



National Institute for Public Health  
and the Environment  
*Ministry of Health, Welfare and Sport*

## NL view on biocide MRLs

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## NL History on Biocide MRLs (I)

Prior to 2008

NL Regulation  
MRLs for  
PPP and BP

After 2008

EU  
harmonisation  
PPP MRLs

NL Regulation  
BP MRLs

- ✓ PTSA
- ✓ ICA
- ✓ CC
- ✓ BrAc
- ✓ QAC



## NL History on Biocide MRLs (II)

- ALARA principle:  
Minimize biocide residues in/on food, feed, water or livestock
- Label: risk mitigation measures
  - Remove or cover food/feed before treatment
  - Obligatory rinsing
  - Treatment out of reach of livestock
- Biocide use should not result in residues in food:  
MRL = LOQ of analytical method



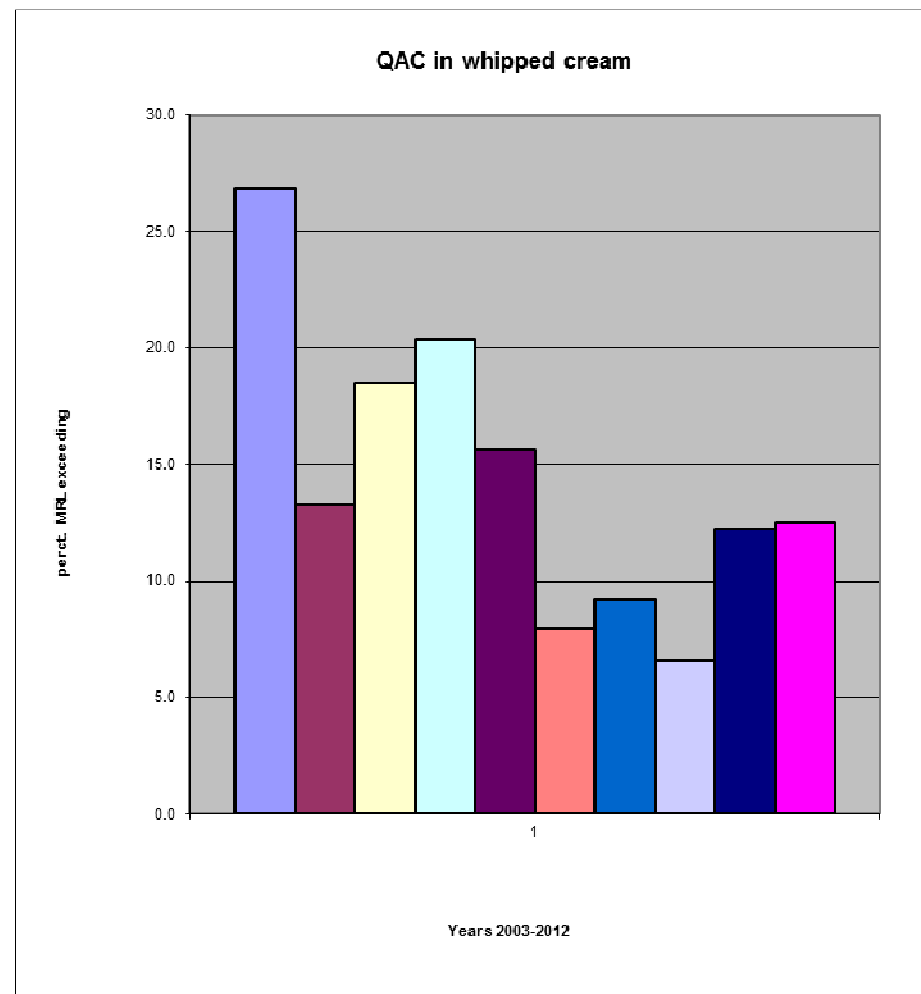
## MRL setting?

- No MRLs
  - residues identified by coincidence
  - problematic food areas and trends not easily identified
  - if identified, ad hoc dietary risk assessments necessary
  - food safety authority too late to act
- MRLs
  - monitoring program is obligatory
  - problematic food areas and trends easily identified
  - food safety authorities can act directly when MRL is exceeded
  - food producing industries and food retailers are triggered
  - ensures risk mitigation measures are followed



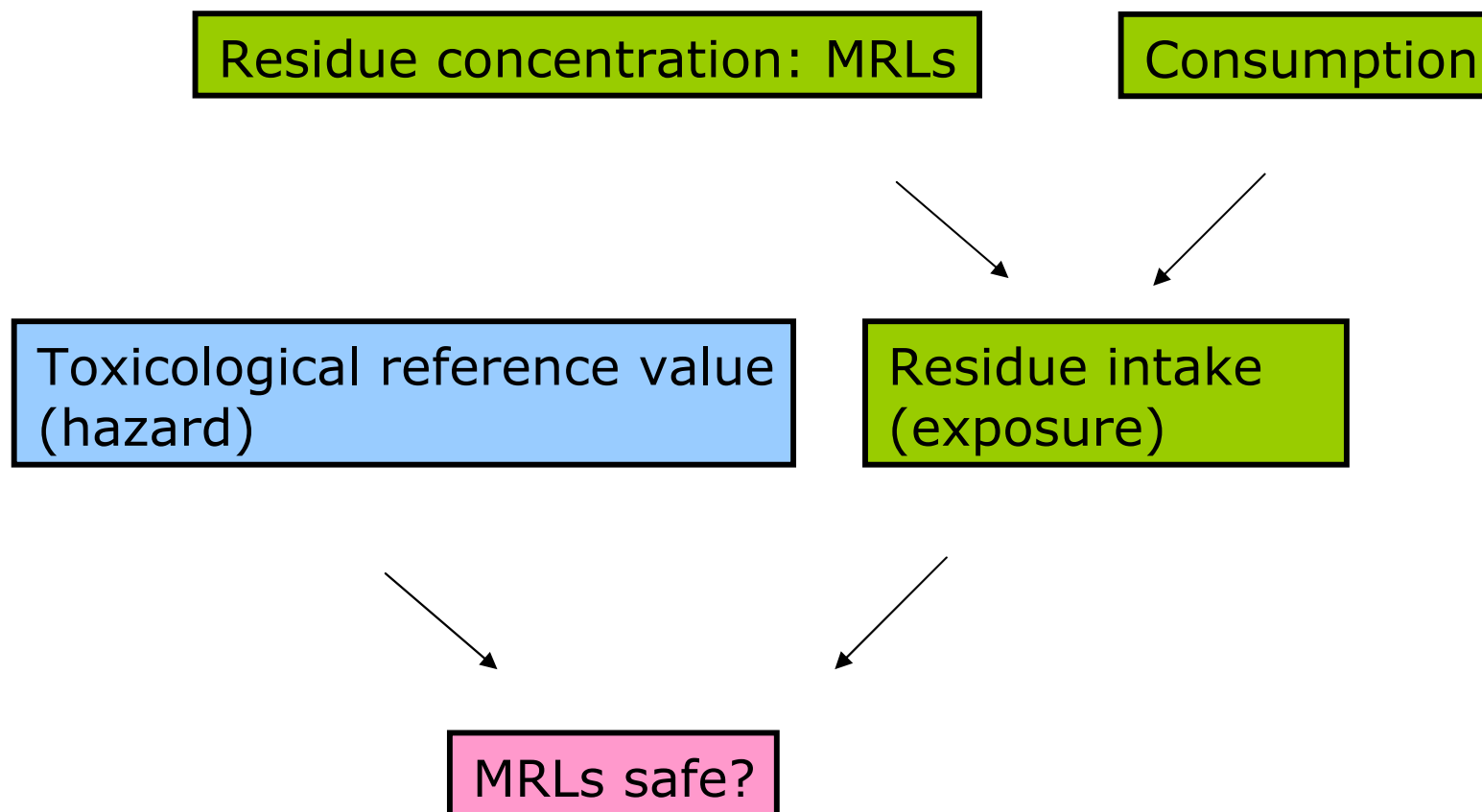
## Enforcement/monitoring in NL

- PT 4 disinfectants  
QAC - 0.5\* mg/kg  
PTSA - 0.1\* mg/kg  
ICA - 1\* mg/kg
- 2000-2012: QAC & PTSA > MRL:  
(soft) ice cream, milkshakes,  
whipped cream, cream cake,  
minced meat/beef/steak, sausages
- PT19 repellent  
DEET - 0.01\* mg/kg
- 2013: DEET > MRL: hand picked  
rosemary, wild mushrooms,  
glasswort



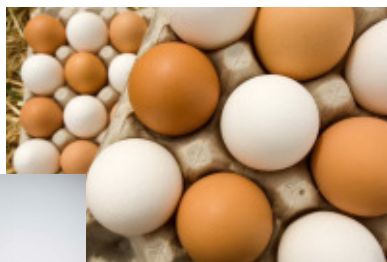
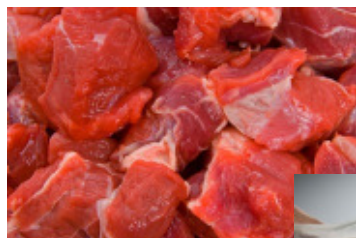


# Dietary risk assessment (I)



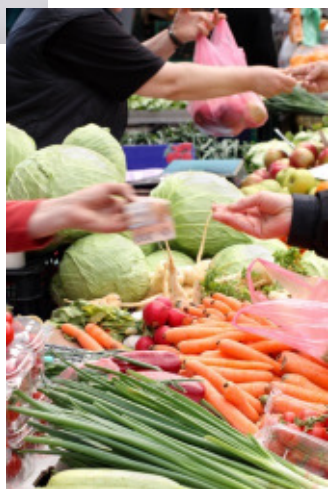


# Dietary risk assessment (II)



VMP

PPP



Raw commodities

BP



Food additives  
Contaminants  
FCM



Processed foods





# Dietary risk assessment (III)

Survey based

Screening

Level of refinement

FCM  
1 kg food  
packaged

FA budget  
method: 1.5  
kg solids and  
6 L liquids

VMP – food  
basket 0.5 kg  
meat + 1.5 L  
milk + 0.1 kg  
eggs

FAIM: 18  
food/drink groups

PPP:  
EFSA  
PRIMo

CONTAM: EFSA  
comprehensive  
database



## Dietary risk assessment (IV)

### Biocide product types identified by DRAWG (now ARTfood)

Disinfectants, Preservatives, Pest control, Antifouling	PT3, PT4, PT5 PT6, PT8, PT12 PT18, PT19 PT 21	raw, processed and mixed foods of plant and animal origin, packaged foods, drinks, water, raw fish and shellfish
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### Similarity with consumption model for food additives

Food additives	Screening	Budget method: 1.5 kg solid foods + 6 L drinks
	Survey based	FAIM: 18 groups covering all foods: raw foods of plant and animal origin (incl fish), processed foods, drinks, sweets, mixed foods, water

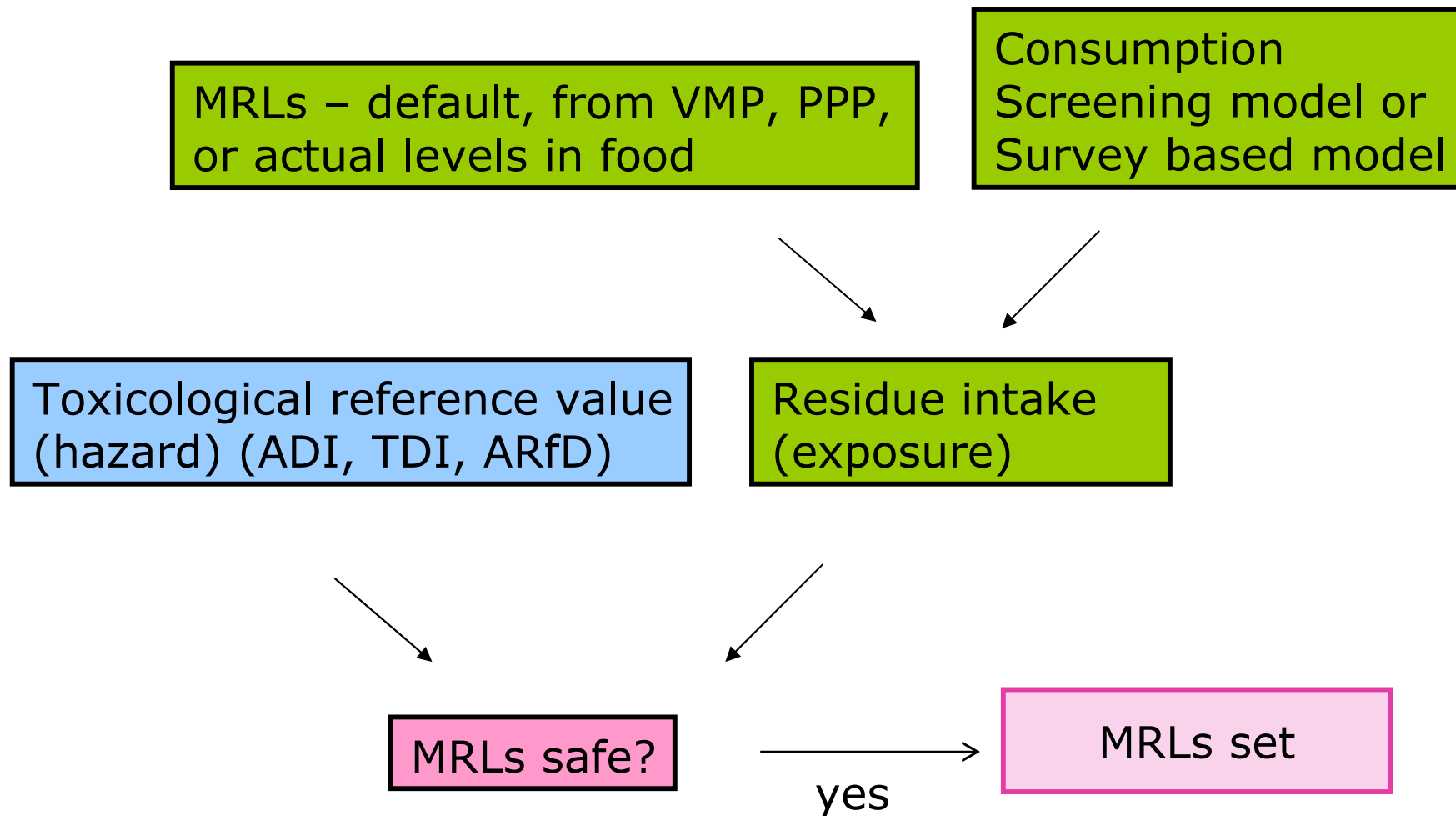


## Possible estimation biocide MRLs

- ALARA –risk mitigation measures  
**default** biocide MRL
  - 0.01 mg/kg food (as in PPP) or
  - LOQ of analytical method (as in PPP)
- **MRLs, MLs already set** for VMP, PPP, FA (in specified foods only) or SMLs set for FCM can be taken over by biocides, assuming biocide use will result in lower residues
- **Actual levels** in specified foods
  - Proposal by Applicant
    - Show biocide use is necessary
    - Show risk mitigation measures are insufficient
    - Substantiate levels in (specified) foods by studies
  - Assessment by CA



## Possible biocide MRL setting procedure





## Legislation

- **VMP** – biocides no veterinary claim, biocide residues may occur post-slaughter during/after processing
- **PPP** – biocides no use on living plants, biocide residues may occur post-harvest during/after processing
- **FA** - biocides no efficacy in final foods
- **CONTAM**– biocide use intended/regulated
- **FCM**– biocide use not limited to use in packaging materials



## Legislation

### Options for biocides

- Prepare amended legislation for biocide residues describing dietary risk methodology and biocide MRL setting procedures
- Merge MRLs in Reg 396/2005 (PPP) with Reg 37/2010 (VMP), if necessary, add additional food groups for biocides
- Committee/Procedure to coordinate VMP, PPP, BP proposals for MRLs



## Pyrethrine/Pyrethrum example

- VMP - MRLs not necessary: 1998 TMDI < ADI
- PPP - Reg EC 149/2008
  - MRLs 0.5-3 mg/kg for all plant commodities
  - MRLs 0.05\* mg/kg for all animal commodities
  - TMDI - PRIMO rev 2 – 330% ADI (3.3 x exceedance)
- BP - PT18 treatment in livestock housing
  - residues > 0.05\* mg/kg in raw animal commodities
- BP MRLs cannot be taken from VMP or PPP
- VMP MRLs <> PPP MRLs;
- 45% ADI for VMP, 55% ADI for PPP ??
- ADI is exceeded, who decides which MRLs go?

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## Recommendations/summary

- Biocide residues are not zero
- ALARA principle –risk mitigation, MRL setting, monitoring
- MRL set at default level of 0.01\* mg/kg or LOQ  
MRL taken over from VMP/PPP  
MRL at actual levels (no alternative & risk mitigation difficult)
- Amend existing legislation – dietary risk model – MRL procedure
- Merge MRL list for VMP and PPP and add biocide MRLs
- Coordination for VMP – PPP – BP MRLs