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)

Standing Committee (Health, Agriculture & Others)

Implementation Sub Committee (Health, Agriculture & Others)

Commonwealth & New Zealand Health Ministers

FSANZ (12 Board members & Staff)

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

Food/Health Laws
States/Territories
New Zealand

Import Controls
Commonwealth &
New Zealand

Environmental Legislation

Agricultural Legislation
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
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)

1. APVMA receives application for use
2. APVMA assesses safety of residues
   - If satisfied APVMA grants use and notifies MRL(s) to FSANZ
3. OCS advises APVMA on toxicology issues
4. FSANZ validates APVMA dietary exposure assessment
5. FSANZ consults on MRLs
   - If satisfied FSANZ approves MRL
7. Council review of MRL
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

- Pork chop
- Pork sausage
- Pork mince
- Bacon
- Ham

MM 0818 Pig Meat
Food consumption data

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

**Acute assessments** – 97.5\(^{th}\) 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)

MRL revised

> RHS

< RHS

MRL adopted
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 \( F_i \times STMR-P \)
  – Where \( F_i \) is average amount of the commodity reported as consumed by the whole population and \( STMR-P \) is the supervised trial median residue level of the corresponding food commodity, incorporating processing/edible portion factors where appropriate.
NEDI example

Chemical Name – X
ADI – 0.03 mg/kg bw/day
Calculation – (STMR x Mean Consumption ÷ 1000)

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

Example of mancozeb

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

however

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 – \( (LP \times STMR) \div bw \)

\( LP \ (Large\ Portion) = \) 97.5\(^{th}\) percentile food consumption

\[ \text{NESTI (all)} = \frac{1.987 \text{ kg Milk} \times 0.02 \text{ mg/kg Milk}}{67 \text{ kg}} \]
\[ = 0.00059 \text{ mg/kg bw/day} \]
\[ = 2\% \text{ of the ARfD} \]

\[ \text{NESTI (2-6y)} = \frac{1.450 \text{ kg Milk} \times 0.02 \text{ mg/kg Milk}}{19 \text{ kg}} \]
\[ = 0.0015 \text{ mg/kg bw/day} \]
\[ = 5\% \text{ of the ARfD} \]
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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