

FACET - its use in the risk assessment of NIAS

Seamus Kelly – Creme global

Cian O'Mahony – Creme global

Mike Simoni – Sun Chemical

Peter Oldring – Valspar Corporation

October 2014

FACET

- FACET – Flavours, Additives (food), food Contact Exposure Tool
- Developed during a 4 year DG Research funded project which ended August 2012
- Since this date the food packaging supply chain and the food industry have been funding developments for food contact materials (FCMs).
- One of these developments is a module to assess exposure to NIAS (Non Intentionally Added Substances)

Contents & Models of/in FACET - 1

- Databases
 - Extended harmonised food consumption database for regional modelling and risk assessment
 - Database on occurrence and concentration of substances in FCMs or their components using data supplied by industry
 - Packaging usage statistics for most EU Member States based on market research data (EuroMonitor).

Contents & Models of/in FACET - 2

- Models/Tools
 - Migration model for multi-layer and multi-material packaging as well as paper & board
 - Exposure Software for estimating exposure to target food chemicals stochastically (Monte Carlo).

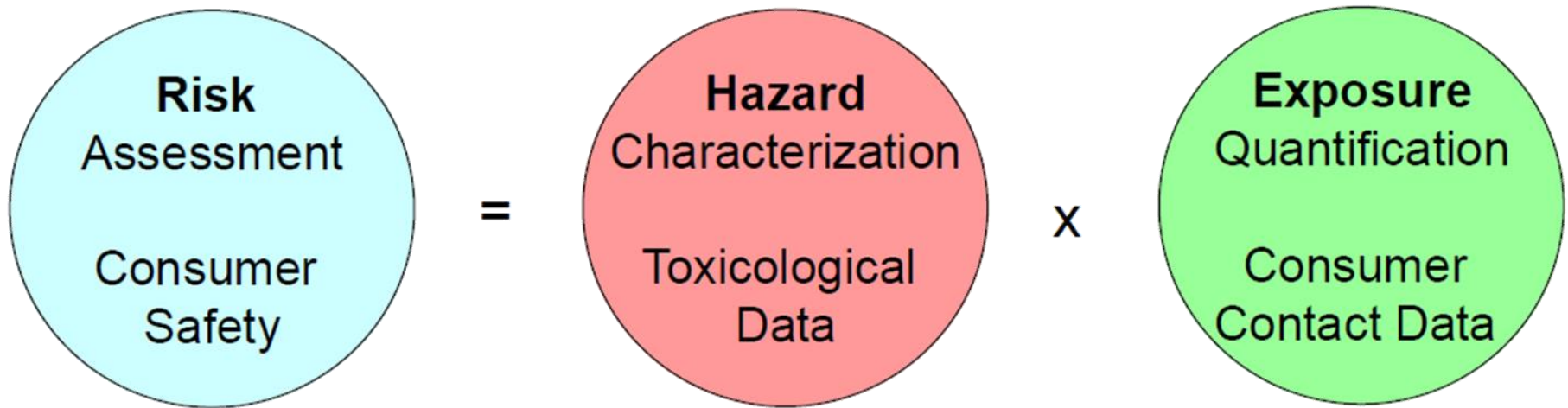
What can FACET do?

- FACET can estimate exposure to existing substances in FCMs at varying levels of sophistication
- FACET can estimate exposure for substances in foods measured in surveillance surveys
- FACET can estimate exposure to substances coming from new packaging for new or existing substances
- FACET can estimate exposure to new substances and NIAS

What can FACET do?

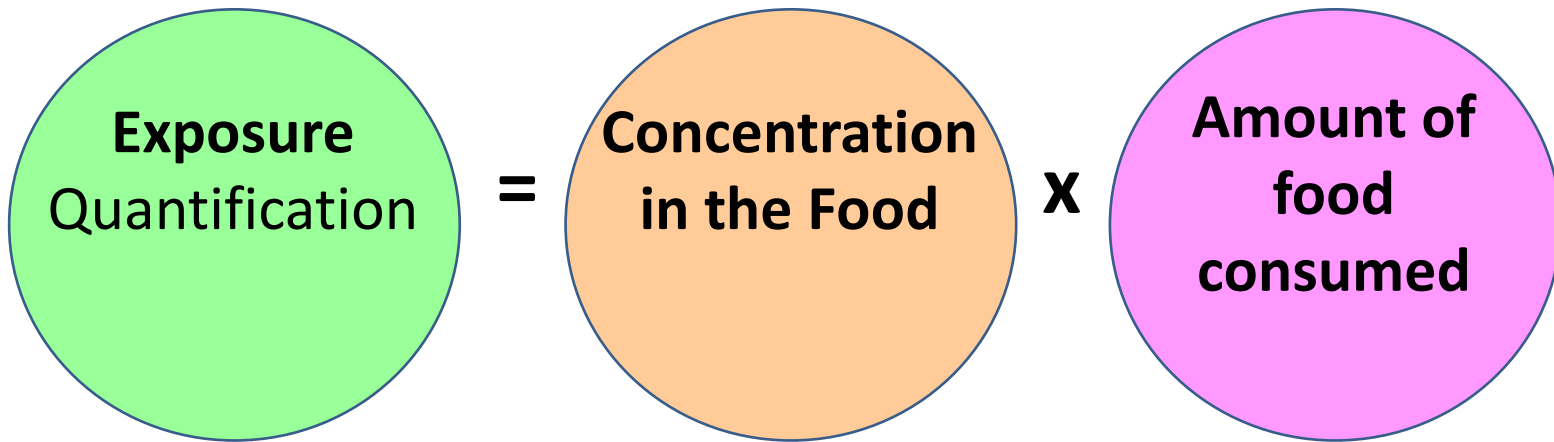
- NIAS is an extension of the new substance functionality.
- Concentration of a substance in a foodstuff is obtained by either migration modelling or using extraction data or measured concentrations (migrations) in (into) foodstuffs
- Having obtained the concentration in the food it is necessary to calculate how much each person consumes per day of that foodstuff using dietary surveys.

Exposure Assessment as part of a Risk Assessment



The most common reason to do an exposure assessment for a substance, is so that you can compare it with the toxicology for that substance and make a judgement on the impact for consumer safety.

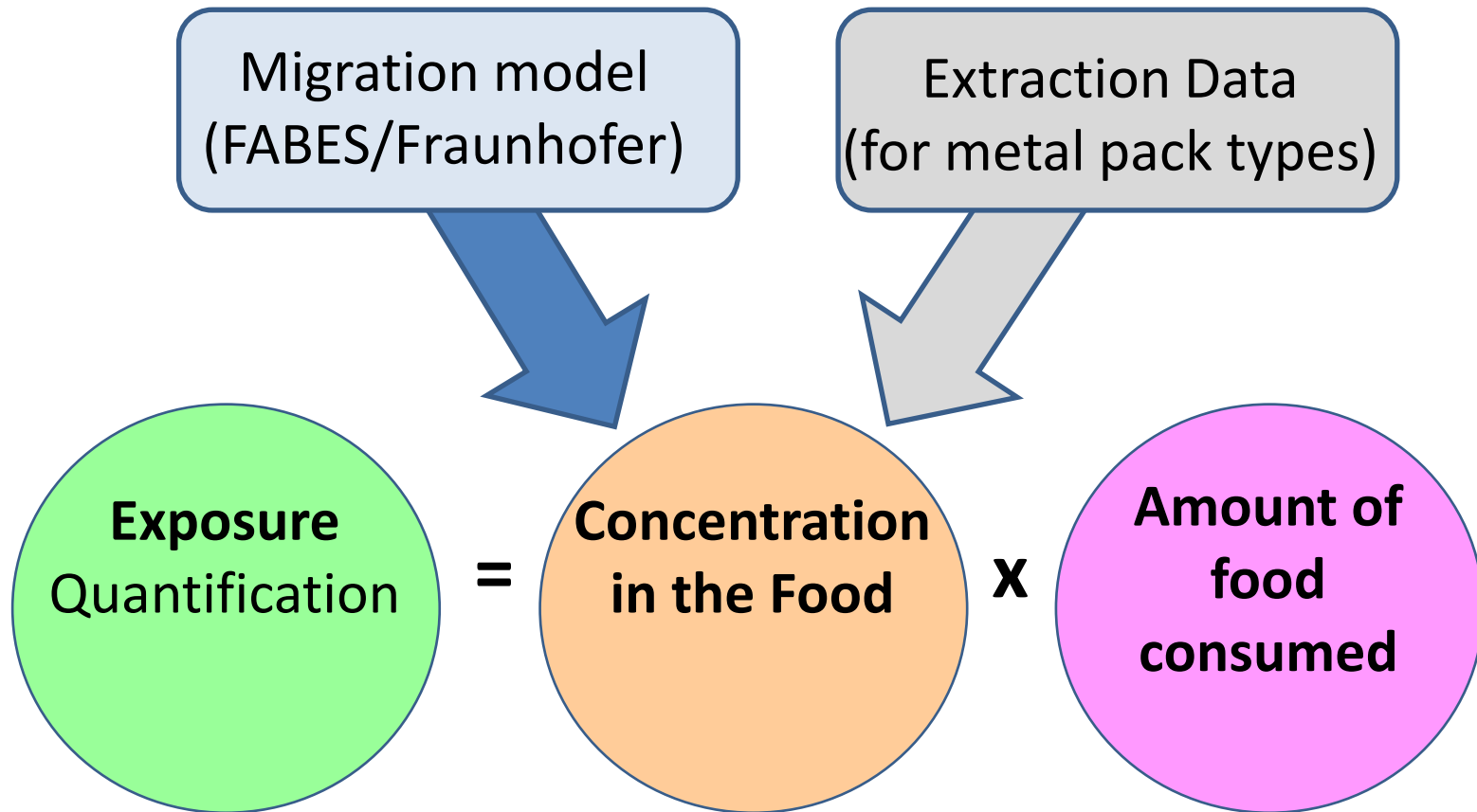
Exposure Assessment



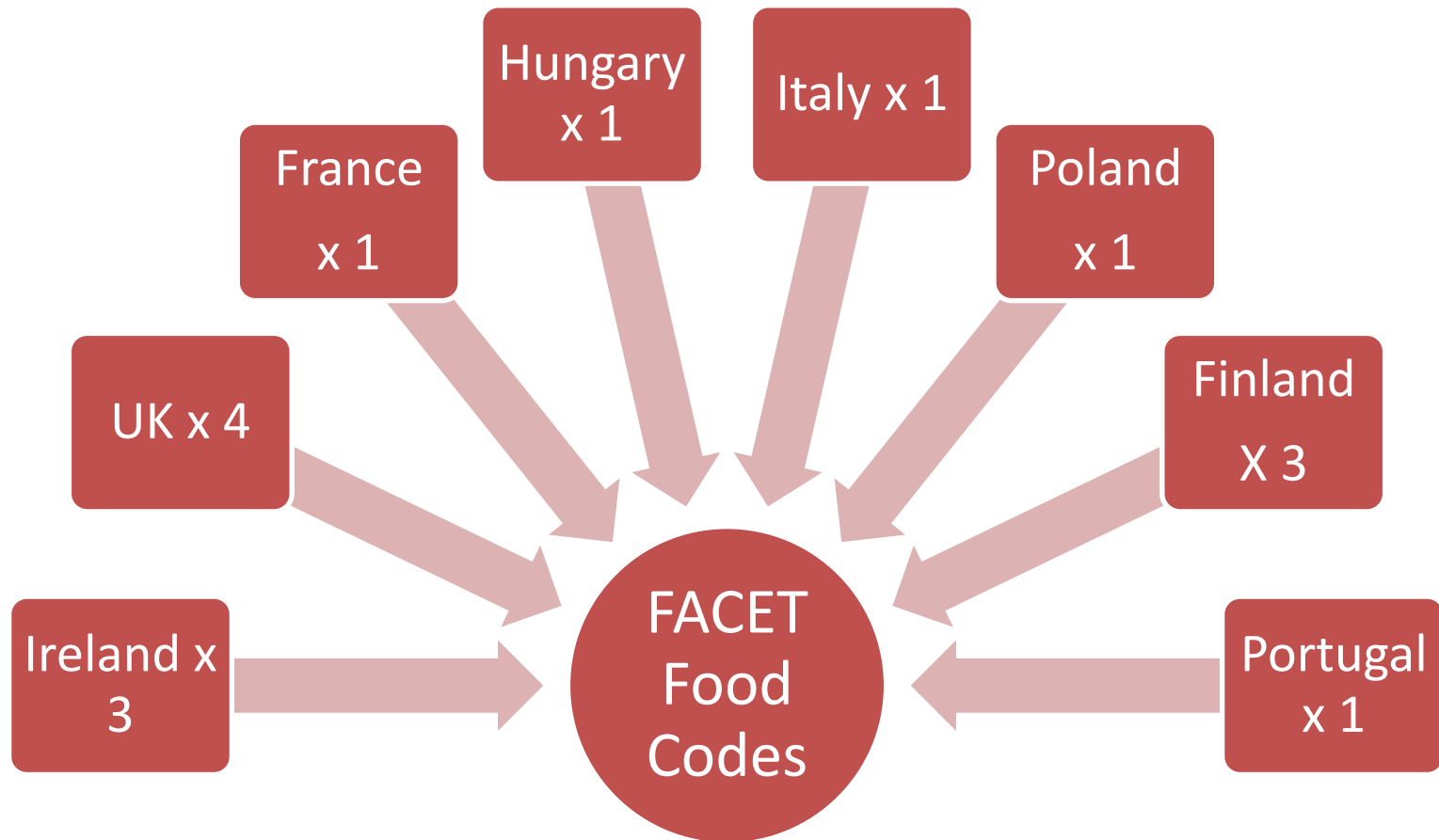
To get to an exposure assessment we need to understand the Concentration of the substance in food, and the Amount of food consumed.

Exposure Assessment

Two potential routes to get to Concentration in food



Food Consumed – Dietary Surveys



How do we know that FACET works?

FACET BPA exposure

FACET was used to estimate exposure to BPA. The methodology along with inputs and results have been published –

Oldring P.K.T, Castle L, O'Mahony C, Dixon J.

Estimates of dietary exposure to bisphenol A (BPA) from light metal packaging using food consumption and packaging usage data: a refined deterministic approach and a fully probabilistic (FACET) approach:

Food Additives & Contaminants: Part A:2014 Vol. 31, No. 3, pp 466–489

Example of FACET exposure estimate to BPA from canned foodstuffs

- FACET exposure estimate (*sent to EFSA before their draft opinion was published*) was compared to Scenario 2 (conservative scenario assuming all food that could be canned was canned) estimate from the July 2013 EFSA draft opinion.
- Conclusion very good agreement between EFSA conservative estimate and that derived from FACET

Estimates of dietary exposure to BPA	Mean	95 th % ile	97.5 th % ile
FACET 2013 ng/kg bw/day Canned foodstuffs estimate	130	395	590
EFSA 2013 ng/kg bw/day Canned foods mainly ranging between 75-90%	126 - 132	355 - 388	-.

Practical Uses - NIAS

- Calculate the exposure to a NIAS from metal and non-metal materials into food.
- Can be as a NIAS (impurity) in an existing substance.
- Can be as a NIAS in a material.
- Exposure calculation for NIAS / impurities in crisis situations.
- Use exposure estimates to assess risk using available toxicological data / approaches (e.g. TTC)

Risk Assessment Question 1 - 1

- Tributyl aconitate (CAS 7568-58-3) is a NIAS substance that is present in ATBC at 7%.
What is the exposure of the UK (19-64 year olds) to tributyl aconitate ?
- What are the risks?
 - Mol Wt. 342.4 ; Log Pow 5.72 (NOTE we can use EPI Suite to get Log Pow)

Risk Assessment Question 1 - 2

- Why can we simply not say that the exposure to tributyl aconitate is 7% of the exposure to ATBC?
 - tributyl aconitate (CAS 7568-58-3), mol wt 342.4
 - acetyl tributyl citrate (CAS 77-90-7), mol wt 402.5

Risk Assessment Question 1 - 3

- Is the exposure of tributyl aconitate in proportion to the exposure of ATBC (7% ATBC)?
- Why is there a difference?
 - Different molecular weight
 - Different log Pow

	Mean µg/Kg bw/day	95 th % µg/Kg bw/day
ATBC	1.64	5.01
tributyl aconitate user 1 (loyal)	0.128	0.421
tributyl aconitate user 2 (non-loyal)	0.124	0.380
Difference (user 1)	7.8%	8.4%

Data include set-off migration and Consumer Loyalty

Risk Assessment Question 1 - 4

- What exposure do the UK adult population have to tributyl aconitate and where does it come from?

Mean exposure, All Foods 0.000128 mg/Kg
bw/day

P95 exposure, All Foods 0.000421 mg/Kg bw/day

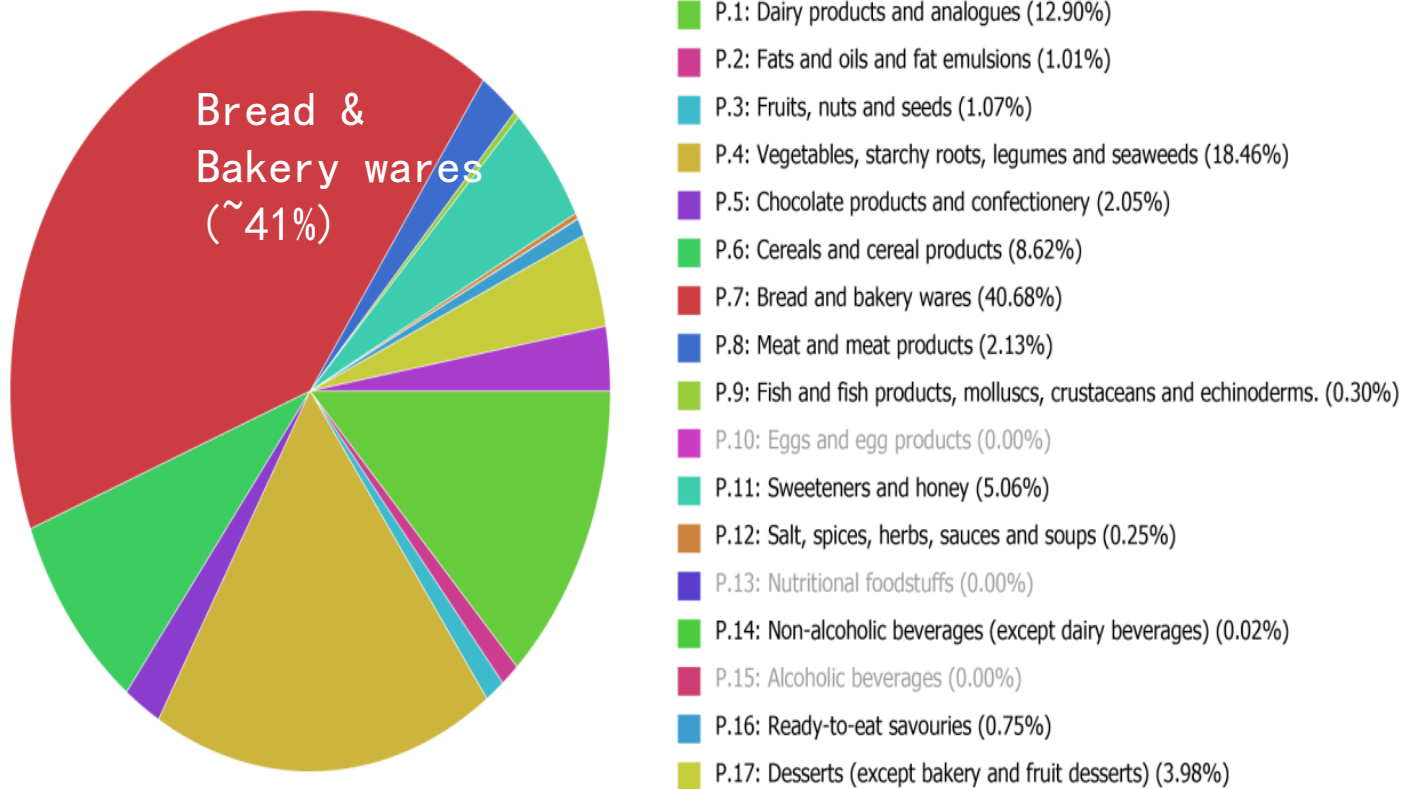
Mean exposure, All Foods 0.128 µg/Kg bw/day

P95 exposure, All Foods 0.421 µg/Kg bw/day

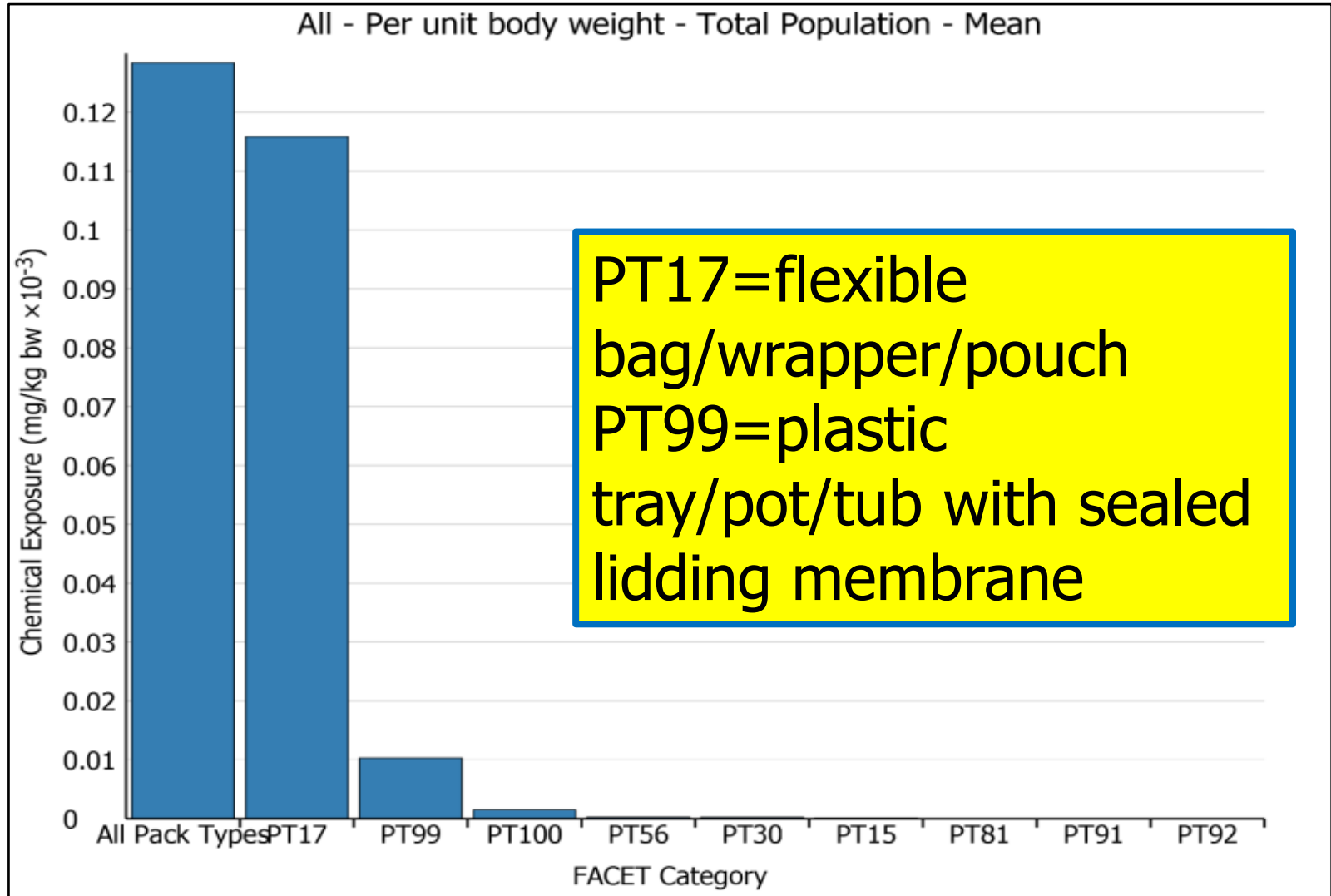
Data include set-off migration and Consumer
Loyalty

Risk Assessment Question 1 - 5

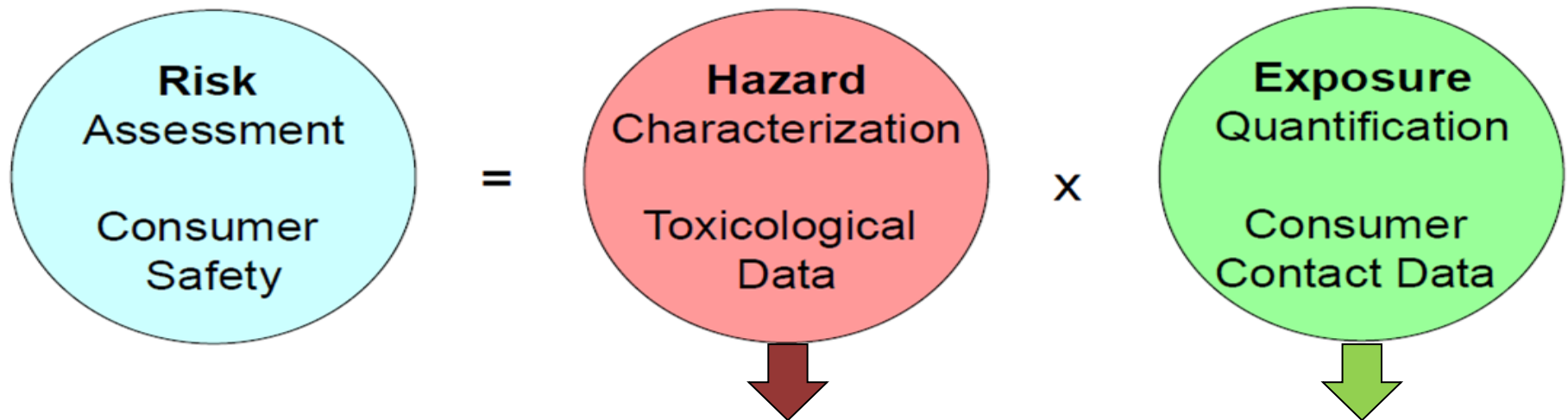
All Pack Types - Per unit body weight - Total Population - Mean



Risk Assessment Question 1 - 6



Risk Assessment Question 1 - 7



No relevant tox data found on tributyl aconitate. Based on structure and that ATBC forms tributyl aconitate in solvent solutions then it would be reasonable to assume that ATBC and tributyl aconitate have similar toxicology (1 mg/Kg bw/day). Therefore acceptable risk in adult population

Risk Assessment Question 2 - 1

- Substance XY is a new plasticiser that gives really good adhesion to polyester films.
 1. If XY used at 5% in the dry ink film in 70% of all Nitrocellulose inks (both gravure and flexo) for polyester, then what would the exposure be in the French population?
 2. If there was a toxicological limit of 0.01 mg/Kg bw day then what would be the risk?
- Parameters for substance XY:
- Mol Wt. 305, Log Pow 3.2

Risk Assessment Question 2 - 2

OUTPUTS

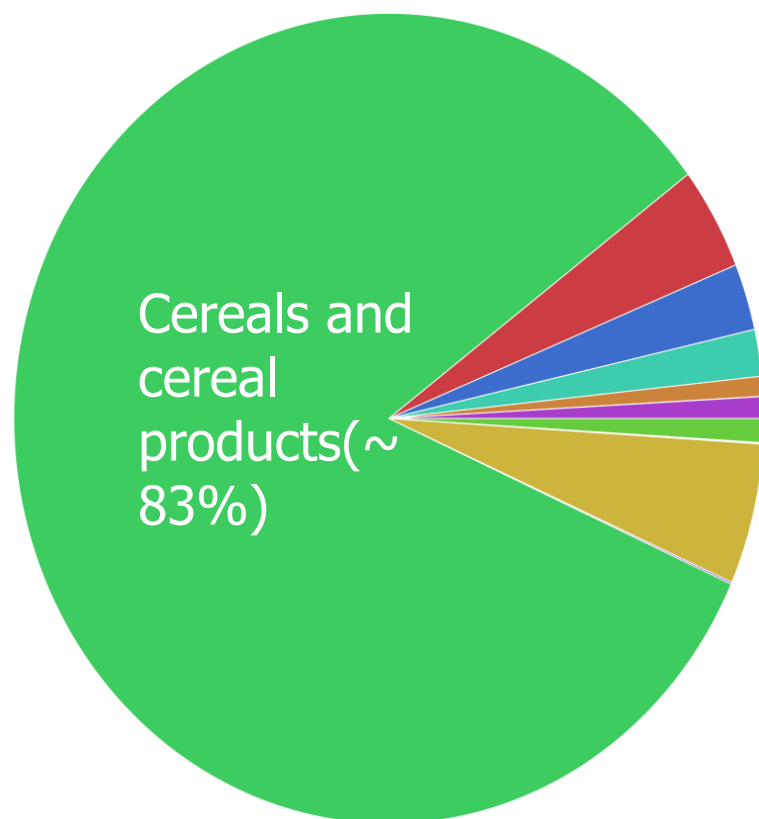
- User 1:
 - Mean exposure, All Foods 0.00274 mg/Kg bw/day - P95 exposure, All Foods 0.0146 mg/Kg bw/day
 - Mean exposure, All Foods 2.74 µg/Kg bw/day - P95 exposure, All Foods 14.6 µg/Kg bw/day
- User 2:
 - Mean and P95 exposure, All foods 3.7 & 11.2 µg/Kg bw/day respectively.

Risk Assessment Question 2 - 3

- Toxicologically the acceptable limit is 10 µg/Kg bw/day.
- Therefore there could be an unacceptable risk
- What is driving this risk?
- Main exposure drivers are:
 - Flexible bag/wrapper/pouch and Cereals and cereal products

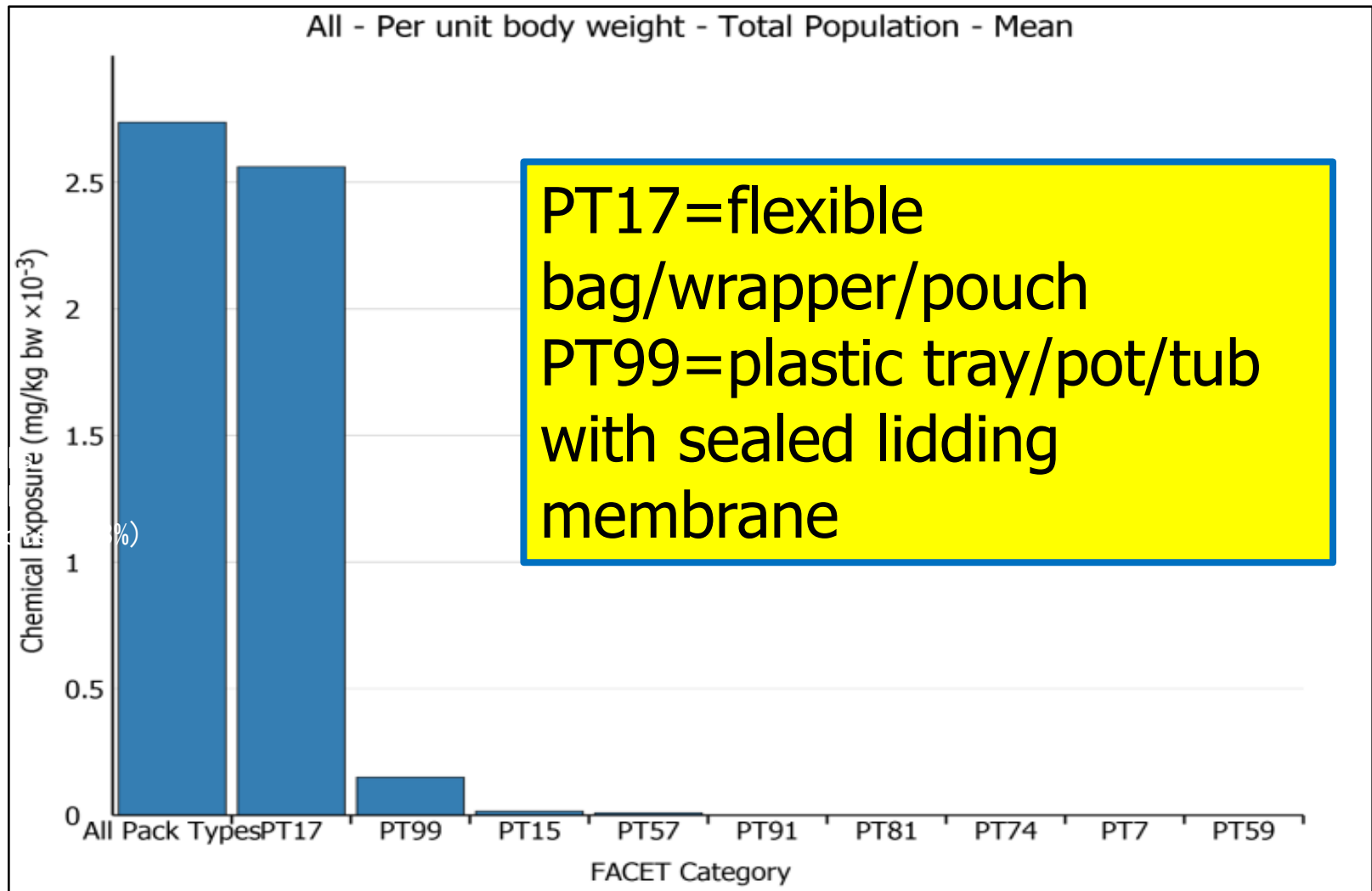
Risk Assessment Question 2 - 4

All Pack Types - Per unit body weight - Total Population - Mean



- P.1: Dairy products and analogues (0.96%)
- P.2: Fats and oils and fat emulsions (0.03%)
- P.3: Fruits, nuts and seeds (0.03%)
- P.4: Vegetables, starchy roots, legumes and seaweeds (5.62%)
- P.5: Chocolate products and confectionery (0.08%)
- P.6: Cereals and cereal products (82.99%)
- P.7: Bread and bakery wares (4.11%)
- P.8: Meat and meat products (2.66%)
- P.9: Fish and fish products, molluscs, crustaceans and echinoderms. (0.00%)
- P.10: Eggs and egg products (0.00%)
- P.11: Sweeteners and honey (1.87%)
- P.12: Salt, spices, herbs, sauces and soups (0.79%)
- P.13: Nutritional foodstuffs (0.00%)
- P.14: Non-alcoholic beverages (except dairy beverages) (0.00%)
- P.15: Alcoholic beverages (0.00%)
- P.16: Ready-to-eat savouries (0.01%)
- P.17: Desserts (except bakery and fruit desserts) (0.00%)

Risk Assessment Question 2 - 4



Data includes set-off migration and Customer Loyalty

Summary

- We have shown how FACET can be used to:
 - Estimate exposure as part of a risk assessment for a NIAS substance and in conjunction with toxicological data / approaches can be used to assess the safety of an FCM.
 - Estimate exposure as part of a screening test for introducing a new substance into the market.
 - Estimate exposure to any FCM substance for which a concern arises.

THANK YOU FOR YOUR ATTENTION

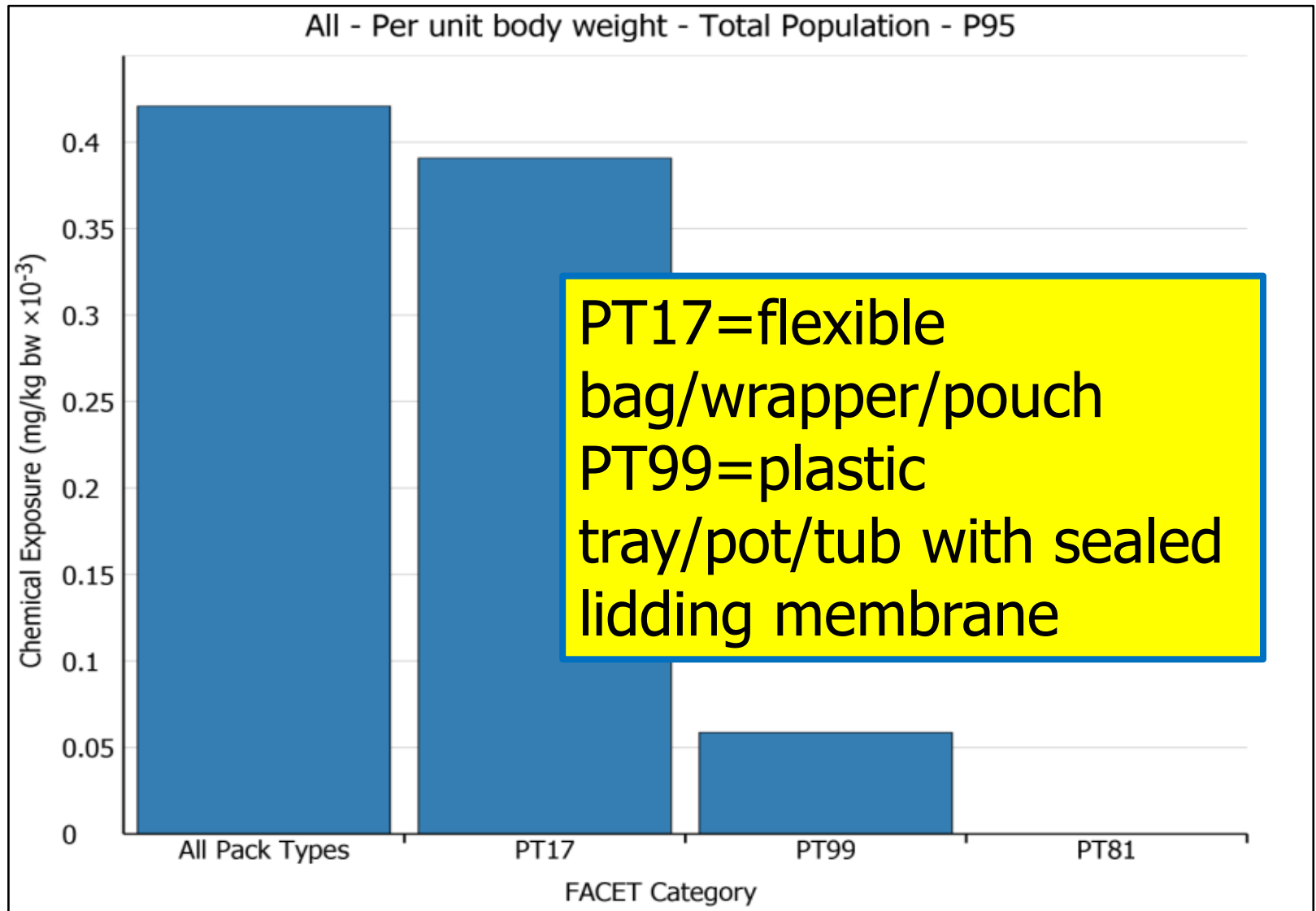
Framework 7 programme - Theme 2 Food,
Agriculture and Fisheries, and Biotechnology,
KBBE-211686

FACET WEB SITE

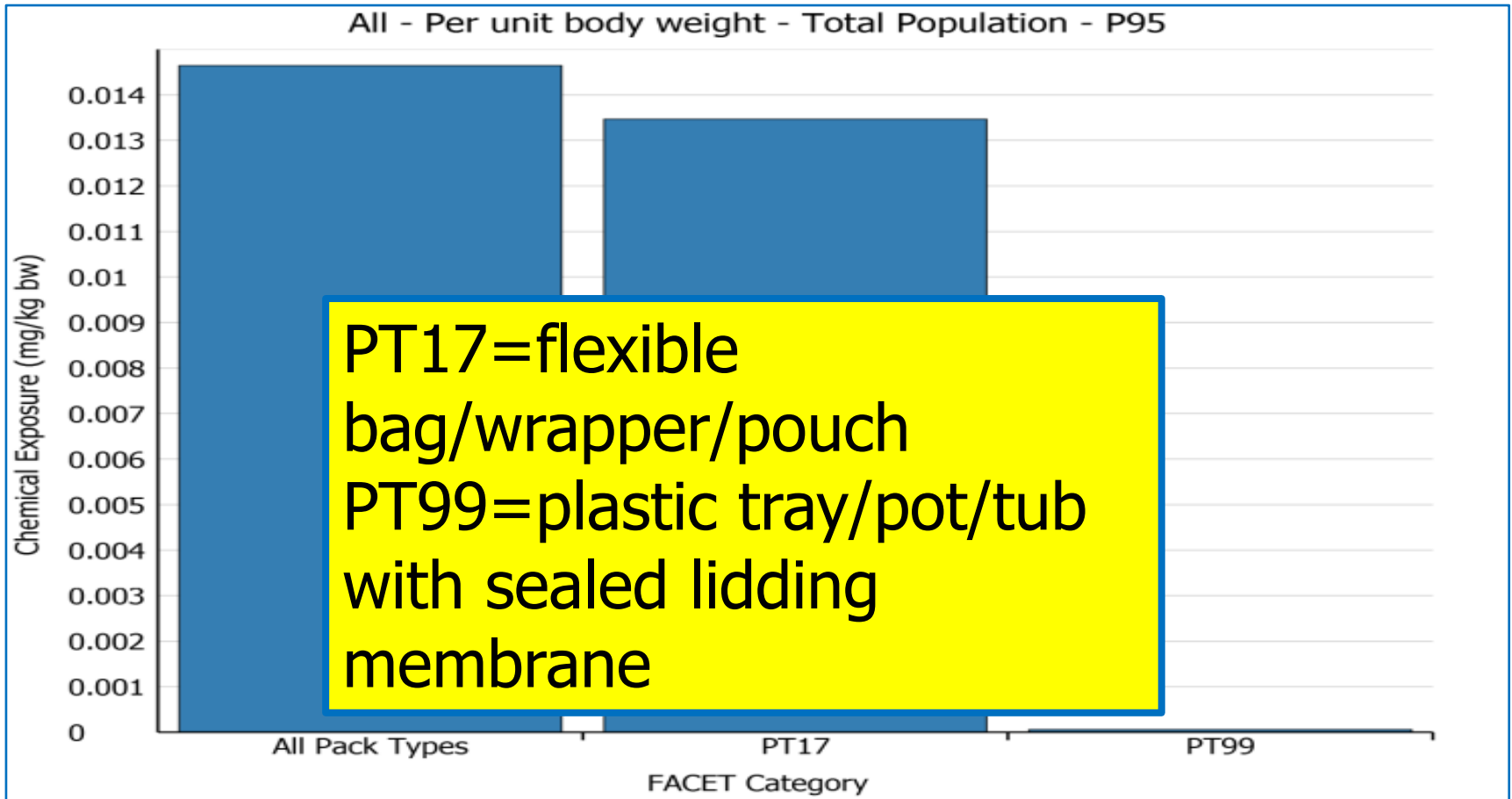
[http://ihcp.jrc.ec.europa.eu/our_activities/food-cons-prod/chemicals in food](http://ihcp.jrc.ec.europa.eu/our_activities/food-cons-prod/chemicals_in_food)

peter.olding@valspareurope.com

Risk Assessment Question 1 - Extra



Risk Assessment Question 2 – Extra



Data includes set-off migration and Customer Loyalty