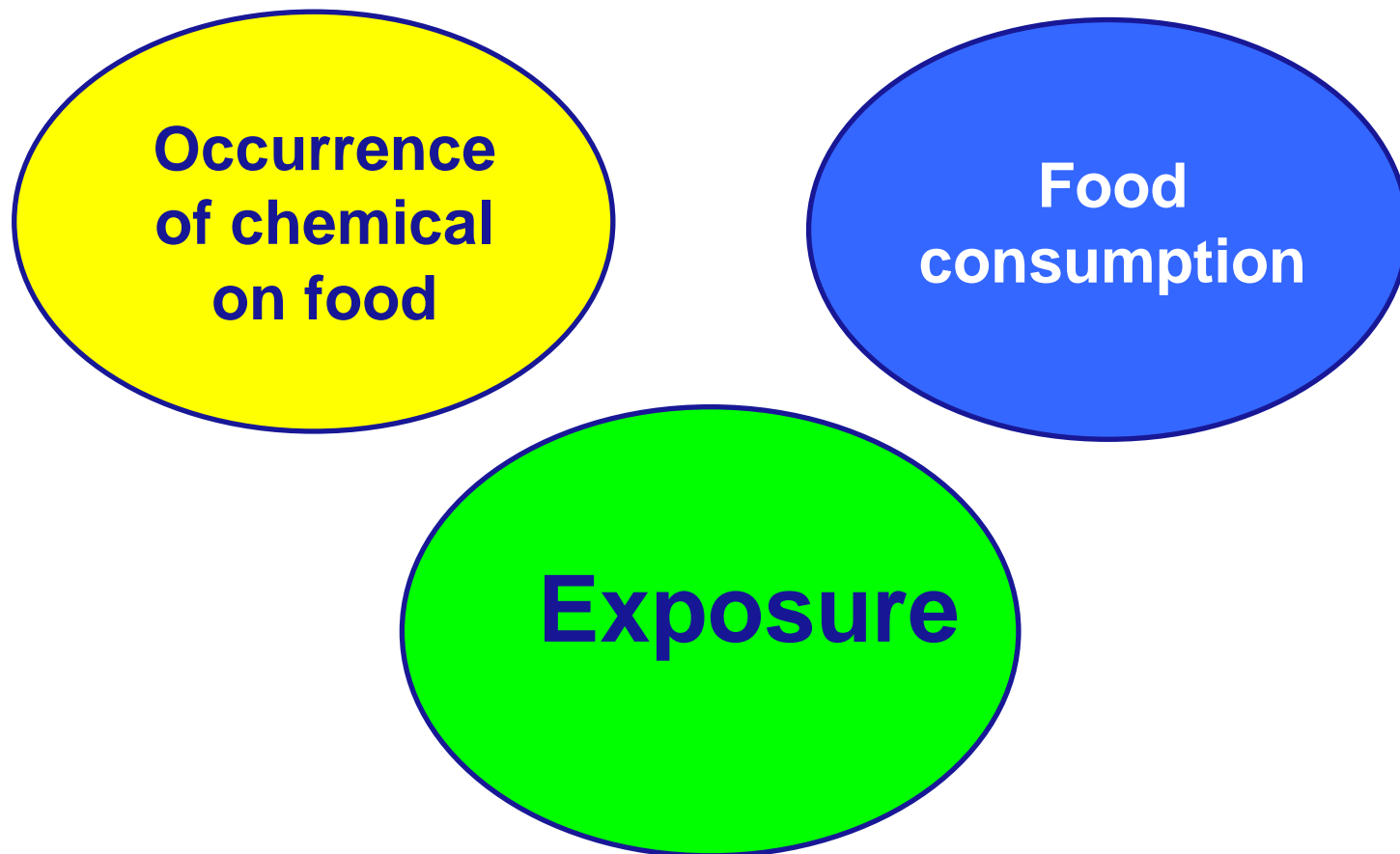
Acute Reference Dose **ARfD**

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





Analytical
methods

Plant
metabolism

Animal
metabolism
studies

Occurrence of residues in food

Plant growth, phytochemistry, feeding studies
and
development

Succeeding
crops

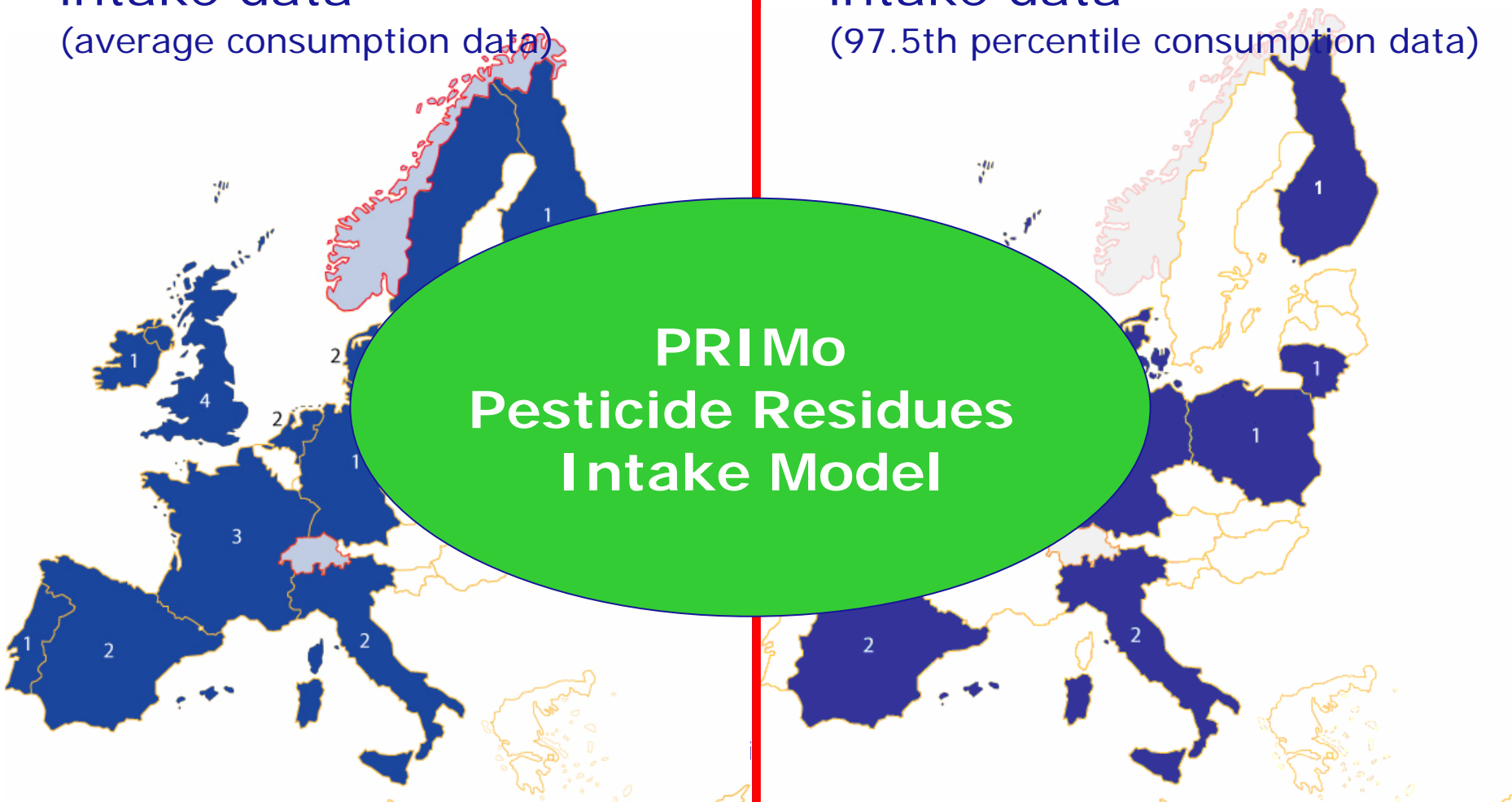
Field
trials

Processing
studies

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)



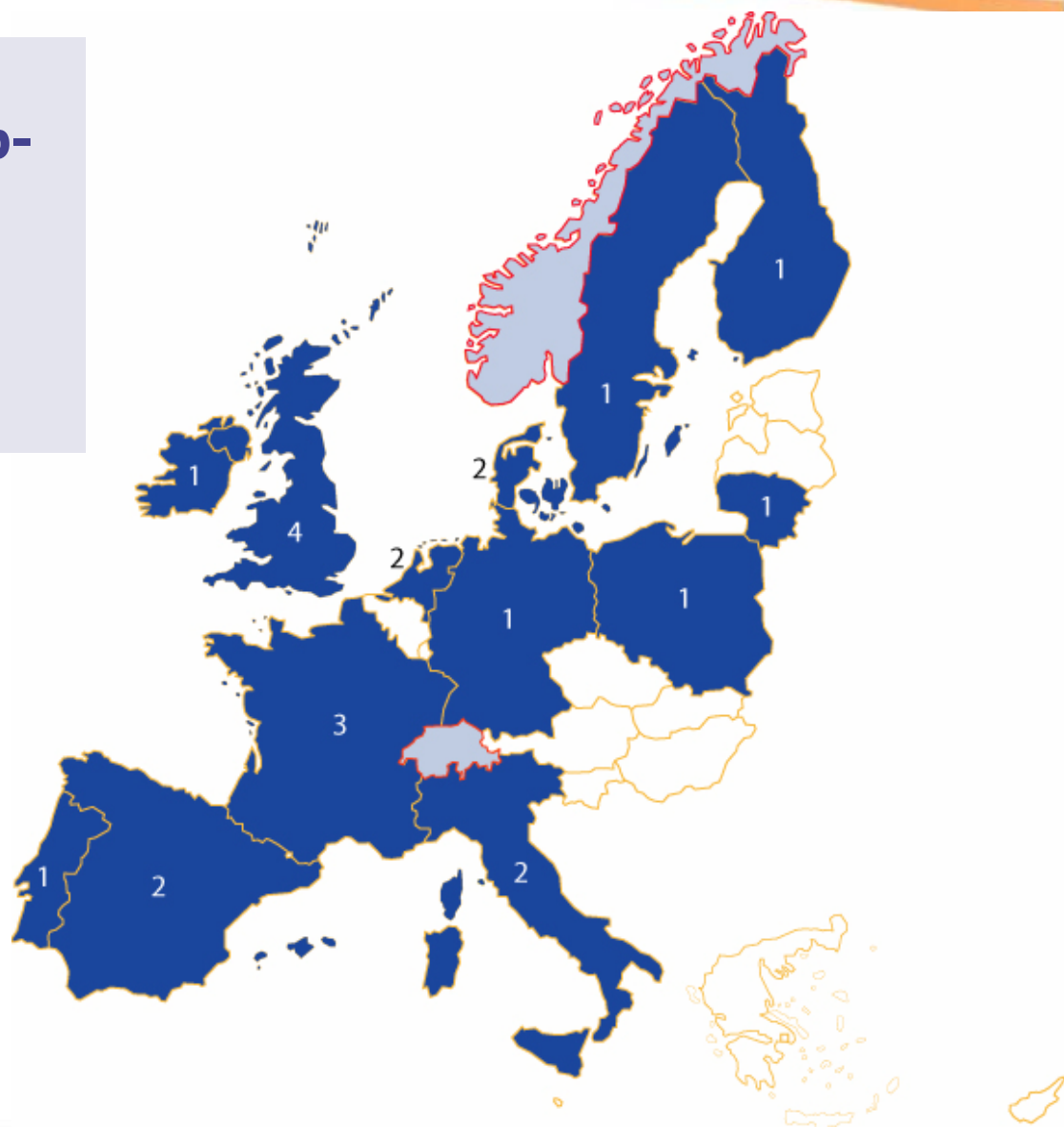
The image shows a map of Europe divided into two panels by a vertical red line. A large green oval is centered over the map, containing the text 'PRIMo Pesticide Residues Intake Model'. The map is color-coded: dark blue for countries with data, light blue for countries without data, and yellow for countries with no data. Numbers 1, 2, 3, and 4 are placed on various countries to indicate data availability. In the left panel, countries like Ireland, UK, France, Spain, and Italy are marked with numbers. In the right panel, countries like Sweden, Finland, Poland, Czech Republic, Slovakia, Hungary, Austria, Germany, and Italy are marked with numbers.

PRIMo
Pesticide Residues
Intake Model

Chronic exposure

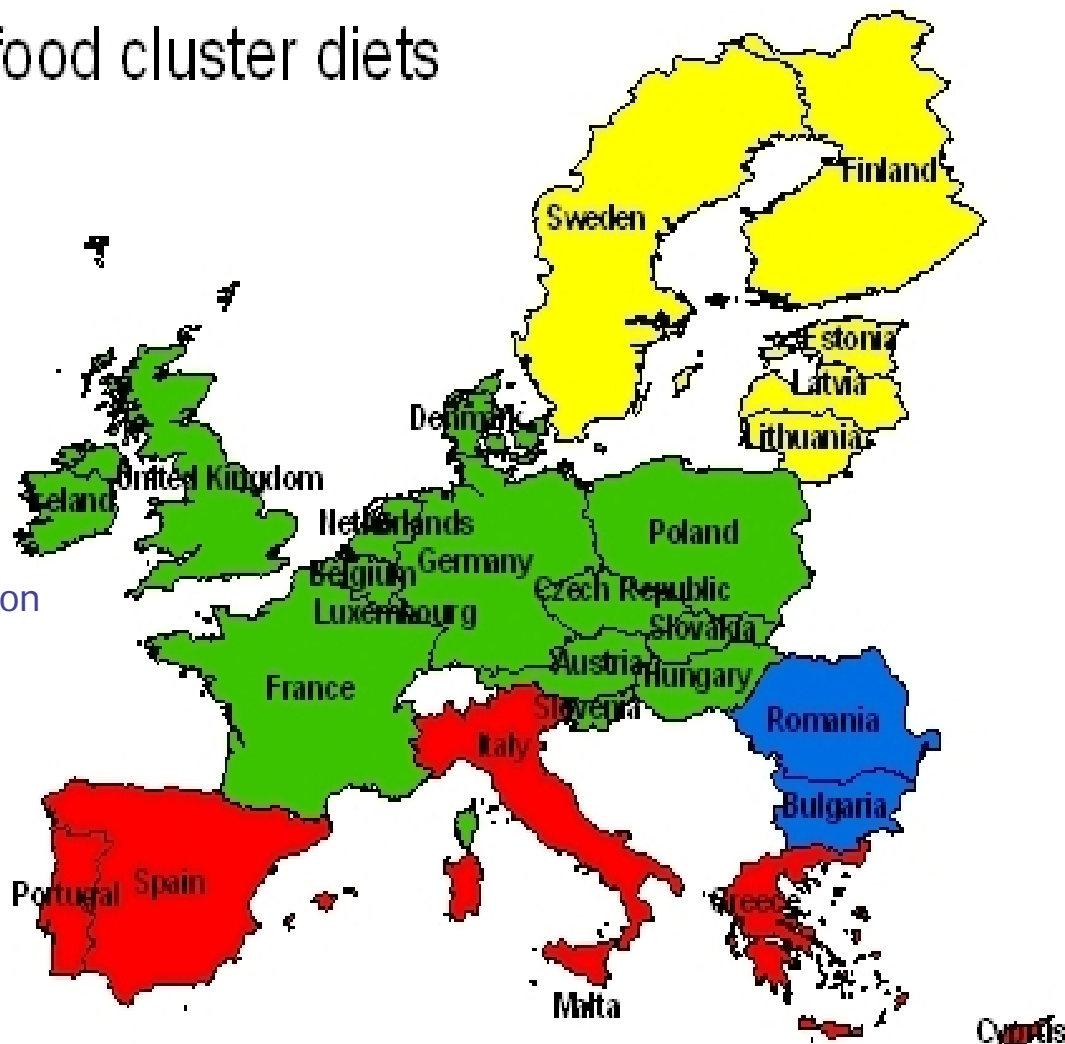
**Average consumption data
from different European sub-
populations**

**Representing consumption
habits of children, adults,
vegetarians etc.**



GEMS/food cluster diets

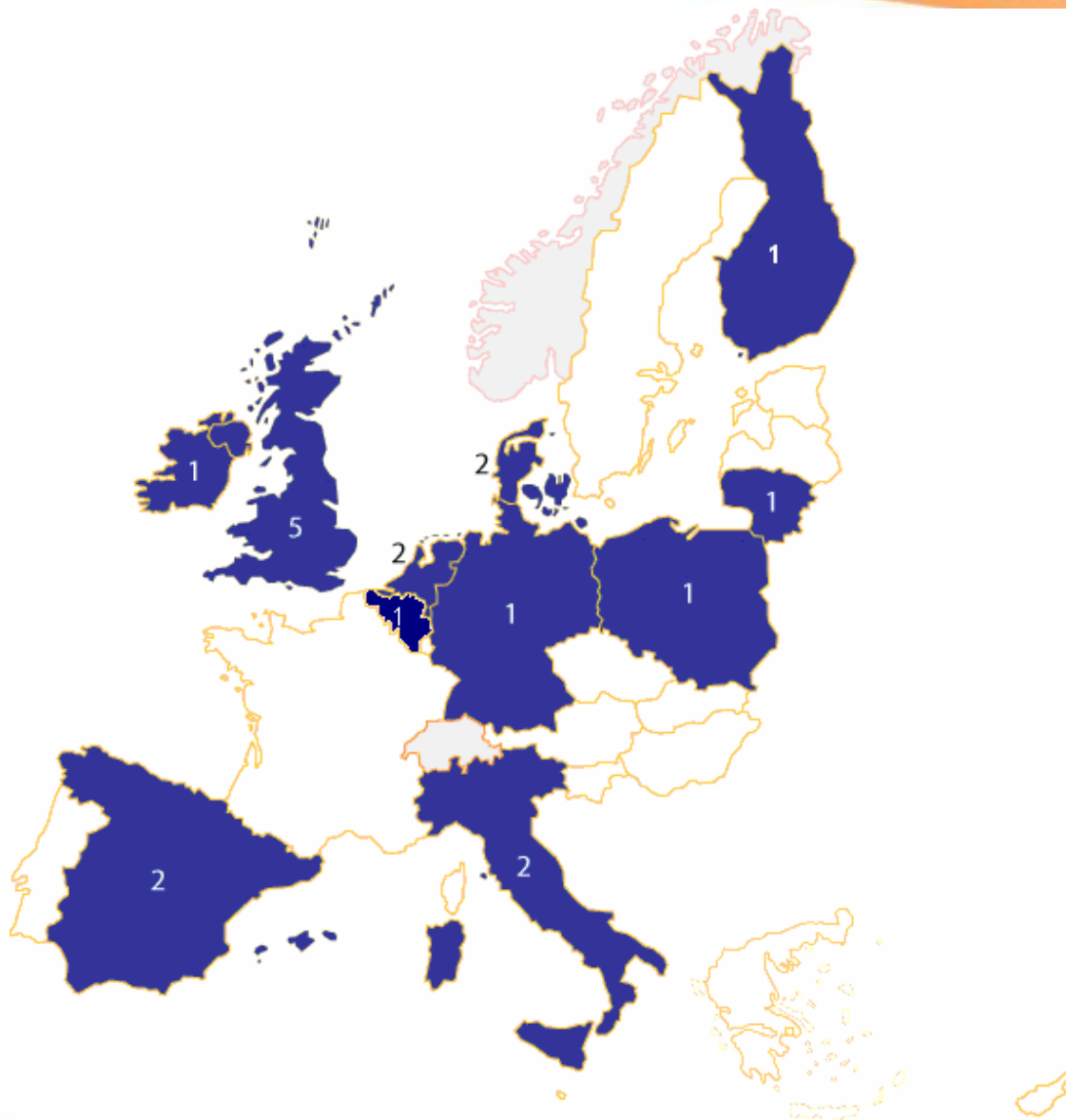
- Cluster F – Nordic/Baltic region
- Cluster E – Central EU region
- Cluster B – Mediterranean region
- Cluster D – Eastern European region

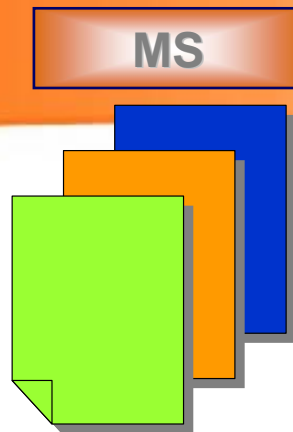
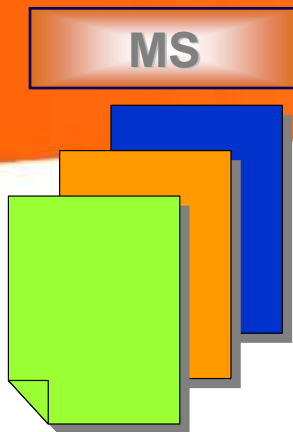


Acute exposure

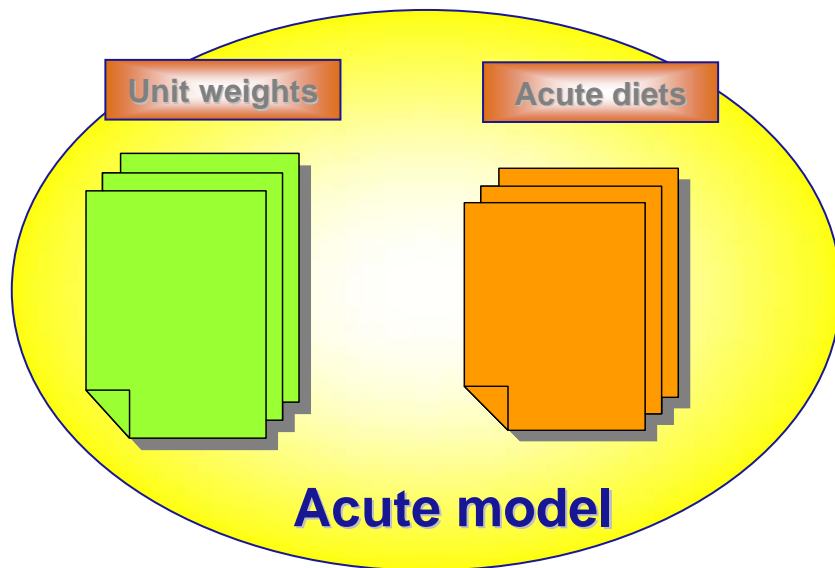
**Consumption data for
“extreme” consumer
(97.5 percentile of
distribution of food
consumption)**

**In general, children are
most critical group**

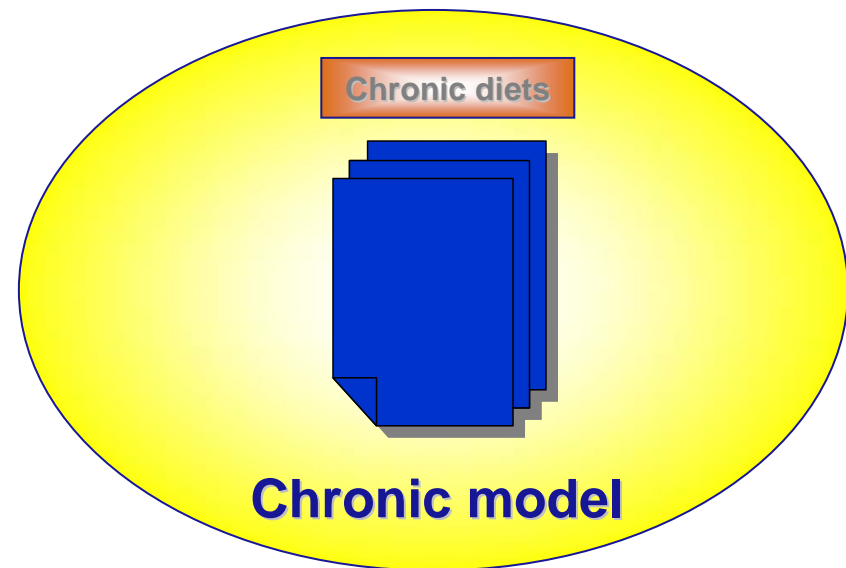




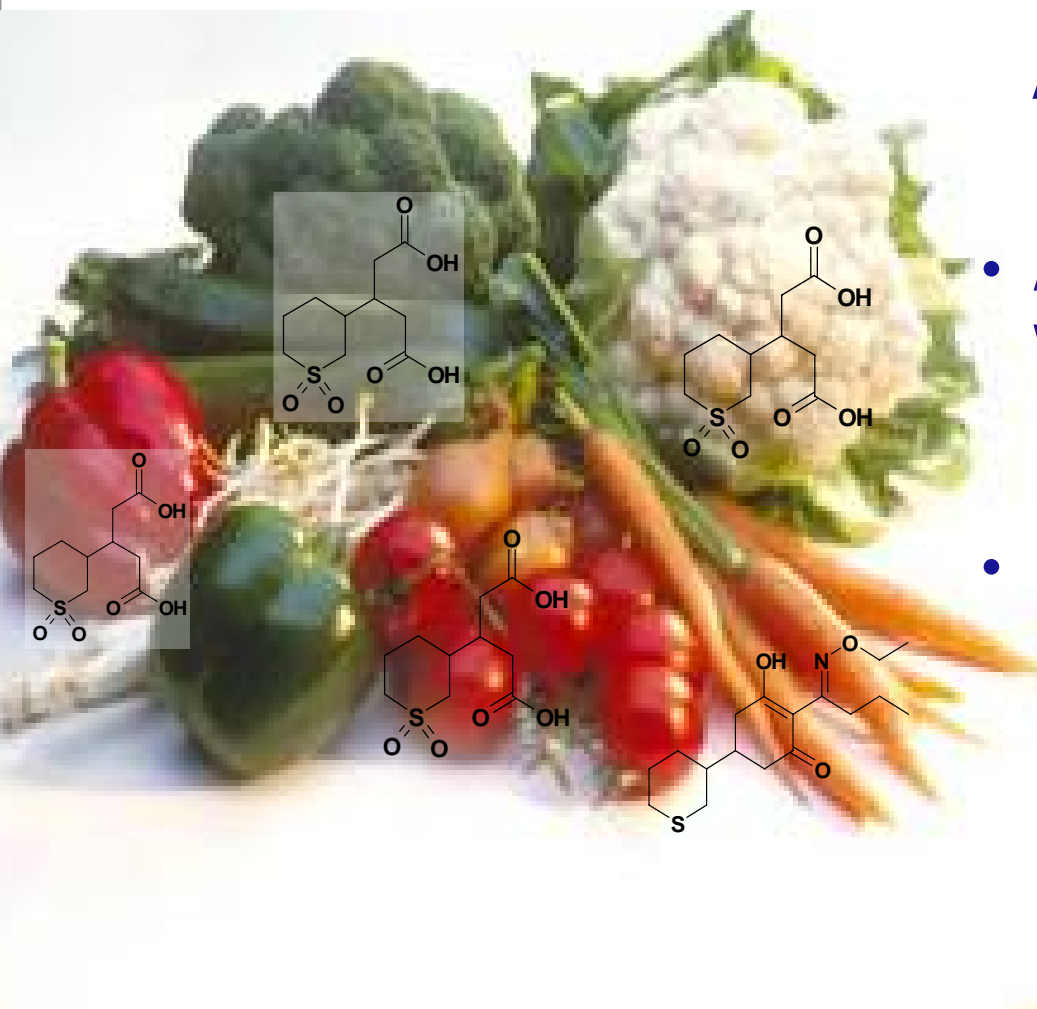
Model for exposure assessment



Identification of critical European consumer for each commodity



Calculation for all diet sets



Assumptions:

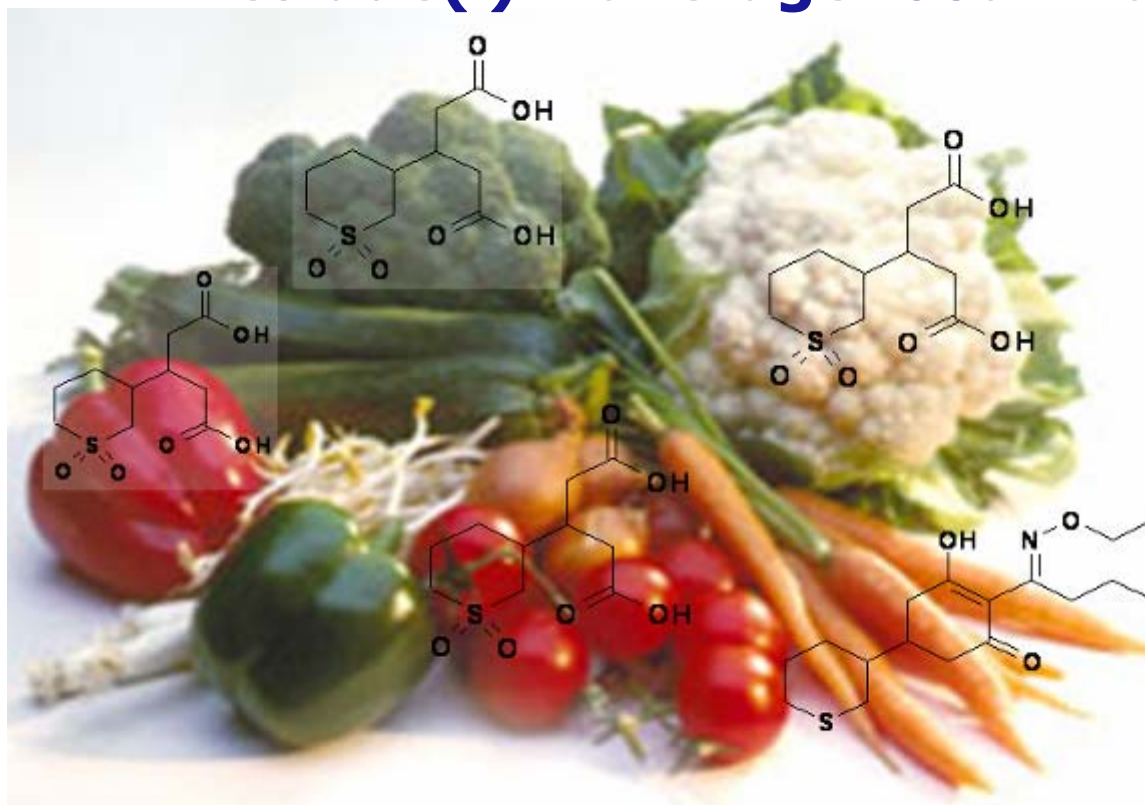
- All food consumed is treated with the pesticide
- Lifetime exposure

How to calculate chronic exposure

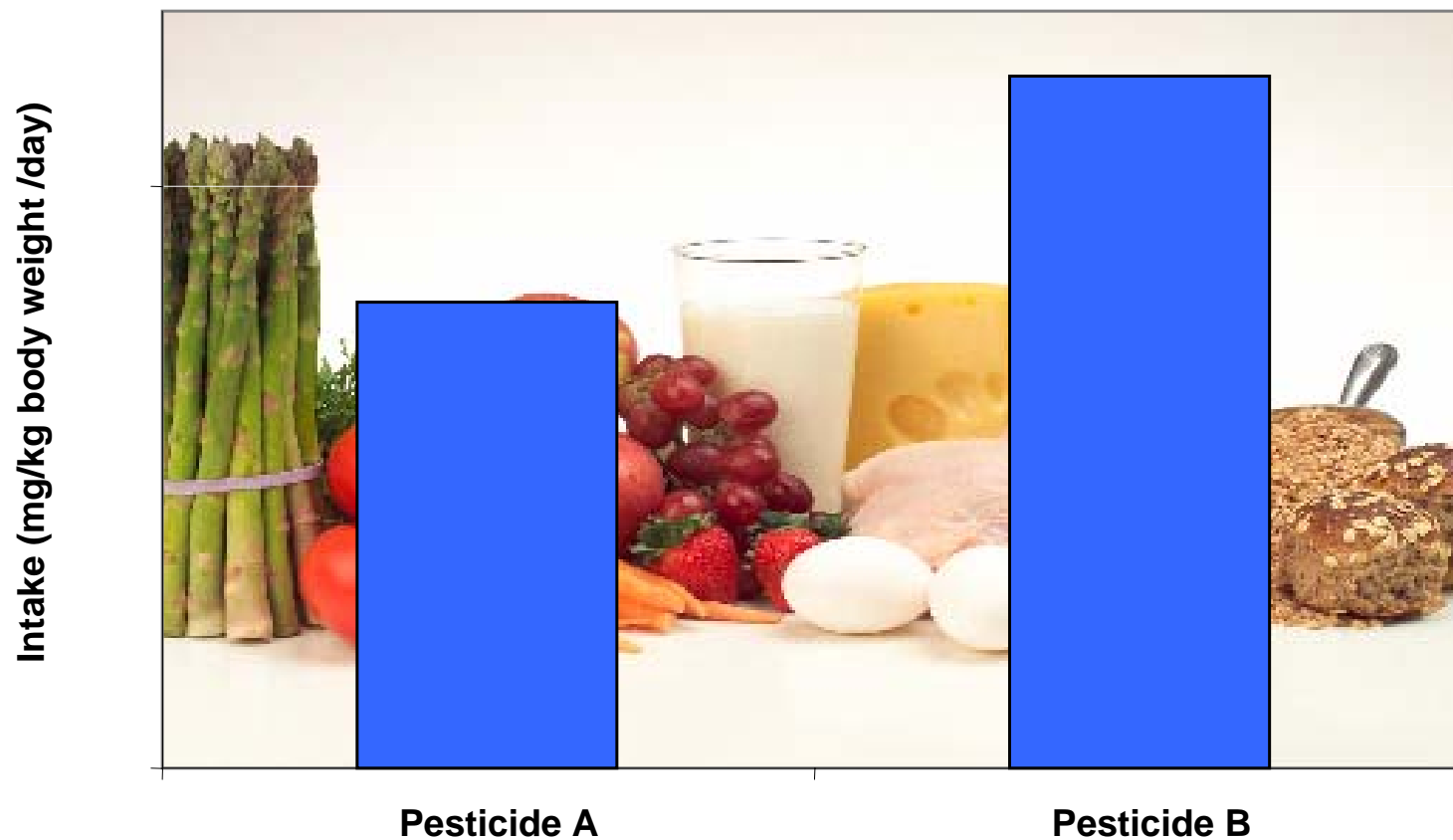
According to agreed international methodology developed
by JMPR (FAO/WHO)/ Codex Alimentarius

Theoretical maximum daily intake

$$\text{TMDI} = \sum \text{residue}(i) * \text{average food intake}(i)$$



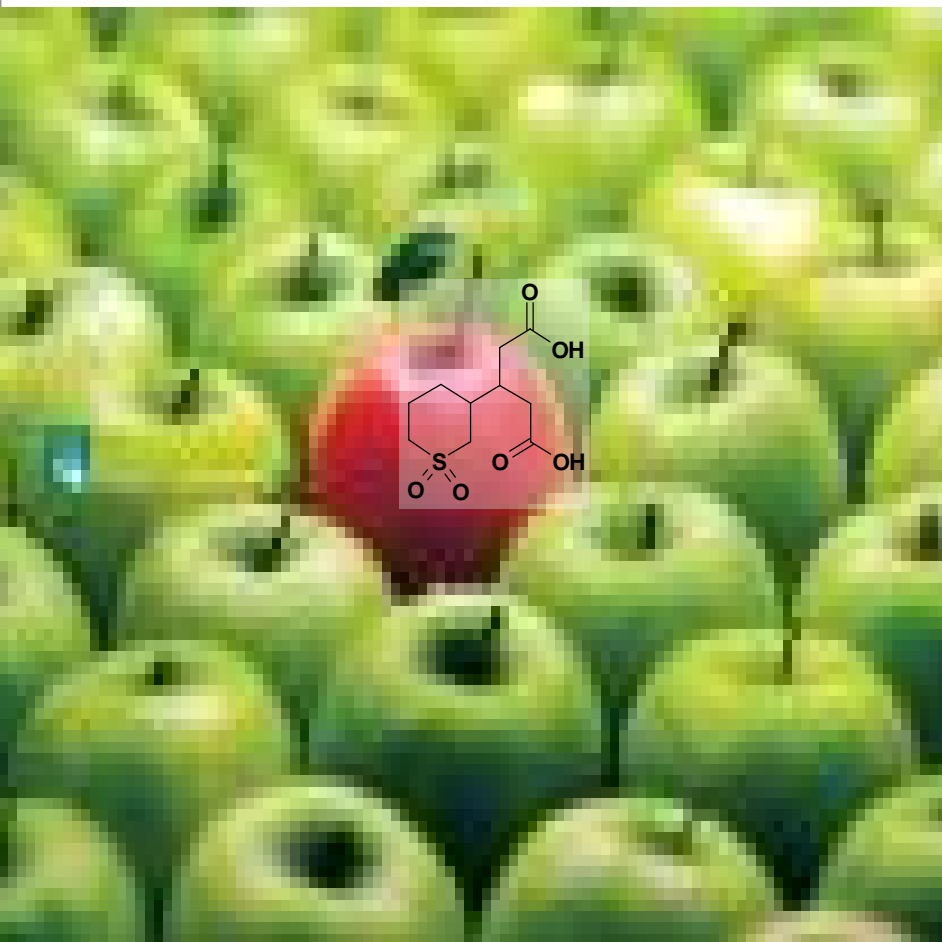
Chronic exposure



Refined intake calculation:

Reduction or concentration after processing

Distribution of residues between edible and inedible part of the crops



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

Acute exposure

National estimated short term intake

$$\text{NESTI} = \text{HR} * 97.5\text{th percentile food intake} * \text{VF}$$

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

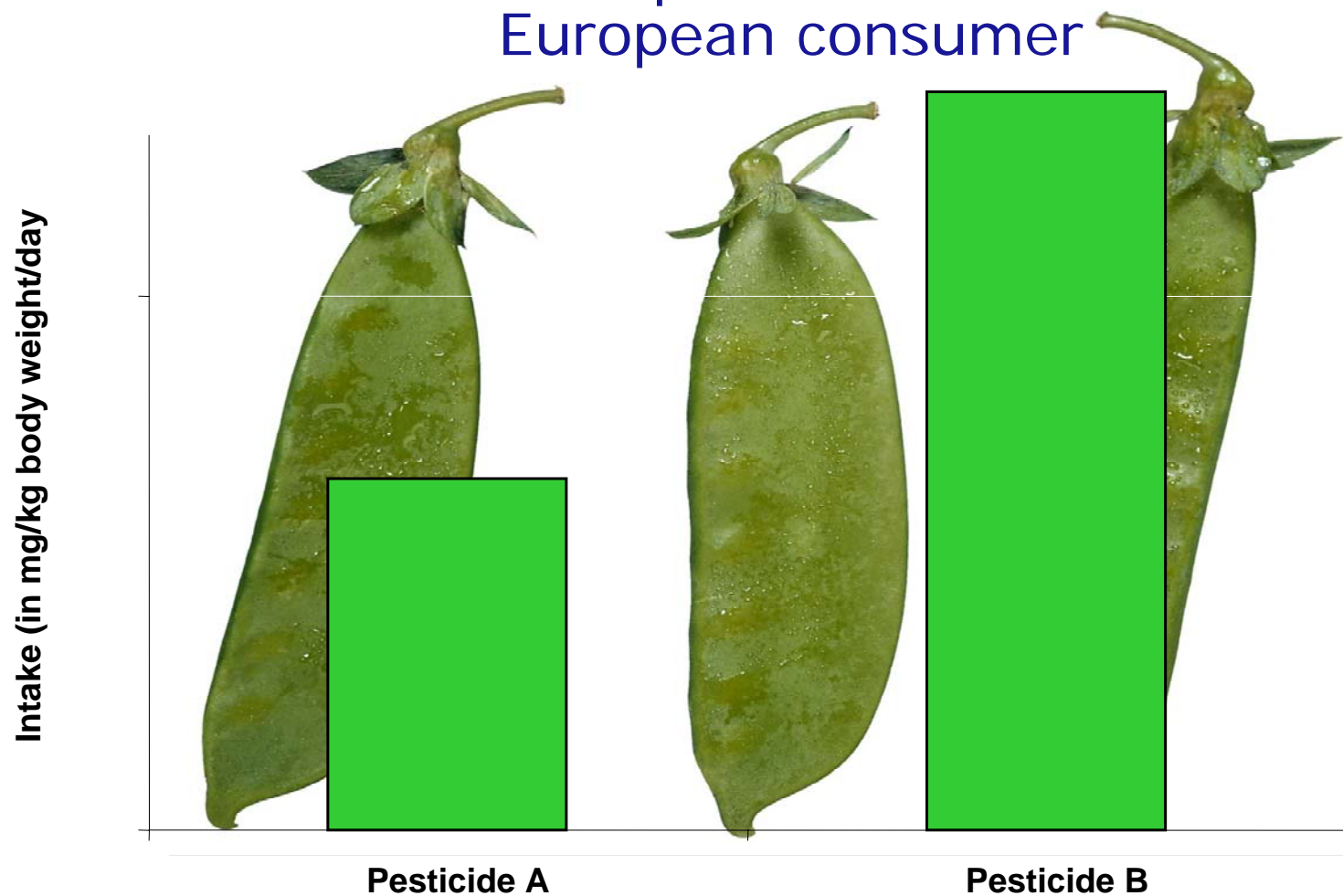
VF: variability factor, inhomogeneous distribution





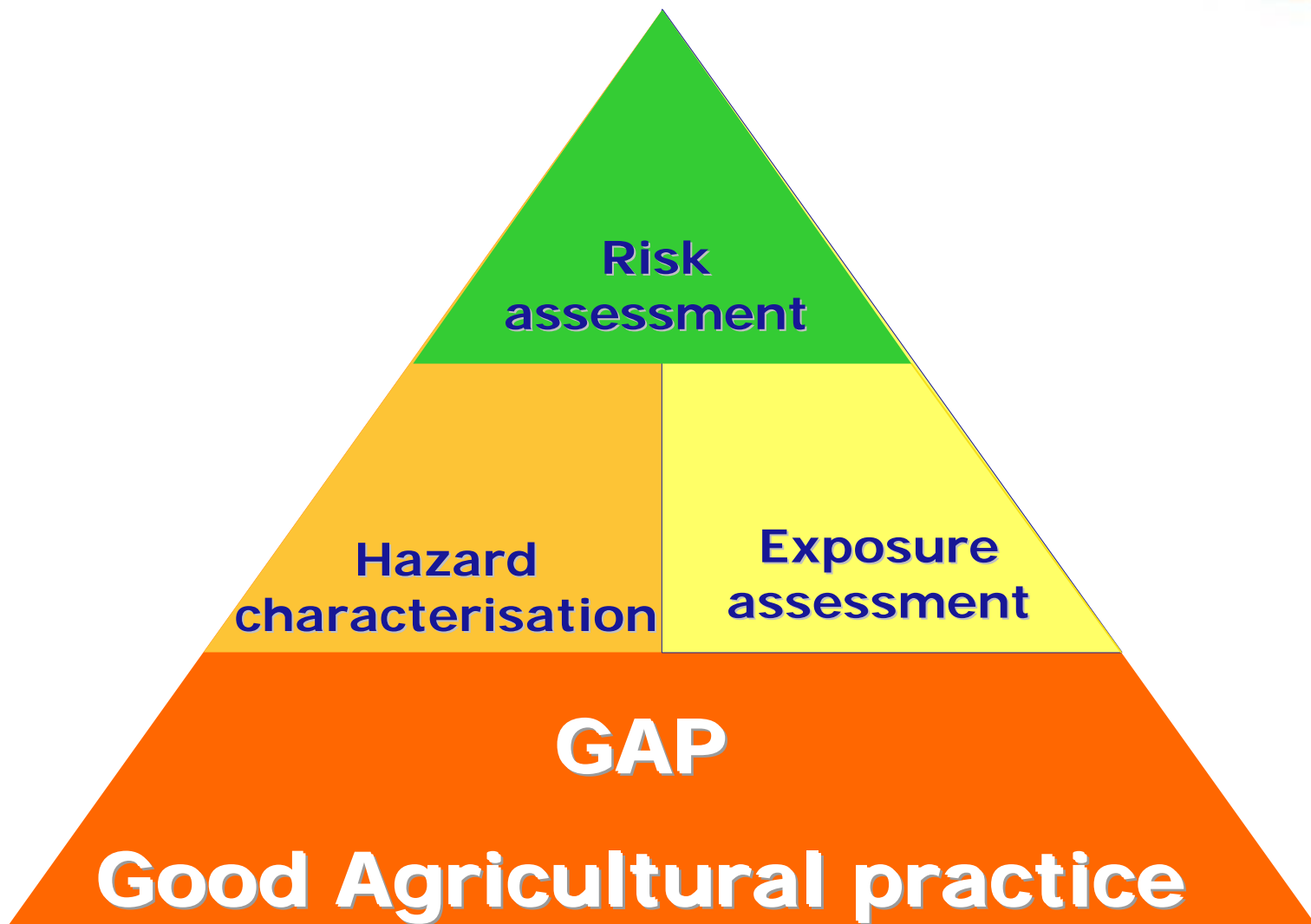
Calculations are performed for each individual commodity since it is not very likely that you are an extreme consumer for more than one commodity and that this extreme consumer finds extreme residues on more than one commodity

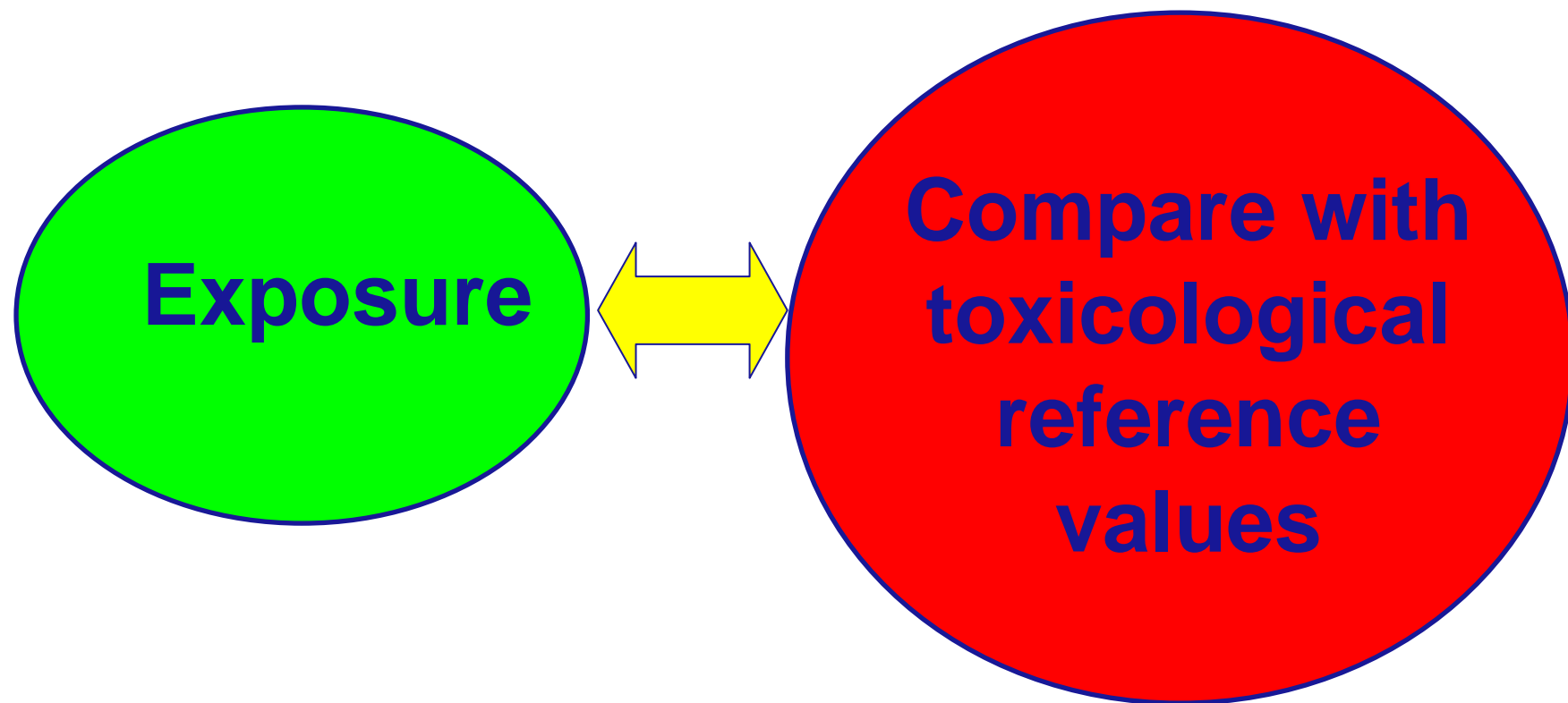
Calculation performed for critical European consumer



Refined intake calculations

Reduction or concentration after processing

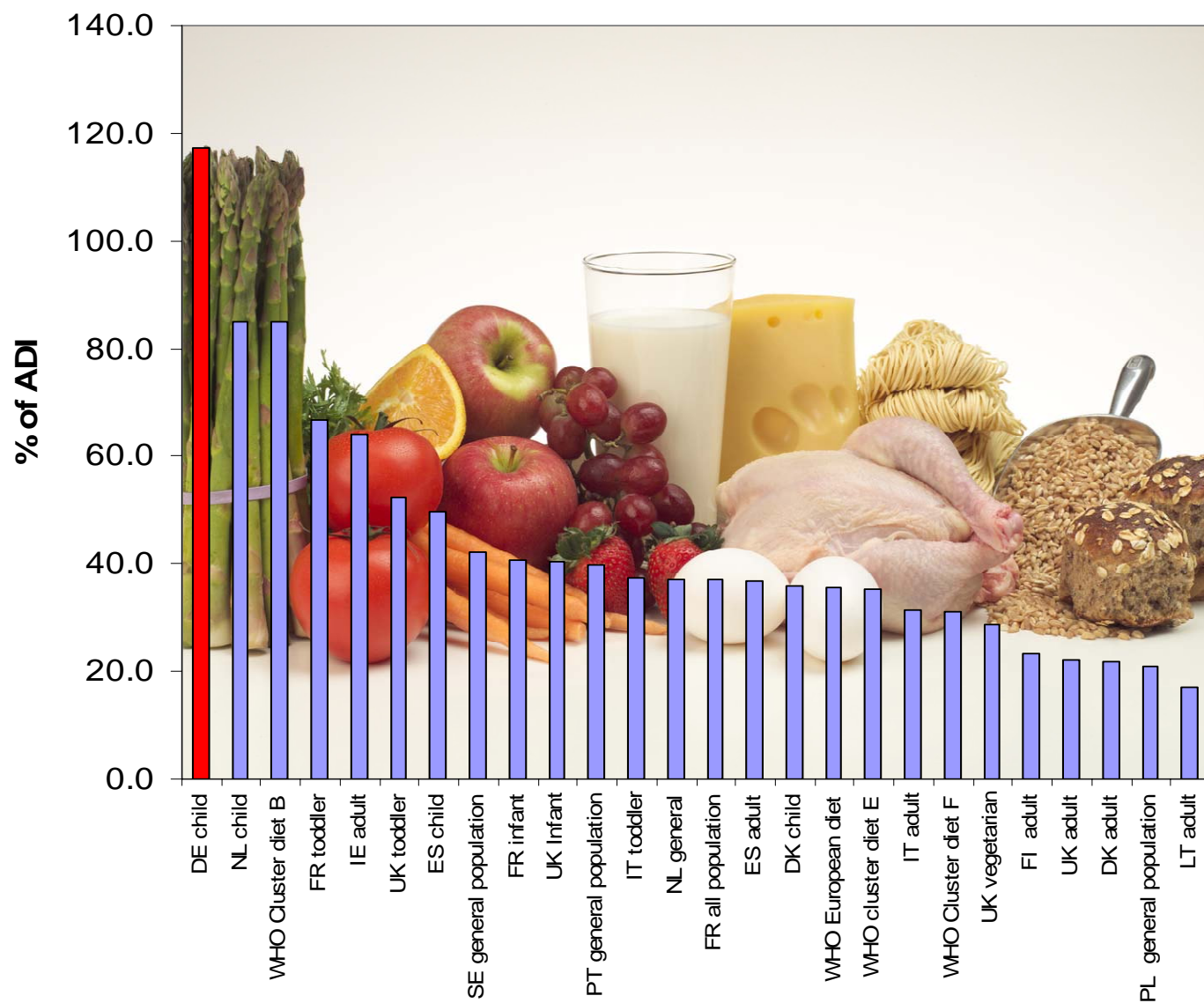




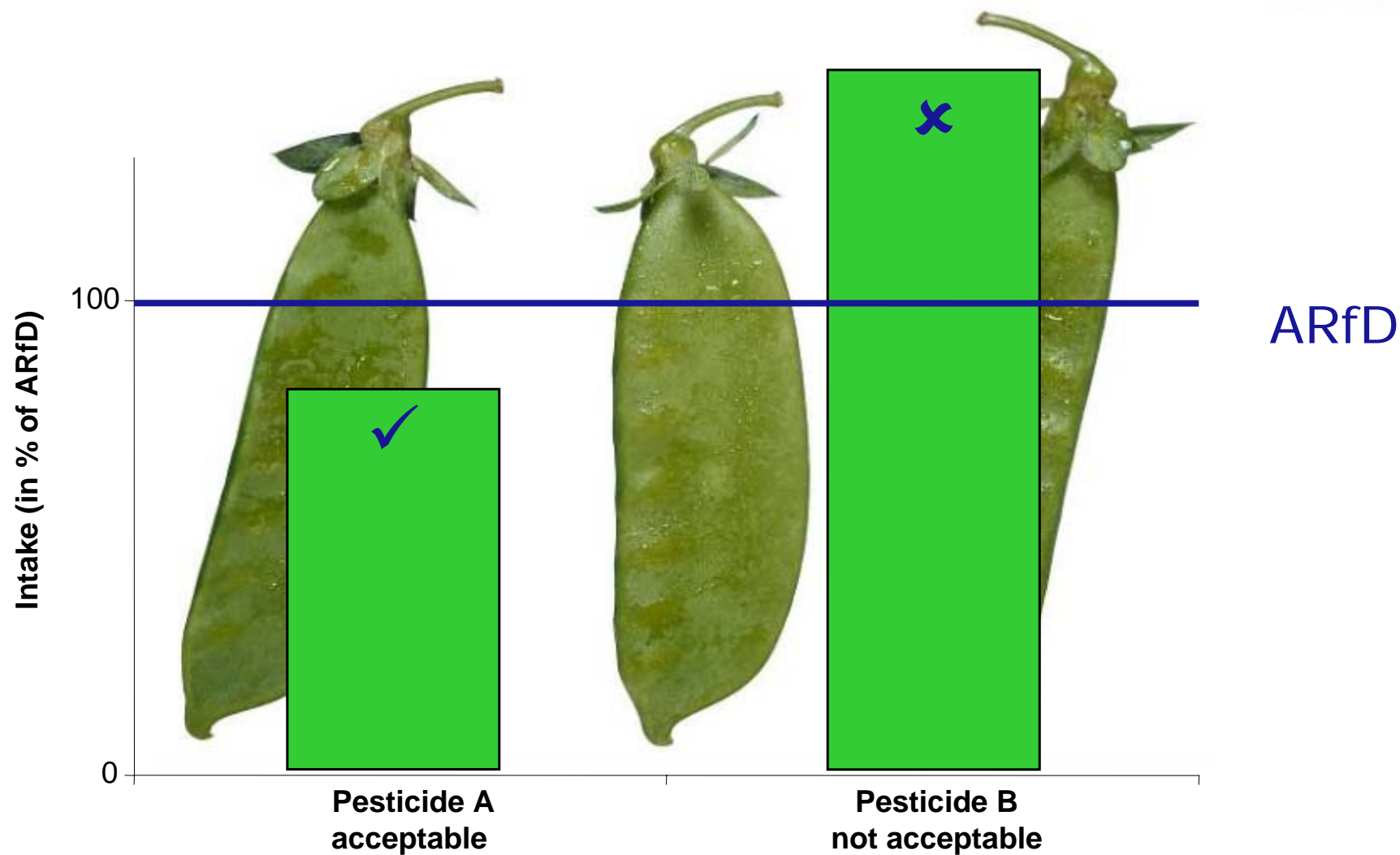
Chronic risk assessment



Chronic risk assessment



Acute risk assessment



- 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

Consumer protection

No unacceptable consumer risk

Certainty 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)

Minimisation principle

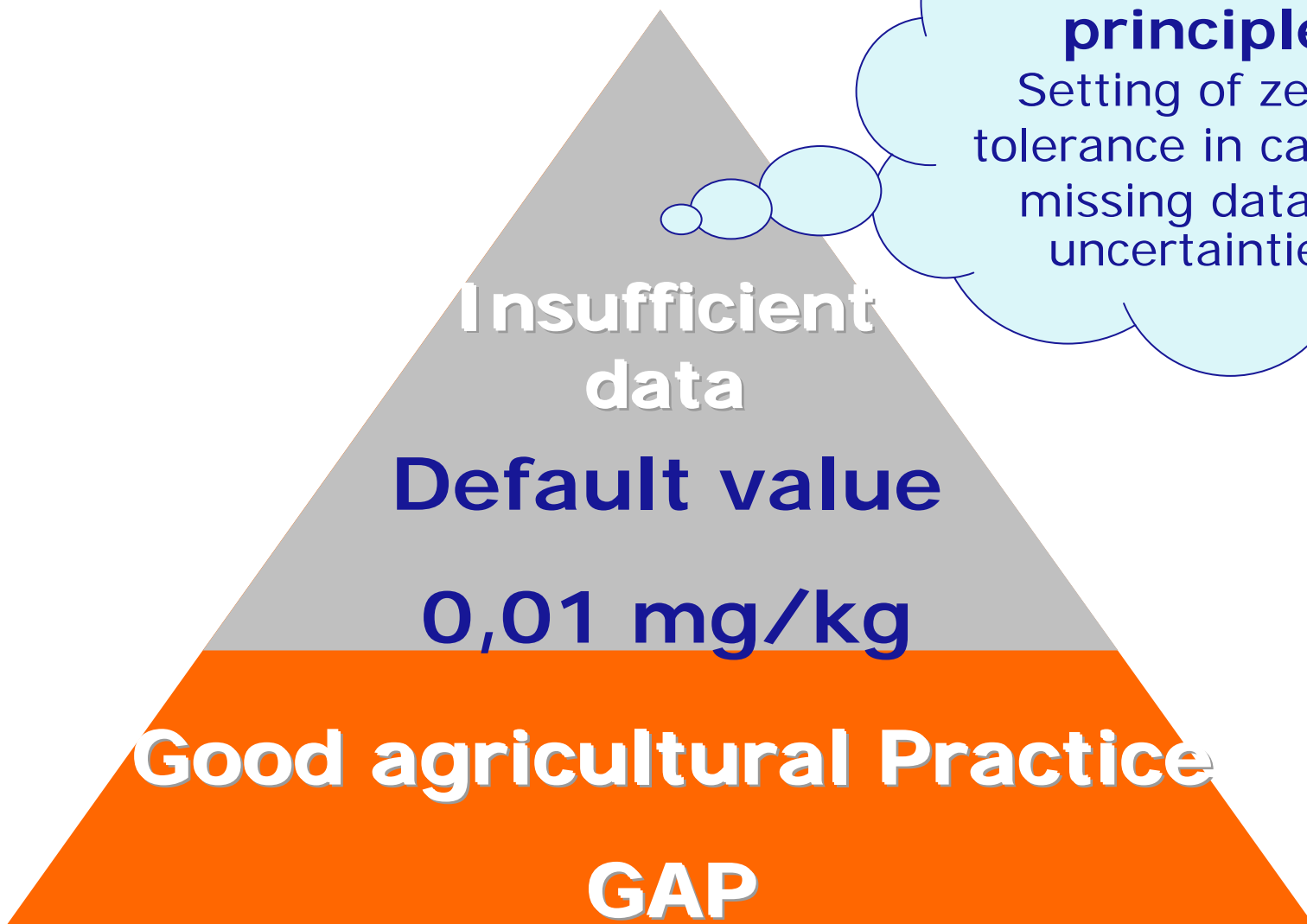
ALARA (as low as
reasonably
achievable)

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

MRL is not borderline



immediate
consumer health
risk

between acceptable residue
concentration on food and



THANK YOU

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