AGENDA

Time	No.	Item	Speaker/presenter
10:00	1	Welcome and introduction to the event • Scope of the info session	Hermine Reich
10:15	2	Introduction to PRIMo 4 – beta-tool • Background databases • Application of the methodology	Zsuzsanna Horvath
10:45	3	Live demo	Violetta Costanzo
11:25	4	Q&A session	All
11:55	5	Wrap-up	Hermine Reich
12:00		End of the Webinar	

HOUSE KEEPING RULES

- You are **automatically connected** to the audio broadcast. One-way audio (**listen only** mode).
- The **event is in English. Questions** should be submitted **in English** via tha **Q&A chat**. Use the **Like** function.
- On questions that cannot be addressed during the webinar, we will provide written answers after the event.
- This event is **being recorded** and recordings will be published on EFSA's website .
- After the event, attendees will receive a **link to a survey** to evaluate the EFSA's event & services.

Presentation window
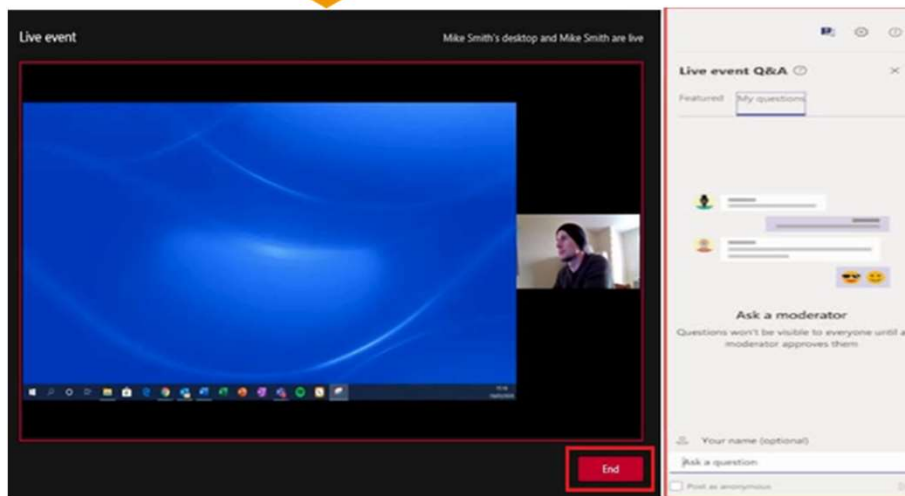
Q&A box: For any questions related to the topic or unexpected IT issues

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- What is the Pesticide Residue Intake Model (PRIMo) ?
    - Tool to estimate chronic and acute dietary consumer exposure to pesticide residues in food
    - Primarily used for the safety assessments of EU maximum residues levels (MRLs)
    - May also facilitate decision making in the framework of enforcement activities
- EFSA is currently developing revision 4 of the model, which will be a new web-based tool, as opposed to the current Excel-based spreadsheets.
- The new online tool will introduce a number of improvements, such as the integration of new consumption data and the calculation of more detailed exposure results.

OBJECTIVE OF THE EVENT

In this webinar we will

- present the concept of PRIMo 4, including information on the food consumption databases and the calculation algorithms;

- introduce a live demo presenting the workflow and the new features of the tool;

- address questions from the participants;

- inform you on the public consultation on the beta tool;

- this consultation aims at gathering feedback from all interested stakeholders on possible enhancements of the final version.

# INTRODUCTION TO PRIMO 4 - BETA TOOL

What's new in PRIMo 4?

- **Web-based tool** on the EFSA R4EU platform

- Integration of most **up-to-date dietary surveys**, received by EFSA until 2018

- More detailed and harmonized definition of **population classes**, e.g. infants and toddlers

- Information on **chronic exposure distribution**, rather than point estimates

- Acute assessment normalised for **individual consumption amounts and body weights**

- Improved assessment for **processed foods** and **minor commodities**

- **New food categories** added, i.e. fish, drinking water and baby foods

- Consistency and **interoperability** with other domains, incl. **FoodEx2**

WEB-BASED TOOL

- Hosted on the EFSA R4EU platform
  https://r4eu.efsa.europa.eu/

- Freely accessible through self-registration

- Interoperable with EFSA Comprehensive Database

- Data entry can be manual or through Excel upload

- Multiple instances can be opened in parallel (up to 5)

- Downloadable reports according to different formats
  e.g. excel, html, etc.

Important note: PRIMo 4 cannot be executed locally to ensure secure access to the food consumption data (i.e. sensitive data)
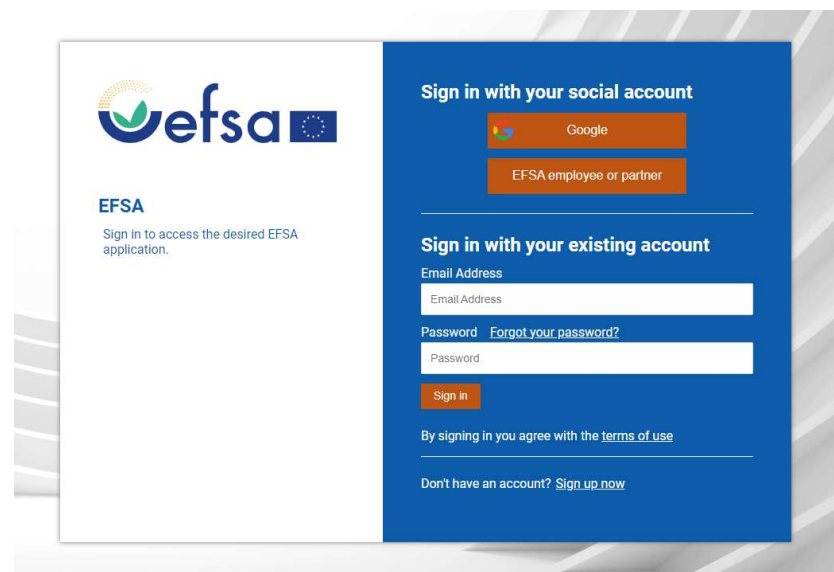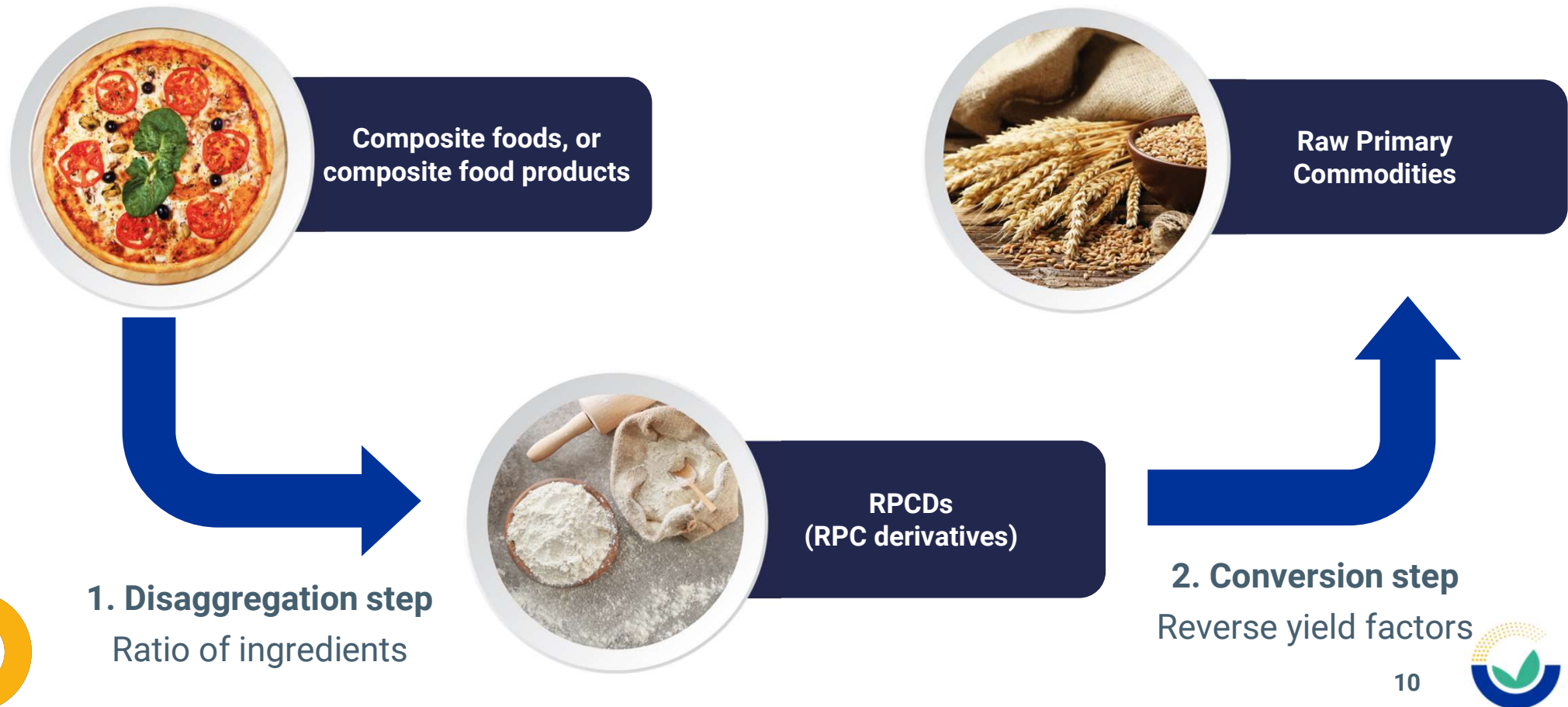
BACKGROUND DATABASES

The **EFSA Comprehensive Database** contains:

- Consumption and bodyweight data collected at individual level:
  - ✓ national surveys with representative samples
  - ✓ 24-hour recall or dietary record methods used in the surveys (at least 2 survey days per subject for chronic assessments)
  - ✓ more than 100,000 individuals
  - ✓ all foods and beverages consumed per day recorded

- Different age classes, special population groups (pregnant women, lactating women) included

- Most recent data within each country
  (may include more surveys per population class for better age coverage)

RAW PRIMARY COMMODITY (RPC) MODEL - 2018

Composite foods, or composite food products

Raw Primary Commodities

RPCDs (RPC derivatives)

1. Disaggregation step
Ratio of ingredients

2. Conversion step
Reverse yield factors

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RPC FOOD CONSUMPTION DATA

- RPC model currently uses data extracted in 2018
- 39 surveys from 22 countries are included in the assessments
- Coded in the FoodEx2 classification and description system, which is used in other food sector areas (*e.g. chemical contaminants, food additives, etc.*)

Population class	Age range	N of Surveys	N of Countries
Infants	< 12 months	5	5
Toddlers	≥ 12 months to < 3 yrs	9	9
Other children	≥ 3 yrs to < 10 yrs	19	16
Adolescents	≥ 10 yrs to < 18 yrs	19	16
Adults	≥ 18 yrs to < 65 yrs	21	20
Elderly	≥ 65 yrs to < 75 yrs	15	14
Very elderly	> 75 yrs	13	13
Pregnant women		1	1
Lactating women		1	1

Important note: RPC model is currently being revised taking into consideration all new surveys submitted since 2018

FOODEX2 CATALOGUE

FoodEx2 efsa

- food/feed classification and description system
- common language
- developed and maintained by EFSA
- food categories are organized in a parent-child relationship, form generic to specific level
- different hierarchies were created depending on the purpose of them (e.g. Human exposure assessments, feed, veterinary drug residues)

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PRIMO HIERARCHY – THE CONNECTION WITH FOODEX2 CODES

- Hierarchy for **Raw Primary Commodities** (RPCs), based on Annex I of Regulation (EC) no 396/2005
- FoodEx2 codes mapped to the **legislation codes** of the pesticide regulation (Matrix codes)

  Note: 'P' added at the beginning of the original code

- Forms the basis for data entry and selection of foods in PRIMo 4
- Can be found in the excel template for data entry → presented later in the Live Demo
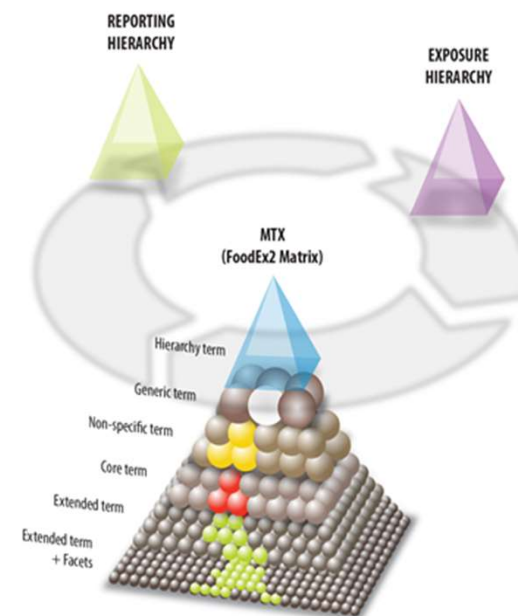
DESCRIPTION OF RPCS AND RPCDS

- No processing information is included in the pesticide legislation

- FoodEx2 system has codes for both processed foods and for raw primary commodities → coding of RPCDs can be managed by them (also the consumption data uses the same codes)

How the FoodEx2 codes are built?

- Base term – defining the food itself

- Facet descriptors - providing additional information for a particular aspect of a food (not always needed)

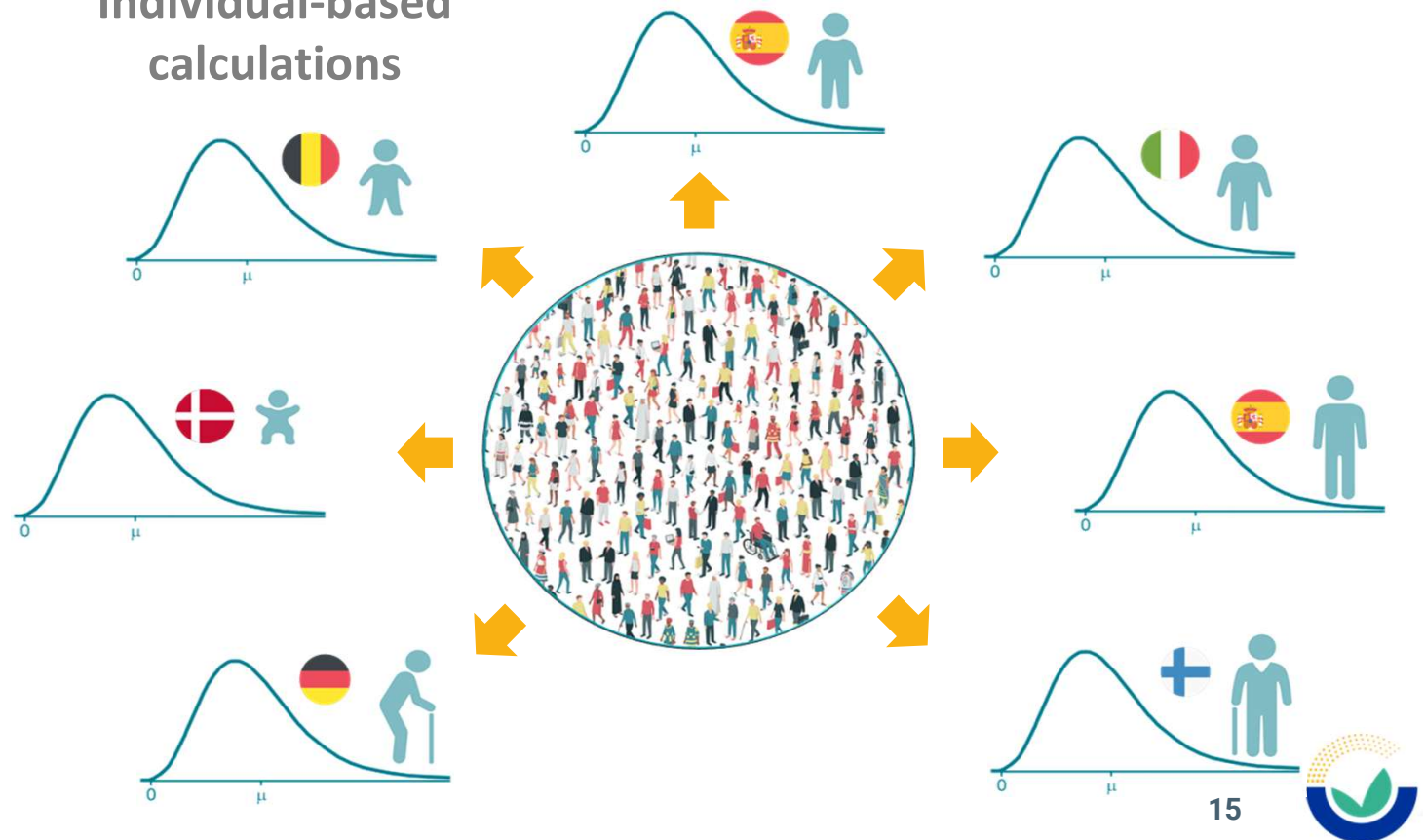| EXAMPLES: Legislation (Matrix) code	RPC FoodEx2 code	RPC FoodEx2 name	RPCD FoodEx2 code	RPCD FoodEx2 Name
	(base term only)		Base term(+facet, if needed)	
P0110020	A01CP	Oranges and similar-	A03AM	Juice, orange
P0110050	A01CB	Mandarins and similar-	A0BY4#F27.A01CD	Fruit juices (100% from named source), SOURCE-COMMODITIES = Mandarins
P0130010	A01DH	Apples and similar-	A01DJ#F28.A0BA1	Apples, PROCESS= Cooking and similar thermal preparation processes
P0130010	A01DH	Apples and similar-	A01DJ#F28.A07XD	Apples, PROCESS= Unspecified

Note: Records with facet "Unspecified" means that information on the processing was not reported and no assumption on the type of processing could be made; expected to be mainly unprocessed.

INDIVIDUAL-BASED – GENERAL PRINCIPLE

Model diet
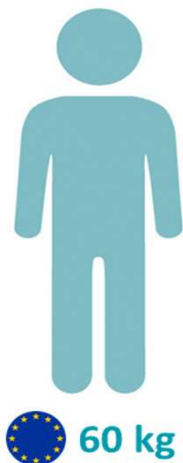
Individual-based calculations

Individual chronic consumption data

Peter

18 kg

Food categories

	Consumption DAY 1 (g)	Consumption DAY 2 (g)	Average consumption (g/day)
	150	250	**200**
	65	0	**32.5**
	200	100	**150**
	0	15	**7.5**

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Individual chronic exposure calculation

Peter

18 kg

Food categories

Average consumption (g/day)	Concentration (mg/kg)	Chronic exposure (mg/day)
200	1.8	**0.36**
32.5	30	**0.98**
150	0.75	**0.11**
7.5	2	**0.02**

Total chronic exposure in mg per day:	**1.47**
Total chronic exposure in mg/kg bw per day:	**0.08**

Distribution of individual chronic exposures

Mean exposure

High exposures
(e.g. 97.5th percentile)

O   μ
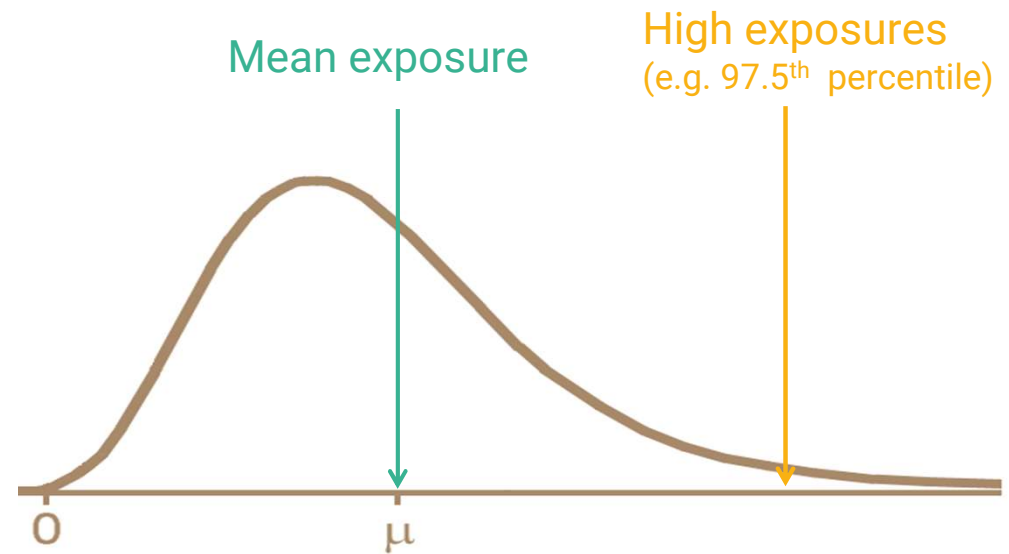
Exposure is presented both in µg/kg bw per day and % of ADI (Acceptable Daily Intake)

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ACUTE EXPOSURE – THE IESTI EQUATIONS

International estimated short term intake (IESTI)

Internationally agreed methodology which includes four different equations for calculating acute exposure depending on the characteristics of the commodity considered in the assessment.

$$IESTI = \frac{(LP \times (HR \text{ or } HR-P))}{bw} \text{ (in mg/kg bw)}$$

$$IESTI = \frac{((Ue \times (HR \text{ or } HR-P) \times v + (LP-Ue) \times (HR \text{ or } HR-P))}{bw} \text{ in mg/kg bw}$$

$$IESTI = \frac{((LP \times (HR \text{ or } HR-P) \times v))}{bw} \text{ in mg/kg bw}$$

$$IESTI = \frac{(LP * STMR-P)}{bw} \text{ in mg/kg bw}$$

Ue – edible portion, LP –large portion, STMR – supervised trial median residue, HR – highest residue, P – processing factor, bw – body weight, v – variability factor.

Case 1: Unit weight (U_{RAC}) is <25 g. This case also applies to meat, liver, kidney, edible offal and eggs.

Case2: U_{RAC} of a commodity is ≥ 25 g. Variability factors are applied in the equations:
- 2a. The unit weight of the edible portion (U_e) is lower than that of the **large portion, LP**
- 2b. The unit weight of the U_e is higher than that of the **large portion, LP**

Case 3: When RPC or RPCD is bulked or blended (e.g. pre-harvestly treated cereal grains, oilseeds, pulses, industrially processed fruit juices, milk)

HOW THE IESTI EQUATIONS ARE APPLIED IN PRIMO 4?

Short-term intake is estimated for each food consumed by each individual subject – total daily **consumption of the subject** of a certain food is normalized with **their own bodyweight**

Novelties:

- **RPCs** are pre-assigned to **Case 1, 2 and 3**

  Standard unit weight data collected from the Member states: **RPC unit weight and RPC edible unit weight**

- **If an RPC** assigned to **Case 2** further checks in the algorithm:

  - the unit weight of the edible portion (U_e) is lower than the **quantity consumed by subject**: Case 2a

  Individual consumption data from the RPC consumption database.

  - the unit weight of the U_e is higher than the **quantity consumed by subject**: Case 2b

- **When RPCD was consumed** the case number is corrected based on **blending** information

  Blending variable (yes or no) assigned to each processed product (e.g. cooked apple→ case 2; apple juice→ case 3)

Note: When RPCD occurrence data is provided, the U_e which is used in the decision of assigning case 2a or 2b, as well as in the equation of case 2a, is adjusted with a yield factor (ratio of consumed RPCD amount and RPC equivalent) and compared to the RPCD amount consumed.

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ACUTE EXPOSURE CALCULATIONS IN SUMMARY

- IESTI equations are used

- Consumption within a single day is considered for each subject

- The exposure is estimated for each RPCD (not summing exposure from raw orange with orange juice!)

- Exposure is presented both in µg/kg bw and % of ARfD (Acute Reference Dose)

- Highest Reliable Percentile (HRP) is calculated (from P50 to P97.5) for each RPC and RPCD

HIGHEST RELIABLE PERCENTILE (HRP)

- Highest Reliable Percentile (HRP) is used to represent **highly exposed consumers** because the 97.5th percentile cannot always be calculated

- Minimum number of observations necessary to estimate a given percentile was defined as follows:

N° of observation	Highest Reliable Percentile (HRP)
5 - 11	50th
12 - 28	75th
29 - 58	90th
59 - 118	95th
> 118	97.5th

Highly exposed consumers
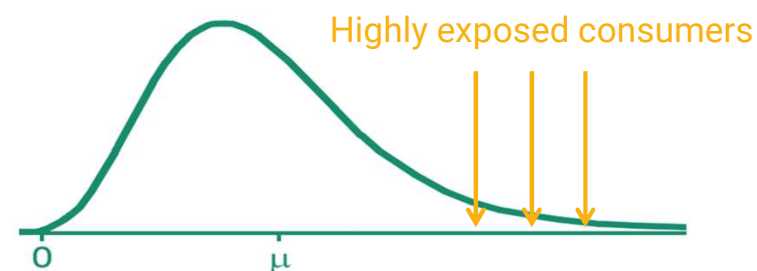
- In case of **chronic** assessment, the cut-off is applied to the number of participants within a population class, country and survey

- For **acute** assessment, the number of consumption days are considered

REFINEMENTS FOR PROCESSED FOODS

	Occurrence		Consumption		Exposure
RPC	**1 mg/kg**	X	0.0043 kg/kg bw	=	0.0043 mg/kg bw *Worst-case assumption*
	Processing factor ⬇		⬆ Yield factor		
RPCD	0.1 mg/kg	X	**0.0030 kg/kg bw**	=	0.0003 mg/kg bw *Refined assessment*

Important note: PRIMo 4 does not allow data entry for composite foods because it relies on disaggregated data to avoid double counting of residues

LIMITATIONS AND FUTURE IMPROVEMENTS

- Update **RPC Consumption Data** as soon as the new RPC model is available, integrating dietary surveys received by EFSA after 2018

- Possibilities for **interoperability** to be further explored:
  - ✓ International Uniform Chemical Information Database (IUCLID) to facilitate the import of input occurrence data from a pesticide dossier and export PRIMo reports back to the dossier.
  - ✓ EU Processing Factor Database to import available processing factors
  - ✓ OpenFoodTox Database to import latest health-based guidance values
  - ✓ Legal Limits Database to import applicable MRLs

- Facilitate **re-use of input data** from previous versions of PRIMo in .xls

LIVE DEMO

LIVE DEMO

- Accessing the tool:
  https://r4eu.efsa.europa.eu/app/primo4
- Entering input data manually
- Uploading input data from Excel
- Executing chronic exposure assessments
- Executing acute exposure assessments
- Generating reports

Q & A SESSION

WRAP UP

WHAT'S NEXT?

- Public consultation on the tool will be open until **30th of June 2023**
  - ✓ Tool, technical report & supporting information (incl. recording of the webinar, test dataset, etc.)
  - ✓ Comments will need to be submitted here

- Final tool and the technical report **by end of October 2023**
  - ✓ Addressing comments & selection of refinements/adjustments to be implemented
  - ✓ Finalisation of the tool
  - ✓ Consolidation of the technical report

- Implementation to be agreed with European Commission and Member States
  - ✓ Assessment of potential impact
 - ✓ Agreement on implementing and transitional measures through comitology procedures

THANK YOU FOR ATTENDING OUR EVENT

- In case we did not manage to answer all your questions, you will find them published on EFSA's website after the event as soon as we can prepare the answers

- The recording of today's event will be available on the EFSA website in few days

- Please take few minutes to fill out the evaluation survey that you will receive via e-mail after the event. Your feedback is essential to improve our future events

STAY CONNECTED
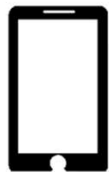
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