FSANZ: standards setting and risk management

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Risk Management and Intelligence Branch
Outline

• The food regulatory system
• Ministerial priorities
• Key Risk analysis principles
• Standards setting
• Risk management
• Examples
• Take home messages
• Questions?
Who are we?

• We are a statutory authority within the Australian Government Health portfolio, established by an Act of the Australian Parliament
  – Canberra: 102 staff
  – Wellington: 13 staff

• Our main function is to develop and administer the *Australia New Zealand Food Standards Code*

• Not responsible for enforcement
Food regulatory system depends on effective collaboration.
Objectives

• Protect public health and safety by maintaining a safe food supply.
• Provides consumers with information about food so they can make informed choices.
• Prevents misleading and deceptive conduct.
• Have regard to:
  – Risk analysis based on best available science
  – Consistency between domestic and international standards
  – Efficient and internationally competitive food industry
  – Fair trade in food
  – Policy guidance given by the Australia New Zealand Food Regulation Ministerial Council
What doN’T we do?

• Not responsible for interpretation or enforcement
Risk analysis at FSANZ

Codex Risk Analysis Framework

Risk Assessment
Science based

Risk Management
Policy based

Risk Communication
Interactive exchange of information and opinions concerning risks

EVIDENCE

SURVEILLANCE/MONITORING
Ministerial priorities

- **Priority 1**: reduce food borne disease
- **Priority 2**: support public health objectives
- **Priority 3**: Maintain a strong, robust and agile food regulatory system
FSANZ and Standards setting

• The process is in the FSANZ Act 1991 - open and transparent (workplan)
• Any individual or organisation, can make an ‘Application’ to FSANZ seeking to change the Code – Application Handbook
• FSANZ may also seek to change the Code by preparing a ‘Proposal’
Standards development

- **APPLICATION RECEIVED**
  - Assessment
    - Public notification (call for submissions)
      - Draft regulatory measures developed
        - Applicant notified
          - Public notification
            - Approval
              - Ministerial Council notified
        - Approval
          - Ministerial Council notified
    - Application accepted
      - Applicant notified
        - Early bird public notification
          - Major Procedure
          - General Procedure
            - Assessment
              - Draft regulatory measures developed
                - Applicant notified
                  - Public notification
                    - Approval
                      - Ministerial Council notified
          - Minor Procedure
            - Assessment
              - Draft regulatory measures developed
                - Applicant and appropriate government agencies notified
                  - Approval
                    - Ministerial Council notified
<table>
<thead>
<tr>
<th>Procedure</th>
<th>Hours</th>
<th>Hourly Charge</th>
<th>Admin Charge</th>
<th>Total Fees $AUD</th>
<th>Indicative Total Fees $NZ¹</th>
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<td>Minor Procedure</td>
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<td>11,500</td>
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<td>Maximum of 1000 hours</td>
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<td>125,000</td>
<td>156,250</td>
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<td>More than 1000 hours</td>
<td>115,000+**</td>
<td>10,000</td>
<td>125,000+**</td>
<td>156,250+</td>
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<td>Major Procedure</td>
<td>1200 hours or more</td>
<td>138,000***</td>
<td>10,000</td>
<td>148,000+***</td>
<td>185,000+</td>
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Our Ministers

• Food Regulation Ministerial Council
  – The Council reviews food standards approved by FSANZ.
  – The Council provides broad policy on food issues, which FSANZ must have regard to when it is developing and approving food standards.
  – The Council is chaired by the Federal Health Minister
Gazettal

• If the Ministerial Council agrees, the change to the Code is gazetted.
• The official government gazettes.
• The changes to the Code automatically become law under food legislation.
The Australia New Zealand Food Standards Code

Chapter 1
General food standards:
- Definitions
- Labelling requirements
- Use of substances added to food
- Use of new foods
- Contaminants & natural toxicants
- MRLs (Aus)
- Food processing requirements (Aus)

Chapter 2
Food product standards:
- Cereals
- Fruits
- Vegetables
- Dairy products
- Beverages
- Special purpose foods

Chapter 3
Food safety standards
- Food safety programs
- Food premises and equipment

Primary production standards
- Production and processing of seafood
- Poultry meat
- Meat, and
- Other commodities

Chapter 4
Permissions for use of:
- substances added to food
- use of new foods
- Permitted MRLs

Schedules
Food technologist’s view of a chocolate fish

• Marshmallow (70%): This is the pink gooey bit inside. Marshmallow probably first came into being as a medicinal substance, since the mucilaginous extracts come from the root of the marshmallow plant (Althaea officinalis), which was used as a remedy for sore throats. In the in early 19th century the French pioneered the innovation of whipping up the marshmallow sap and sweetening it, to make a confection similar to modern marshmallow. Eventually the sap was replaced by either egg albumin or gelatine as the sap was too hard to extract and hey presto, modern marshmallow was here! (so much for the sore throat). The sugar and water is heated to a certain brix (% of dissolved soluble solids), then the gelatine is added and the mass is aerated to a specific density (which will give a specific deposited weight) and then cooled to around 60°C and deposited into trays of corn starch, in which a fish shape has been made. The starch (dried to approx. 6% moisture) has an oil content also to repel the marshmallow, but allow some transfer of moisture into the starch at the same time. The trays are traditionally wooden but have been replaced by plastic because of risk of splinters which you don’t want in a fish. The trays are stacked into trolleys and imaginatively named “stacks” and are left to dry in humidity controlled starch ovens (read a big warm room) for several days. After this, they are emptied and excess starch is removed by compressed air and then the starch is recycled for the next round. Dark Chocolate (30%): Note this is dark chocolate (full of antioxidants and makes you feel good!) made using cocoa butter and not dark “compound chocolate” which contains vegetable oil. Enrobed with approx. 12 PaS chocolate, PaS (or Pascal Second) is the measure of viscosity for chocolate which measures the resistance of a rotating cylinder in chocolate measured at 40°C. Chocolate needs to be tempered properly, it has 6 (I-VI) types of fat crystals that melt at difference temperatures, initially its heated to around 43°C to melt all types, then cooled to set the types I-V (around 28°C) and re-heated (up to 32°C) with the aim forming the most of the type V crystals as possible, which are the most stable. The ripples on top are from the enrober blower removing excess chocolate to ensure target enrobing % is met, as chocolate is expensive! Sugar; Used for the marshmallow and in the chocolate to counteract the bitterness of the cocoa beans. Glucose Syrup; Used as a humectant to keep the marshmallow soft during its shelf life. Water; Used to dissolve gelatine and liquefy the sugar to form the marshmallow. Cocoa Mass; Finely ground roasted kibbled cocoa beans which are refined down to a determined micron size to ensure a smooth mouthfeel. Mixed with cocoa butter to form a paste. Invert Sugar; Prevents the re-crystallisation of the granular sugar and ensures a nice smooth marshmallow. The term invert refers to the rotation of the linkages between the glucose and fructose molecules of sucrose when treated with acid in the presence of heat. The molecules rotate backwards and appear to stand on their heads or are upside down, or “inverted”. Gelatine; Forms the protein structure that traps the air in the marshmallow and firms product on cooling. Halal suitable as well!

• Vegetable Fat; Ah ha, vegetable fat (personally, I’d call it “oil”) which is from the milk chocolate compound used to bottom the marshmallow prior to enrobing with chocolate. The bottom (or “bottoming”) is the hardest part to enrobe, so a low PaS (thin) compound is used to fill any bubbles/holes left from depositing the marshmallow and is difficult for the chocolate to fill. The bottoming used to emboss the Cadbury name onto the base of the fish, however the cost of the embossed belts and the increasing numbers of non-Cadbury branded products made now, put a stop to that in the early 2000’s. Cocoa Butter; Contained in the chocolate, with extra used to viscositise (thin) the chocolate for enrobing. Milk Solids; Contained in the chocolate compound used for bottoming. Emulsifier (Soya Lecithin); Increases the “yield” for the chocolate, that is, the degree to which chocolate flows outwards on a surface. It also emulsifies the chocolate ingredients and prevents bloom on storage. Flavour; In the marshmallow, Strawberry I’m guessing. Colour (120); Cochineal (Carmine dye), sourced from the Cochineal insect. The dye is be extracted from the body and eggs, then mixed with aluminium or calcium salts to make carmine dye, also known as Cochineal. Beware vegetarians! It contains soy, sulphites, nuts and milk but is a gluten free confection. Hooray, at least it’s gluten free!
Principles for managing risks

- Protecting the ‘population at large’
- Evidence base
- Consultation
- Options to mitigate risk
- Response is proportionate to risk
- Meeting international and legislative obligations
Examples

• Food Irradiation
• Bisphenol A
• Cassava
• Mercury
• Fortification of food with plant sterols
Food Irradiation
Food

Ionising Radiation

Food

Radiation Source

Cobalt-60
Caesium-137

Electron beam
≤ 5 MeV

X-ray
≤ 10 MeV
<table>
<thead>
<tr>
<th>Dose Range</th>
<th>Effects</th>
<th>Application</th>
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</thead>
<tbody>
<tr>
<td>0.1 to 1.0 kGy</td>
<td>Inhibit sprouting</td>
<td>Tubers</td>
</tr>
<tr>
<td></td>
<td>Delay ripening</td>
<td>Bananas</td>
</tr>
<tr>
<td></td>
<td>Insect disinfestation</td>
<td>Fruit (quarantine treatment)</td>
</tr>
<tr>
<td></td>
<td>Parasite inactivation</td>
<td>Pork (trichinella)</td>
</tr>
<tr>
<td>1 to 10 kGy (30 kGy spices)</td>
<td>Reduce non-sporulating pathogens</td>
<td>Meats, fish, spices</td>
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<tr>
<td></td>
<td>Reduce spoilage organisms (extend shelf-life)</td>
<td>Strawberries, mushrooms, dried fish</td>
</tr>
<tr>
<td>Above 25 kGy</td>
<td>Reduce pathogens to point of sterility</td>
<td>Hospital/space/army diets; ready-to eat lightweight foods</td>
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</tbody>
</table>
The Standard

• Standard 1.5.3
  – Requirements
  – Approvals to date
  – Safety: chemiclearance; feeding studies; 2ACB’s; cat and dogs (?)
  – Nutrition
  – Current strategic issues
  – Labelling (next slide)
Labelling

- Irradiated foods required to be labelled or information otherwise provided in connection with the food, to give consumers an informed choice
  - Radura symbol optional
  - Electronic pasteurisation (NO!)
  - Positive labelling (yes)
Bisphenol A

• Effects in animals led to focus on possible effects in humans
  – Reviews by several agencies (USFDA, EFSA, Canada, Japan)
  – Tolerable daily intake (TDI) established
  – Exposure levels low and do not pose a risk

• Recent events:
  – Banned in Canada, Denmark, France, Germany, Sweden and some US States
  – Ongoing studies in US

• FSANZ targeted survey of BPA
  – Collaborate with other domestic and international regulators
Mercury in fish

• MLs in place for mercury in the Code
• JECFA (2003) lowered its recommendation on safe consumption of methyl mercury
• FSANZ revised its risk assessment
• Risk Management
  – dietary advice for general population especially pregnant woman and women intending to become pregnant to limit consumption certain species of fish
• WHO/FAO expert meeting 2009 on risk/benefits of fish
Apricot kernels

- Cyanogenic glycosides (hydrocyanic acid)
  - Consumed in excess (cyanide poisoning)
  - High risk of becoming ill
  - Alert issued Nov 2011, recall initiated July 2014
  - Must be rendered safe before consumption
Plant sterols

• Approved in range of foods (Novel)
  – Edible spreads, low-fat milk, yoghurt, lower fat cheese, breakfast cereals
• Robust risk assessment supports safety
• Managed by limits, labelling statements and education initiatives
• Issues
  – Suitability of Food vehicle
  – Stakeholder management
  – Transparency (Fact Sheets)
Key messages

- Australia and New Zealand’s food regulatory system is a unique partnership between both countries
- Open and transparent statutory processes for food standards
- FSANZ value submissions from stakeholders
- FSANZ continues to keep watch on
  - Emerging hazards/risks
  - We use risk management principles to manage risks in the food supply
  - We manage uncertainties in the science
Our strategy is to be:

• a trusted source of advice on food
• a leader in its areas of expertise
• the source of wisdom on emerging risks
• deeply engaged with stakeholders
• effective and efficient
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