Regulation and assessment of chemical residues in Australia

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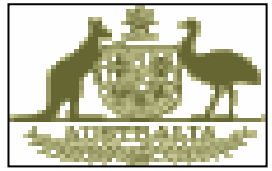
Overview of presentation

- Overview of food regulatory environment
- Introduction to Maximum Residue Limits (MRL)
  - Role
  - Agencies involved
- Previous approach (Applications)
- New procedure (Proposals)
- Reforms (COAG) that are underway
- Dietary exposure assessment
- Summary

About FSANZ



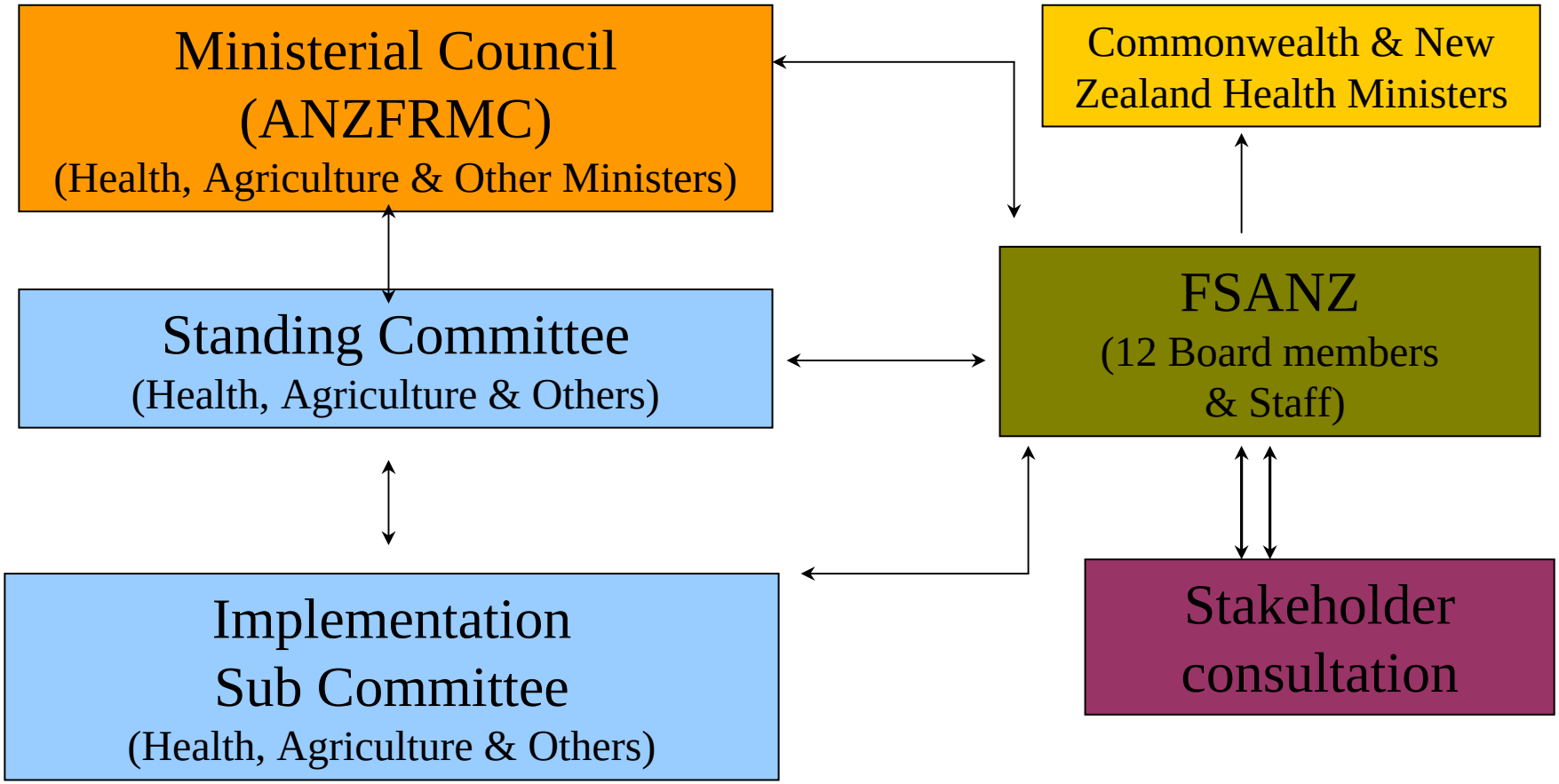
- A bi-national government agency
- Partnership between Australian Government, States and Territories of Australia (8), and New Zealand Government
- Role:
  - Ensure safe food by developing effective food standards in Australia and New Zealand
  - Open and accountable system
- Strong scientific/technical capability

OUR OBJECTIVES

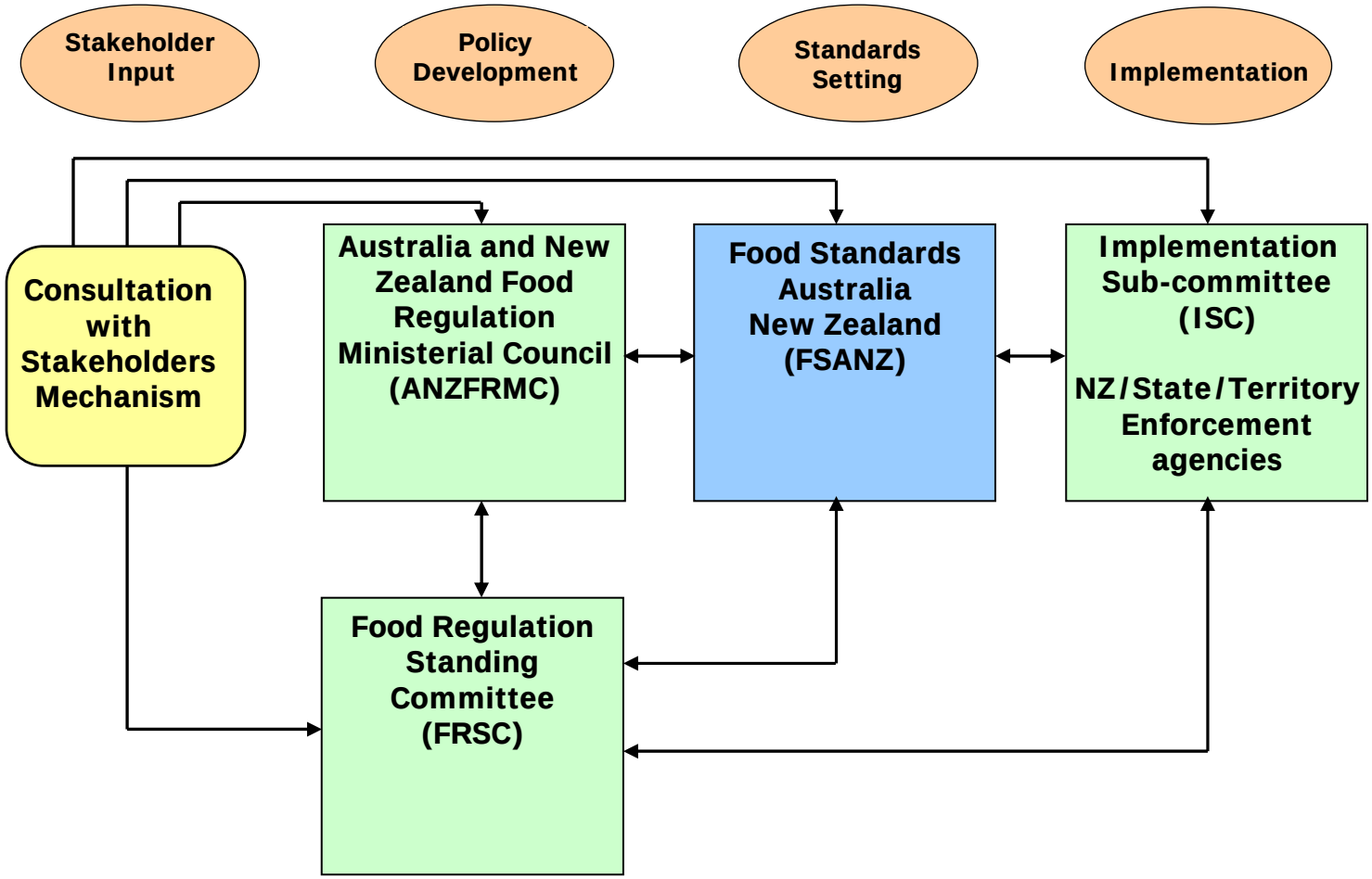
- Protection of public health and safety
- Provision of adequate information relating to food to enable consumers to make informed choices
- Prevention of misleading and deceptive conduct

UNDERLYING PRINCIPLES FOR ACHIEVING OUR OBJECTIVES

- Standards based on risk analysis using the best scientific evidence
- Promotion of consistency between domestic and international standards
- Desirability for an efficient and internationally competitive food industry
- Promotion of fair trading in food
- Other principles as formulated in Ministerial Council policy guidelines

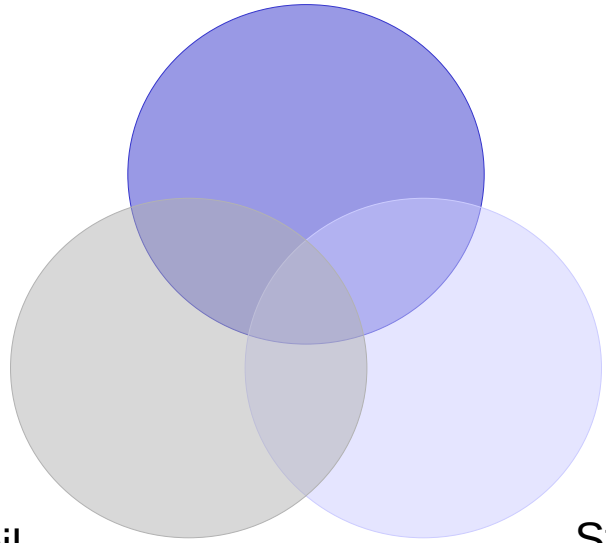

Ministerial Council (ANZFRMC)
(Health, Agriculture & Other Ministers)
Commonwealth & New Zealand Health Ministers
Standing Committee
(Health, Agriculture & Others)
FSANZ
(12 Board members & Staff)
Implementation Sub Committee
(Health, Agriculture & Others)
Stakeholder consultation

FSANZ's role in food regulation system



Food regulatory system

Standard setting
FSANZ (consistent with Codex)



Policy
Ministerial Council
(States/Territories/Aust/NZ)
(health/agriculture portfolios)
FSANZ Act

Enforcement
States/Territories/ISC
FSANZ (monitoring)
AQIS (imported foods)
Local government

Legislative Framework for food

Trade Practice/Fair Trading
Commonwealth, States/Territories & New Zealand

FSANZ FOOD STANDARDS CODE

Environmental Legislation

Agricultural Legislation

Food/Health Laws
States/Territories
New Zealand

Import Controls
Commonwealth &
New Zealand

Maximum Residue Limits (MRL)

- The maximum permitted level of a chemical that may be in a food based on agricultural data not the level that is usually present in a treated food
- Supports the enforcement of Good Agricultural and Veterinary Practices
- Allows the legal sale of safe and legitimately treated food.
- Protect the consumer by ensuring that residues are no higher than is necessary for effective disease and pest control

Agencies involved in MRL setting

- Australian Pesticides and Veterinary Medicines Authority (APVMA)
  - Registration agricultural and veterinary products
  - Setting of MRLs based on Good Agricultural Practice (GAP)

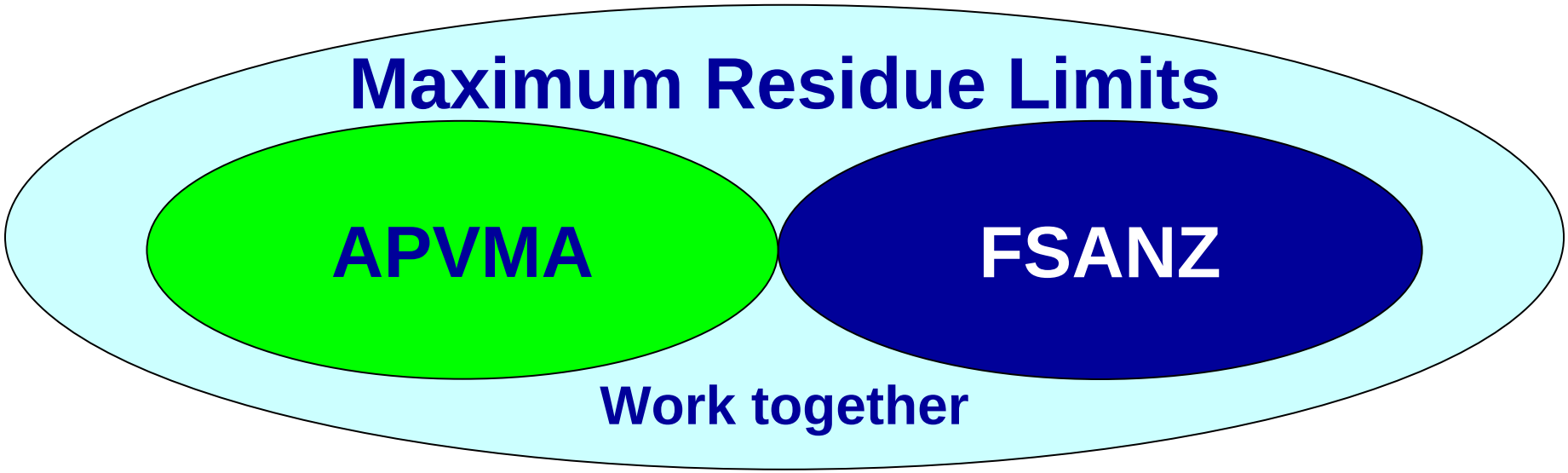
- Australian Office of Chemical Safety
  - Establishes reference health standards
  - Acceptable Daily Intake (ADI) and Acute Reference Dose (ARfD)

Agencies involved in MRL setting

- Food Standards Australia New Zealand
  - Review dietary exposure assessment
  - Adopt MRLs into Food Standards Code

- State and Territory Health and Agricultural agencies
  - Monitoring and compliance of residues in food

Collaborative approach

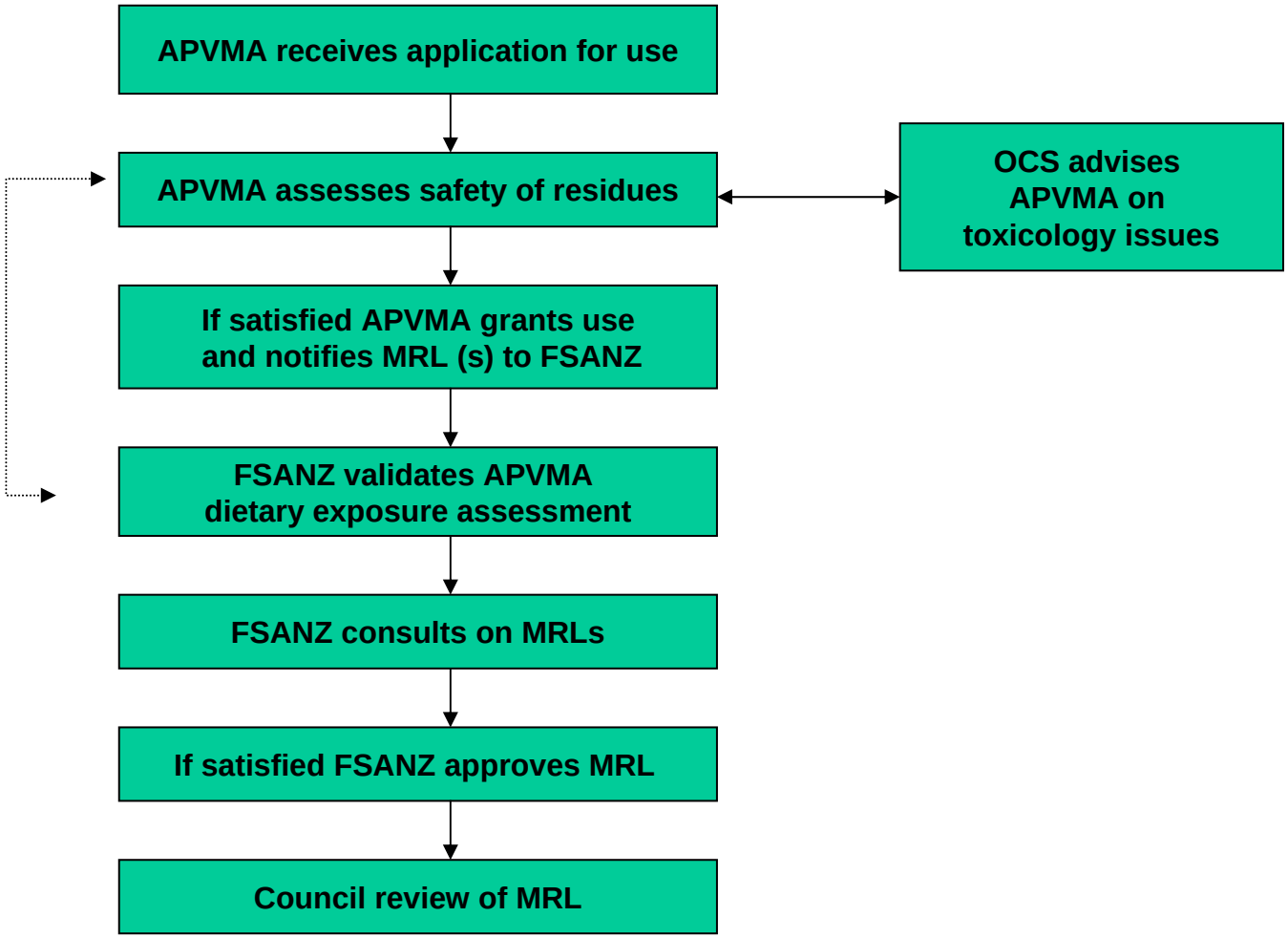


To ensure that the **use of chemical products** and **any subsequent chemical residues in food** are **safe for human consumption**.

Approach (pre October 2007)

- MRL notified to FSANZ by APVMA via application to change Code
- MRL based upon the domestic use in Australia.
- Specific MRL adopted in Code (Standard 1.4.2) for various commodities
- One round of public consultation

Approach (pre October 2007)



Role of FSANZ

- Dietary exposure assessment check for MRLs notified by the APVMA
- Assesses submissions to FSANZ which could make a legitimate case for an MRL different from that notified by the APVMA
- Applications may be made direct to FSANZ for any MRL

Note: FSANZ does not have expertise in assessing residue data or determining an appropriate MRL from residue data

MRLs and New Zealand

- MRLs are outside the scope of the joint food standards setting system (the Treaty)
- New Zealand and Australia separately and independently develop their own MRLs

Problems with previous approach

- Time delays
  - Legally treated food could not be sold under food legislation
- Does not allow sale of imported food that have residues that are safe and from legitimate use that are higher than domestic MRLs
- Therefore, does not currently allow recognition of:
  - Codex MRLs
  - Other countries MRLs

New approach for MRL setting

- New amendments to the FSANZ Act (1 October 2007)
  - Streamlined MRL setting procedures to reduce time delays
  - FSANZ raises a Proposal rather than receive an Application
  - Allows FSANZ to consider MRLs other than APVMA's
- FSANZ undertakes an assessment and final approval (includes one round of public consultation)
- MRLs are notified to Ministers for consideration

New reforms

- Productivity Commission Report
  - Early harvest reforms on plastics and chemicals regulation agreed by Council of Australian Governments (COAG) on 3 July 2008
  - Recognition by FSANZ of APVMA risk assessment and promulgation of MRL into the Code
- Aim
  - To improve the efficiency between FSANZ and APVMA
  - MRLs set by APVMA automatically adopted into Code

Proposed overall framework

- Development of MRLs must be a scientifically robust, open and transparent process
- FSANZ will conduct all dietary exposure assessments as apart of APVMA's risk assessment process
- Ministerial Council (MINCO) retains right to review MRL
- FSANZ will still have the capacity to consider MRLs for imported foods (eg Codex)

Dietary Exposure Assessment

- Combines food consumption data and food chemical data to estimate dietary exposure to food chemicals

$$\text{Dietary Exposure} = \frac{\text{Food consumption} \times \text{Food chemical concentration}}{\text{Body weight}}$$

Food consumption data

Most recent Australian National Nutrition Survey (NNS) data:

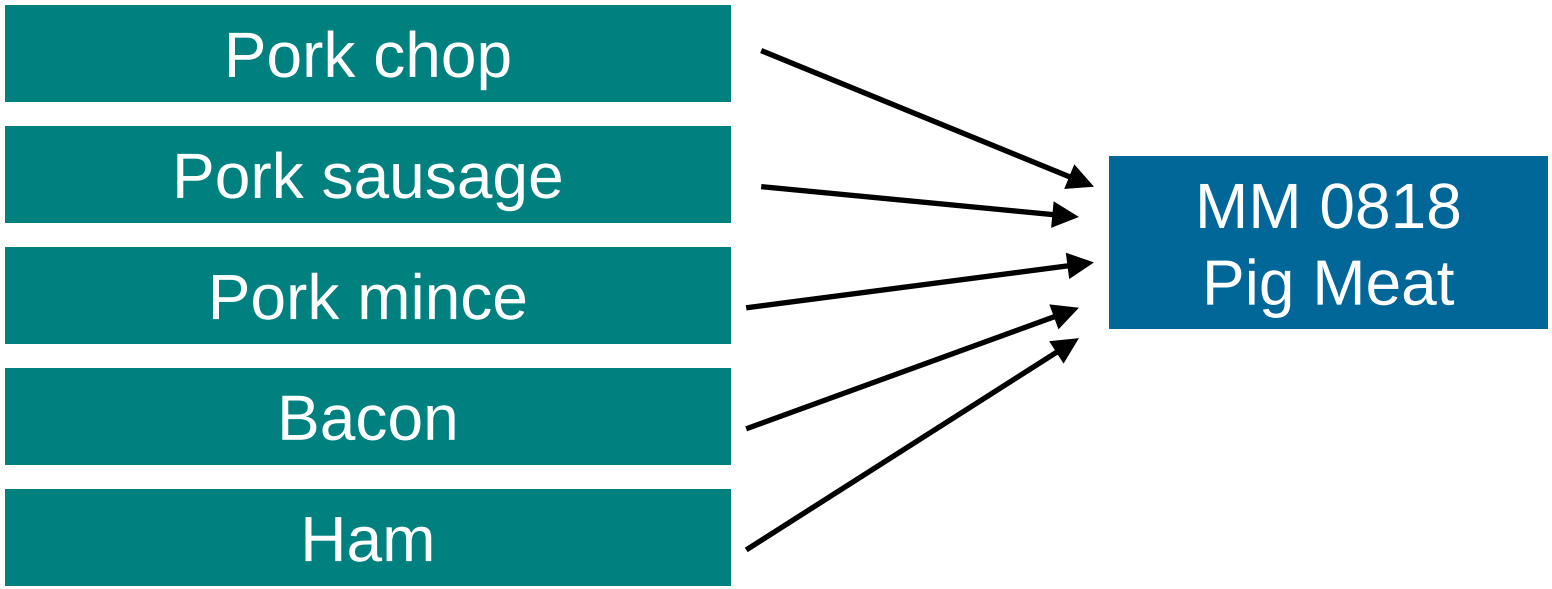
- Conducted 1995 over 12 months
- 13 858 respondents
- Aged 2 years and above
- 24-hour food recall method

2007 Children's Nutrition & Physical Activity Survey data:

- In use mid 2009

Food consumption data

Foods eaten in nutrition survey matched to commodities assigned MRLs

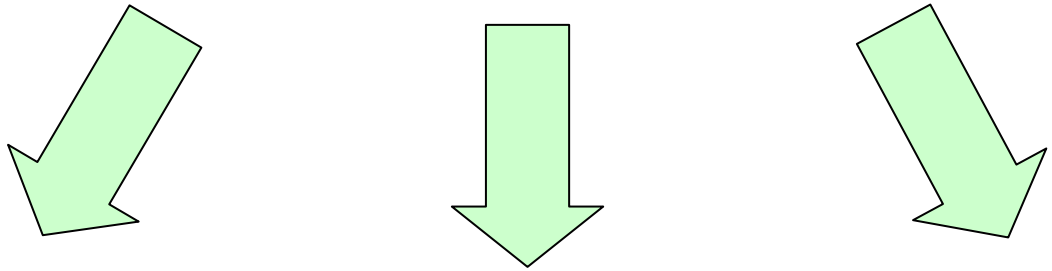


Food consumption data

Chronic assessments – mean daily consumption for the whole population 2 years and above

Acute assessments – 97.5th percentile consumption over 24-hours for the consumers of food of interest for population 2 years and over and children 2-6 years

Sources of pesticide residue data

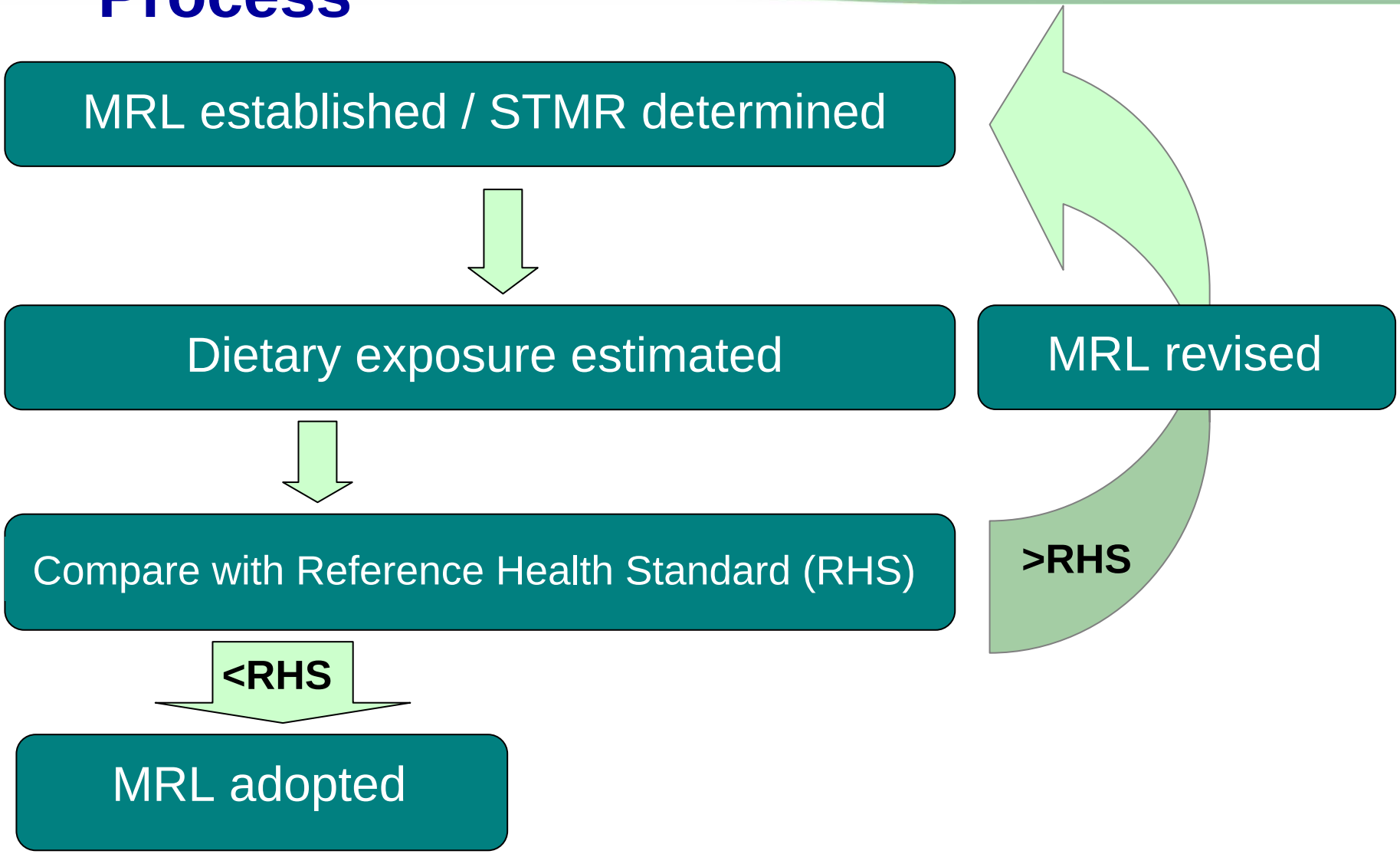


Maximum Residue Limits

Analytical/ Trial/Survey Data

Processing Factors

Process


MRL established / STMR determined
Dietary exposure estimated
Compare with Reference Health Standard (RHS)
<RHS
MRL adopted
>RHS
MRL revised

Chronic Dietary Exposure Assessment

- National Estimated Dietary Exposure (NEDI)
  - Mean food consumption x STMR x PF
    (MRL used if no STMR supplied)
  - Total exposure calculated with all commodities listed for a specific chemical/s
  - Compared to the ADI

STMR – Supervised Trials Medium Residue
PF - Processing Factor

- The NEDI can be defined as:
  - NEDI =Sum of Fi x STMR-P
  - Where Fi is average amount of the commodity reported as consumed by the whole population and STMR-P is the supervised trial median residue level od the corresponding food commodity, incorporating processing/edible portion factors where appropriate.

NEDI example

Chemical Name – X

ADI – 0.03 mg/kg bw/day

Calculation – $\frac{(\text{STMR x Mean Consumption} \div 1000)}{\text{ADI}}$

Food Code	Food Name	STMR (mg/kg)	Mean Consumption (g/kg bw/day)	NEDI (mg/kg bw/day)	%ADI
FP0226	Apple	0.4	0.9	0.00009	
FC	Citrus Fruits	0.5	2	0.001	
MO0105	Edible Offal (mammalian)	0.02	0.02	0.0000003	
ML	Milks	0.02	9	0.0002	
	TOTAL			**0.0012903**	**4.0**

Additional information

- Australian Total Diet Study (ATDS)
  - Includes assessment of many pesticide residues
  - Past studies:
    → dietary exposures well below Australian or international reference health standards
    →no public health and safety risk

http://www.foodstandards.gov.au/monitoringandsurveillance/australiantotaldiets1914.cfm

Example of mancozeb

- NEDI calculation estimated that mancozeb exposure is 120% of the ADI

<u>however</u>

Results from the 19th ATDS estimate that mancozeb exposure is less than 1% of the ADI

Acute Dietary Exposure Assessment

- National Estimate of Short-term Intake (NESTI)
  - Exposure calculated for individual commodities only
  - Follows the approach outlined by the Joint FAO/WHO Meetings on Pesticide Residues

    Compared to the ARfD
  - Equation used depends on type of commodity (3 different equations – Case 1, 2, & 3)

Commodities in Case 1, 2 & 3 equations

- Case 1 – Composite samples e.g. small sized fruit & vegetables (peas), meat, grains/oilseeds/pulses if post-harvest use of pesticides
- Case 2 – Single fruit & vegetable units (orange, apple)
- Case 3 – Bulked or blended commodities e.g. milk, grains/oilseeds/pulses if pre-harvest use of pesticide

NESTI example – Case 3 commodity

Milk with an MRL of 0.02 mg/kg for chemical X

ARfD – 0.03 mg/kg

Calculation – (LP x STMR) ÷ bw

LP (Large Portion) = 97.5th percentile food consumption

NESTI (all) = (1.987 kg Milk x 0.02 mg/kg Milk) ÷ 67 kg

= 0.00059 mg/kg bw/day

= 2% of the ARfD

NESTI (2-6y) = (1.450 kg Milk x 0.02 mg /kg Milk) ÷ 19 kg

= 0.0015 mg/kg bw/day

= 5% of the ARfD

Summary

- Co-operative approach with other agencies to set MRLs
- Rigorous risk assessment assures safety of residues in food
  - Follow international best practice
- New reforms will improve efficiency of incorporating MRLs into the Code
  - Other countries' MRL and Codex MRLs can still be considered

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