

# The Optimal Regulatory Model

## *The application of risk management to government regulation*

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### **Abstract**

Since 1984 New Zealand has been involved in an ongoing examination of the rationale for Government's involvement in various aspects of the economy. In particular it has examined and re-formed the way Government interacts with businesses through regulatory frameworks

This paper examines how one particular aspect of government regulatory activity is now undertaken: the setting and operation of the regulatory framework in which food producers, manufacturers and retailers operate. The focus of this examination is on the application of what we call the Optimal Regulatory Model. The paper explains the component parts of this model and their interrelation, and the roles or responsibilities undertaken at each level of the model, and what the model is expected to achieve. A brief discussion of the application of the Optimal Regulatory Model to several pieces of New Zealand legislation, the results of this application, and the domestic and international response, follows.

As New Zealand's major food statutes are reviewed and amended to reflect the Optimal Regulatory Model the New Zealand Government has also been considering how best to ensure effective and efficient administration of that legislation, particularly at the central government level. The paper concludes with a short update on recent developments.

### ***Abbreviations used:***

MAF – Ministry of Agriculture and Forestry

HACCP – Hazard Analysis Critical Control Point

ISO – International Standards Organization

## **Introduction**

Since 1984, New Zealand has been involved in an ongoing examination of the rationale for government's involvement in various aspects of the economy. From this has come a progressive reduction of government participation and intervention in many sectors. The process has had a profound effect. An independent review of the New Zealand reforms, carried out by Prof. Allen Schick, went so far as to state that "The reforms in New Zealand have been truly remarkable<sup>1</sup>". This refocusing of government's role has seen the complete reform of the public sector and the way in which government departments and agencies undertake their functions. A departmental briefing, prepared for the incoming Minister of State Services in December 1996, put it quite clearly:

*The entire landscape of the State sector has been transformed - no significant corner of the sector remains unaltered, either in its shape and form or in the way its business is done, or both.* <sup>2</sup>

## **Background to New Zealand reforms**

The high level of government intervention in all aspects of the economy was not unique to pre 1984 New Zealand, which was but one example of a managed economy. In its purest form the philosophy of the managed economy saw citizens and businesses protected from the effects of 'destabilizing events', often by subsidies and tariff barriers, and full employment was maintained. However, a managed economy was also often one where business innovation was stifled. Like many other such economies New Zealand in the early 1980's was a country living well beyond its means with high overseas borrowing and low economic growth.

Boston and Holland noted that the 'programme of economic liberalization and institutional reform', which was aimed at creating a 'more open, competitive, market-led economy', was not unique in the western world in the direction it took. Similar changes were made in the late 1970s and early 1980s in Australia, Britain, France and West Germany. What was unusual in New Zealand's case was the 'scope of the reforms and the determination and speed with which, they were instituted'. <sup>3</sup>

It is also important to recognise that the changes introduced by the Fourth Labour Government (1984-90) picked up and pushed forward both economic management and public administration changes/reforms that were already being considered and in some cases introduced in the public and private sector<sup>4</sup>.

## **Focus of this paper**

This paper looks at how one particular aspect of government activity is now undertaken, the setting and operation of the regulatory framework in which businesses operate. While most of the examples drawn upon are related to the food and agriculture sector there are similarities with other sectors. The focus of this examination is the Optimal Regulatory Model, the various parts of the model, how they relate to each other, and the roles or responsibilities undertaken at each level of the model. The paper will also examine briefly some of the reasons why this model was

developed and what it is expected to achieve.

## **Origins of the Optimal Regulatory Model**

### ***Structure of the public sector***

Two of the comments made by Prof. Schick are particularly relevant when trying to identify the origins of the Optimal Regulatory Model. He noted that the New Zealand reforms placed a particular “emphasis on managerial discretion and accountability and governmental departments in New Zealand are no longer the organisational cocoons many once were ...they increasingly resemble business organisations”.<sup>5</sup>

A key outcome of this move to a business-like environment, and the overt application of management theory, was the separation of the provider, purchaser, and policy, regulatory and service delivery functions within government. The changes within the New Zealand state sector occurred progressively throughout most of the 1980’s. In the 1984 to 86 period, the establishment of State Owned Enterprises, for such services as rail, tele-communication and electricity supply was the main area of change. Post 1987 there was a further reshaping of the public sector. This period increasingly saw the establishment of policy focused ministries and related, but distinct, regulatory and service delivery agencies. In some cases these agencies were set up as separate Crown Entities headed by boards.

The aim of these later changes was to remove what the New Zealand Treasury identified as ‘conflicting objectives’. In the 1987 report to the incoming government, the Treasury argued that the conflicting objectives that arise when policy advice provision and policy implementation are combined within one organisation leads to ‘producer capture’<sup>6</sup>. This theory implies that an agency responsible for implementing a policy could skew advice to government to suit the interests of the agency and this in turn may see a less ‘efficient’ regime put in place, particularly if this favours existing processes and structure.

### ***Move to ‘user pays’***

Another major component of the reforms initiated in the 1980’s was the gradual implementation of ‘user-pays’ and ‘cost recovery’ policies across many of the industry and business sectors in which government intervened. A fundamental principle was that those who used or benefited from services or the products produced should pay the real cost. There was a drive to reduce waste, improve the efficiency and clearly identify and minimize cross subsidization.

In some sectors this led to the establishment of State Owned Enterprises, some of which were eventually privatized. In others the identification of service delivery functions resulted. For example, in the postal services area the identification of true costs and removal of cross subsidization saw rises in the prices generally but a proportional reduction in the total price paid by business customers.

Charges for government “product inspection” services to New Zealand’s primary production

industries were moved in a step-wise manner to full cost recovery by the late 1980's. This had the effect of increasing the focus on the efficiency of such services and led to many industries seeking devolvement of such services to the private sector and the creation of a contestable service delivery market in a drive to reduce costs.

### ***The rise of 'risk management'***

During the time that New Zealand was reforming its state sector, changes were also occurring in the way in which commercial businesses operated. There was increasing sophistication in the use of risk management and quality control systems and other manifestations of the 'managerial discretion and accountability' factors Prof. Schick referred to.

Risk management has been described as "an iterative process consisting of well-defined steps which, taken in sequence, support better decision-making, by contributing a greater insight into risks and their impacts"<sup>7</sup>. Further, risk management is recognised as an integral part of good management. To be most effective, [it] should become part of an organisation's culture"<sup>8</sup>.

Risk management is as old as mankind, but as noted by Elms<sup>9</sup> has tended to develop independently in a number of areas. The first written evidence of a systematic risk management approach can be found in an ancient Babylonian code dated from 1800 BC. Development of probability theory can be traced back to the 17<sup>th</sup> century. The 18<sup>th</sup> century saw the development of the science of statistics. The 'remarkable advances' in risk management and risk assessment techniques have, however, occurred since World War II with aerospace, telecommunications, nuclear, chemical and civil engineering all making significant contributions. It is only now in the later years of the 20<sup>th</sup> century that organisational risk management has come to prominence.

The attraction of a process that works through the steps of identification, analysis, evaluation assessment, treatment/management, monitoring and review is now well recognised. These fundamental processes are now widely applied across a range of different fields.

With the coupling of the move to quality management systems, such as ISO<sup>10</sup>, or product safety management systems, such as HACCP<sup>11</sup>, in the private sector, with the policy/ regulatory/ service delivery split in the public sector and the implementation of 'user-pays' policies, the origins of the Optimal Regulatory Model begin to emerge. The application of risk management in the food sector has been the subject of much work in the Codex Alimentarius Commission<sup>12</sup> and World Trade Organization over the last five or so years. The influence of this work can also be identified as a core component when discussing the Optimal Regulatory Model as applied to food safety and food regulation.

Before going on to examine the makeup of the model it may be useful to consider briefly why government has, and continues to take, a regulatory interest in the wider food sector.

## **Government involvement in the food sector**

There has long been agreement that certain products, including food, are 'safer' if they make their way to the purchaser or consumer through a controlled or regulated system, rather than an uncontrolled system. In the main this view has grown to general acceptance as trade has increased and individual end consumers have less direct knowledge of the origins of products and their ingredients, and little or no control over the processes through which products pass before they are purchased or consumed. Consumers have historically looked to government to be the protector of the public interest and in particular the guardian of public health. There has been an expectation that government should act as the rule maker and enforcer. In many instances government did not wait to be asked but saw this role of protector as its duty. A philosophy of 'command and control' developed and government officers and inspectors delivered the instructions on what was to be achieved and, more often than not, how it was to be achieved.

### **Consequences of Government involvement**

As a generalisation, this 'command and control' form of governmental intervention has had two major consequences. Firstly, society in general developed a sense of security that all risks and hazards were managed on their behalf. Individuals did not have to make decisions about the safety or fitness of the goods they were purchasing or using because they came from 'approved', 'licensed' or 'registered' participants within a regulated system. Secondly, many businesses did not have any incentive to understand or even know about the risks and hazards associated with their products or production processes. The belief grew that they had 'passed inspection so everything must be okay'. Government was responsible for ensuring all aspects of product safety usually through the mechanism of manual inspection by an official inspector. In many instances government officials thus became involved in the on-line, micro management of businesses - the meat industry offering a prime example of this development.

The command and control approach also fostered an 'us and them' mentality where business operators were automatically assumed not to be trustworthy, therefore they had to be 'controlled'. In a parallel sense, customers and consumers came to assume that a 'licence' or 'approval certificate' on the wall of a business meant they were 'safe'.

Enforcement activities developed into a game of 'catch me if you can'. Government had to prove non-compliance rather than industry being required to demonstrate that they were complying. The costs of maintaining the inspectorate necessary to ensure compliance across the whole sector and to unearth, prevent and punish non-compliance also fell on government. The bigger and more complex a sector became the bigger the control system needed became, and the rule books and regulations became bigger and more complex as every eventuality had to be catered for.

Government regulations became the recipe books, standards or instruction manuals without which businesses could not operate. However if a business wanted to do something different, new, or innovative, they had to get approval or in many instances the regulations or standards had to be changed. This was often a lengthy process and it could sometimes be years before any new

product or variation of an existing product could be legally marketed.

### **What is Government's role?**

The moves for government agencies to have clear objectives has also resulted in a clear definition of government's role both generally and also in respect of specific sectors.

Today the executive arm of government, and particularly the elected Ministers, focus on setting the policy direction and legislative framework, rather than managing the day to day operation of their departments. Departmental chief executives now focus on running their organisations in the most effective and efficient manner to deliver the policy outcomes government wants in respect of the economy and for a particular sector. Such outcomes are usually to be found specified in the purchase and performance agreements made between Minister's and the chief executives of their departments.

The 1996/1997 Independent Scoping Review Team<sup>13</sup>, when undertaking a strategic review of MAF Quality Management, identified a key role of government as that of 'the nation's risk manager'. They stated that government manages the risks related to agriculture in four ways, including the following:

- by providing a regulatory framework for management of the risks associated with food safety, pest and disease control, and the welfare of animals; and
- by being accountable for official assurances that agricultural products meet the standards required by domestic law or importing countries.

They added that "in fulfilling the role of risk manager, Government is the arbiter of acceptable or tolerable risk. It is therefore forced to make difficult judgements about what is, or is not, acceptable". It was acknowledged "that while scientific analysis can be applied to the assessment of risks and of the adverse consequences should an event occur, the decision as to what amount of risk is acceptable is almost always a judgement, and often a political judgement<sup>14</sup>".

These roles of rule maker and provider of assurances are at the core of what the Optimal Regulatory Model is intended to deliver. However, as will be discussed later, they are also only one aspect of the overall role of government in the context of the ORM.

### **The Changing Face of Administration of Food Safety**

The last five to ten years has seen an increasing application of risk management. There is now a world-wide trend toward the introduction of process control and management as a means of producing safe food. These mechanisms or systems are progressively replacing quality control through end-point inspection as the principal safety assurance measure. The introduction of risk-based management systems, such as HACCP, is an example of this.

The onus for producing safe food is shifting to the producer, processor, manufacturer and retailer,

while the onus on government is to assure safety, rather than act as the quality controller. This approach to food safety regulation reduces direct government intervention, and places the responsibility for systems management on industry. As such it achieves greater flexibility and economic control for individual business and allows government to focus its resources thus reducing the call on public funds.

When attempting to identify what is driving these changes, as might be expected, different answers arise depending on the context or perspective taken. However, some overriding themes do appear. Consumers and users of products want to know what it is they are getting, where it has come from and if it's safe. Government is able to move out of the business of 'doing and directing'. Instead it can concentrate its efforts, and tax dollars, where they will have the most effect. Government still maintains overall control of the system, and is able to provide consumers, or other government's on behalf of their consumers, with the assurance they require. For industry, a driving force has been the desire for greater control over their costs and an ability to pursue innovation.

## **The Optimal Regulatory Model**

In its most general form, there are three key players within the optimal regulatory model each with separate roles/ functions/ responsibilities within an overall risk management system.

These players are:

- government
- independent or third party verifiers/ auditors
- regulated businesses

[see also Figure One]. There is a fourth player, the consumer or user, whose needs and demands are essentially the outcomes that the Optimal Regulatory Model should deliver.

### **The players**

#### ***Government***

The role of government has three levels within the Optimal Regulatory Model: ministerial/parliamentary, policy development/advice, and regulatory. While clearly connected, each area of activity is generally carried out separately. Although the third level is where the greatest range of activity occurs, it is at the Ministerial or Parliamentary level that an issue often has the highest profile .

- Government ministers decide on the strategic policy direction and bring recommendations for law to Parliament either directly in the form of Acts or indirectly in the form of regulations.
- Policy sections of government departments provide policy advice on the need for, and nature of, government intervention to ensure identified risks are managed.

- The government regulators undertake functions related to approvals or accreditations; standard setting; compliance; and enforcement. In relation to food regulation these functions or responsibilities include:
  - administration of legislation and maintenance of the necessary administrative systems;
  - approval or recognition or acceptance of risk based management programmes for individual businesses;
  - approval or accreditation of third party/ independent verifiers, auditors and laboratories;
  - setting and implementation of New Zealand and in some instances Australia/New Zealand standards, including verification or audit standards;
  - negotiating the acceptance, by New Zealand's trading partners, of product, production and other standards;
  - providing technical input to laws and regulations;
  - ensuring, through overall system monitoring and audit, that the relevant standards and specifications are being met by verification/audit/testing delivery agencies across the sector;
  - having accountability for food safety (and export certification) assurances, that standards and specifications are being met and food safety risks are managed;
  - investigation of illegal activities, including those operating outside the food safety system, and responding as necessary and appropriate;
  - undertaking enforcement activities within the food safety system including prosecutions when necessary.

### ***Third Party Verifiers/Auditors/laboratories***

This group is made up of individuals or agencies accredited by government to perform specified functions that usually fall into the following:

- carry out inspections/audits/analysis and otherwise assess that requirements set out in standards, specifications or risk based management programmes are being met;
- take action under the risk based management programmes when legal and/or regulatory requirements are not being met;
- assess the continued validity of the risk based management programme (when a business is operating under such a programme);
- report to the regulator as necessary or as required (either by statute or as a condition of accreditation, or as specified within a programme).

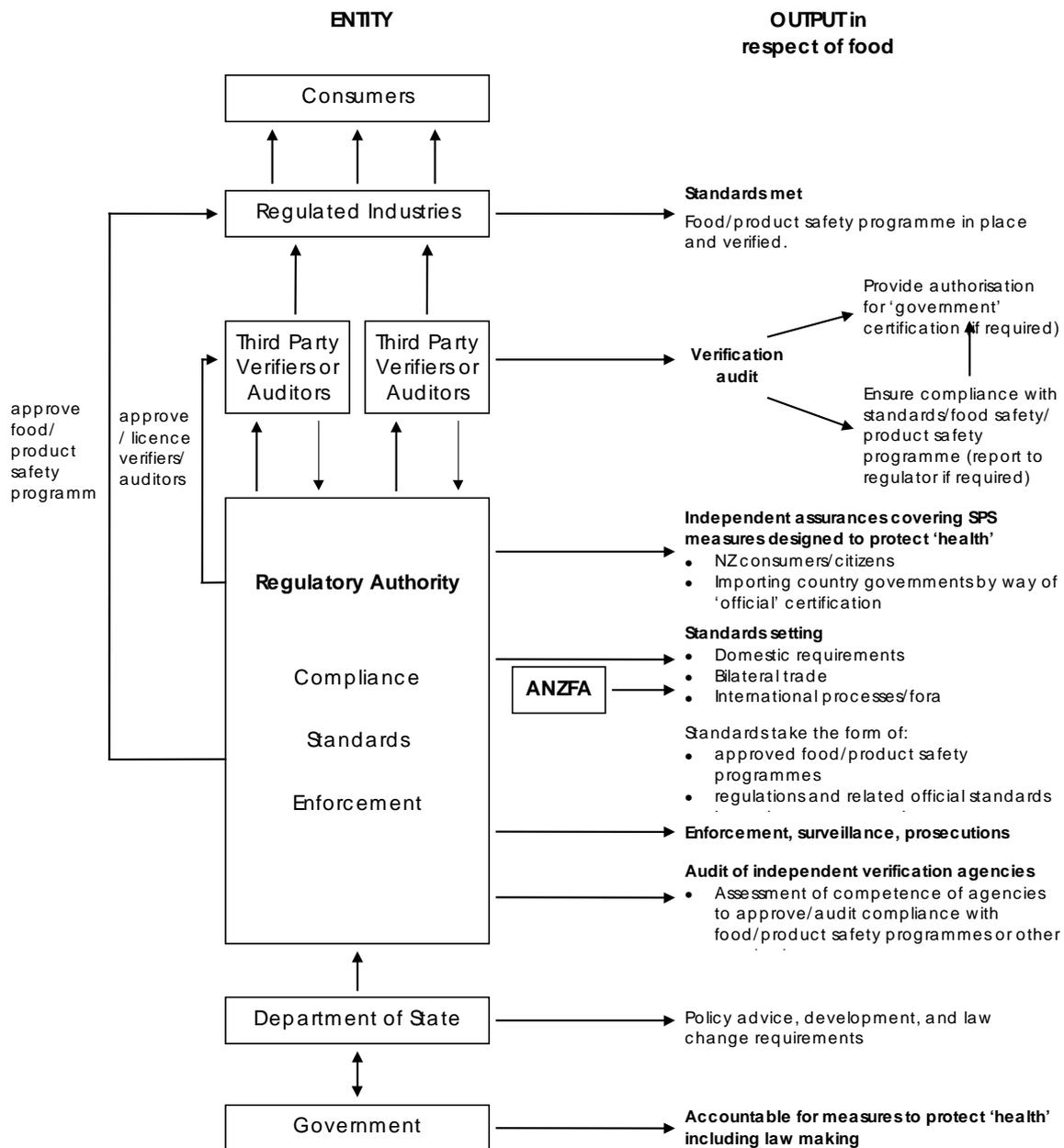
### ***Regulated Industries***

- Regulated industries or individual businesses develop and (following government

approval or acceptance) implement risk based management programmes within the framework set by the relevant legislation.

- Maintain compliance with the risk based management programme, including engagement of third party verifiers.
- Inspection, process and quality control tasks are devolved to industry and become part of a company's recognised process control programme.

**Figure 1: The optimal regulatory model**



### **Setting the legislative or regulatory parameters**

A new approach also applies to the way in which the legislative and regulatory framework, (within which the Optimal Regulatory Model operates), is set. Standards (or regulations) are no longer detailed prescriptive instructions, rather they are outcome focused, generic and enabling. For example, in respect of food specifically, the standards for composition and labelling are expected to focus on those aspects necessary to ensure safety, prevent fraud and deception and allow for consumers to make informed choices in the products they purchase.

The mechanisms used by government and government agencies to arrive at the standards or regulations that will apply to a particular sector have also undergone change in recent years. Perhaps the most important feature is the ability for all interested parties, including industry and consumers, to participate in, or contribute to, the development of standards or specifications. This is an important factor in the acceptability of the regulatory framework that applies to a particular sector. When standards or outcome specifications are set by, or on behalf of, government judgements about what is an acceptable level of risk will be influenced by the social, economic and political environment as well as the other obligations government has entered into. However, it is also essential that such judgements are informed by scientific analysis and the best information available.

However, as has become obvious in recent times and particularly in respect of sensitive or high profile issues, the ability to participate or make comment on proposed standards or regulations does not of itself guarantee that the resultant standard will meet the expectations of all interested parties.

The World Trade Organization Sanitary and Phytosanitary Agreement and Technical Barriers to Trade Agreement continue to impact on food standards and the international trade in food, particularly affecting countries like New Zealand where trade in food is a substantial part of the economy. There is a large amount of work being undertaken in several fora, particularly in the areas of risk management, equivalence, acceptable levels of risk, appropriate levels of protection, and food safety objectives. The outcome of this work can be expected to have an impact on the regulatory and legislative framework in coming years.

### **Intended outcomes of the Optimal Regulatory Model**

The following benefits of adopting the Optimal Regulatory Model in the food and agriculture sector have been identified<sup>15</sup>:

- improving the management of the regulatory regime, by refocusing the role of government from the delivery of regulatory services to management of the regulatory system;
- managing the whole range of risks to public health, including those (e.g. microbes, residues) that are not adequately dealt with in traditional organoleptic inspection;
- placing an appropriate level of responsibility on food processors for the safety of their product, rather than depending on a Government mandated, “command and control”

inspection regime;

- facilitating innovation and efficiency within the sector, for example, food processors accepting responsibility for quality systems to manage all food quality requirements of consumers, including those required by governments, or adopting modern process control methodologies such as “hazards analysis critical control point” (HACCP);
- supporting the development of direct relationships between consumers and producers arising from increasing consumer and retail driven demands for quality products.

With the changes that have occurred to the New Zealand public sector and the changes that are still occurring in New Zealand legislation, which are discussed later in this paper, these identified benefits are now being, or are about to be, delivered.

## **Roles and Relationships within the Optimal Regulatory Model**

Government remains in overall control. It retains: the right to set the legal framework within which the risk management system operates; to approve the programmes developed by industry to demonstrate their compliance with those standards; and by approving or registering the independent verifiers or auditors of those programmes. This government activity also defines the relationships with the other key players in the model.

The independent verifiers or auditors are aligned closer to the regulator than they are to the various businesses they provide services to. Independent verifiers or auditors must be registered or approved by government to undertake their work and the threat of cancellation can be an effective “bonding mechanism”<sup>16</sup>. To gain such registration or approval they must not only be able to demonstrate their technical competence to undertake their work, but they are also bound to remain free of any conflict of interest. They can not, for example, be the verifier or auditor of a programme that they were commissioned to design.

The independent verifier or auditor may not have any ‘power’ but there are in-built mechanisms that allow prompt action to be taken to prevent serious risks or hazards going unchecked or being hidden by the unscrupulous operator. Thus it is the system itself and the legislative requirements, in particular, that give an element of authority to the independent verifier or auditor that an industry self regulated system can not provide. In an industry self regulated system everything can run very well when there are no problems, however, the temptation to hide or cover up problems can be accentuated if a so-called independent verifier or auditor can be threatened with cessation of their contract if they do not ‘co-operate’. Under a system where an independent verifier or auditor has a statutory duty, or legislative requirement, to report significant failures or non-compliance to the regulator, or that their contract has terminated there is nothing to be gained by an operator threatening to cancel the verifier/auditor’s contract. In effect the legislation ‘backs-up’ the independent verifier or auditor as they carry out their functions making them less susceptible to pressure from an operator to not report failures or problems.

Also, Government does not place any restriction on the number of third party auditors who can

seek approval. This has the potential to create a pool of providers who will compete to provide audit or verification services and thus help to keep costs to industry down. Unfortunately what is not clear is how quickly such a pool will develop. Trebilock<sup>17</sup> identified, when discussing the disadvantages of limited competition, that “collusion among licensees [can be] easier making it more likely than not that the market price will be somewhat higher than the truly competitive level”.

Another issue is the acceptance by consumers and some trading partners of ‘non-government’ provision of audit or verification services. This may present problems in the development of a ‘pool’ of providers. However, as more and more countries move to HACCP and risk based management the logic of the Optimal Regulatory Model should become more apparent, thus increasing its acceptability.

The Optimal Regulatory Model maintains the relationship between consumers and government. The control of the overall regulatory framework by Government provides consumers with a baseline assurance that appropriate safety levels are in place through the setting of appropriate outcome specifications or standards. As noted earlier, consumers, along with other interested parties, are able to participate in the standard setting process thus providing a mechanism to increase the acceptability of such standards. The requirements for approval of programmes and of programme verifiers or auditors are also another check on the system.

The relationship between industry and consumers continues to be regulated by market forces. However, it is important to note that the market place is not without rules and there are options available to those who believe they have been unfairly dealt with or harmed. The move to the Optimal Regulatory Model is strongly supported by many industry sectors and the move to an explicit risk management approach has also found favour with several consumer and public health interest groups. What will be important in the future is that this support is built on and the right balance is struck between reducing constraints on industry while maintaining the confidence of consumers in New Zealand, and overseas, that appropriate safety levels have been set and are being maintained.

### **Relationships within the Government component of the Optimal Regulatory Model**

With the introduction of private sector management practices or “managerialism” and its corresponding separation of the various functions, the clearer identification of the role of Ministers and the role of the State sector, and the policy/regulatory/service delivery split, the component parts of the government role can be readily identified within the Optimal Regulatory Model. According to Walsh the virtue of “managerialism lives in the explicit setting and prioritising of objectives, the development of relevant indicators to evaluate the degree to which they have been achieved, and the rational allocation of resources to these tasks”<sup>18</sup>. What has also occurred, in some instances, is that the functions or roles undertaken by the State sector have been assigned to separate agencies. The New Zealand state sector has seen a large number of new agencies established in the last ten years. There is no longer a ‘single public service’ rather a number of separate agencies, with greater or lesser connection to Ministers, parliament or other government agencies. In turn this means that issues such as ‘client capture’ or ‘ivory tower’

policy can still arise. Other dangers are duplication of regulation and re-invention of the wheel, particularly where the boundaries of a specific sector are not well defined. In short, while the separation of functions can lead to more easily identified responsibilities it does not necessarily lead to a more effective or efficient regulatory framework or system.

Perhaps the clearest statement on this issue was made by the Treasury in 1987, (although it is acknowledged that the Treasury believed the case could be ‘overstated’). When proposing the separation of policy from operational activities they noted “Too rigorous a separation would, however, be likely to impose costs at the expense of little gain. An assessment of the costs and benefits of alternative forms of intervention requires a knowledge of the way in which particular government actions impact on the behaviours of individuals in their varying roles as consumers, producers ... Policy advice divorced from considerations of reality is bad advice”.<sup>19</sup>

The Treasury went on to identify that ‘appropriate mechanisms’ could be put in place to ensure and encourage communication between the various agencies. It is perhaps this aspect that is at the heart of the matter. The separation of various functions into separate groups within one large agency can also be a powerful mechanism for ensuring that communication is maintained. Separation into completely separate agencies adds another dimension to the need for good communication and information exchange.

## **Identifying the Optimal Regulatory Model in the NZ Regulatory framework**

There are a number of New Zealand laws, which can be identified as being either examples of the Optimal Regulatory Model or certainly precursors to that model.

### *Dairy Industry Regulations 1990*<sup>20</sup>

In terms of regulatory regimes, the dairy industry was the first food industry sector in New Zealand to have a risk management approach applied through legislation. This was reflected in the Dairy Industry Regulations of 1990. The regulations are made under the Dairy Industry Act 1952, an Act that is premised on a regulatory framework of government intervention and which embodies a highly prescriptive approach to the role of government. The interconnections between the 1990 Regulations and the principal Act are therefore difficult because the Regulations, as far as they go, are outcome focussed and specify the requirement that dairy companies implement "product safety programmes".

The 1990 Dairy Industry Regulations reflected in part the Optimal Regulatory Model by providing for the separation of functions between the three key players: the government as regulator, the independent verifier/auditor, and the industry. However, there were significant omissions to the application of the model simply because of the particular scope of the principal Act. This is most noticeable in that:

- there is only limited provision for third party involvement (limited explicitly to laboratories for testing etc or to the appointment of part-time, non-public servants as inspectors);

- the penalties are not applicable to the degree of responsibility (penalties are limited to \$100 compared with \$20,000 in the Food Act and up to \$500,000 in the Animal Products Act); and
- the regulations contain a high level of prescription (the regulations require product safety programmes to provide, for example, for the cooling of milk in the farm dairy and its storage at or below 7° Celsius until it is collected).

### *Animal Welfare Legislation*

The main elements of the Optimal Regulatory Model are present in the proposed Animal Welfare Bill. The government is the rule maker and approver thus maintaining overall control. The regulated sector has responsibility for developing and complying with audited (or reviewed) programmes (or codes) or in the case of individual animal owners has a duty of care. Features of the proposed model were described as follows:

- consumers demand that the use of animals in research, testing, and teaching be subject to a rigorous decision making process and other adequate safeguards;
- government, through specific provisions in the Bill and through its approval of codes of ethical conduct, sets the standards and guidelines for decision making and monitoring;
- government is accountable to the public for assuring compliance with the legislation and approved codes;
- independent reviews of code holders and their Animal Ethic Codes form the base information that enables the Government to ensure adequate compliance;
- reviews are provided by accredited reviewers on a contestable basis (the performance of reviewers is subject to audit by the MAF);
- failure to comply can lead to the approval of an organisation's code of ethical conduct being revoked.

### *The Food Act regime<sup>21</sup>*

The 1996 amendment of the Food Act 1981 permits food manufacturers to choose to operate to their own food safety programme, rather than follow the highly prescriptive Food Hygiene Regulations 1974. The amendment contained framework provisions, based on HACCP, for the implementation of food safety programmes. The amendment was designed as an interim arrangement to precede full-scale implementation of the model across the entire food sector. Food safety programmes remain voluntary and to date around 50 programmes have been approved although a number of these are variations of a couple of templates developed by corporations for chains of operations.

The Food Act has been amended many times and now reflects a mix in both structure and approach. For example, the Food Hygiene Regulations reflect a prescriptive regulatory approach while food safety programmes a risk management and enabling approach. The Act requires thorough review and this is expected to be undertaken in the near future. That provides the opportunity to provide for a broader and possibly mandatory application of food safety programmes over time.

### *Animal Products Act 1999*

The recently enacted Animal Products Act commences on 1 November 1999 and will completely replace the Meat Act 1981 by November 2002. The new legislation is strongly and clearly based on the Optimal Regulatory Model. It incorporates a move to risk management programmes, developed by industry, approved by Government and to the maximum extent possible, while meeting the requirements of foreign governments, contestable verification. The on-line inspection task currently undertaken by government inspectors will be the responsibility of each operator.

The new Act, establishes a regulatory regime that requires all animal products traded and used to be 'fit for intended purpose' through meeting New Zealand animal product standards. The risk management system forms this regime. The risk management system potentially covers all animal material because the optimal point at which to manage a risk may be anywhere along the production chain from the source to the market. The risk management system comprises the following main types of controls: risk management programmes; regulated control schemes; and controls relating to animal material and products exports.

The risk management system identifies the following key areas of responsibility:

- Businesses are required to have risk management programmes — responsible for the development and operation of such programmes. Duties will apply to all risk management programme operators.
- Exporters are required to be registered — responsible for assisting in maintaining the integrity of the risk management system through the duties that will apply to them.
- Businesses are subject to regulated control schemes will also have responsibilities within the relevant schemes.
- MAF is responsible for administering the Animal Products Act, including:
  - setting New Zealand animal product standards and specifications (after consultation with affected parties);
  - providing official assurances;
  - providing statements that product meets the New Zealand standard;
  - monitoring and auditing the risk management system and addressing non-compliance. In practice this will involve auditing verifiers and may include checking risk management programmes and procedures required for official assurances.
- Independent, MAF-accredited persons under the management of MAF-recognised agencies — responsible for routine compliance monitoring, verification and other functions. Specific duties will apply to recognised agencies and accredited persons.

### *The Transport Sector*

In the early 1990's New Zealand's transport sector was completely restructured. Elements of the Optimal Regulatory Model are evident. A Ministry of Transport responsible for policy and three

regulatory agencies, each with a separate Act and headed by a board, were established. The restructuring was a move to establish a safety audit and monitoring approach, to separate enforcement from regulation setting, and place responsibility on the sector for having appropriate safety management systems in place. The Land Transport Authority, the Civil Aviation Authority and the Maritime Safety Authority were responsible for their relevant sectors and were each designed to give industry more involvement in and ‘ownership of’ the safety regulation of their sector.

One of the roles of the authorities was to recommend, following consultation with the relevant sector, standards or regulations that were then managed through the government and Parliamentary processes by the Ministry of Transport. Each was also responsible for licensing activities. The responsibility for delivery of enforcement in respect of the land transport sector (i.e. road traffic officers) was moved to the police thereby separating it from the regulatory agency. However, because of the international obligations associated with aviation, air traffic control and safety enforcement was retained with the Civil Aviation Authority but was the subject of a specific performance agreement or contract with the Minister of Transport.

The transport sector reflects in some parts elements of the Optimal Regulatory Model. The separation of function, within the land transport sector for example, of the regulator as standard setter, and independent third party operators who can certify vehicles against set standards is recognisable. There has from time to time been some disquiet expressed about some aspects of the transport regulatory environment. These have included: that the regulatory authorities are too distant from government; that in some cases standards serve the businesses operating in a particular sector rather than their customers; or the reverse or that they serve no-one other than the regulatory authority. As at October 1999 the author is not aware of any of these general concerns leading to review of any aspects of the current regulatory structure.

#### *Occupational health and safety legislation*

The Health and Safety in Employment Act 1992 established a system of safety control for employees. Each employer is responsible for establishing and maintaining a safety plan for his or her business. The Occupational Health and Safety Group within the New Zealand Department of Labour is responsible for administration of the Act. Occupational health and safety does reflect, in some parts, elements of the Optimal Regulatory Model.

The Act is based on a risk management approach with each business site being responsible for development of a workplace safety plan. Such plans are developed with the involvement of the staff working at that site and include identification of significant hazards and the steps to be taken to minimise these. There has from time to time also been some disquiet expressed about the risk management approach that the Health and Safety in Employment Act established. Concerns have included: that the approach is too demanding on businesses; or that there is not enough government involvement to ensure desired outcome or sufficient level of compliance. Again at October 1999 the author is not aware of any of these general concerns leading to review of any aspects of the current regulatory structure.

## **The Future Structure of New Zealand's Food Administration**

In December 1998 the New Zealand Government announced the establishment of a single food regulatory agency in the Ministry of Agriculture and Forestry (MAF) from 1 July 1999. This new agency was to combine the food related functions previously undertaken by the Ministry of Health (largely related to domestic food safety) and those undertaken by MAF (largely related to the primary production sectors and export). Following Parliamentary Select Committee consideration of a Bill which would facilitate the establishment of such an agency the Government decided not to proceed with the establishment of the single agency at that time. The New Zealand Government is currently seeking further advice from officials on these matters and officials currently have a report back due to Government in early 2000. This report back will follow the General Election, which will be later in 1999.

## **Conclusion**

In adopting the optimal regulatory model the New Zealand Government has provided a regulatory framework which, without ceding ultimate management accountability, can assign much more responsibility to others to manage the risks. It allows Government to participate as it sees fit, without having to assume overall responsibility, however, Government retains a controlling interest.

To ensure the full potential of the benefits of the Optimal Regulatory Model are achieved it is critical that the various players participate in the system, particularly the standard setting. Such participation, coupled with the maintenance of transparency of decision making ensures all the players feel a sense of ownership and responsibility for the outcomes both in terms of the standards or regulation set at government level and the 'fit for purpose' products produced by the regulated industries. For its part government, or more particularly all those agencies and office holders with specific roles or responsibilities in respect of the range of functions undertaken by government, it is vital that the lines of communication are kept open and that elements of the overall system do not fall into the traps of 'client capture' and/or 'ivory tower' policy making.

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**END**