



Evaluation of active substances in plant protection products – Residues

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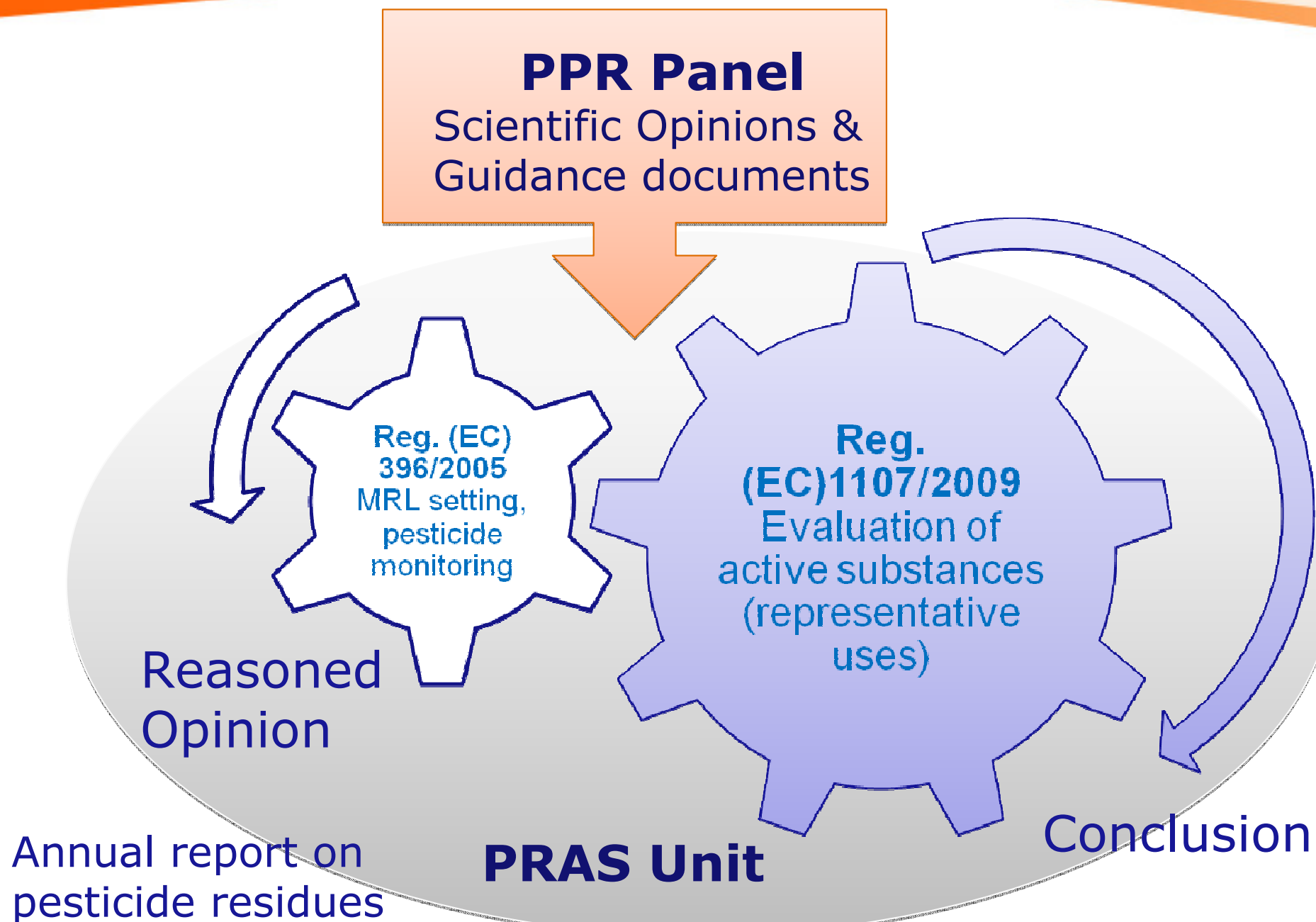
**European Conference on MRL-Setting for Biocides
Berlin, 18-19 March 2014**

Active substances

- (EC) No 1107/2009 of EP & Council concerning the placing of PPP on the market
 - (EU) No 283/2013 setting out data requirements for active substances
 - COM Communication 2013/C 95/01 providing list of test methods and guidance documents for the implementation of (EU) No 283/2013 [OECD and EU Guidance documents, EFSA PRIMo]

MRLs for residues of active substances

- Regulation (EC) No. 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC

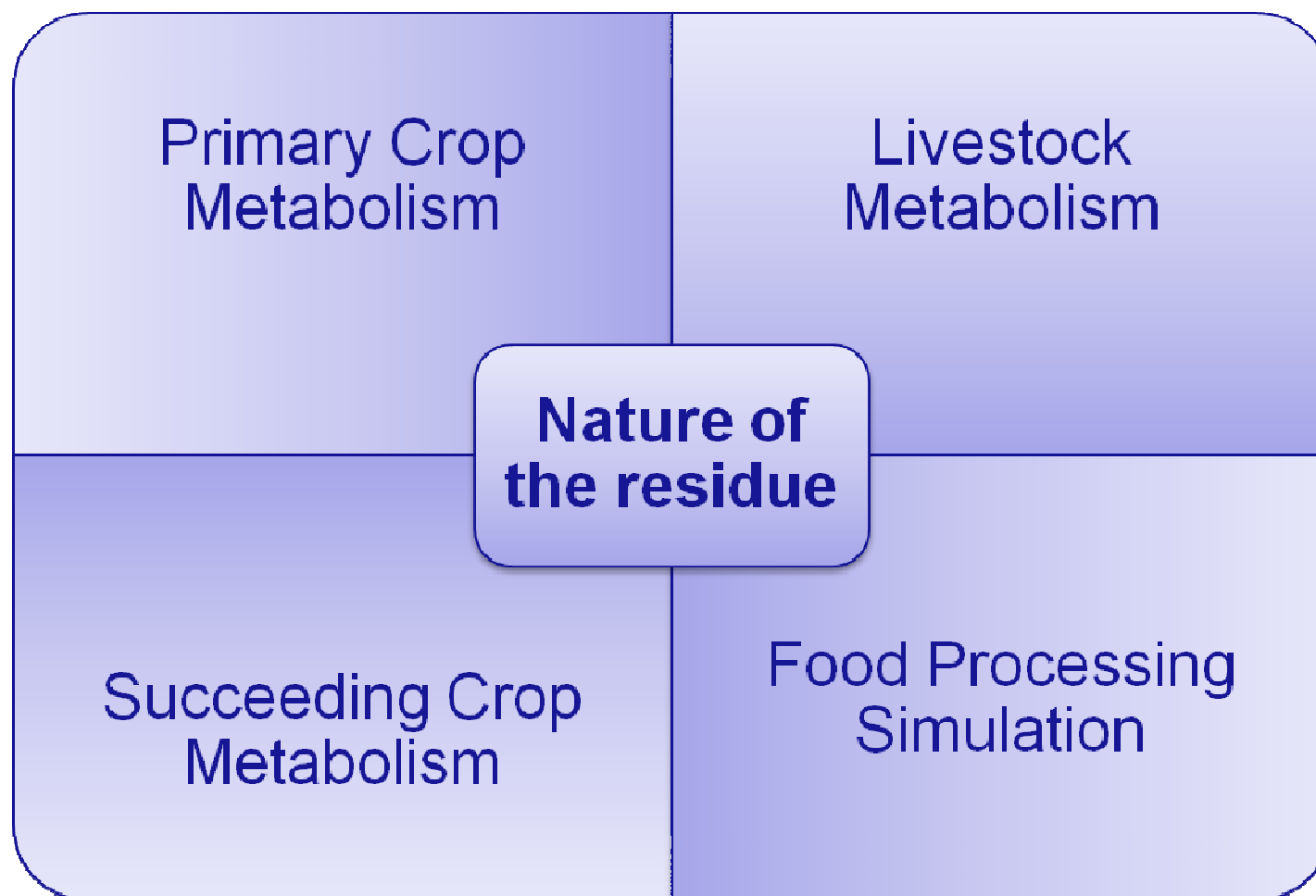


- Pesticide residues = active substance and pertinent metabolites and/or degradation products in:
 - crops and processed plant commodities used as food or feed items
 - food of animal origin
 - drinking water, if relevant
- Data required and methodologies are the same for residue assessments in the framework of (EC) No.1107/2009 and (EC) No.396/2005

Data required for Residues Overview

- Critical GAPs
- Analytical methods
- Storage stability of the residue
- Metabolism in:
 - primary crops
 - processed commodities
 - rotational crops
 - Livestock
- Toxicological relevance of metabolites
- Residue levels in:
 - primary crops
 - processed commodities
 - rotational crops
 - Livestock
- Dietary exposure calculation

Data required – Part 1



Investigation of:

- absorption, translocation, distribution and bioaccumulation processes
- identity of alteration products of a pesticide in food from physical-chemical processes incl. metabolism, photolysis, thermal degradation etc.
- differences and similarities across crop groups / livestock species, when raw or processed, by route of exposure for crops
- composition (proportions) and semi-quantitative estimates of levels of residues

- reflect representative use pattern and processing conditions
- radiotracer method
- **Primary crops:** categories of fruit, root/tuber, leafy crops, cereals, pulses/oilseeds; post-harvest uses
- **Succeeding crops:** root/tuber crop, leafy crop, cereal or oilseed crop
- **Livestock:** ruminant, chicken, fish
- **Food processing:** hydrolysis simulating most common processes such as pasteurization, baking, boiling, brewing

Residue definition

for risk assessment

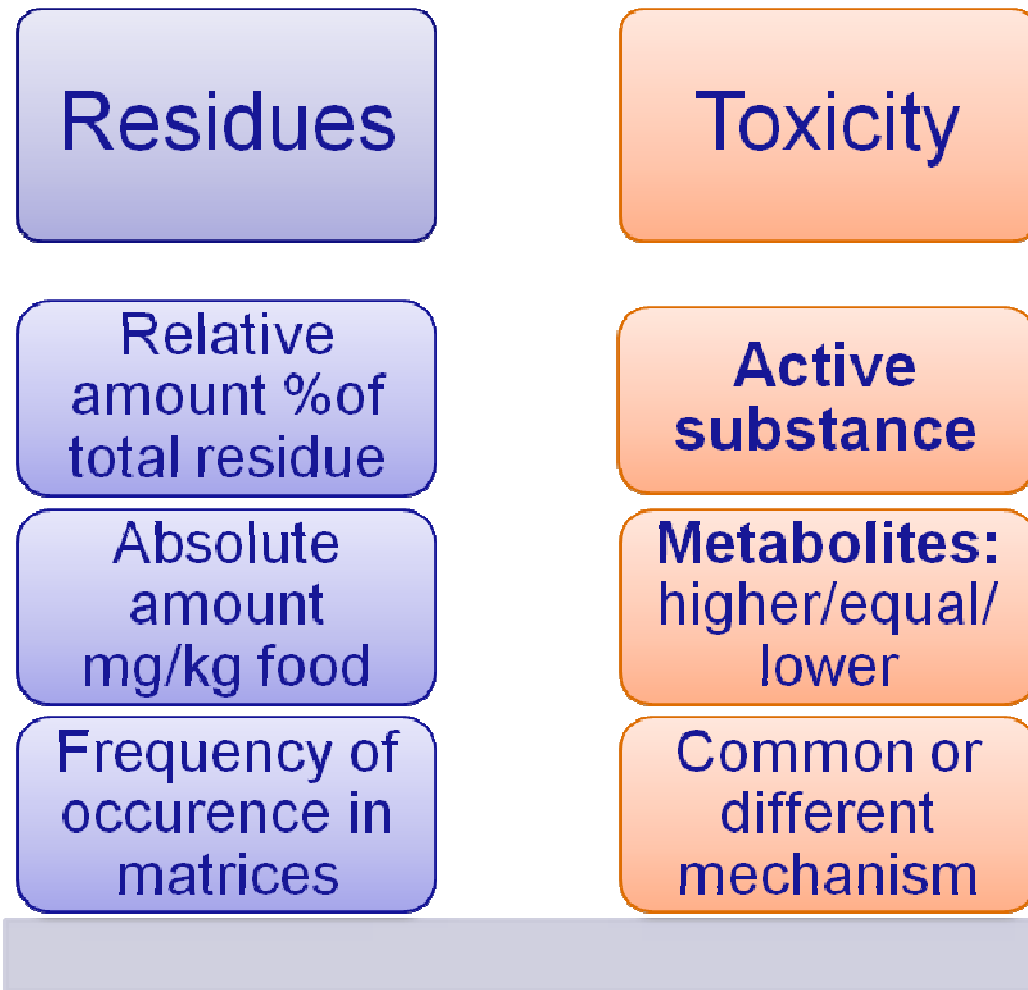
for MRL enforcement

Potential for exposure
in human diet

Relative toxicity
metabolite vs. parent

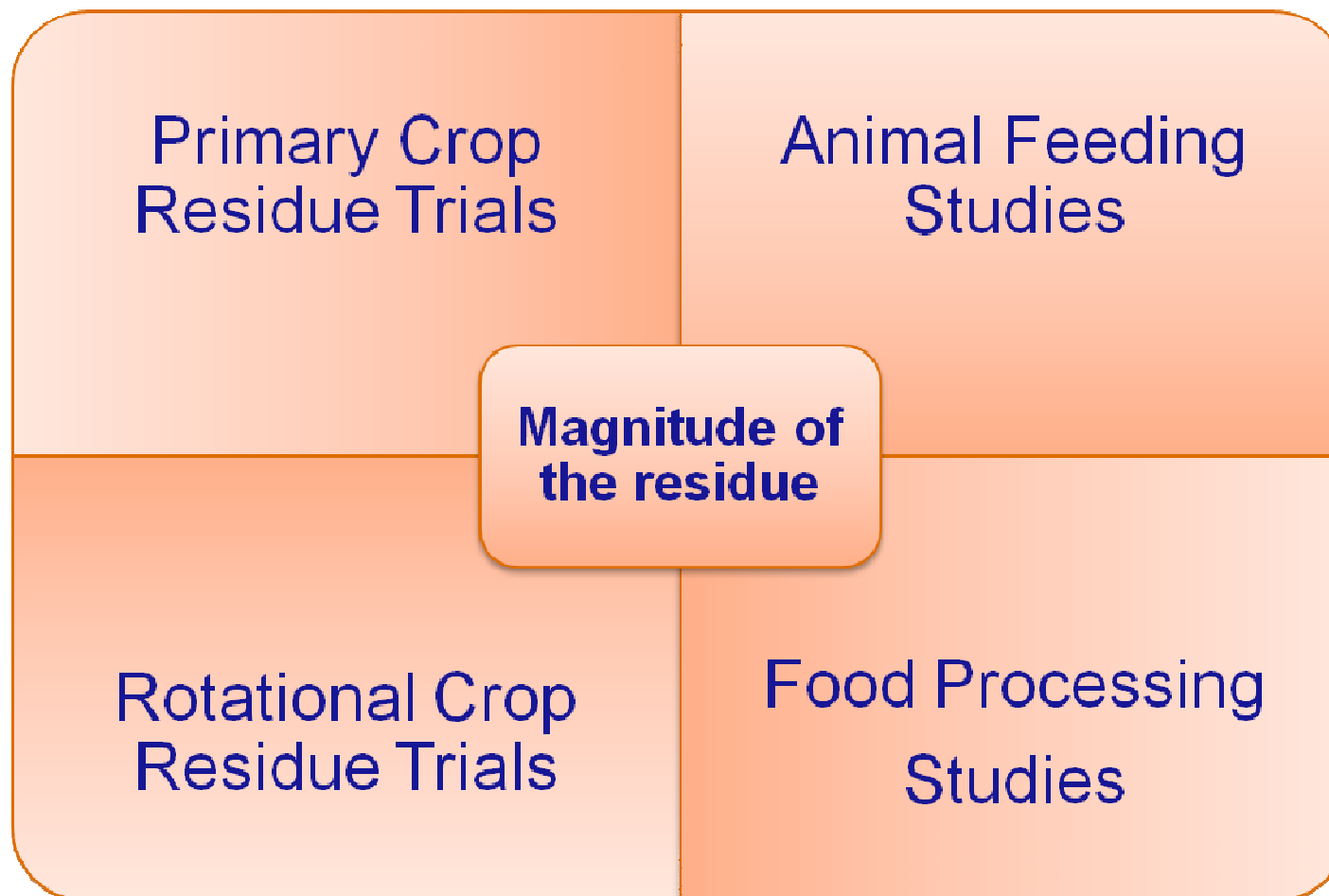
Marker compound
simply and cost effective analyses

Residue definition for risk assessment



Representative of toxicological burden

Data required – Part 2



Residue field trials

- Establish residue levels in **primary crops** and **succeeding crops** (food and feed) at harvest in accordance with residue definition/s
- Defined minimum number of trials per data set to derive **Median & Highest residue**, and **MRL** with sufficient certainty
- Representative of cGAP (crop, geographical zone, application method, rate & timing, formulation type, different seasons, plant back intervals ...)

OECD MRL Calculator

- harmonising the calculation of MRLs across the OECD countries
- Excel spreadsheet, simple to use without extensive statistical knowledge
- Outputs: lowest, highest and median residue, MRL estimate
- <http://www.oecd.org/chemicalsafety/pesticides-biocides/oecdmaximumresiduelimitcalculator.htm>

Food processing trials

- Distribution and levels in intermediate and end products, applying representative commercial practices
- Calculation of processing factors (reduction or concentration of residues in processed products)
- Default factors for simple operations possible (drying, pressing ...)
- Refining of dietary intake estimates
- Facilitate enforcement of residues in processed food and feed items (MRLs are applicable to processed / composite products)

Livestock feeding studies

- Required if significant residues in food of animal origin are expected
- Investigate different doses of pertinent residues in feed items
- Dosing (≥ 28 days) until plateau concentration in animal products reached
- Estimation of residues in muscle, liver, kidney, fat, milk, eggs; derive Median & Highest residue, MRL

Surrogate data - Extrapolations

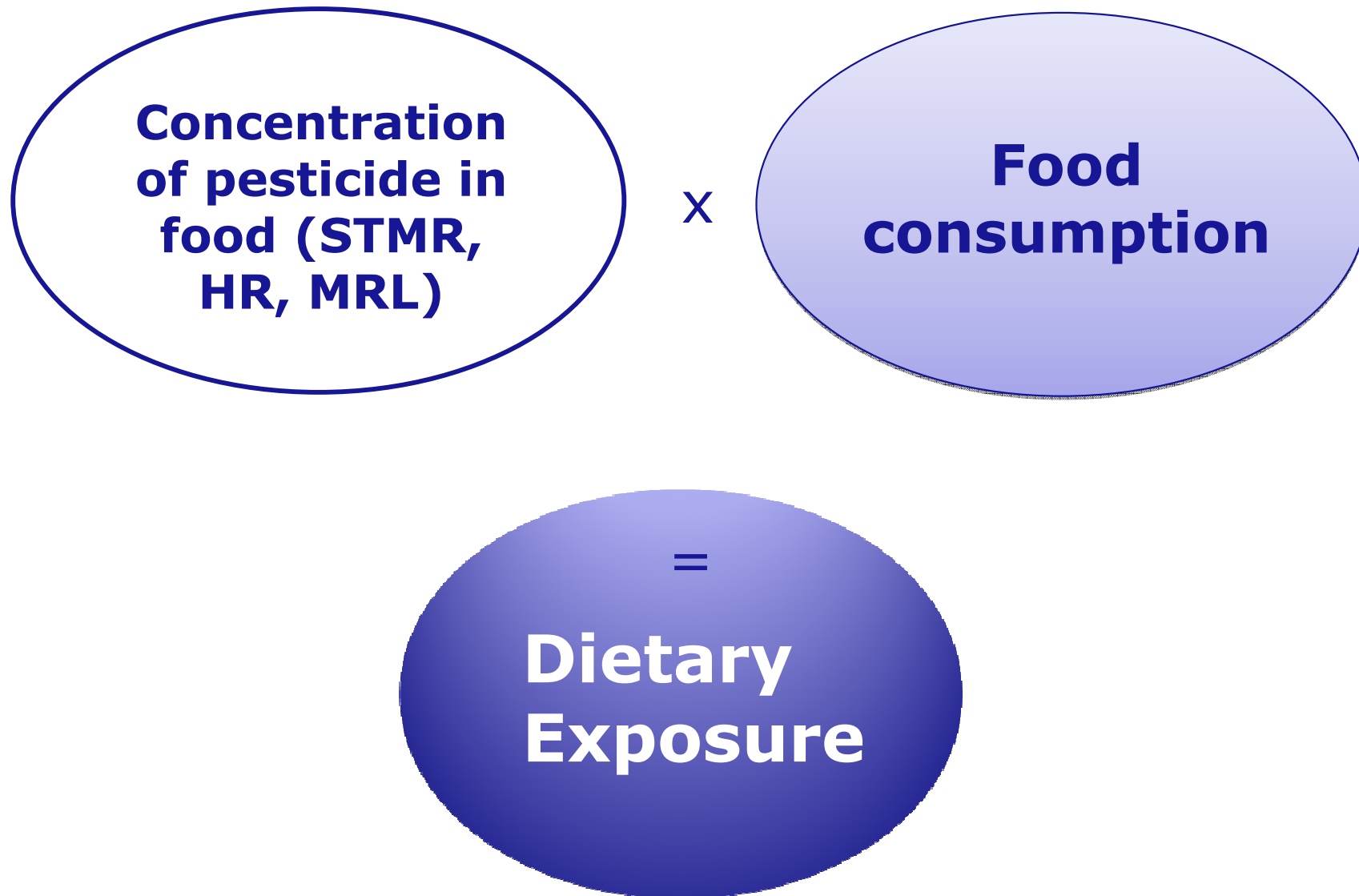
... can reduce data to be generated



Magnitude of residue

Nature of residue

Dietary exposure assessment



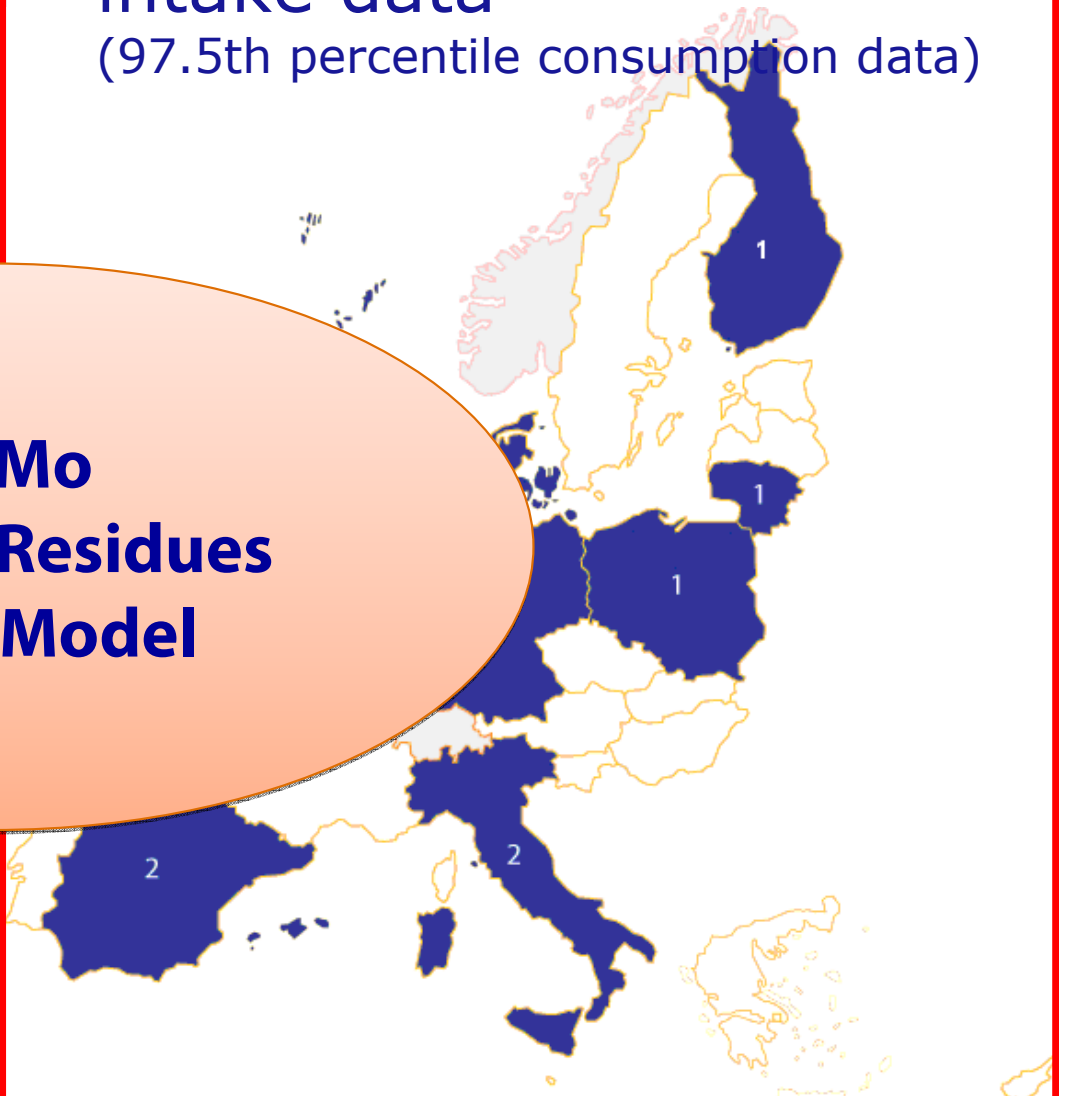
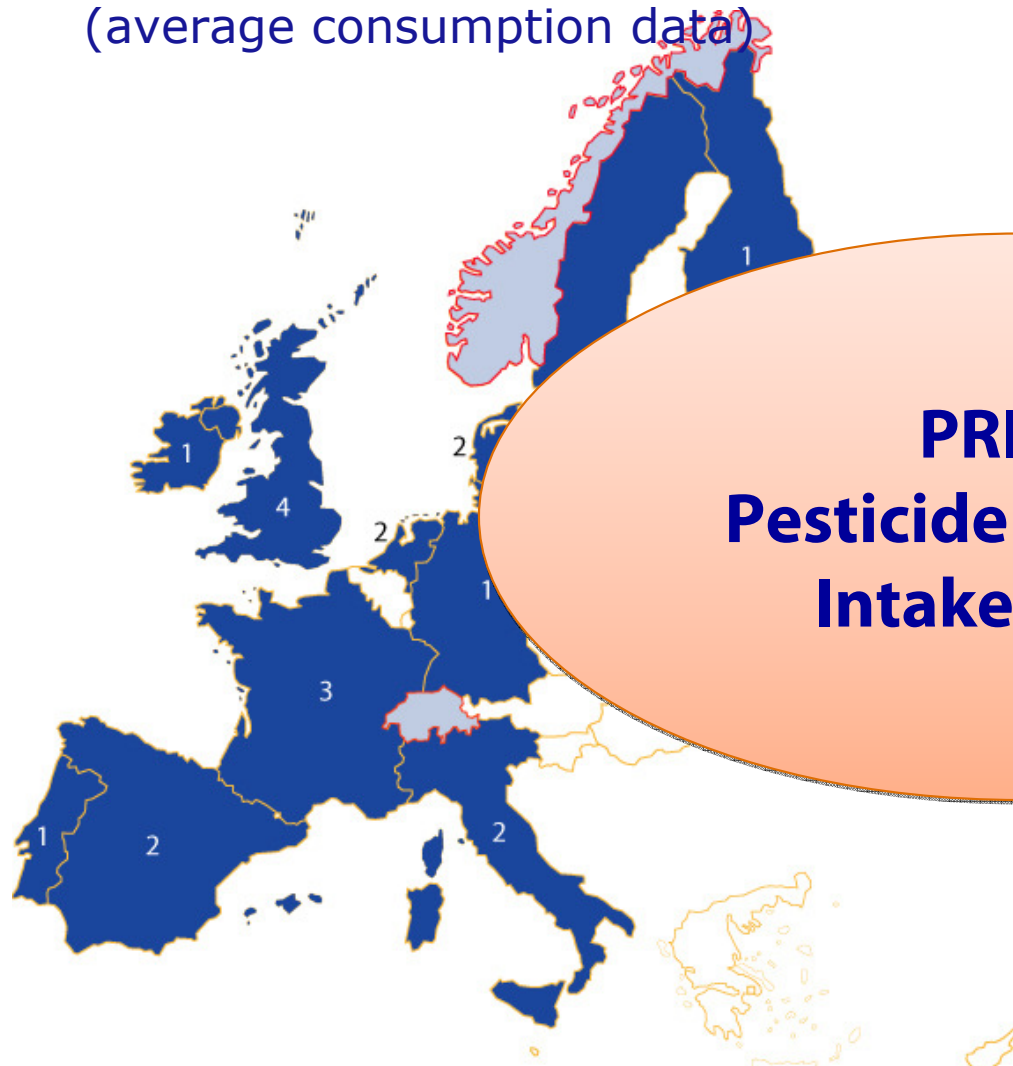
EFSA Model - consumer dietary intake assessment of pesticides

Long term dietary intake data

(average consumption data)

Short term dietary intake data

(97.5th percentile consumption data)



PRIMo
Pesticide Residues
Intake Model

Chronic:

- Lifetime exposure
- All food in a mixed diet is treated with the pesticide according to the authorised or intended uses
- Median residue level, ADI

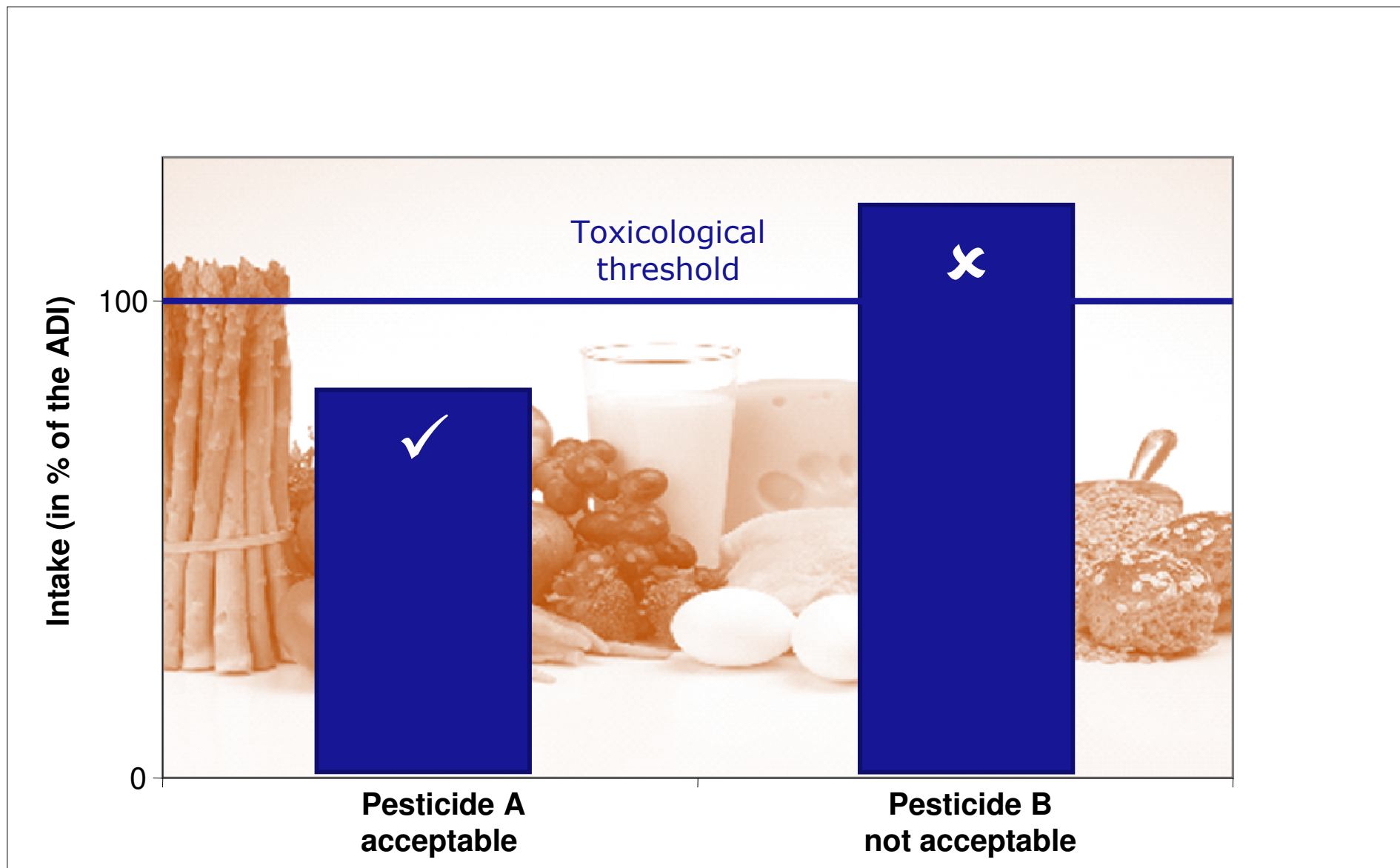
Acute:

- only one food item treated with the pesticide, consumed at a large portion with one meal or during one day
- Highest residue level, variability factor, ARfD

Cumulative: *(under development)*

- based on Cumulative Assessment Groups (phenomological effects, Mode of Action), dose addition

Dietary Risk Assessment



MRLs are established...

- on the basis of a GAP,
- if residue data requirements are sufficiently addressed,
- using a statistical-method-based calculation tool (OECD MRL calculator)
- if expected residues do not pose a consumer health risk.

Avoiding of trade barriers

Common market-
free movement of goods,
WTO agreement

Consumer protection

No unacceptable
consumer risk

MRL

Precautionary principle

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

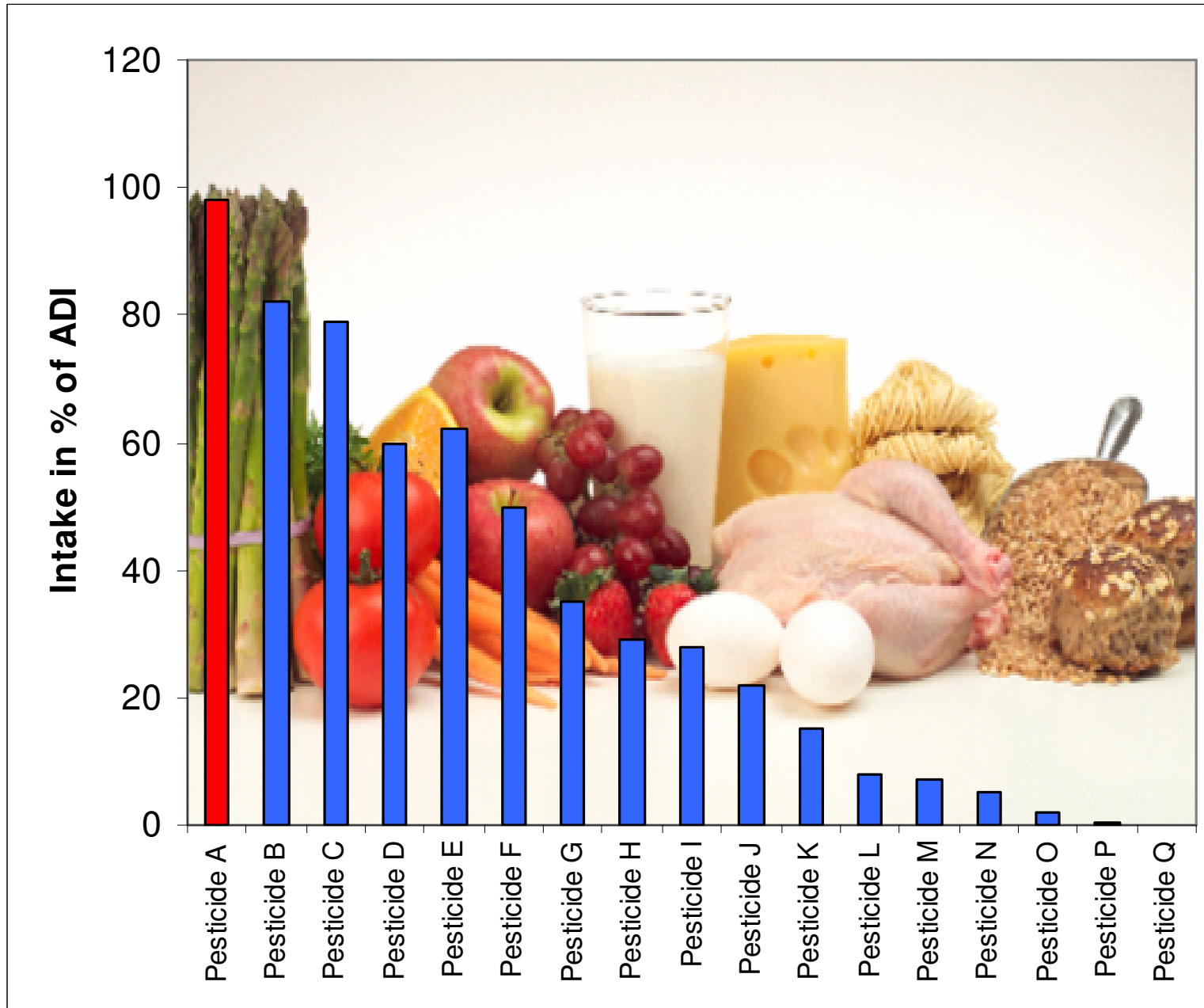
Guarantee for producers

Compliance with MRL
provisions if pesticides
are used according to
label (GAP)

Minimisation principle

ALARA (as low as
reasonably achievable)

Safety margins for MRLs

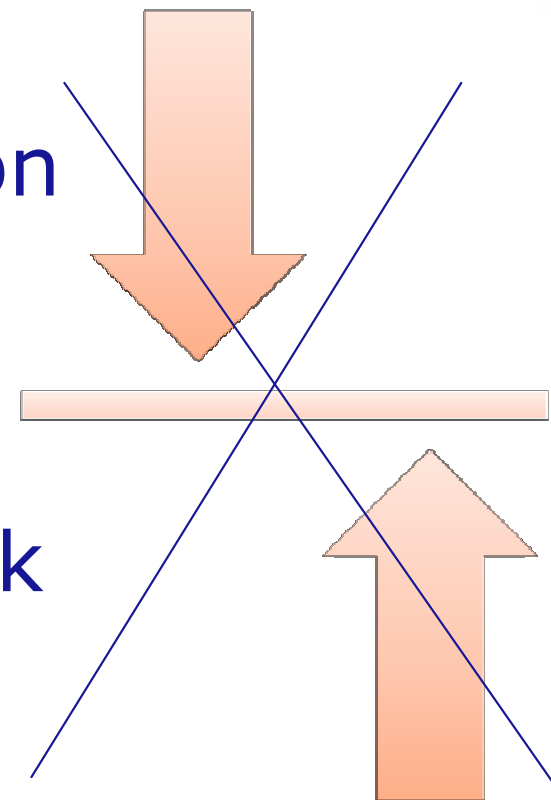


Pesticide MRL is NOT ...

Borderline between
acceptable residue concentration
on food

And

Immediate consumer health risk



Thank you for your attention!

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