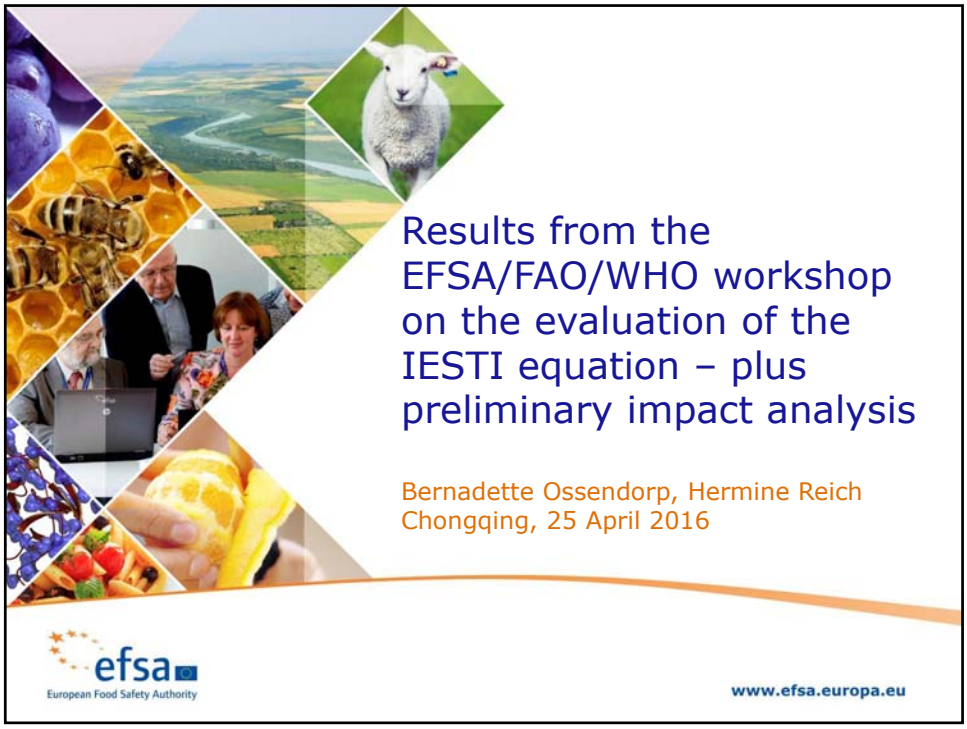
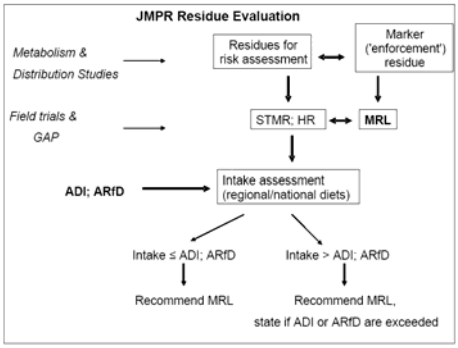

Results from the EFSA/FAO/WHO workshop on the evaluation of the IESTI equation – plus preliminary impact analysis
Bernadette Ossendorp, Hermine Reich
Chongqing, 25 April 2016
efsa
European Food Safety Authority
www.efsa.europa.eu

efsa
Revisiting IESTI
HISTORY OF IESTI
1997 FAO/WHO Geneva Consultation
1998 York International Conference on Pesticide Residues Variability and Acute Dietary Risk Assessment (PSD, UK)
ad hoc Expert Meeting held before the 1999 CCPR (Annex V in JMPR 1999 report)
JMPR meetings 1999, 2000, 2002, 2003, 2005, 2006
changes consolidated at FAO/WHO 'Annapolis' workshop (WHO, 2008 = EHC 240)
2

RH1

HOW IESTI EQUATIONS ARE USED

In the process of MRL setting:



IESTI = **I**nternational **E**stimate of **S**hort-**T**erm dietary **I**ntake

Short-term = 24 hours (for comparison with ARfD)

3

HOW IESTI EQUATIONS ARE USED; EU SPECIFIC

- **In the pre-authorisation risk assessment**
- **In the EU annual reports on the monitoring programme for pesticide residues**
- **In the process of enforcement:**
  - EU Rapid Alert System for Food and Feed (RASFF)
  - PSTI = Predicted short term intake from sampling result
  - Uses 'OR' = observed residue in equation instead of HR, but is essentially identical to IESTI. **OR refers to residue definition for monitoring!**

RASFF
Rapid Alert System for Food and Feed

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Slide 3

RH1 Please check the condition in the right bottom corner:

Intake > ADI; ARfD

REICH Hermine; 25-2-2016

IESTI EQUATIONS

Select case 1, 2 a, 2b or 3:

- Case 1
  Unit weight (U_{RAC}) < 25 g
  (e.g. green beans)
- Case 2a
  Unit weight (U_{RAC}) >= 25 g
  edible portion (U_e) < large portion
  (e.g. potatoes)
- Case 2b
  Unit weight (U_{RAC}) >= 25 g
  edible portion (U_e) >= large portion
  (e.g. red cabbage)
- Case 3
  bulked/blended commodity
  (e.g. tea)

CURRENT IESTI EQUATIONS

- Case 1
  Unit weight (U_{RAC}) < 25 g
  (e.g. green beans with pods)

$$IESTI = \frac{LP \times HR}{bw}$$

- Case 2a
  Unit weight (U_{RAC}) ≥ 25 g,
  v=3, 5, 7, 10
  edible portion (U_e) < large portion
  (e.g. potatoes)

$$IESTI = \frac{\{U_e \times HR \times v\} + \{(LP - U_e) \times HR\}}{bw}$$

- Case 2b
  Unit weight (U_{RAC}) ≥ 25 g,
  v=3, 5, 7, 10
  edible portion (U_e) ≥ large portion
  (e.g. red cabbage)

$$IESTI = \frac{LP \times HR \times v}{bw}$$

- Case 3
  bulked/blended commodity
  (e.g. tea, cereals)

$$IESTI = \frac{LP \times STMR}{bw}$$

CURRENT IESTI EQUATIONS

Effect of the unit weight

Spinach-total LP = 420.3 g/p/d, bw = 14.2 kg, South Africa (ZA) HR = 2.5 mg/kg, ARfD = 0.1 mg/kg		
Bunch of spinach	Spinach plant	Spinach leaf
$U_{RAC}=U_e$ = 300 g, JPN	U_{RAC}=45 g, U_e =33.3 g, AUS	U_{RAC} = U_e = 1.5 g, NLD
Case 2a, v=3	Case 2a, v=3	Case 1, v=1
180% ARfD	90% ARfD	70% ARfD

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HISTORY OF MRL VERSUS HR (WHO/JMPR)

- Initially, MRL instead of HR in IESTI
- In 1999, MRL was replaced by HR, because:

  - the JMPR practice of recommending MRLs within 'MRL classes'. This may lead to the IESTI not being sufficiently discriminatory to be used as a screening technique.

  - wish to consider total toxicologically relevant residue; use of residue definition for risk assessment (HR) instead of residue definition for enforcement/monitoring (MRL)

  - no rounding in the middle of a calculation

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HISTORY OF VARIABILITY FACTOR

- Definition for variability factor (v): 97.5th percentile of the residues present in single crop units divided by the mean residue of the lot
- 2002 JMPR: default factors of 3,5,7,10
  2003 JMPR: default factor 3; 2005 JMPR confirmed this (new data)
- Not accepted in EU; EFSA PPR Panel opinion 2005. Variability factor is itself variable, 3 is the mean of the distribution. How conservative do risk managers want to be?
- 2007 EFSA PPR opinion; influence of changing v on Level of Protection

REASONS TO REVISIT IESTI - 1

- Check against current science and practicalities after 15 years of use
- Communicating that the legal standards (MRLs) are assessed may contribute to building trust among the general audience
- Harmonizing the IESTI methodology will increase the acceptability of Codex MRLs and as such contribute to a level playing field in international trade.

REASONS TO REVISIT IESTI - 2

- Use of OECD MRL calculator and harmonised MRL classes:
  - MRLs are derived in the same way everywhere
  - using the MRL instead of the HR will no longer lead to different conclusions in different countries

- HR is based on a small dataset.
  - In reality, residue levels may vary outside the dataset. The 'OECD – MRL calculation unrounded' is a statistically more reliable estimate of the highest residue. The OECD – MRL calculation in many cases results in a level at approximately 2x the HR

2006/2007 JMPR RECOMMENDATIONS

for issues to address in a global workshop/consultation on IESTI

- Uncertainty and variability of the parameters
- Investigation of the practicalities of using the MRL
- Ways to improve the consumption, unit weight and bodyweight data
- Identification of additional subgroups of the population for which the assessment should be conducted, e.g. toddlers
- The adequacy of the IESTI/NESTI equations when residues from monitoring/enforcement are used
- How to improve the communication between risk assessors and risk managers and the public on the output of the risk assessment

IESTI EVENT GENEVA SEPT 2015

Stakeholder meeting 7 sept

- AIM: to collect views and contributions of stakeholders in order to use this input in the EFSA/FAO/WHO scientific workshop on 8 + 9 sept
- Attended by representatives of risk management bodies, of producing and exporting countries, of NGOs, of Industry
- Expectations of participants for workshop:
  - Global harmonisation of the equations;
  - Development of a roadmap describing the activities needed to reach that goal.

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Revisiting IESTI

IESTI EVENT GENEVA SEPT 2015

Stakeholder meeting 7 sept

Discussion on purpose of IESTI calculations:

1. evaluation of the dietary risk related to a specific use or

2. evaluation of the dietary risk related to a specific MRL

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FURTHER MESSAGES FROM STAKEHOLDERMEETING

- PAN- Europe (NGO):
  'Priority in the EU is to protect human and environmental health'
  'IESTI being over conservative is a myth'
  'IESTI must be modified according to cumulative risk assessment'

- *ECPA:*
  'Keep current IESTI equation (as applied by JMPR) until full impact is known and further work is completed'
  'Promote international harmonization between JMPR, Japan, Europe and USA / Canada'

FURTHER MESSAGES FROM STAKEHOLDERMEETING

- European Commission:
  - *'All residue levels entered up to and including the MRL should not result in ARfD exceedance'*
  - *'Revised IESTI equation should be acceptable at international level, notably Codex/JMPR'*
  - *'Overall LoP should not be lowered'*

- Exporting country (Thailand):
  - *Use MRL in IESTI as tier 1 in tiered approach*
  - *Develop guidelines on establishing unit weights*
  - *Consider processing / cooking factors*
  - *Establish a guideline for inspection on pesticide residues based on risk*

สำนักงานมาตรฐานสินค้าเกษตรและอาหารแห่งชาติ
National Bureau of Agricultural Commodity and Food Standards

IESTI EVENT GENEVA SEPT 2015

Conclusions workshop 8 + 9 sept.

IESTI EVENT GENEVA SEPT 2015: WORKSHOP

Proposal for new IESTI equations

- New IESTI equation replacing case 1 and case 3 of the current IESTI equation:

$$IESTI = LP_{bw} \times MRL \times CF \times PF$$

- New IESTI equation replacing case 2a and case 2b of the current IESTI equation:

$$IESTI = LP_{bw} \times MRL \times \nu \times CF \times PF$$

IESTI EVENT GENEVA SEPT 2015: WORKSHOP

Main recommendations

- Replace the HR and STMR by the MRL in all cases of the IESTI equation
- Use a a default variability factor of 3
- Derive the P97.5 large portion from the distribution of consumption values expressed as g/kg body weight
- Proposal to remove the unit weight from the IESTI equations
- applicable to both MRL setting for individual commodities and enforcement purposes

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IESTI EVENT GENEVA SEPT 2015: WORKSHOP

Future work - 1

- Develop a list of commodities for which the variability factor is not applicable
- Information on bulking and blending practices needs to be gathered.
- Further guidance on the derivation of conversion factors is needed (OECD?)
- Conversion factors and processing factors should be made publicly available by the risk assessors in a database.

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IESTI EVENT GENEVA SEPT 2015: WORKSHOP

Future work - 2

- Develop a harmonized and comprehensive list of commodities and certain pre-defined processed commodities for which large portion data need to be derived
- Develop a harmonized list or database compiling the large portions for the different diets at global level. Data should comply with agreed quality criteria.
- Further guidance on how to derive a large portion is required.

REFERENCES

- Info on Stakeholder meeting + workshop + presentations given:

  http://www.efsa.europa.eu/en/events/event/150907

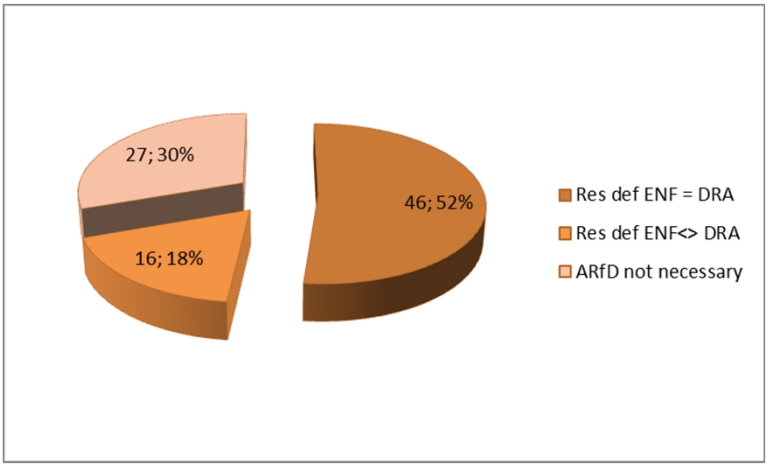
- Event Report:

  http://www.efsa.europa.eu/en/supporting/pub/907e

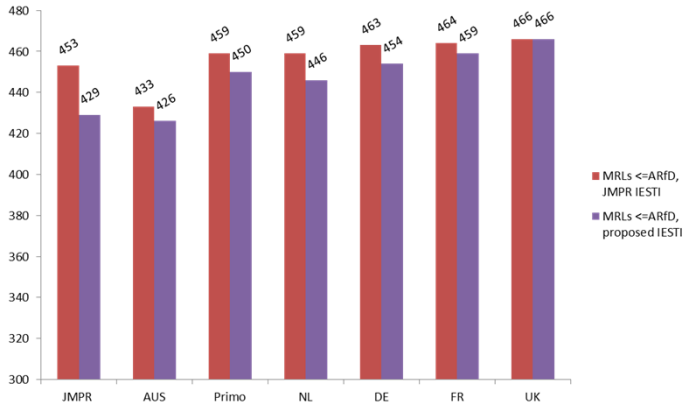
PRELIMINARY IMPACT ANALYSES

- An *ad hoc* working group with members from
  ANSES (FR), APVMA (AUS), BfR (DE), CRD (UK), EFSA, RIVM (NL) has prepared a preliminary impact assessment on the proposed changes. The assessment includes:
  - impact on number of MRLs
  - ratio of current versus proposed exposure estimates (case 1, 2a, 2b, 3)
  - commodities affected
  - influence of the number of trials in the derivation of the MRL

IESTI impact assessment; JMPR vs proposed



JMPR method versus proposed, MRLs=466 (total)



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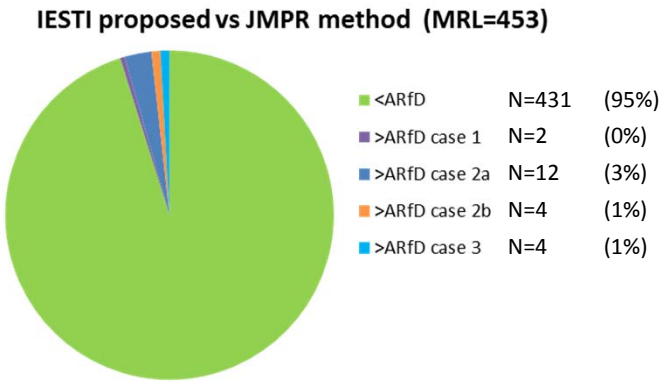
Number of MRLs affected in the proposed method



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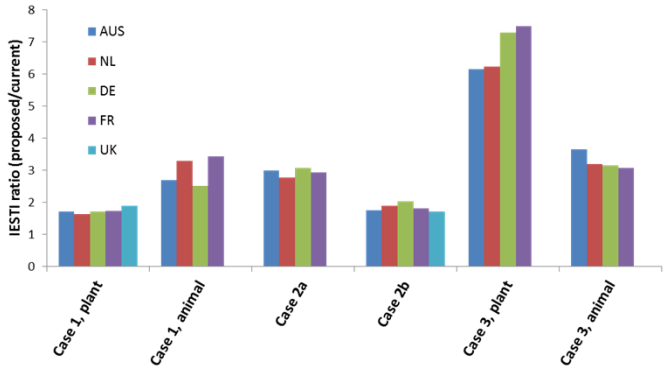
IESTI ratio proposed over current per case



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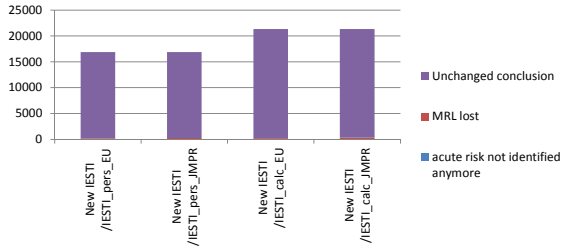
anses
alimentation, environnement, travail

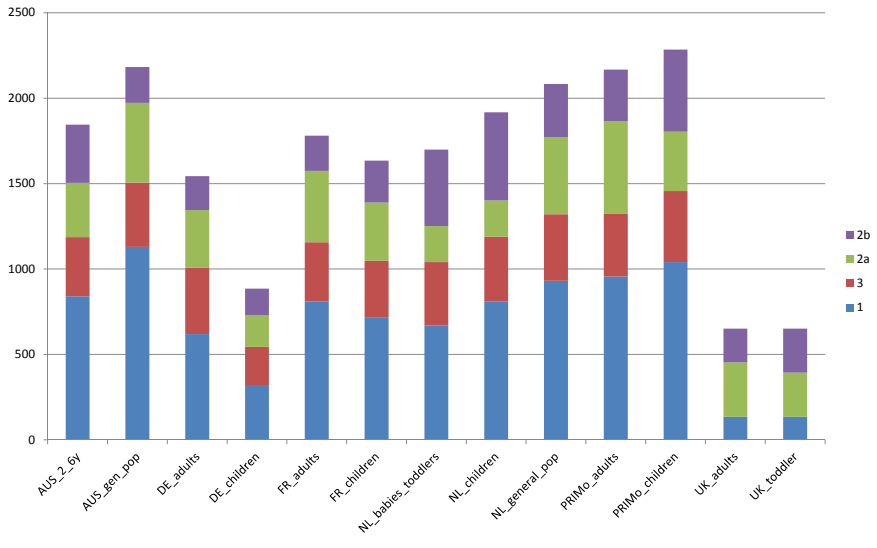
Impact of changes in IESTI calculations : use of the residue data from EU Art 12 review

Conclusion for all diets (cumulated)

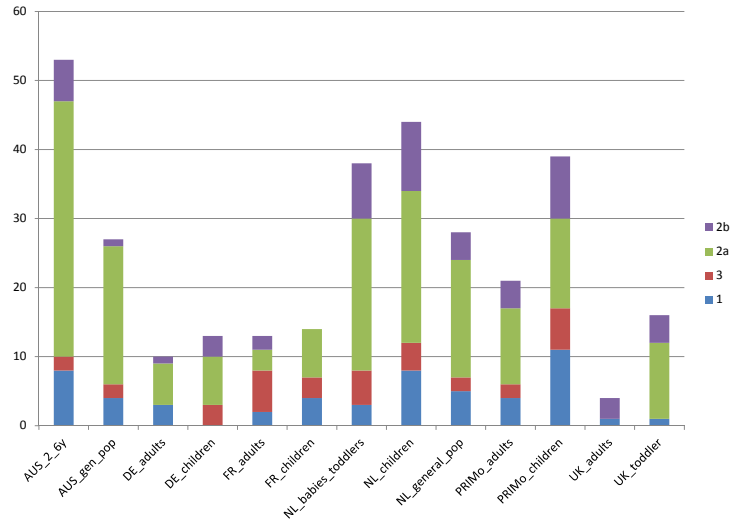
	Acute risk not identified anymore	MRL lost	Unchanged conclusion	No comparison possible	TOTAL
New IESTI /IESTI_pers_EU	29	178	16664	23559	40430
New IESTI /IESTI_pers_JMPR	1	268	16602	23559	40430
New IESTI /IESTI_calc_EU	47	203	21072	19108	40430
New IESTI /IESTI_calc_JMPR	0	320	21002	19108	40430



MRL by case for each diet

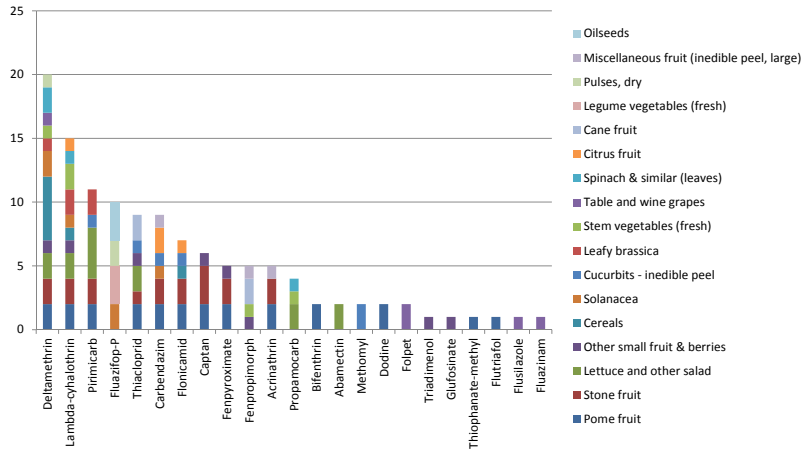


MRL lost by diet and by case



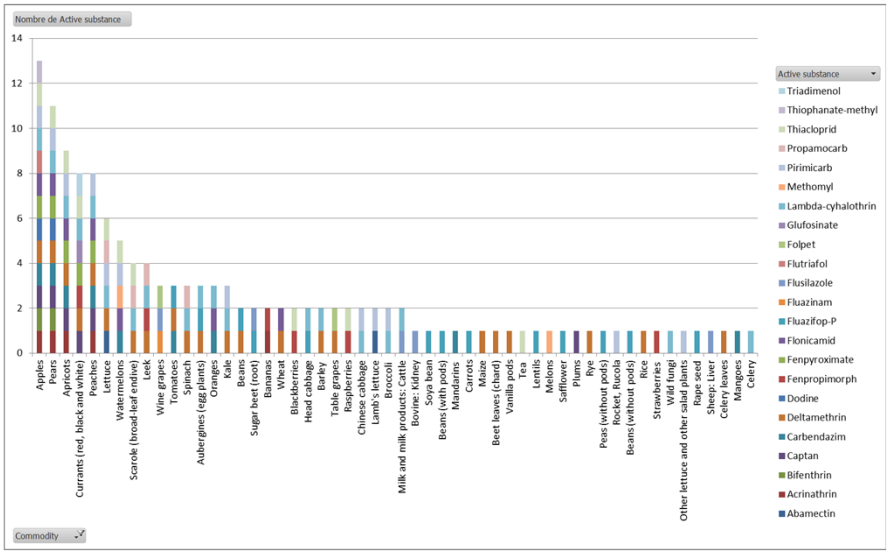
New IESTI vs IESTI-calc-JMPR

MRL lost by AS and commodity group



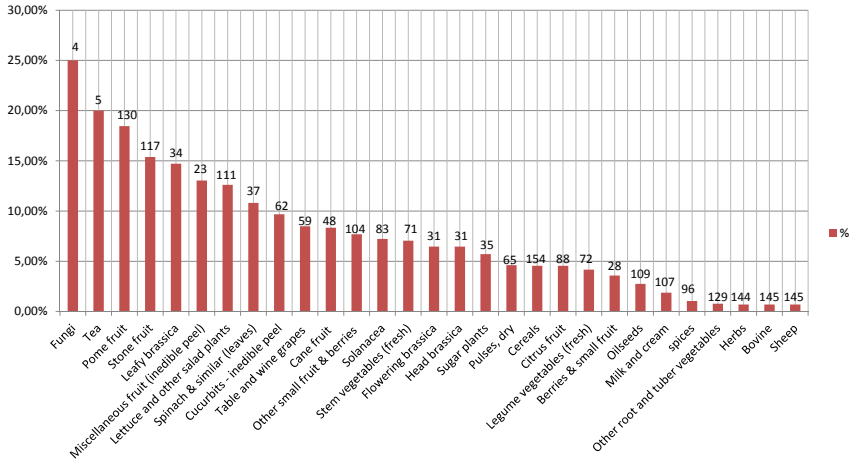
New IESTI vs IESTI-calc-JMPR

MRL lost by commodity



New IESTI vs IESTI-calc-JMPR

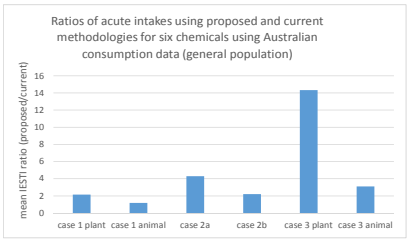
% of MRL lost by commodity group

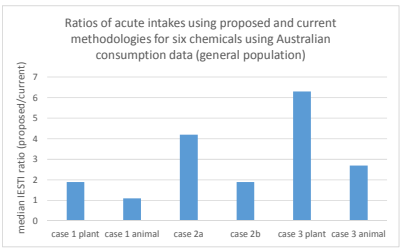


New IESTI vs IESTI-calc-JMPR

Total number of MRL for each commodity is indicated above each bar

APVMA: MEAN VERSUS MEDIAN, GEN. POP





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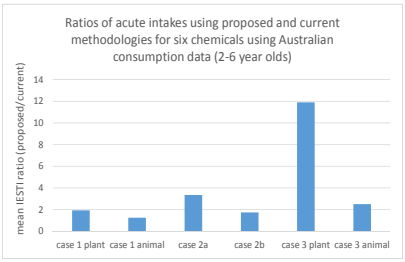
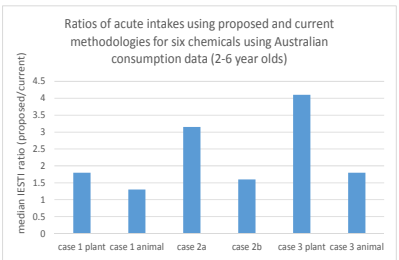
APVMA: MEAN VERSUS MEDIAN, 2-6 YEAR OLDS





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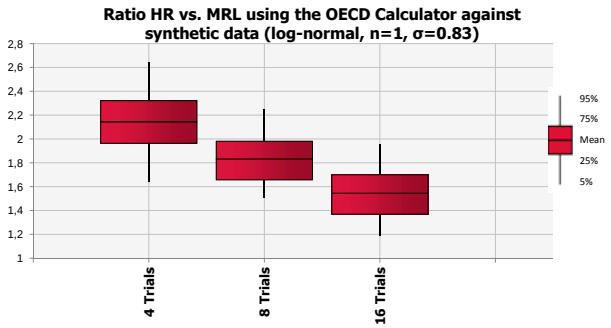
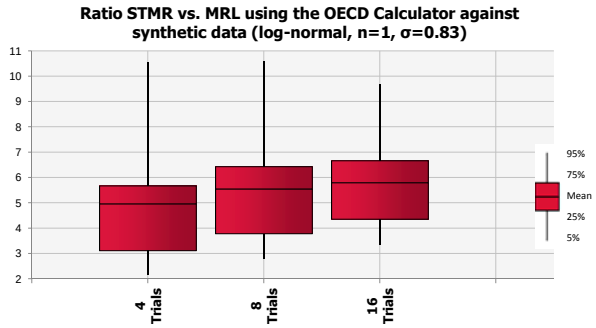
BFR: INFLUENCE OF NO. OF TRIALS

Impact of changing input parameters: HR → MRL (case 1, 2a & 2b)



BFR: INFLUENCE OF NO. OF TRIALS

Impact of changing input parameters: STMR → MRL (case 3)



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- anses
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  - Jason Lutze
  - Raj Bhula
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- HSE Health & Safety Executive /CRD:
  - Paul Hamey
- efsa European Food Safety Authority
  - Hermine Reich
  - Luc Mohimont
- National Institute for Public Health and the Environment, Ministry of Health, Welfare and Sport
  - Trijntje van der Velde-Koerts
  - Jacqueline Siljee
  - Karin Mahieu
  - Anton Rietveld
  - Bernadette Ossendorp

ROADMAP

- EFSA event report by end 2015 ✓
- Draft report considered by JMPR 2015 ✓
- Side-event at CCPR 2016 (25-30 April) ✓
- Need for further international discussions with JMPR and stakeholders and dissemination of information ✓
- Please refer to CRD3 for background information and proposal for future work ✓

THANK YOU FOR YOUR ATTENTION!

謝謝