



Challenges for implementation of cumulative risk assessments in practice

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Workshop on Cumulative Risk Assessment
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Cumulative risk assessment:

What has been done so far ?

- 2006 **EFSA's 7th Scientific Colloquium - Cumulative Risk Assessment of Pesticides to Human Health: The Way Forward**
<http://www.efsa.europa.eu/en/supporting/pub/117e.htm>
- 2008 **Scientific Opinion to evaluate the suitability of existing methodologies** and, if appropriate, the identification of new approaches to assess cumulative and synergistic risks from pesticides to human health with a view to set MRLs for those pesticides in the frame of Regulation (EC) 396/2005
<http://www.efsa.europa.eu/en/efsajournal/pub/705.htm>
- 2009 **Scientific Opinion for a selected group of pesticides from the triazole group** to test possible methodologies to assess cumulative effects from exposure through food from these pesticides on human health
<http://www.efsa.europa.eu/en/efsajournal/pub/1167.htm>

EFSA outputs on Cumulative Risk Assessment

2012 Guidance on the use of **probabilistic methodology** for modeling dietary **exposure** to pesticide residues

<http://www.efsa.europa.eu/en/efsajournal/pub/2839.htm>

2013 Scientific Opinion on the identification of **pesticides to be included in cumulative assessment groups** on the basis of their toxicological profile

<http://www.efsa.europa.eu/en/efsajournal/pub/3293.htm>

2013 Public Consultation Report of the Scientific Opinion on the identification of **pesticides to be included in cumulative assessment groups** on the basis of their toxicological profile

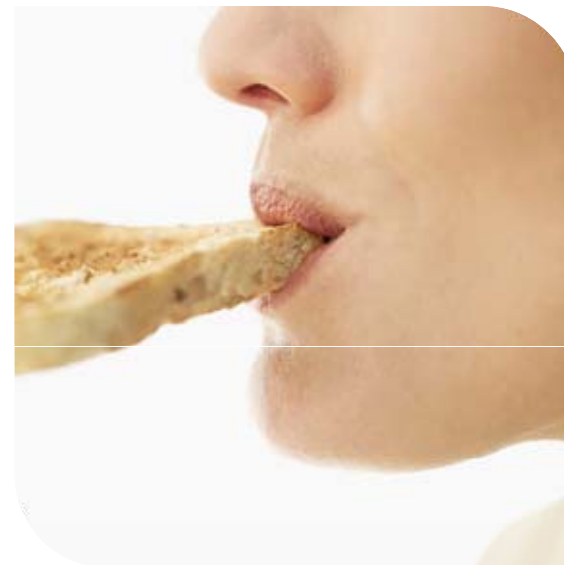
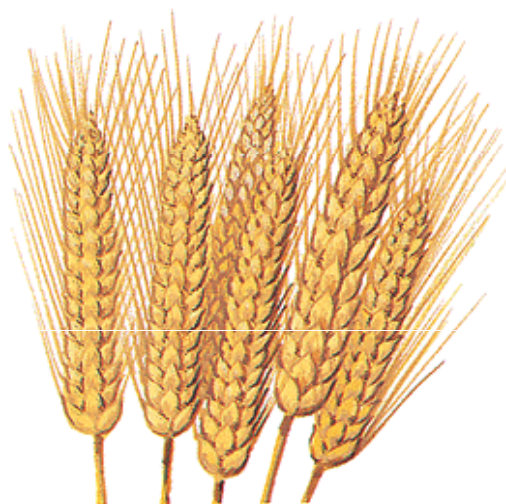
<http://www.efsa.europa.eu/en/supporting/pub/538e.htm>

2013 Scientific Opinion on the **relevance of dissimilar mode of action** and its appropriate application for cumulative risk assessment of pesticides residues in food

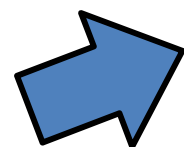
<http://www.efsa.europa.eu/en/efsajournal/pub/3472.htm>

Other activities of EFSA related to Cumulative Risk Assessment

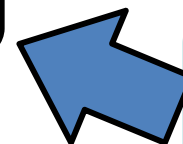
- Development of **new format for reporting monitoring data** on pesticide residues (SSD – Standard Sample Descriptor)
- Increased **quantity** and **quality of monitoring data**
- Establishment of the **comprehensive food consumption data**
- Development of **EFSA PROFile** (Pesticide Residue Overview File) to collect data in the framework of the MRL review in a structured format
- Development of **EFSA PRIMo** (Pesticide Residue Intake Model)
- **Indicative cumulative risk assessment for OP pesticides and carbamates** using PRIMo (deterministic approach) (see 2010 EU Report on Pesticide Residues)



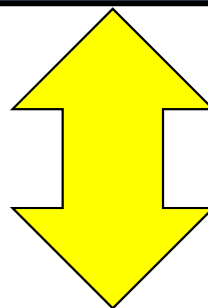
**Chemical
Occurrence**



**Exposure
Assessment**

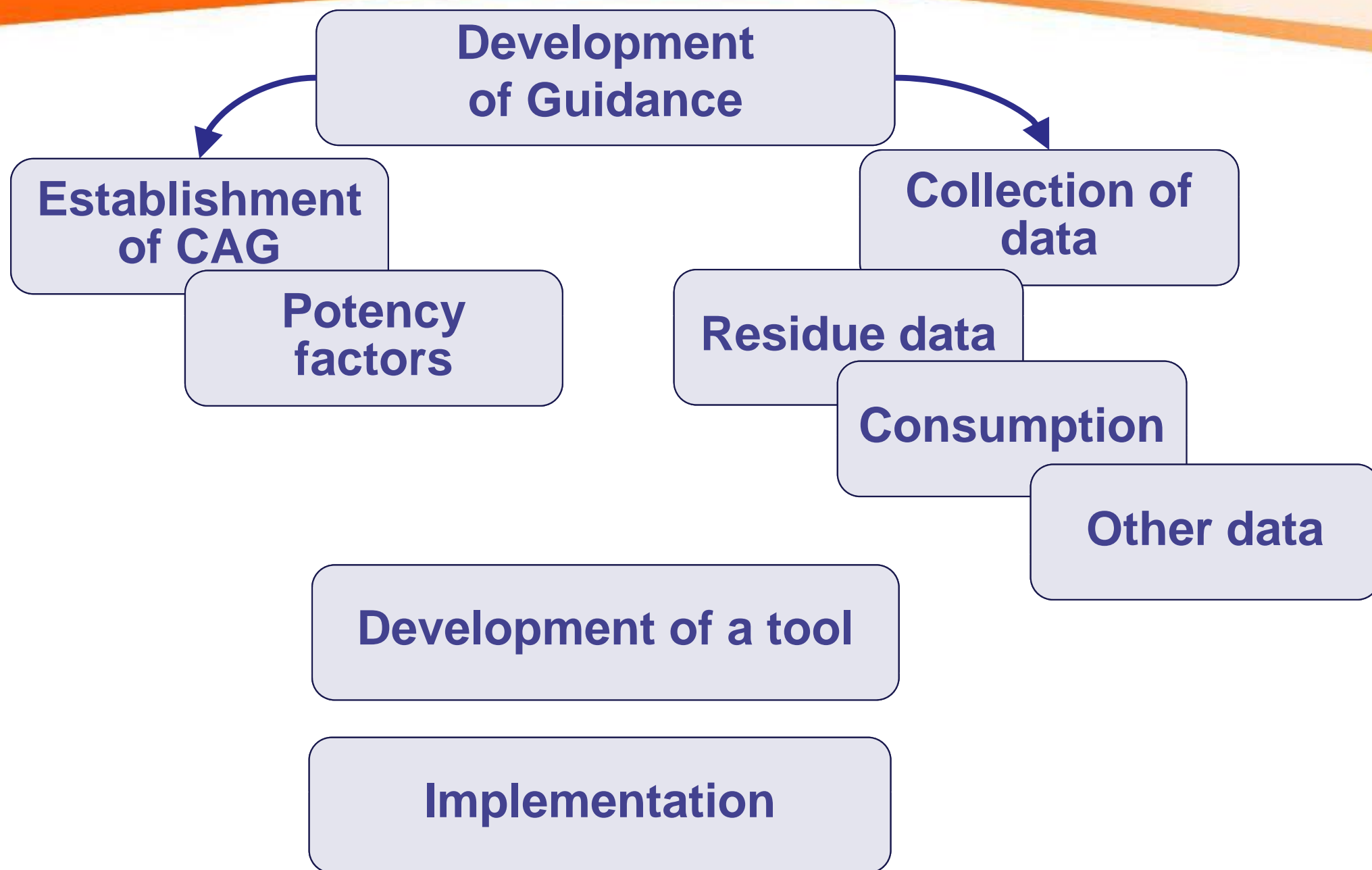


**Food
consumption**



**Toxicological
reference value**

Cumulative risk assessment: work packages



Toxicological data

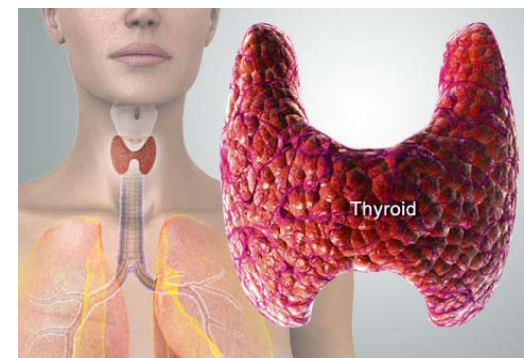
Where are we today?

287 active substances were screened



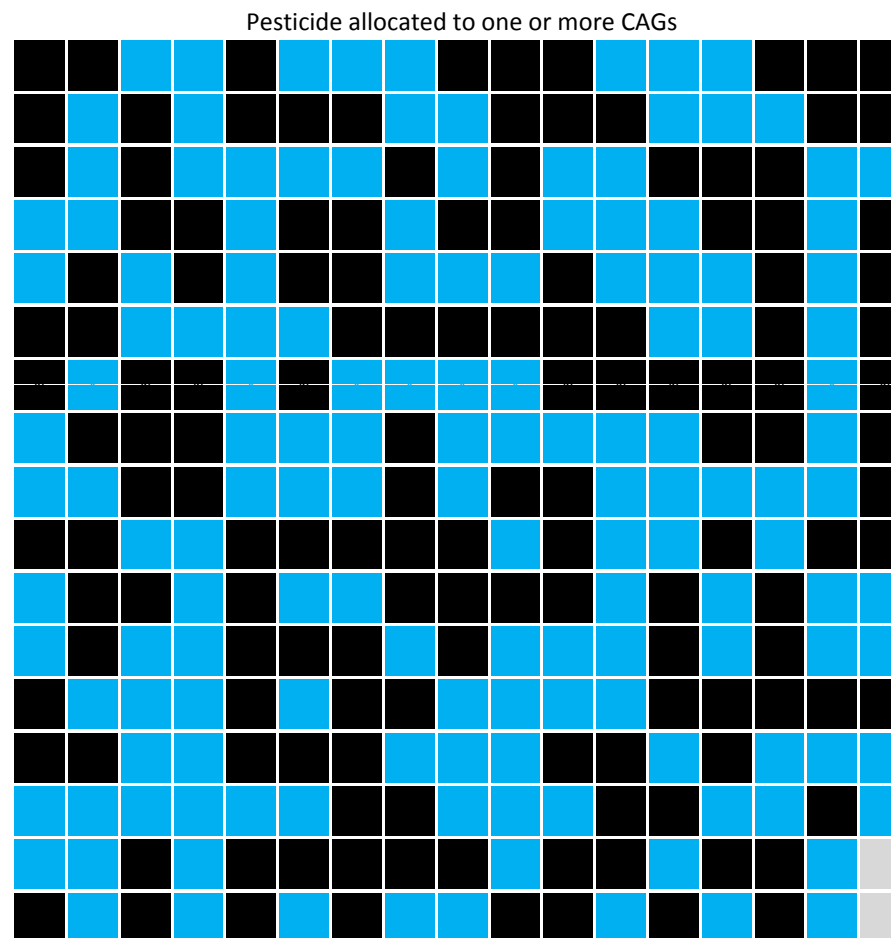
✓ **Nervous system
(65 substances)**

No	Active substance
1	1-Methylcyclopropene
2	1-Naphthylacetamide (1-NAD)
3	1-Naphthylacetic acid (1-NAA)
4	2,4-D
5	2,4-DB (metabolized to 2,4-D)
6	2-Phenylphenol (including sodium salt)
7	6-Benzyladenine
8	Abamectin
9	Acetamiprid
10	Acibenzolar-S-methyl (benzothiadiazole)
11	Aclonifen
12	Alpha-Cypermethrin (aka alphamethrin)
13	Aluminium phosphide
14	Aluminium ammonium sulphate
15	Amidosulfuron
16	Amisulpride (amisulpride)



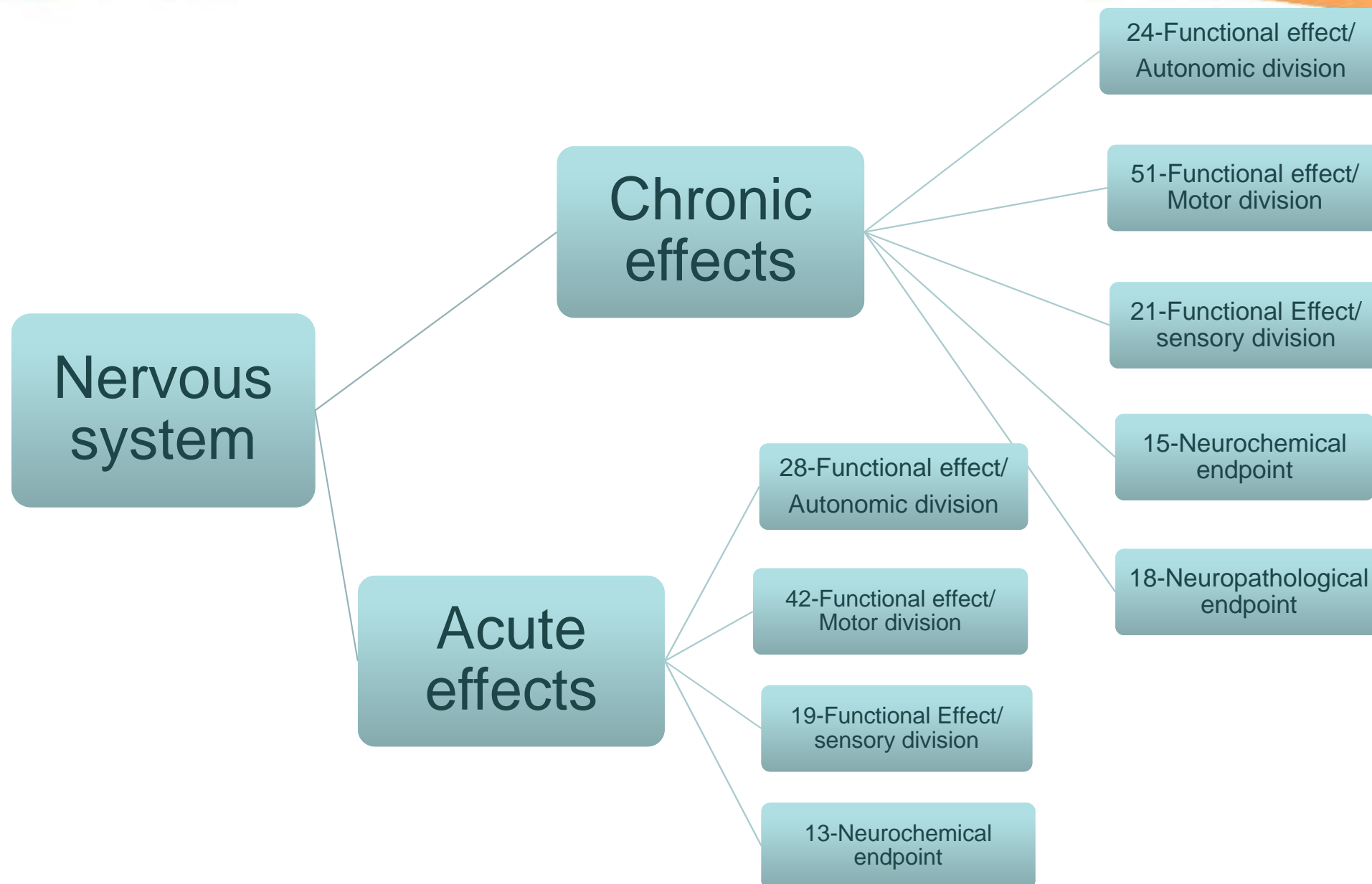
✓ **Thyroid system
(101 substances)**

Pesticides allocated in one or more CAG



142 pesticides not relevant for the first 2 CAG (black squares)

145 substances were allocated in one or more CAGs



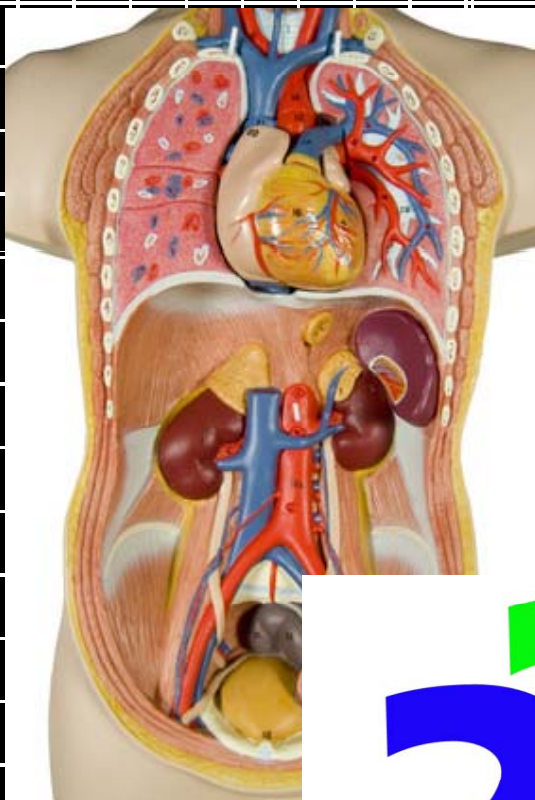
Thyroid
system

Chronic
effects

22 substances:
Effects on the
parafollicular (C-) cells
or the calcitonin
system

96 substances:
Substances affecting
follicular cells and/or
thyroid hormone
(T3/T4) system

Nervous and thyroid system



Non-approved
and pending
substances



Liver, adrenal, eye reproduction and development system

- Grant on “ Toxicological data collection and analysis to support grouping of pesticide active substances for cumulative risk assessment of effects on the **nervous system, liver, adrenal, eye reproduction and development and thyroid system**”
 - Final report publication by end 2015
 - Toxicological data collection for the **liver**, the **nervous system**, the **thyroid** and the **reproductive and developmental system** for **pesticides approved** in the period 01-01-2012 to 31-05-2013 as well as those **pending** for approval and pesticide active substances that are **not approved** for use within EU, but are detected as residues
 - Toxicological data collection for the **adrenal** and **eye** for all pesticide active substances approved until 31-05-2013 as well as those pending for approval and those not approved in EU but detected as residues

Occurrence data

Where are we today?

Monitoring data

- Since 2009 the monitoring results are reported at detailed level (individual determinations) using the SSD format, including a lot of background information
- Residue definition for enforcement
- 27 EU MS + NO, IC
- ca. 70.000 samples/year
- ca. 15 to 20 Mio determinations/year



**EU-
coordinated
Monitoring
Programme**

**Ca. 12.000
samples**

**In 3 yr. cycle
covers 30-40
food
commodities**

**Ca. 180
pesticides**

National Monitoring Programmes

**Ca. 300 different commodities
(range from 12-170)**

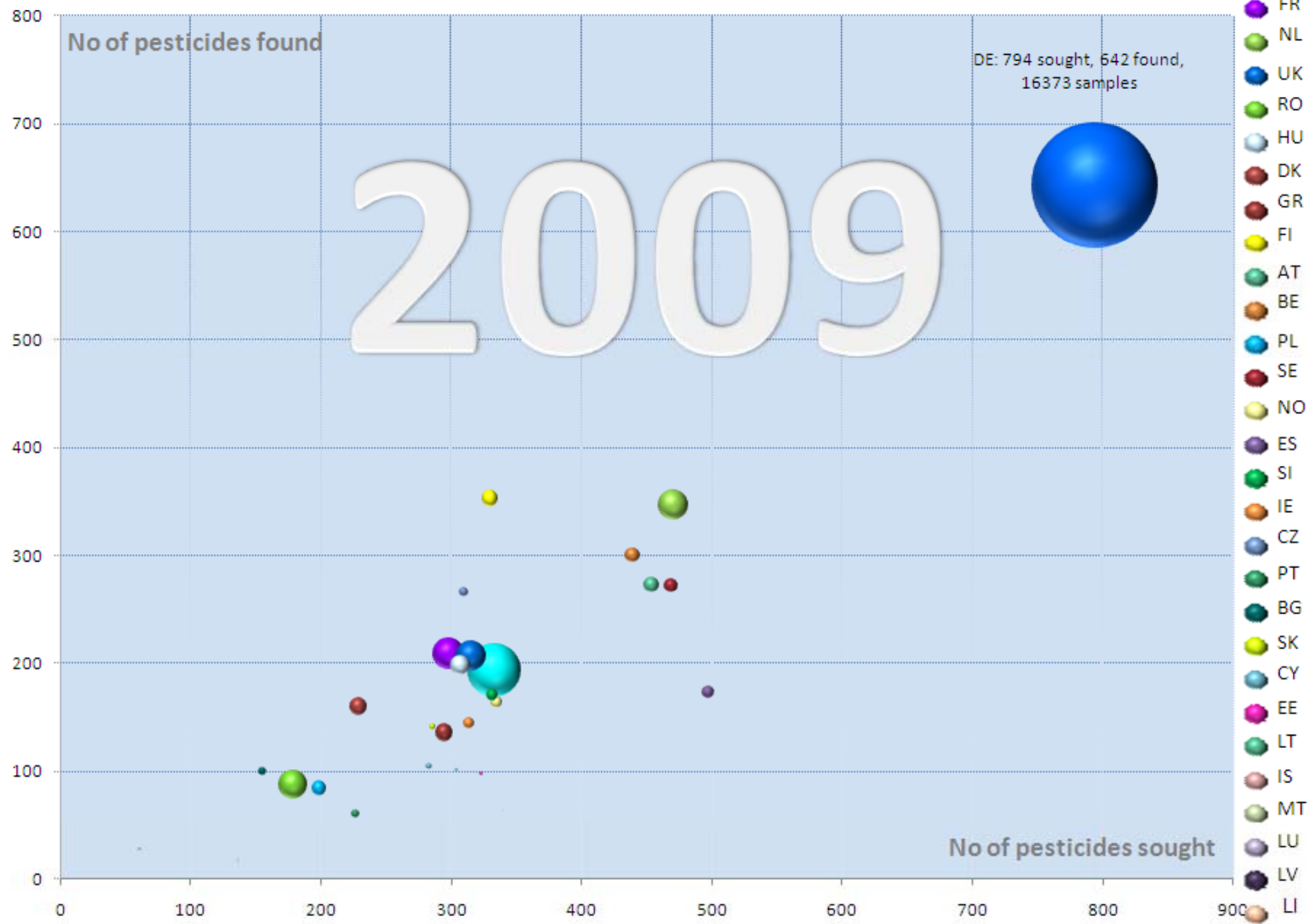
**Less representative
(geographical distribution)**

Many commodities less than 10 samples

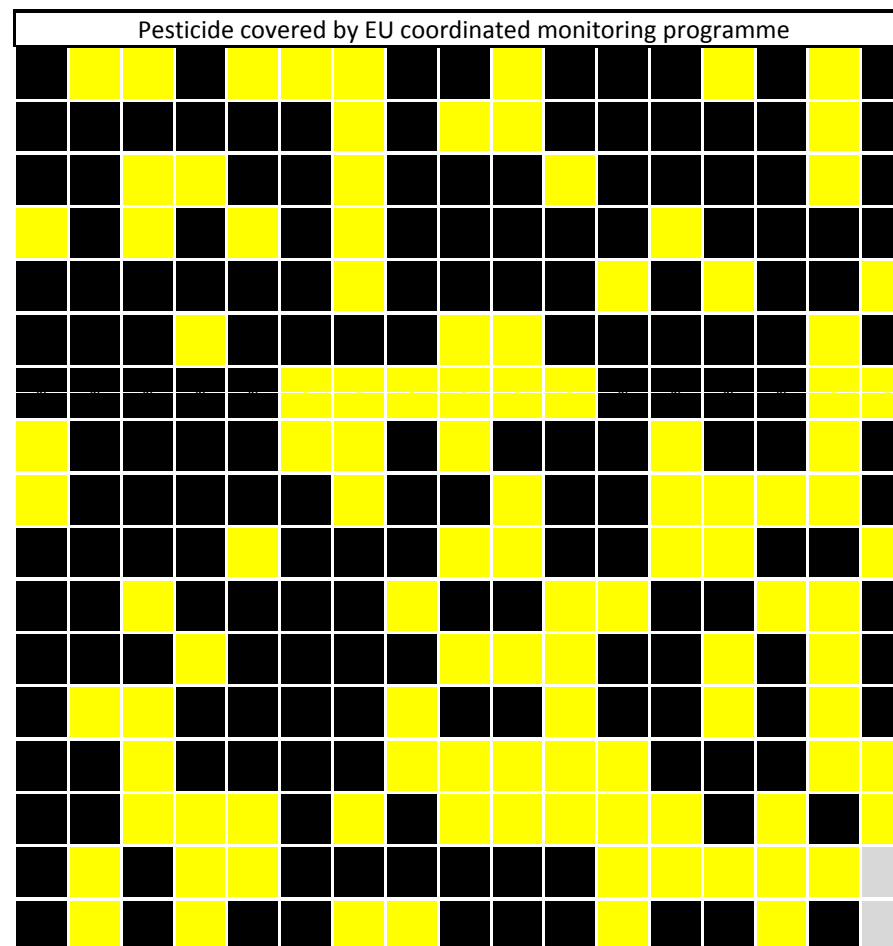
**More than 900 different pesticides
(range from 60-840)**

**Ca. 5 %
Enforcement
samples**

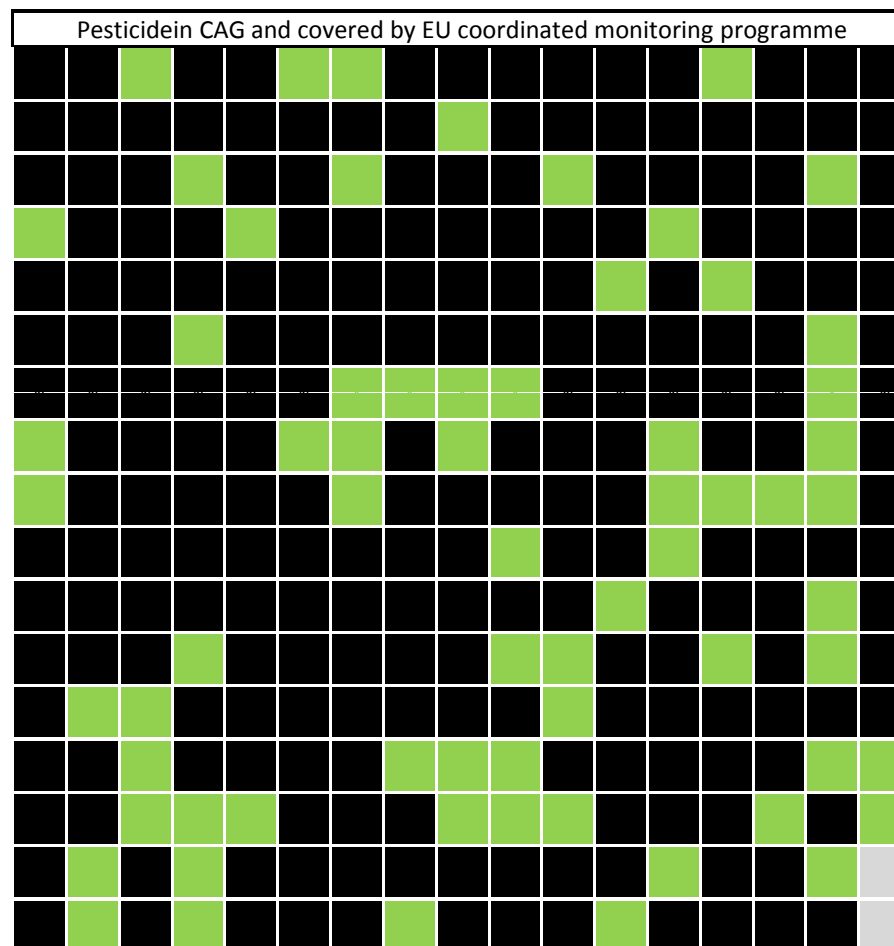
Comparison of national monitoring programmes



Monitoring data – pesticides covered

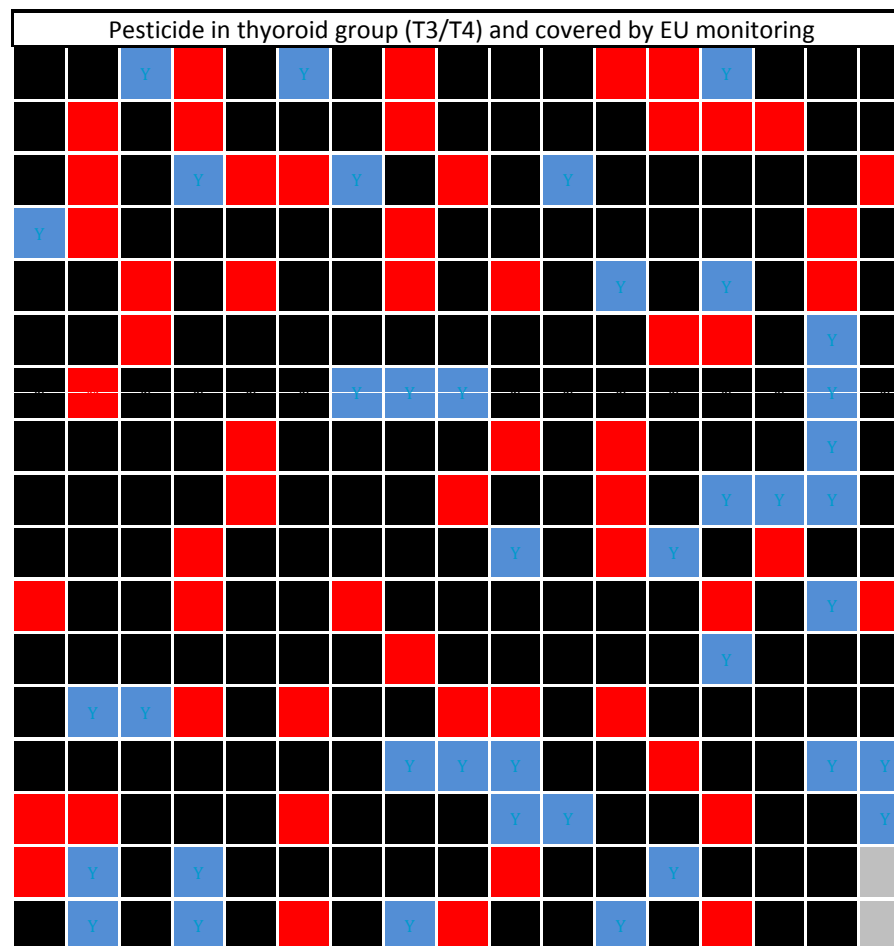


Monitoring data – pesticides covered



Is there a need to adapt scope of EU coordinated monitoring programme, considering the potency of the active substance and the likelihoods to find measurable residues (“significant contributors”)

Overlap thyroid group (T3/T4) – EU monitoring



Is there a need to adapt scope of EU coordinated monitoring programme, considering the potency of the active substance and the likelihoods to find measurable residues (“significant contributors”)

Cumulative exposure

Monitoring data

EU coordinated programme

National control programmes

Other data sources ?

Supervised field trials

reflecting realistic worst case situation for critical GAPs

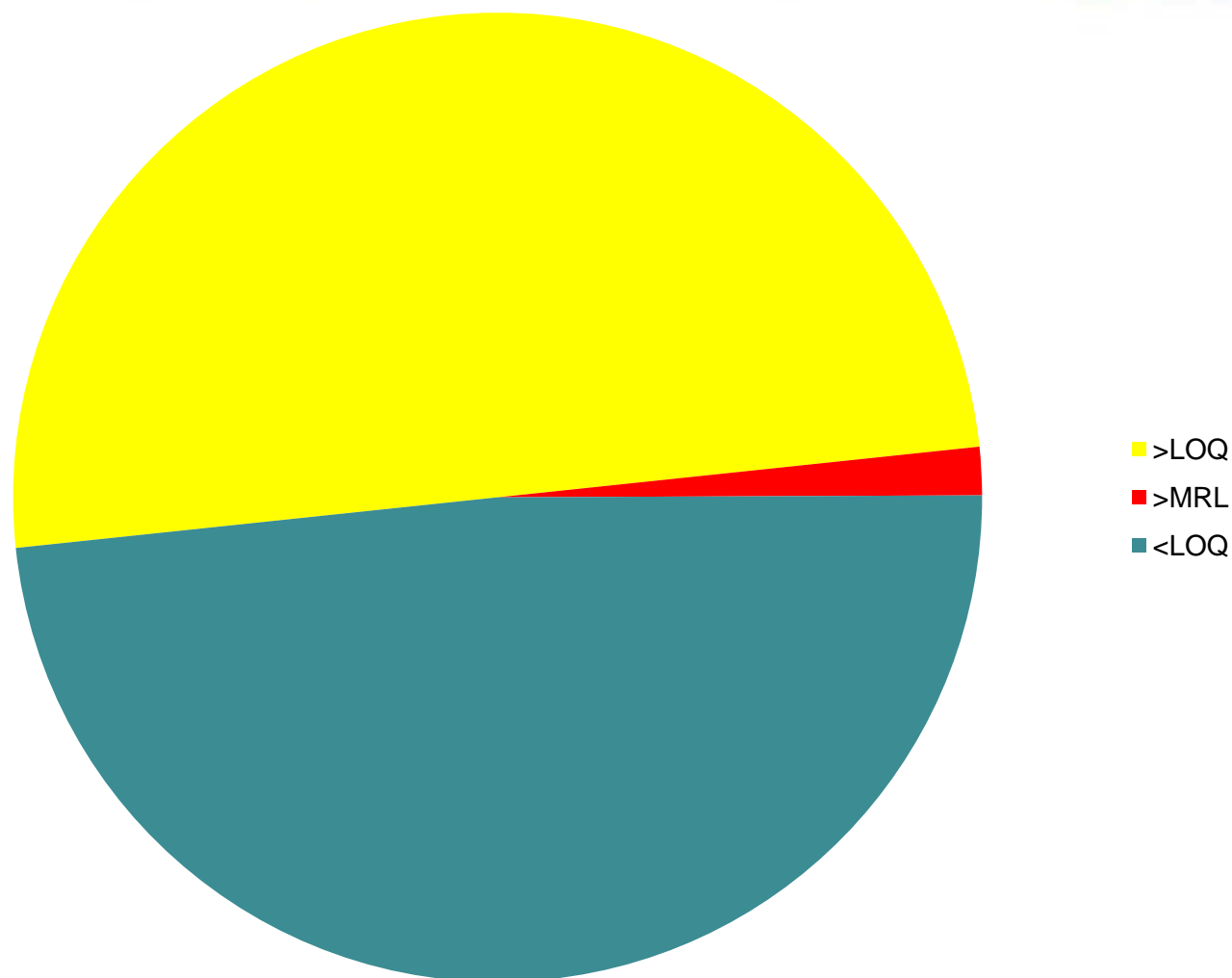
STMRs / HRs for RAC, sometimes for edible portion

Data reflecting residue definition for risk assessment and enforcement (parent compound and metabolites where relevant)

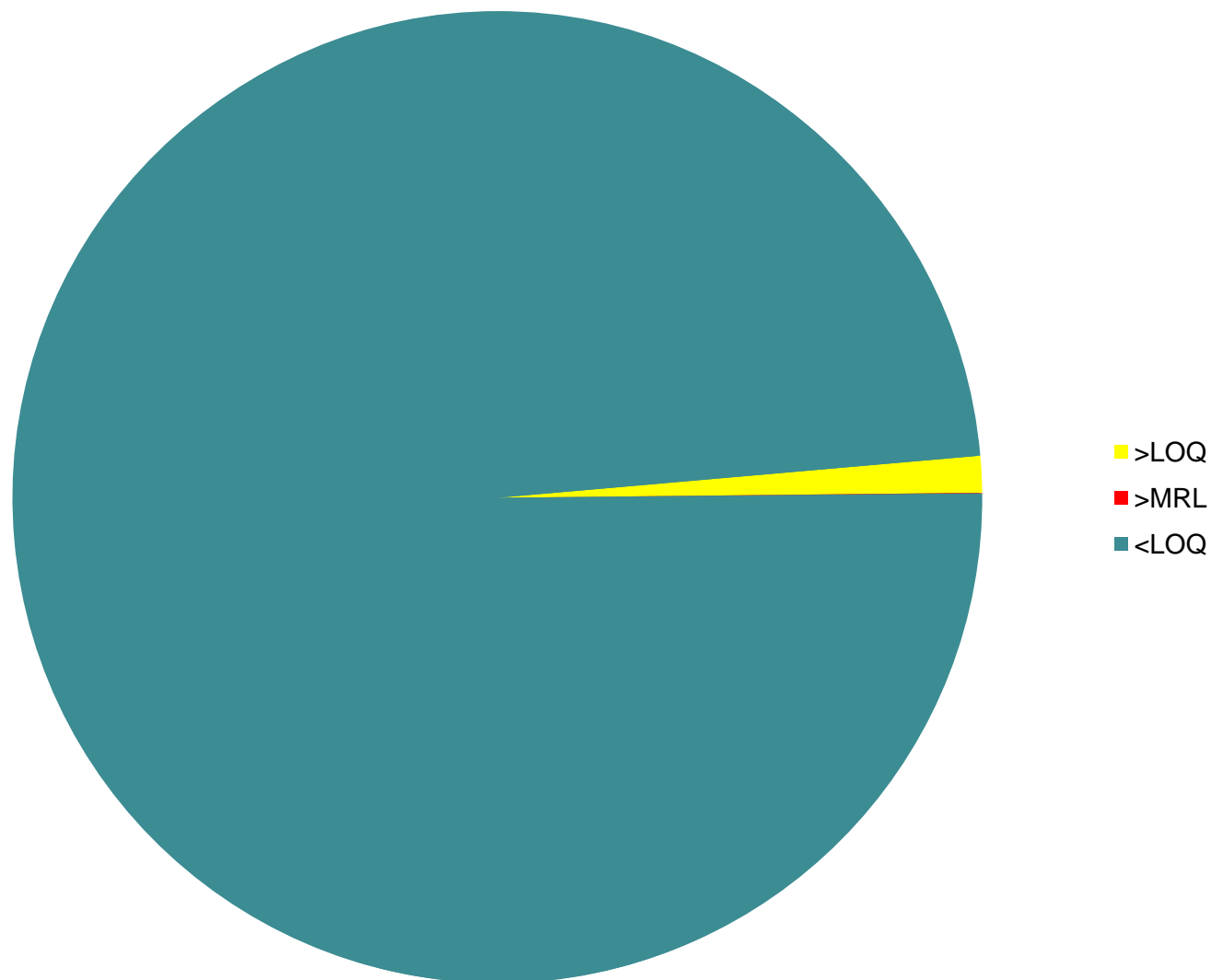
- Outdoor NEU / SEU /Third countries
- Indoor conditions

Number of samples per commodity (EU coord. + national programmes)

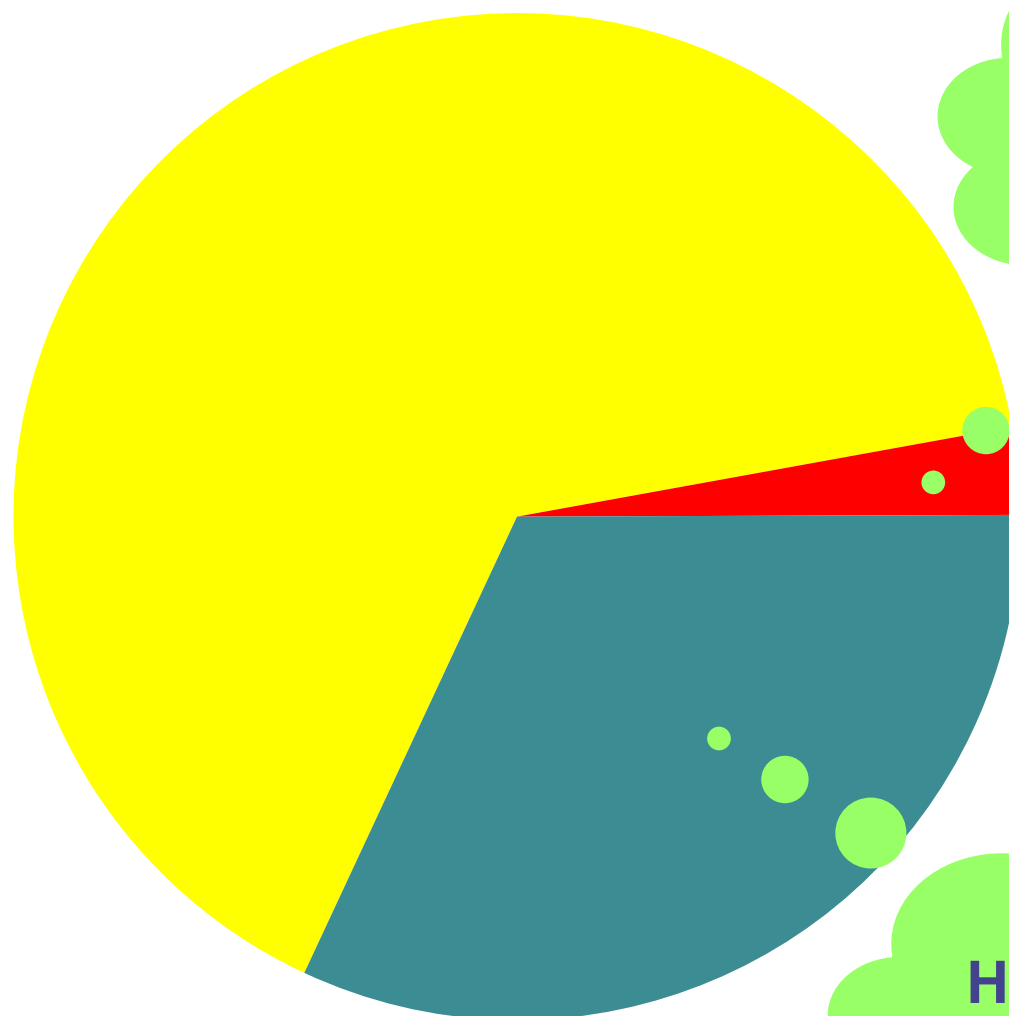
[illegible]



All commodities covered by EU coordinated programme



Monitoring data results: sample level



How to handle
results
exceeding the
MRL ?
Illegal uses ?

How to handle
non-detects?

Strawberries

Monitoring data results: MS/sample level

What to do for cases where approval has changed ?

Refinement

■ >LOQ

■ >MRL

■ <LOQ

Refinement

Is the product authorised in MS A for this crop?
Percentage crop treated?

How to handle non-detects?

Strawberries from Member State A

LOQ of 0.01 mg/kg?

Olympic pool



length

50 m

width

25 m

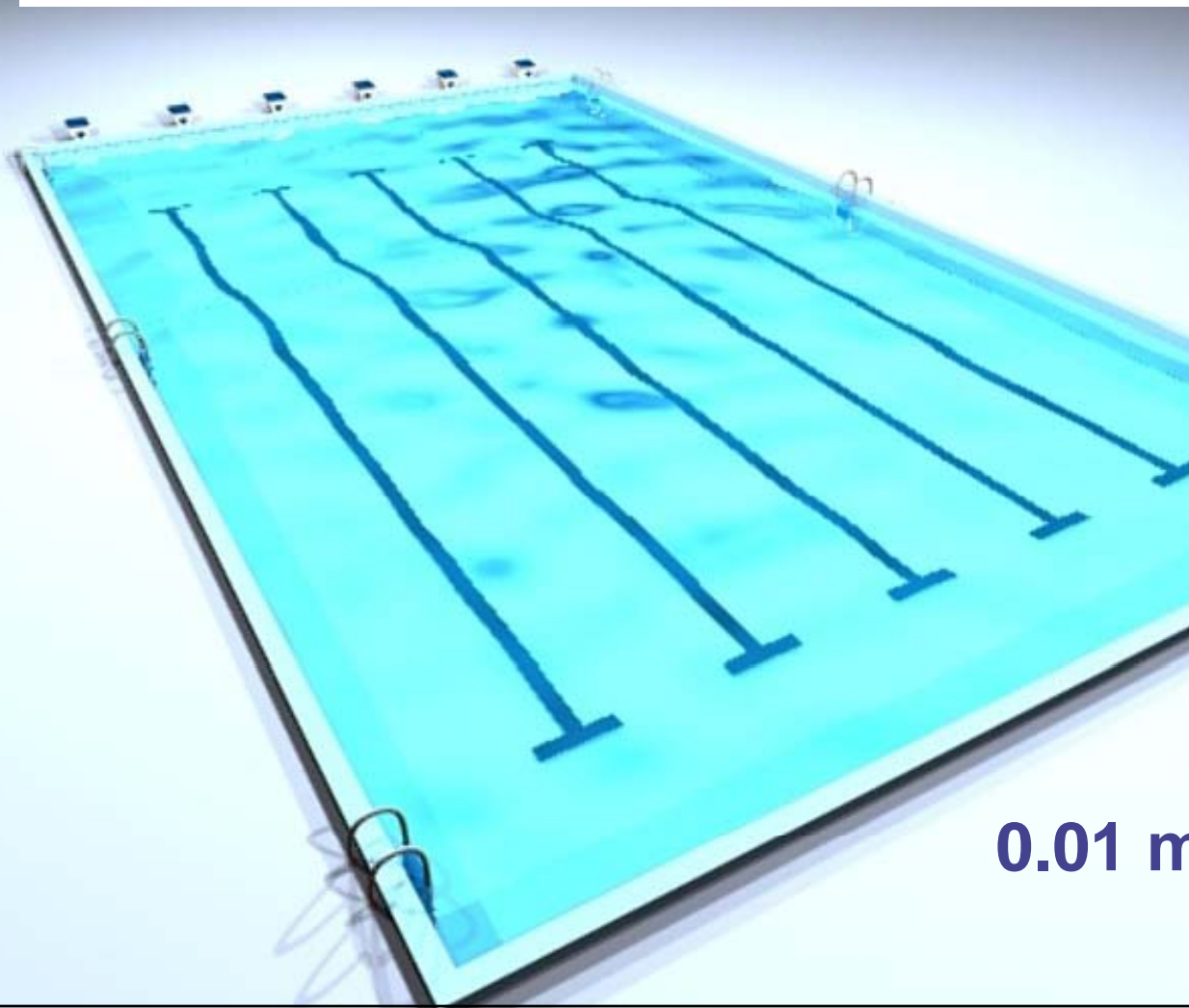
Depth

2.0 m

Volume

2,500,000 L

Equiv. 2500 t water



$$0.01 \text{ mg/kg} = 25 \text{ g/2500 t}$$

- Which food commodities need to be considered?
- Which occurrence data should be used ?
 - **Monitoring data**
 - *EU coordinated programme*
 - *National monitoring programmes*
 - **Supervised field trials (in combination with market share information ?)**
- How to fill the gaps for pesticides not sufficiently covered by the monitoring programmes
- How to trim the data ?
 - **Non-detects?**
 - **MRL exceedences?**
 - **Conversion factors for risk assessment ?**

- Data trimming – replacement/complement occurrence data
- Identify need for further data collection
 - **Authorisation status**
 - **% crop treatment**
 - **Processing data**
- Transparent handling of data, documentation of manipulation
- Identify limitations of available data, uncertainty of estimations

EFSA comprehensive food consumption database

Dietary surveys	32
Member States	22
Number of subjects	66,492
Number of different foods	63,495
Number of different FoodEx codes	1,504
Number of consumption records	6,309,489

The Comprehensive Database will be updated in 2014 with the addition of 10 new surveys.

Examples of differences in survey methodology:

- 24 h dietary recall vs. food record
- broad survey period, from 1997 (Estonia) to 2009 (Spain)
- from 1 to 7 days per subject
- individual vs. household sample unit
- from 28% to 98% response rate
- week end days not evenly represented in 6 surveys
- seasonality not fully covered in 10 surveys (only one season represented in 4 surveys)
- body weight and height measured or estimated
- food classification

Comprehensive food consumption data:

Age classes

Age class	Age range	Number of surveys	Number of countries
Infants	0 - 12 months	2	2
Toddlers	12 - 36 months	8	8
Children	3 - 10 years	16	14
Adolescents	10 - 18 years	14	12
Adults	18 - 65 years	21	20
Elderly	65 - 75 years	9	9
Very elderly	> 75 years	8	8
Total		78 diets	22 MS

Do the consumption data match with the occurrence data ?

Number of different FoodEx codes: 1,504

- Unprocessed food
- Processed food
- Composite food

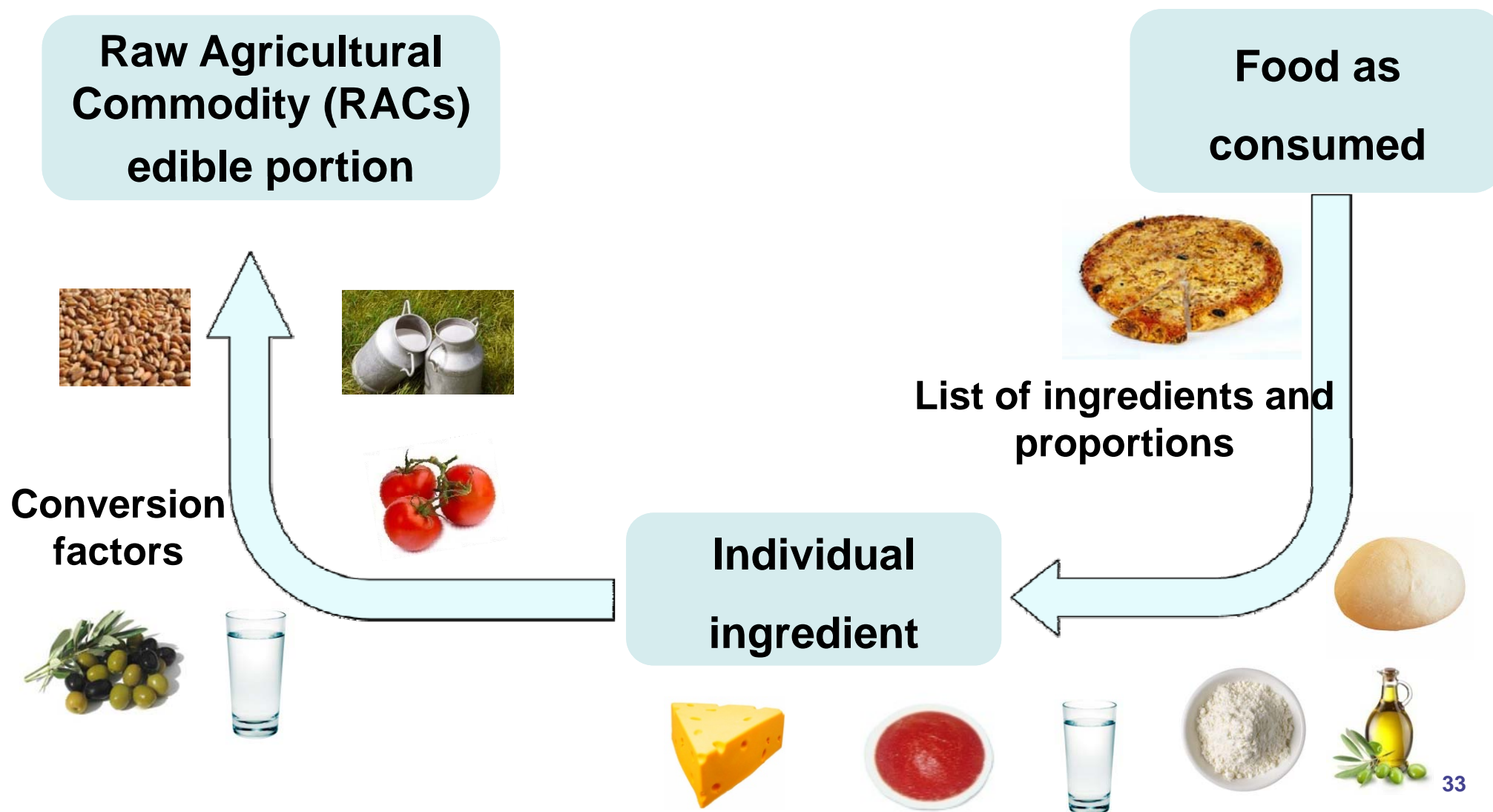
edible portion



Number of commodities for which monitoring data are available: ca. 300

- Mainly unprocessed food
- Results reported for commodity as described in Annex I of Regulation (EC) No 396/2005 (e.g. orange with peel)

Food as consumed vs. RACs



- EFSA has the right to use raw individual food consumption data for carrying out risk assessments and other scientific analyses within the activities related to EFSA's mandate.
- A formal authorization from the data provider must be requested for any other use of the data.



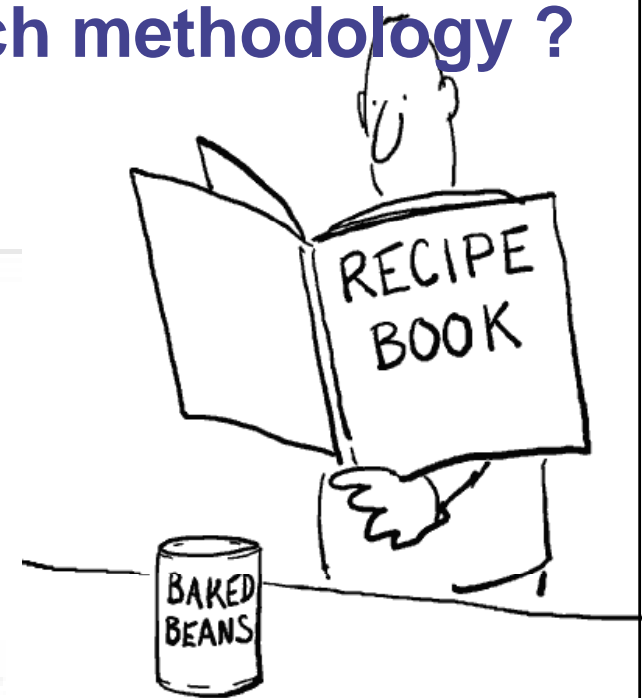
- Which are the representative diets to perform cumulative exposure assessments ?
 - **Which age groups?**
 - **Which geographic regions?**
 - **Specific groups (e.g. vegetarians, breastfeeding women) ?**
- Which recipe data to use for calculation of ingredients?
- Can we use a standard conversion model to derive food consumption expressed in edible portion of raw agricultural commodity for aggregation of the consumption data ?
- How to do refined calculations for processed food ?
- Legal questions: permission to use consumption data

Which tool should be used for the calculation ?

Which data to use ?



Which methodology ?



Which tool can be used?

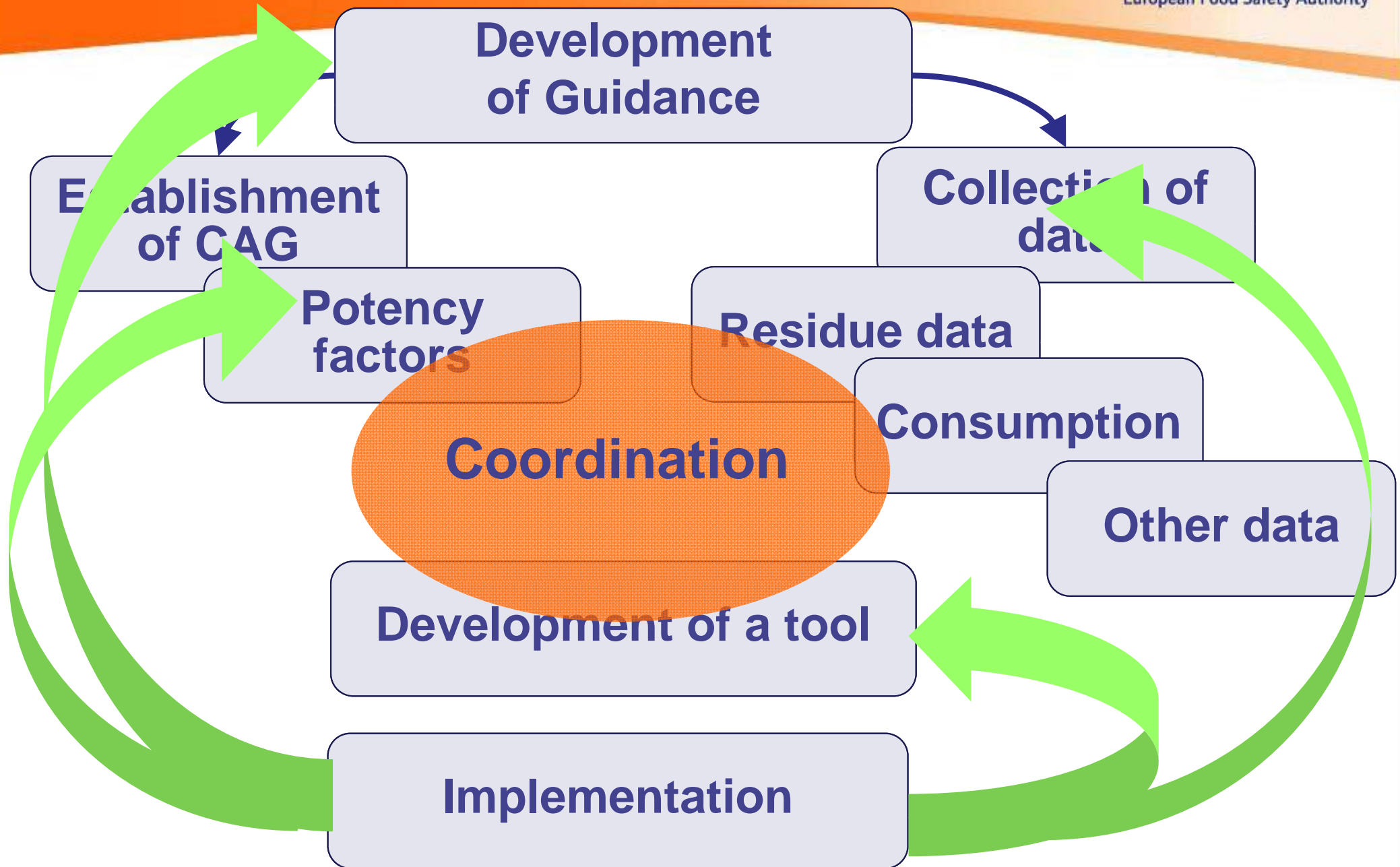
Which tool should be used for the calculation ?

Criteria

- Performance of the tool:
 - **Number of pesticides in CAG**
 - **Number of CAG**
 - **Number of diets**
 - **Number of commodities**
- Are the available tools capable to perform these calculations?
- Tool should be accessible for risk assessors and stakeholders
- Flexibility: possibility to adapt the tool for needs
- Clarity: documentation how the calculations are performed
- Costs



- Implementation of cumulative risk assessment is an iterative process
- Need to gain experience
- Identify the relevant questions that have to be solved
- Close dialogue with risk managers to address their needs
 - **Protection goal**
 - **Level of uncertainty**
- Need to be transparent how the calculations are performed ; uncertainties and limitations of calculation
- Regular evaluation of guidance implementation is needed



Thanks for your attention !