Performance-based and cost-effective regulation: New Zealand’s experience with a shared government / industry model

Steve Hathaway
10 February 2016

Growing and Protecting New Zealand

www.mpi.govt.nz
Our Strategy 2030 – Growing and Protecting New Zealand

MPI is focused on the success of the primary industries for the benefit of all New Zealanders. We are striving to help the primary sector double the value of its exports by enabling industries to grow, and to strengthen their environmental performance. To achieve this, we must play a pivotal role in New Zealand’s system of trade, as part of our work on biosecurity, food safety and primary production.

**OUR PURPOSE**
To achieve our purpose we must:

- Grow and protect New Zealand
- Maximise export opportunities
- Improve sector productivity
- Increase sustainable resource use
- Protect from biological risk

**OUR OUTCOMES**

- Biosecurity
- Food Safety
- Primary Production

**OUR SYSTEMS**
MPI delivers across four major systems that are central to the success of the primary industries:

- Trade

**OUR PRIORITIES**
We are driving change across our systems through seven priorities:

- Smart Regulation
- Operational Excellence
- International Access
- Provenance and Traceability
- Precision Production and Investment
- Enduring Relationships
- Integrated Information, Insight and Knowledge

**OUR MPI**
In delivering on our priorities we will ensure MPI is:

- Smart in the use of intelligence and knowledge to reduce complexity
- Trusted by the public and consumers
- Enabling to do business with and within
- Productive to meet demand growth within baselines

**OUR VALUES**

- Respect Value people, value our work
- Connect Work together, build partnerships
- Trust Give responsibility, take responsibility
- Deliver Act with purpose, achieve results.
A connected and aware MPI

Our six branches work together and with our stakeholders to deliver MPI’s vision of Growing and Protecting New Zealand.

DIRECTOR-GENERAL
Marty Dunne
• Societies are increasingly risk averse

• Innovations based on technology and science are essential to meet challenges such as emerging risks, food security, aging populations, scarce resources

• Asymmetric incentives i.e. regulators who stop something from happening that would have caused benefit will likely not be challenged

What are the information needs to reach “good” decisions and how do we improve connections between decision-makers, scientific experts and citizens?
MPI regulatory system: A work in progress!

- 85 000 food premises, 45 000 regulated businesses
- Commitment to international benchmarks / Codex
- Food safety primarily an industry responsibility
- Risk-based safety and suitability standards
- Regulatory model
- Performance standards
- VADE
- Cost recovery
- Commercial incentives to perform
MPI regulatory model

- Beginnings in modernisation of meat inspection 1990s
- Less government but strong regulator at the core
- Private sector more cost-effective and efficient?
- From prescriptive “command and control” end-product type inspection (with the onus on Government to prove non-compliance); to industry demonstrating compliance
- Impetus gained from HACCP and risk analysis
Regulator

Accredited Verifiers
AUDIT  AUDIT  AUDIT

Industry

Risk-based food control programmes
Regulator

- Audits and monitors the overall system
- Provides technical and policy input to laws and regulations
- Develops and sets (risk-based) standards
- Provides official assurances, including export certificates
- Defines competency criteria for, and approves or recognises the verifier
- Monitors and audits the performance of the verifier
- Approves, recognises or appoints other components e.g. labs
- Develops resources to help industry
- Approves and/or registers food control programmes
- Enforcement
Verifier

- Independent audit to ensure food control programmes are in place, appropriate and being met
- Evaluates validity of risk management programmes (RMPs) (Note: the same person cannot design and verify a programme)
- Reports, and has a primary obligation to, the regulator
- Meets performance and competency standards and/or criteria set by the regulator, including accreditation to relevant NZ or international standards
- Initiates and/or takes action where non-compliance
- Wherever possible, services are provided on a contestable basis
- Regulator may also be the verifier e.g. Territorial Local Authorities
MPI Verification Agency

- Accredited to AS/NZS/ISO/IEC 17020;2000 (Inspection Body)
- Primary role in meat processing – importing country requirements
- Verifies the risk management programmes of animal product processors and provide export certification
- Verification intensity according to performance level: 1 to 6
- Online scheduling and recording system
- Information available to anyone with access rights
Industry

• Responsible for developing and implementing food control programmes as appropriate
• Maintains and demonstrates compliance
• Engages and pays for verifiers
• Gains measurable benefits from behaviour change e.g. flexibility in process control, performance-based verification
• Must produce food that is safe and suitable
### Legislation across the food chain

<table>
<thead>
<tr>
<th>Primary Production</th>
<th>Primary Processing</th>
<th>Export</th>
<th>Domestic Sale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Animal Products Act 1999</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Agricultural Compounds and Veterinary Medicines Act 1997</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Food Act 1981</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wine Act 2003</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Food Act 2014</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Biosecurity Act 1993</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Food Act 2014

- New platform for NZ food safety legislation (into force 1 March 2016)
- Industry has primary responsibility for safety and suitability
- Outcome focused - managing risk at the appropriate level through regulatory processes and limits
- Focus on key hazards and HACCP
- Harmonising regulatory principles and expectations across all sectors
- Minimise cost of government involvement
- Three-year transition period
Risk ranking and prioritisation

- Risk-based approach, with implementation in high-risk businesses first, subject to a pragmatic transition strategy
- **Risk ranking** - food safety risks across 30 food sectors
- **Prioritisation** – position in the food supply chain, cross-sector food links, available competencies, current sector organisation, current level of regulation, public interest – to determine transition schedule for implementation
- High, medium, low risk foods, ready-to-eat foods
Implementation of the Food Act

- MPI-administered national database of all food businesses from 1 March 2016
- Schedules 1 – 3 describe food sectors and assign risk-based measures
- Specific recognition of needs of small to medium-sized businesses (SMEs) – templates, codes of practice, guidance tools
- ISO standards and accreditation applied (personnel, agencies, laboratories)
Custom food control plan

• High risk, individualised management
• E.g. manufacturers of higher risk food
• Flexible, supports innovation
• Subject to evaluation

Template food control plan

• High risk, common processes
• E.g. restaurants, cafes, caterers, supermarkets, butchers
• Written plan – but focus on ‘tell me what to do’

National programmes

• 3 levels, moderate to low risk
• E.g. manufacturers of lower risk food, horticulture, retailers of prepacked food
• ‘Just tell me what to do’
### How the food business shows compliance

<table>
<thead>
<tr>
<th>Category</th>
<th>Action</th>
<th>Custom FCP</th>
<th>Template FCP</th>
<th>NP3</th>
<th>NP2</th>
<th>NP1</th>
<th>Exempt</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing External Verification</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial External Verification</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Get custom FCP evaluated</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Validate custom FCP</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Document Control</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operator Verification</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Follow Good Operating Practice</td>
<td>Documented</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HACCP</td>
<td>Included</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Keep Records</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Train</td>
<td></td>
<td>Custom FCP</td>
<td>Template FCP</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Register</td>
<td></td>
<td>Custom FCP</td>
<td>Template FCP</td>
<td>Business</td>
<td>Business</td>
<td>Business</td>
<td>Exempt</td>
</tr>
</tbody>
</table>

### What the food business must do

<table>
<thead>
<tr>
<th>Category</th>
<th>Requirements</th>
<th>Custom FCP</th>
<th>Template FCP</th>
<th>NP3</th>
<th>NP2</th>
<th>NP1</th>
<th>Exempt</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relevant Regulations and Notices</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Food Act and Food Standards Code</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Animal Products Act 1999

• Risk management programmes (RMPs)
• Regulated control schemes (RCSs) – monitoring and control programme imposed where a RMP not practical e.g. residues, transport, specific provisions for overseas market access
• Official assurances, including exporter registration
• Recognised agencies and persons
• Requirements for evaluators

eLibrary for industry

- Codes of practice - documents reflecting acceptable industry-agreed practice, identifying and providing information on ways of meeting regulatory requirements
- Industry standards
- Templates for RMPs, RCSs, FCPs
- Food hygiene guidance documents for exempt food businesses

Example: Dairy regulatory requirements

Consolidated Dairy Documents

- Dairy Risk Management Programme Specification
- Dairy Processing Specification
- Farms Criteria
- Manufacturing Criteria
- Storage & Transportation Criteria
- General Dairy Processing Criteria
- Official Assurances and Export Requirements Specifications
- Recognised Agency Specification
- Verification Criteria & Conditions
Performance metrics

Wide range of metrics used to describe required regulatory outcomes, including:

- Compliance with documented food control programmes
- Microbiological process control criteria
- Regulated limits for microbial pathogens
- Limits for chemical hazards
- Zero Faecal Tolerance specifications for red meat
- Assessment of inspector performance (red meat SPCS)
- Regulatory model: verifier competencies
### VADE approach to compliance

- A primary vehicle for introducing a new piece of legislation and achieving behaviour change

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. <strong>Voluntary compliance</strong></td>
<td>- achieved through education, engagement, communication</td>
</tr>
<tr>
<td>2. <strong>Assisted compliance</strong></td>
<td>- interventions heavily reliant on monitoring, inspection, response</td>
</tr>
<tr>
<td>3. <strong>Directed compliance</strong></td>
<td>- range of tools to direct a desired behaviour change</td>
</tr>
<tr>
<td>4. <strong>Enforced compliance</strong></td>
<td>- “iron fist” / application of full extent of the law</td>
</tr>
</tbody>
</table>
Strengthening food safety stakeholder engagement

- Primarily in Regulation & Assurance Branch of MPI
- **Strategic** e.g. market access, **Technical** e.g. standard development, **Funding** e.g. operational research
- Representative stakeholders empowered to make decisions
  - Strategic Directions Group: for the meat industry
  - Dairy Products Safety Advisory Council
  - Agricultural Compounds Veterinary Medicines Advisory Council
  - AP e-Cert Steering Committee
Cost recovery policy

- Public good / private good / industry good
- Fees, charges or levies may be set at a level that takes into account costs not directly provided to the industry sector (generic services costs)
- Utilise fixed fees, annual charges, and hourly rates (where a large variation in cost of individual outputs)
- Risk-based fees can be charged where appropriate

For: *non-generic* standards / export activities and official assurances / approvals, accreditations and registrations / compliance (monitoring, system and business audits)
Implementing the cost recovery programme

- 2014/15
  - Crown revenue ~ $321m
  - other revenue (mostly fees/levies) ~ $104m
  - more than 330 fees, charges and levies
- Industry seeks greater transparency and more consultative processes
- Review - consultation throughout 2016

Private standards

- MPI an early adopter of ISO systems and accreditation, both for itself and industry; regulatory requirements added as needed
- NZ industry heavily committed to private standards as a condition of market access e.g. horticulture
- Used to provide some specific regulatory assurances e.g. keeping of spray diaries, efficacy of treatments and contributes to performance-based regulatory audit
Most third party verification agencies accredited by MPI as well as being accredited to audit a range of private standards

MPI is working to further reduce inefficiencies e.g. single visits, use of single food control programme document for multiple purposes, use of results from farm assurance private standards to reduce the number of on-farm audits

But government does not encourage businesses to operate in a “cost plus” regulatory environment through over recognition / reliance on private standards

Note new Canadian Food Inspection Agency policy: Enables the CFIA to use the results of private certification to inform its risk-based inspection activities
System performance: the Intervention Logic Model approach

- **Policy**
  - Objective

- **System**
  - Outcome
  - Outcome

- **Inputs / activities**
  - Output
  - Output
  - Output
Workshop example: Application of an ILM
KPIs

- KPIs should be combination of:
  - lead
  - maintenance
  - aspirational
- Must be SMART
- Example of a lead KPI: Annual incidence of human cases of food-borne campylobacteriosis in 2015 is reduced by 10% by the last quarter 2020
- A series of KPIs are currently being finalised by MPI, collated at quarterly intervals
- Reported to Food Safety Governance Board in dashboard format
Case study: Modernising meat inspection

- Risk-based review of inspection procedures and process control (RMF)
- Implementation of National Microbiological Database in all premises
- Industry risk management programmes / flexibility / performance standards
- Alternative post-mortem meat inspection (APMMI) using company inspectors for non-food safety / process defects (part of RMP)
- Highly significant reduction in number of government inspectors
- Enhanced control of unseen microbial pathogens e.g. STECs
Case study: Reducing foodborne campylobacteriosis

- High level of engagement with poultry industry (PIANZ)
- Joint operational research, public health surveillance
- Risk-based standards at appropriate steps in the food chain
- National Microbiological Database: National performance and ranking of processors
- Rigorous risk management programmes implemented by industry
- Industry-agreed regulatory target and VADE compliance; regular review
- New public health goal established by Food Safety Governance Board
Human cases of campylobacteriosis
Concluding comments

- Risk analysis – driving change in regulatory decisions
- Regulatory model – driving change in industry (and regulatory) behaviour
- No abrogation of traditional regulatory powers but demonstration of performance against expected outcomes becomes a primary characteristic of regulatory programmes
- Continuous improvement in food safety and suitability sought
- Commercial gains for government and industry need to be realised
Thank you