Ministry for Primary Industries
Manatū Ahu Matua

Innovation in the production of infant formula and avenues to regulate these products

Presented by Dr Tasha Williams
Senior Market Access Counsellor
New Zealand Ministry for Primary Industries

Introduction

Overview

- New Zealand food safety story
- Regulation of infant formula in New Zealand
- Food Standards Australia New Zealand (FSANZ) update
- Codex update
- Innovation in infant formula
- Reactionary regulation changes

Ministry for Primary Industries
Manatū Ahu Matua

New Zealand Food Safety

Haumaru Kai Aotearoa

Ministry for Primary Industries
Manatū Ahu Matua

New Zealand Story

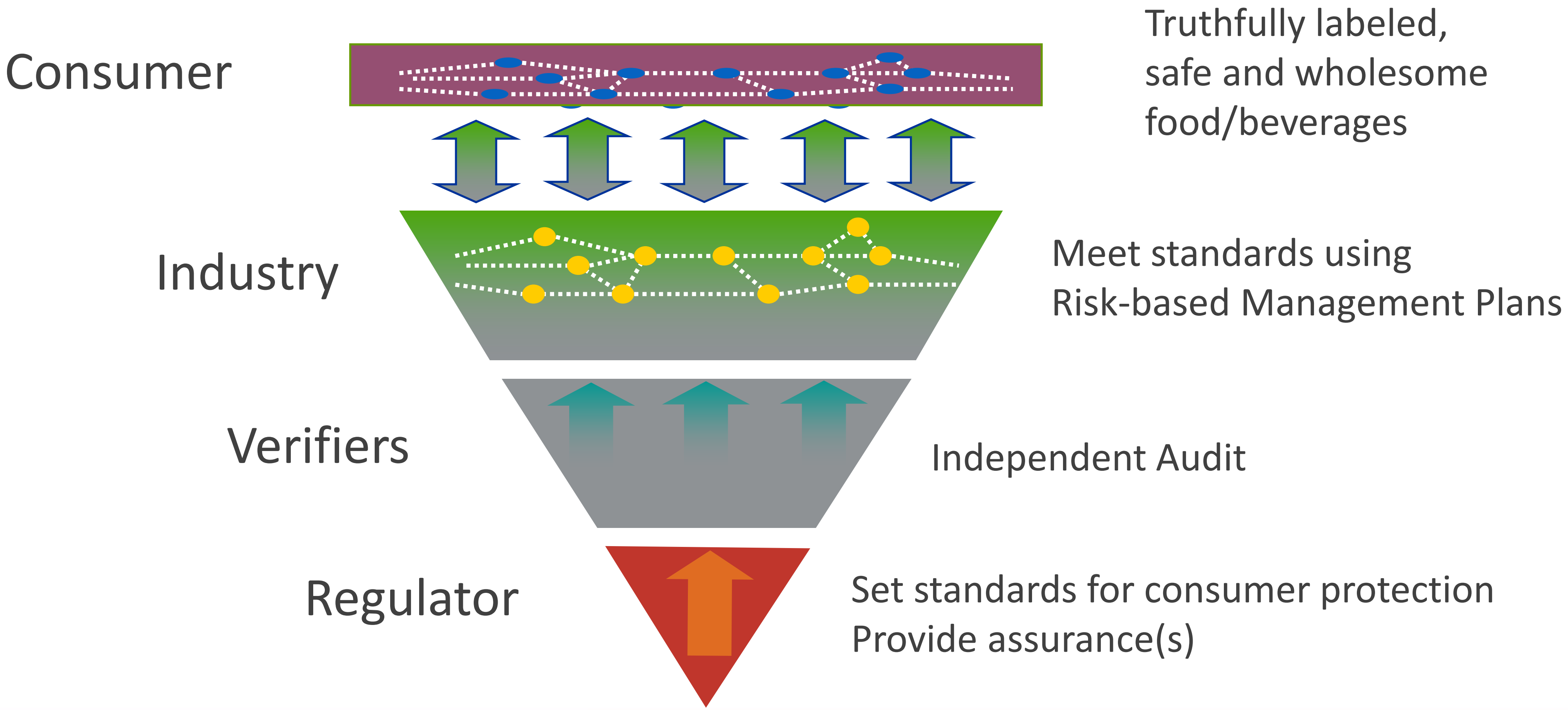
New Zealand Story

- Systemic approach
- Science-based evidence
- Risk analysis
- WTO Sanitary and Phytosanitary Agreement

New Zealand Story

- Food Safety Risk Management Framework
- Operational Regulatory Model
- Operator “ownership”
- Third Party Performance Based Verification

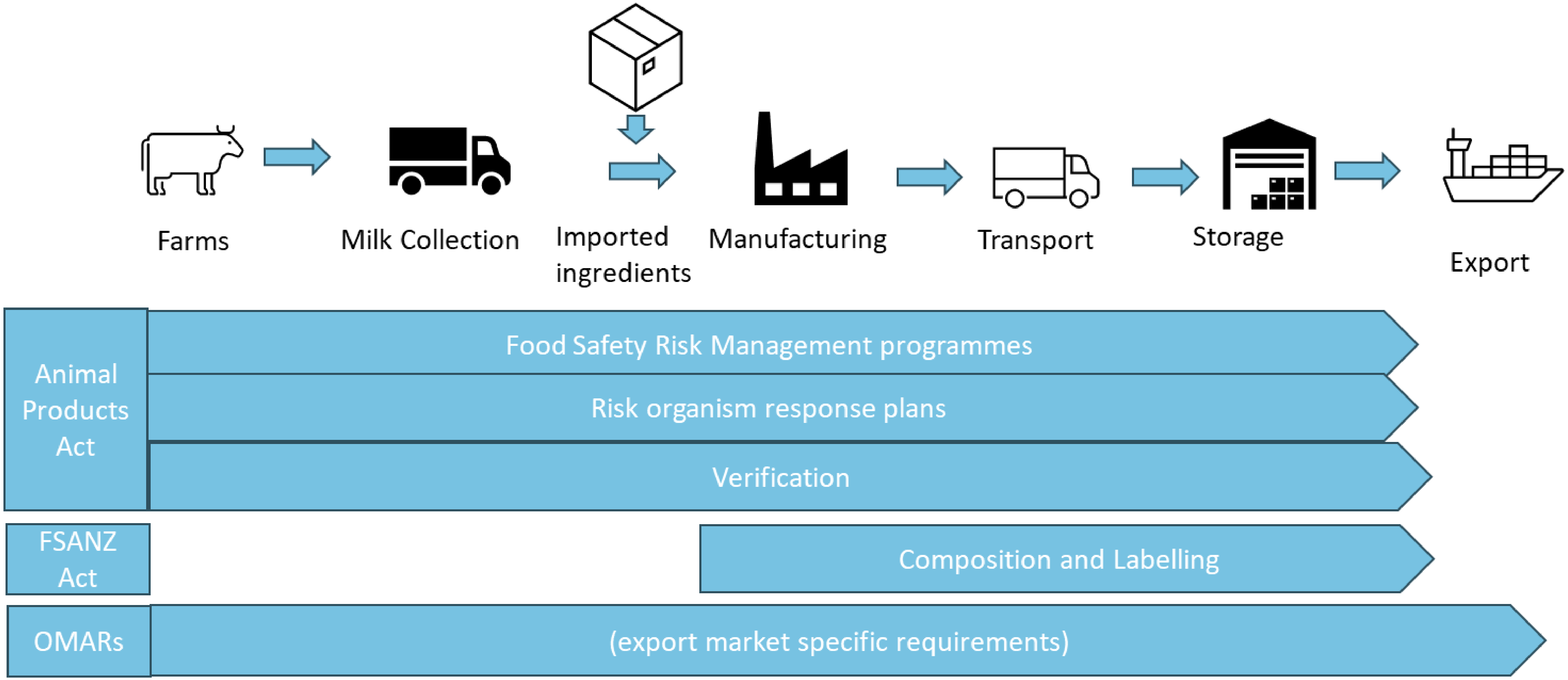
Regulatory model



Regulation in New Zealand

- **New Zealand government recognise that breastfeeding is the recommended way to feed infants. Although breastfeeding is the recommended way to feed infants, a safe and nutritious substitute for breast milk is needed for infants who are not breastfed.**
- Preventative system
- Those who trade in food are responsible for the safety and suitability of that food
- Food processors have responsibility to demonstrate compliance
- Risk and science based system (HACCP and risk analysis)
- A change from a heavily prescriptive production, processing, inspection system model to a balance of outcome-based, process-based with some prescriptive regulations
  - Risk Management Programme

Food regulatory context



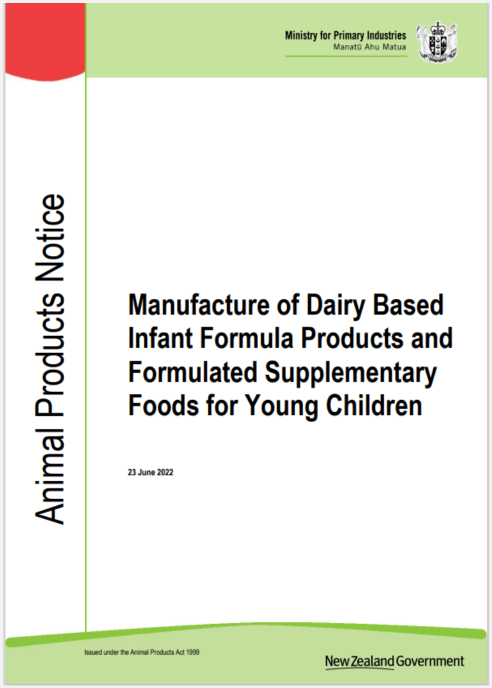
RMP Amendment Process

Any significant change in a process (including changes to supporting systems) that could introduce new risks the operator must:

- Apply to MPI for a significant amendment
- Have updated RMP evaluated
- On-site 3rd party evaluation
- Gain MPI approval

- https://youtu.be/jrrPn9Aun7U

Regulation of infant formula


Animal Products Notice

Ministry for Primary Industries
Manatū Ahu Matua

Manufacture of Dairy Based Infant Formula Products and Formulated Supplementary Foods for Young Children

23 June 2022

Issued under the Animal Products Act 1999

New Zealand Government

- Importing country requirements for composition, microbiological criteria and labelling must also be met before exporting

FSANZ – Regulation of infant formula

General compositional requirements:

- Final product composition **must** meet mandated energy, fat, protein, vitamin, mineral and electrolyte levels
- The composition and labelling requirements for Infant Formula and Follow-on Formula are regulated through the Australia and New Zealand Food Standards Code
- Vitamins and minerals are specified, with minimum and maximum levels set (or a Guideline Upper Level)
- Express permission required to add novel foods, nutritive substances, genetically modified (GM) foods, food additives and processing aids
- Permitted voluntary addition for certain substances (e.g. 2'-FL, L-carnitine, lactoferrin, lutein)

FZANZ – Regulation of infant formula

General labelling requirements:

- Prescribed nutrition information to be declared on the label
- Required warning, directions and statements
- Nutrition content claims and health claims are prohibited
- Prohibited representations (e.g. no pictures of an infant, or that idealise the use of formula product) to align with WHO Code
- Prohibition on label = prohibited in advertising

Changing the Food Standard Code

- Anyone can apply to FSANZ to change the Code – via an application
- Applicants must provide certain information to demonstrate safety, suitability and evidence of a benefit.
- Approval generally 9-12 months from assessment start
- Public consultation – either 1 or 2 rounds
- Food Ministers' Meeting – consider whether to accept, amend or seek a review of the change

FSANZ Proposal P1028 – Infant formula

- To revise and clarify standards relating to infant formula products in the Food Standards Code
- Regulatory objectives:
  - Protect the health and safety of formula-fed infants
  - Require adequate information to ensure their safe preparation and use, and enable carers to make an informed choice
  - Consistency and advances in scientific knowledge
  - Align with relevant international and overseas regulations (e.g. Codex), as appropriate in the Australian and NZ context
  - Industry innovation and/or trade is not hindered
- Anticipate gazettal in Food Standards Code in mid-late 2024 with a 5-year transition period

New Zealand and Codex

- Founding member
- Recognise the importance of international standard development
- Support the mandate of Codex: protecting consumers’ health and ensuring fair practices in the food trade
- Actively involved in leading the development of Codex standards
- New Zealand’s food regulatory systems and food standards are informed by and aligned with Codex standards, guidelines, and recommendations to the extent possible

CODEX ALIMENTARIUS
INTERNATIONAL FOOD STANDARDS

Codex review of the follow-up formula standard

- Lead by New Zealand
- Covers products for older infants (6 – 12 months) and young children (12 – 36 months)
- Extensive review informed by a strong global evidence base
- The updated Standard is significantly improved from the previous 1987 version

Innovation in infant formula

OECD definition of “innovation”:

The implementation of a new or significantly improved product (good or service), or process, a new market method, or a new organisational method in business practices, workplace organisation or external relations.

18th century	**First chemical analyses of human milk and animal's milk began to appear**
1760	Jean Charles Des-Essartz published his Treatise of Physical Upbringing of Children, which discussed and compared the composition of human milk to that of the cow, sheep, ass, mare, and goat
Pre 19th century	Infants fed inadequate breast milk substitutes suffered from high mortality (sevenfold higher than in breastfed infants). Only alternative to wet nurses – cow, sheep and goat milk – few of these infants survived. Included child suckling directly from an animal's teat
1810	Nicholas Appert developed a technique to sterilize food in sealed containers (food preservation)
1835	Invention of evaporated milk patented by William Newton
1845	First Indian rubber nipple was introduced
1851	first feeding bottles created in France. Contained a cork nipple and ivory pins at air inlets to regulate flow
1853	68 different formulations for infant feeding were recommended in Germany suggesting that none of them was satisfactory
1853	Gale Borden (US) added sugar to the evaporated milk, canned the substance, and sold it as Eagle Brand Condensed Milk, which became a popular infant supplement
1865	Justus von Liebig (Professor of chemistry, University of Giessen, Germany) developed and patented 'soup for infants', the first breast milk substitute based on chemical human milk analysis made from a combination of cow's milk, wheat flour, malt flour, and potassium bicarbonate - human milk analysis was first used as guidance for designing macronutrient composition
1867	Heinrich Nestle who was born and trained as a pharmacist in Frankfurt/Main (close to Giessen) marketed his 'Kindermehl' ('children's flour') in Vevey, Switzerland
1880s	Attempts made to decrease the poorly tolerated casein in cow's milk, for example by treatment with pancreatic extracts
1885	John B. Myerling developed an unsweetened condensed milk, labeling it as "evaporated milk." Myerling's product was also a popular choice for infant feeding and was highly recommended by pediatricians from the 1930s to the 1940s
1885	Alexander Backhaus, Professor of agriculture at Göttingen, Germany, introduced a further major innovation – a whey protein-dominant formula, which was well tolerated

Late 1880s	Backhaus opened a laboratory to analyze milks made according to his recipe, the ‘Nutricia-Zentrale’.
1896	A simpler, open-ended, boat-shaped bottle was developed in England, became popular, and was sold well into the 1950s
1896	Backhaus sold the rights both for this formulation and for the name ‘Nutricia’ to Martinus van der Hagen in the Netherlands, who opened his company Nutricia (now Danone Baby Nutrition) in 1901 and produced products following the ‘Backhaus method’
1899	Joseph Hipp in Pfaffenhofen, Germany mixed a rusk flour with cows’ milk to feed infants
1901	Martinus van der Hagen opened his company Nutricia (now Danone Baby Nutrition) and produced products following the ‘Backhaus method’
1910	Finkelstein and Meyer pediatricians in Berlin developed Eiweissmilch an infant formulation acidified by bacterial fermentation with the aim to enhance tolerance and to reduce infectious risk
1912	Rubber nipples that were easy to clean became available, and many homes were able to store milk safely in an icebox
1915	Formula contained cow milk, lactose, oleo oils, and vegetable oils; powdered form
1920s	Researchers were removing the cow milk fat and substituting it with vegetable oils, decreasing protein levels, and adding specific vitamins and minerals
1929	Introduction of commercially available soy formula (soy flour)
1930	Emil Pauly produced ‘Pauly’s nourishment’ along lines of the Hipp formula
1930s	Günther Malyoth (paediatrician, Hauner Children’s Hospital, University of Munich) developed a lactose-based sugar preparation that presented prebiotic effects of infant feeding and achieved enhanced growth of bifidobacterial in infant stools. A predecessor of later products with added prebiotic oligosaccharides
1935	Protein content of formula considered
1948	Johann Baptist Mayer proposed concept of benefits of live bacteria in infant feeds, and developed an infant formula with added lactic acid producing bacteria that achieved modification of the infant stool flora. A predecessor of current probiotic formula concepts

1951	**The first non-powder infant formula hit the shelves and rapidly became the most popular product available on the infant formula market**
1959	Iron fortification introduced
1960	Renal solute load considered; formula as a concentrated liquid
1962	Whey:casein ratio similar to human milk
Mid 1960s	Amino acid taurine Taurine fortification introduced which helps with fat absorption and liver function
1984	Isolated soy protein introduced
1994	Lonnerdal and Hernell identified that the high bioavailability of iron from lactoferrin in human milk allows for a much lower concentration of iron in human milk compared with infant formulas and thereby decreases competition between iron and other divalent cations, such as copper and zinc
Late 1990s	Nucleotide fortification introduced, which help with weight gain and head growth
Early 2000s	Long-chain polyunsaturated fatty-acid fortification introduced (in the form of DHA and ARA), which are meant to help with brain development
2000s	Approach to formula science in the 21st-century represents a philosophical sea change - a chemical approach to food Which is to say that we took breast milk apart, looked at the combination of protein, carbohydrate, fat, and vitamins, and tried to make formula a chemical surrogate for breast milk
2000s	Introduction of extensively hydrolysed formula for allergy management
2003	Formulas containing hydrolysed protein for prevention of allergy and food intolerance in infants
The Future	Not everything in breast milk needs to be replicated in formula. Components that are not essential nutrients but provide other benefits are only now being recognized. The new approach looks at what breast milk does, not merely what it is. What is breast milk doing that formula isn't doing? For one, using protein much more efficiently. "Breast milk protein is unusually effective as a source of protein," German Paediatric Professor says

References

Koletzko B (2010)"Innovations in Infant Milk Feeding: From the Past to the Future"

Gose J "Creating a Better Formula"

Institute of Medicine (U.S.). Committee on the Evaluation of the Addition of Ingredients New to Infant Formula (2004) Infant formula : evaluating the safety of new ingredients / Committee on the Evaluation of the Addition of Ingredients New to Infant Formula, Food and Nutrition Board.

Stevens E et al (2009) A History of Infant Feeding

Innovation in infant formula products

- Recent FSANZ approvals for new substances (with associated conditions):
    - 2′- fucosyllactose
    - lacto-N-neotetraose
    - Bovine lactoferrin
    - 3'-sialyllactose sodium salt
    - 6'-sialyllactose sodium salt
- 15-month period of exclusive use may apply

Government – Industry initiative

https://youtu.be/b59PEyDlW0w

Sustainable Food and Fibre Futures

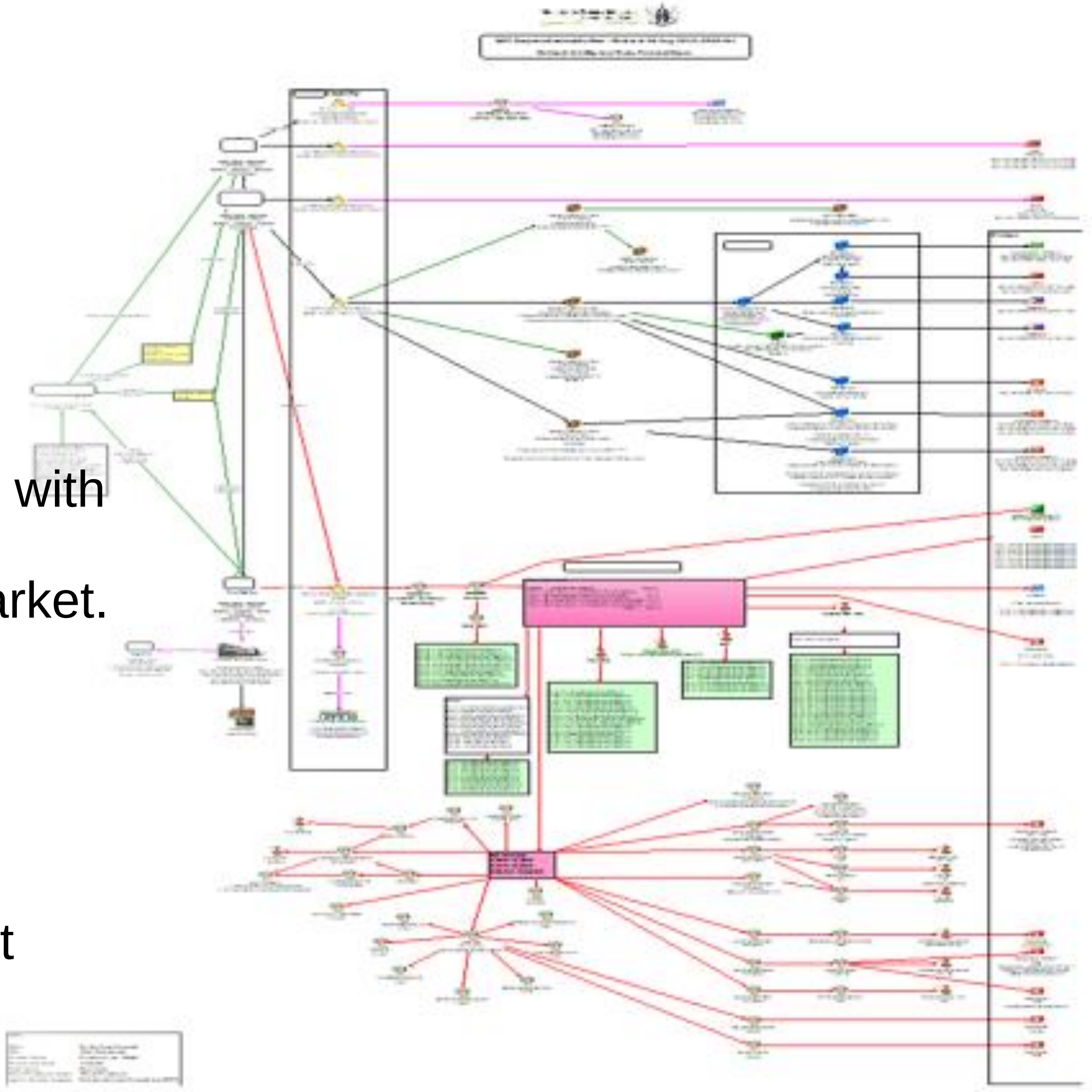
Goat milk infant formula

The challenge

- The industry needs to show that goat milk infant formula has benefits for infants compared to conventional formula. This has to be backed by clinical evidence and market insights.
- To enhance the natural features of goat milk for infant feeding, the industry needs:
  - farm system innovation – to deliver a proven superior and natural infant formula alternative
  - the right tools – to grow in a sustainable manner.

How can events bring about regulatory change?

- WPC 2013
- Potential contamination event with potentially affected product, including infant formula, in market.
- Extensive investigation and traceability exercise.
- In the end it was deemed no product affected.
- This resulted in a Government Inquiry and many regulatory changes.



Threats

- 2014 threat to poison infant formula with the poison 1080
- Involved MPI, police, other government agencies and industry
- Changes enacted immediately:
  - increased security at infant formula factories
  - Introduced a new 1080 testing programme
  - Increased vigilance throughout the supply chain
  - Increase audits
  - Strengthened security at retail stores
  - Messaging to consumers

Summary

- A robust food safety system is an essential platform to enable innovation in infant formula products;
- Regulatory change may also be necessary to enable innovation.
- Events and issues may be a useful trigger for regulatory change.

I would like to acknowledge the following who contributed to this presentation

- Helen Riley, MPI Manager Food Science
- Charlotte Channer, MPI Market Access Counsellor (and Codex Rep)
- Dr Chris Kebbell, MPI Food Safety Officer
- Dairy Companies Association of New Zealand
- Australia and New Zealand Infant Nutrition Council

Ngā mihi

Contact us for more information:
Tasha Williams

Ministry for Primary Industries
Manatū Ahu Matua