# Discussion Paper: Innovation and Assurance – Trade off or value add?

Prepared by McGuinness and Associates
wmcg@paradise.net.nz
23 August 2004

## Purpose

1. This paper considers the relationship between 'innovation' and 'assurance' in regard to the biotechnology industry, in particular the management of genetically modified organisms in the outdoors. The debate has arisen as a result of these terms being used in the biotechnology strategy, in particular, how to 'assess whether the regulatory regime and its operation are achieving an appropriate balance between assurance and innovation'. [1] This paper looks at the relationship between innovation and assurance and considers a way forward in regard to robust analysis and performance measurement of the tool[2] 'biotechnology'.

## Background

2. The development of a biotechnology strategy was one of the recommendations of the Royal Commission on Genetic Modification. The Minister noted:

> Wrestling with the opportunities and challenges presented by a fast-moving and complex sector is not easy, but standing still is not an option. That's why the strategy calls for action in three areas — growth, community engagement and effective regulation.[3]

3. In the growth area, the strategy draws on the work of the Biotechnology Taskforce, set up under the Government's Growth and Innovation Framework. We are not advised how the strategy developed its conclusions in regard to community engagement and effective regulation.

4. One of the key goals of the strategy was – 'Manage the development and introduction of new biotechnologies with a regulatory system that provides robust safeguards and allows innovation'.[4]

5. The objectives that relate to this goal are:

    1) Ensure regulation effectively assesses and manages risks from the introduction of new biotechnologies.
    2) Complete and implement the reviews of the Patents Act, the Plant Variety Rights Act and bioprospecting regulation.
    3) Promote greater transparency and best regulatory practice in the sector.

---

[1] Biotechnology Strategy 2003, page 32
[2] Much debate has focussed on whether biotechnology should be called an industry. Generally, many stakeholders tend to think of it as a tool rather than an end in itself.
[3] Hon Pete Hodgson Press Statement - A Biotechnology Strategy for New Zealand, 25 May 2003
[4] Biotechnology Strategy 2003, page 27

4) Maintain an overview of the biotechnology-related regulatory system to ensure effectiveness and efficiency, and provide for assessments of how well it is achieving a balance between assurance and innovation.[5]

6. In regard to goal 4, oversight of the regulatory system to ensure effectiveness and efficiency was assigned to MoRST. The strategy noted;

> While, as the sector taskforce has noted, it is in our trading interests to keep a gold standard for safety, we must do so in a way that supports innovation and does not load the system with unnecessary complexity and costs….There is, however, a need to assign responsibility for oversight of the system as a whole, to consider the multiple and dynamic links, and particularly the interactions between regulation and innovation. ..In line with MoRST's whole-of-government co-ordination role for biotechnology, it is appropriate to assign overview to MoRST, in liaison with other key agencies and industry.
> As part of this overview activity, the Government has made provision for the conduct of periodic independently contracted system audits to assess whether the regulatory regime and its operation are achieving an appropriate balance between assurance and innovation.[6]

7. The strategy assigned two key actions;

1) Assign MoRST an overview role in relation to biotechnology-related regulation, in liaison with key agencies and sector bodies.
2) Conduct periodic independently contracted system audits to assess whether the regulatory regime and its operation are achieving an appropriate balance between assurance and innovation. [7]

8. Interestingly, one of the other recommendations of the Royal Commission on Genetic Modification that was not implemented, was the appointment of a 'Parliamentary Commissioner on Biotechnology to undertake futurewatch, audit and education functions with regard to the development and use of biotechnology in New Zealand'.[8] If this recommendation had been implemented, the second action in Paragraph 7 above, would have been completed by the Parliamentary Commissioner on Biotechnology as part of his/her wider role. Much of the subsequent gaps have resulted from this recommendation not being implemented.

# Methodology

9. The approach taken to achieve the purpose of this paper is to complete four stages, as outlined below.

Stage 1: Define context and objectives

Stage 2: Define innovation in terms of context and objectives

Stage 3: Define assurance in terms of context and objectives

Stage 4: Design a framework in order to analyse and therefore 'assess whether the regulatory regime and its operation are achieving an appropriate balance between assurance and innovation. [9]

---

[5] Biotechnology Strategy 2003, page 27
[6] Biotechnology Strategy 2003, page 32
[7] Biotechnology Strategy 2003, page 32
[8] Royal Commission on Genetic Modification, Recommendation 14.3, page 360.
[9] Biotechnology Strategy 2003, page

## Context and Objectives

10. The context must be considered in terms of the biotechnology strategy and the objective must be considered in regard to sustainable and equitable growth, being growth that does not cause economic, social, cultural or environmental harm to a portion of current or potential future generations.

11. This is supported by the Growth and Innovation Advisory Board Research (April 2004), which researched and reported on 'What is Important to New Zealanders? In response, the research findings state;

> New Zealanders today appear to be far different from the passionless people they were branded several decades back. They indicate clearly defined goals and values that come through strongly in the research data.
> A clear majority of respondents in all three groups - New Zealanders in general, Maori and Business –rated the following lifestyle and personal factors as most important to them:
>
> - quality of life
> - quality of the environment
> - quality of education
> - quality of health services
>
> These form a 'top tier' of priority that is evident not only in the survey information, which is presented in the following graph, but is even more strongly reinforced in the qualitative elements of the research programme.
>
> Also important, though not with quite the same intensity of conviction, is a second tier of factors which are largely financial and vocational such as potential to increase personal wealth, employment prospects and the level of wages and salaries.[10]

## Define innovation

12. Innovation is often considered a key factor in developing growth. Two definitions are as follows:

> Innovation consists in "the introduction of new or improved processes, products or services based on new scientific or technical knowledge and/or organisational know-how[11]
>
> Innovation is the dynamic process of creating and introducing new ideas and new ways of doing things. Innovations may be incremental (small, stepwise improvements), major (substantial improvements), or radical (new lines of business, paradigm shifts). The traditional view of innovation is from two perspectives: innovation as an output and innovation as a process. From a policy perspective, a more integrated and useful viewpoint also considers innovation as a system.[12] [bold removed]

13. Hence, innovation can be analysed as an output, process or system.[13]

---

[10] Research Summary www.giab.govt.nz , pa ge 2.
[11] OECD
[12] Growth and Innovation Framework http://gif.med.govt.nz/aboutgif/innovation.asp
[13] Excerpt: Growth and Innovation Framework http://gif.med.govt.nz/aboutgif/innovation.asp
Innovation systems occur at a variety of levels. They may relate to specific sectors, geographies or markets. All are open systems and they overlap with one another. A group of businesses, for example, will at the same time be part of a sectoral, a regional and a national system. Thinking about innovation from a systems approach highlights important factors that impact on how innovation actually occurs in the economy**.**

1. Innovation as an output - Innovation as:
- a new or improved product, service or production process
- the opening up of a new market
- the adoption of a new technology
- a change to the organisation of a business.

2. Innovation as a process - This is the process of taking an invention through to commercial introduction and can include:

- basic or applied research
- development
- commercialisation
- diffusion and marketing.

3. Innovation as a system - This means looking at innovation as a system of interconnected organisations and institutions that influence the development, diffusion and use of innovations[14]

## Define assurance

14. Assurance has been defined by the American Institute of Certified Public Accountants (AICPA) as:

> Independent Professional Services that improve information quality or its context[15]

15. It highlights that assurance is about 'independence' and 'quality of information' in order to 'improve' outcomes by protecting/managing resources and reporting performance (e.g. enhancing reputations).

16. Stewardship is the traditional concept underlying auditing in that is demonstrates that information providers and decision makers (management) have fulfilled their

---

- Collaboration: Firms do not innovate in isolation but in interaction with other organisations, both locally and offshore
- Creativity: Innovation involves creativity. There is no such thing as a general order of how innovations come about. They can be unexpected and in response to opportunities that arise in the environment.
- Tacit knowledge: Personal experience and informal, unwritten aspects of knowledge are as valuable for innovation as formal, written knowledge.
- Geography: Despite the advances in communications technology, sharing knowledge, skills and experience is simply easier when the participants in a learning network are in the same place.
- Demand: The sophistication and requirements of purchasers (which includes governments and other businesses as well as household consumers) play an important role in stimulating innovation.
- Evolution: Innovation processes take time, sometimes decades. Therefore a long-term perspective is important.
- Cross-sectoral: Innovation occurs in all parts of the economy, not just in high-technology sectors. Bringing together business in different sectors, e.g. IT and agriculture, can also be important.

[14] Growth and Innovation Framework http://gif.med.govt.nz/aboutgif/innovation.asp
[15] American Institute of Certified Public Accountants (AICPA)

duties to stakeholders and encourages them to do so with the threat of additional assurance and/or penalties if they fail in their duty.

> The audit is, in effect, a monitoring cost used to assess manager-agents… The explanation also suggests that the audit would be demanded by (presumably honest) managers so that they can prove their worth.[16]

17. Public interest theory and social accountability suggest that regulation should be enacted by the state in the public interest and that regulators can be expected to act in a manner that furthers the public interest. This theory argues for the existence of state-mandated audit and postulates an audience much wider that just shareholders (see Peursem)[17].

18. In the context of biotechnology, assurance could be defined as having three purposes:

    (1) Ensuring that decision makers have an appropriate level of information to ensure:

    - 'bad' applications are declined,
    - 'good' applications are approved with controls if appropriate
    - assess uncertainty in order to take into consideration 'prudence' (the precautionary principle). This will in effect mean that some good decisions may be declined until more evidence proves that they are good and can be managed; and
    - prevent illegal practices.

    (2) Ensuring New Zealand citizens have the appropriate level of information to make judgements about accountability and governance, in particular that information is of the necessary quality to ensure that processes and decisions are transparent and that decisions and actions are traceable.

    - the decision makers (bio)
    - the decision making process
    - the decision
    - any controls
    - the monitors of those controls (bio)
    - the process of monitoring those controls
    - the outcomes of decisions over time (eg annual audits if appropriate)

    (3) Ensuring both New Zealand and International consumers and investors have the information and assurances they need (eg. EUREPGAP accredited) to make:

[16] Peursem & Pratt, Auditing – Theory and Practice in new Zealand, Fourth Edn – page 25
[17] Peursem & Pratt, Auditing – Theory and Practice in new Zealand, Fourth Edn – page 27and 28

- investment decisions and
- purchasing decisions for products (including food, health and other non directly consumed products like trees and grasses) and services (marketing and branding advice).

19. Determining, agreeing and informing users about the appropriate level of assurance is essential in order to apply effective assurance in a timely, cost-effective, complete and relevant manner.

20. The belief underlying assurance is the greater the effort (and therefore cost) that goes into gathering evidence to support an opinion/view/decision; the greater external parties should have confidence that the opinion reflects a true and fair view. This does not necessarily follow in practice although those providing assurance have been made increasingly aware that the provision of assurance also requires evidence of strong process, cost-effective audit design, proof of independence and transparency, and any failure to apply agreed levels of rigour has a high risk of sanctions and penalties.

21. Stakeholders determine the level of assurance they require based upon their perceived net outcomes if the information/decisions result in harm. This harm can be in terms of reputation, contingent liability (eg cleaning up contaminated sites), legal liability or other punishments (e.g. MAdGE consumer-led campaigns). Therefore in the same way we discuss the need for cost-effective information, we also can discuss the need for cost-effective levels of assurance.

22. For example, stakeholders require a very high level of assurance (via legislation) when a company seeks to raise capital, but a private company with a few shareholders may require a limited level of assurance to meet the needs of annual reporting for management and a few outside users such as banks or other credit suppliers.

23. In the context of biotechnology, the level of assurance tends to be frequently analysed and debated in terms of the quality of the decision, in particular the level of rigour needed to match the level of risk. However although this is relevant, there are other aspects, like accountability, transparency and governance issues, as discussed in Para 18, (2+3) above, that also characterise assurance. One of the concerns in recent debates on assurance is that participants either do not define what they mean by assurance or define assurance so narrowly, that they talk past each other.

24. In addition, the nature of the risks and the nature of the benefits are frequently only discussed in terms of (i) probability and (ii) magnitude; whereas other aspects are equally important, being (iii) who bears the risks and benefits, (iv) the degree of uncertainty of outcomes (precautionary approach) and (v) over what timeframes, all of which is contained in sections of the HSNO legislation.

**Hazardous Substances and New Organisms Legislation**

25. Parliament does prescribe levels of assurance in the legislation where there is a high degree of certainty as to outcomes and often follow pre-determined internationally recognised standards. This is apparent in the Low-Risk Regulations and the Hazardous Substances Regulations (e.g. like Compressed Gases 2004).

26. However, and this is important, the legislation does not prescribe a level of assurance to high risk new organisms, but prescribes a methodology and legal tests (two tests for imports, develop and field tests - being section 45 (1) (a)) and (three for releases including conditional releases – being the two above plus the test of 'minimum standards'. These tests may be proposing levels of assurance in the conceptual sense, but they are not descriptive. The actual lines or the 'assurance bar' has been delegated to the decision making body, ERMA, who has complete discretion over how to interpret very broad concepts.

27. The delegation of assurance has a rationale to the extent that new organisms is a new and highly changeable area and therefore requires up-to-date expert analysis in order to determine the best outcomes for New Zealand. But this is a poor justification for the extent of lack of specificity of bottom lines. As New Zealand is heavily reliant on its agricultural based economy for sustainable growth, assurance is extremely important in order to market our produce in a traceable and certifiable manner.

28. Consequently, the lack of transparency in regard to the level of assurance ERMA is applying is a major failing for those engaging in the process of either applying or submitting on applications where the proposition involves placing organisms in the outdoors. Key questions as to what ERMA would not approve remain unanswered.

**Genetically Modified New Organisms in the Outdoors**

29. There is a great deal of on-going debate, which will benefit from projects like 'Hands across the water' [18], funded by the MoRST Dialogue Programme.

30. One of the drivers of concern (or 'noise' as it is often called), besides uncertainty, ethics of using human genes, co-existence and irreversibility, is the lack of transparency over the level of assurance.

31. In regard to assurance, the issue can be discussed in terms of responding to two key questions:
    1) What is the level of assurance ERMA is obliged to supply? and
    2) Does the current level of assurance (a) hinder or (b) add-value to growth via managed innovation?

**Question 1: What is the level of assurance ERMA is obliged to supply?**

[18] Cronin, Karen and Jackson, Laurie – School of Earth Sciences, Victoria University of Wellington

32. Considering under the current legislation;

1) For outdoor experiments, being developments or field tests, there is no requirement to meet a minimum standard.

2) For outdoor releases, being conditional release or release, the legislation (HSNO) does refer to a 'minimum standard' but the legislation uses terms like 'likely' or 'significant' without any clarification as to what this means. ERMA is yet to provide guidance on what 'minimum standard' means in regard to conditional releases and releases and as yet, there have been no completed applications.

3) The legal test of containment is termed 'adequately contained' not 100 percent contained (e.g. Corngate etc) as indicated by current debates on zero-tolerance with some industry players would prefer a small percentage of tolerance), and

4) Lastly, weighing positive and negative effects, is not a bar/hurdle that is transparent, but a question of professional judgement. The underlying question is how do you identify, measure, and weigh different effects overtime with uncertainty in a meaningful and transparent manner.

Consequently, it is clear that there is no transparency in regard to the level of assurance in the legislation apart from reporting the reasons for the decision (see HSNO (Methodology) Regulations 1998).

33. In addition, it is important to note that:

1) One point of difference with any other international regulatory system to date is that ERMA does not place a level of rigour just on the risks (like Australia), but also on the benefits and then weigh them. Consequently, a high risk application can be approved if ERMA considers the benefits are worth significant risks (as has been the case in a number of decisions). This is a very high level 'professional' judgement call that should be transparent.

2) To date all field test applications and development in the outdoors have been approved by ERMA.

3) The HSNO (Methodology) Regulations 1998 has been under review since 2002 and creates considerable uncertainty for those engaging in the process.

**Question 2: Does this level of assurance (a) hinder or (b) add-value to growth via managed innovation?**

34. Without being able to answer question one, this question cannot be comprehensively responded to, except in very general terms.

35. In response to question 2 (a), the real measure is whether worthwhile products (without risks or the benefits exceeds the risks) are being declined? Considering ERMA has declined no field tests, no outdoor development applications and very minimal laboratory developments and the subsequent 'noise' from applicants has focussed on 'administration costs' and 'timing' (being issues around the delivery process), an analyst would argue that based on the big picture, innovation is not being stymied by the current level of assurance. This does not mean that process issues should be ignored, but that they are delivery issues requiring less consideration.

36. There is an argument that an ineffective delivery system can act as a determinant to decision making authorities receiving applications, but this needs to be carefully evaluated in order to ensure that delivery issues are the underlying cause. For example, if global markets continue to indicate strong resistance to eating GM food, and at the same time ERMA does not receive applications for GM food crops, then it is hard to argue that delivery mechanisms are the key cause, when it is far more likely to be 'market'. Consequently, such claims must be assessed on their own merits.

37. In response to question 2 (b), the remaining question is whether the level of assurance is adding value to growth via managed innovation? The answer is clearly yes, in that the 'gold standard' regulatory process is being promoted by the applicants in the industry (see also Biotechnology Taskforce report).

## An innovation and assurance framework

38. The purpose is to design a framework in order to analyse and therefore **'**assess whether the regulatory regime and its operation is achieving an appropriate balance between assurance and innovation'. [19]

39. Figure 1 considers the above points and proposes an innovation and assurance framework. It is not necessarily a balance as implied in the Biotechnology strategy, in that although we can assume most innovation is good, it is equally important to realize some innovation is not good for sustainable and equitable growth. Consequently, balance is not achievable by just 'trading' innovation for assurance or vice versa. In reality, assurance, if managed well, is a highly effective 'value add' and true innovators appreciate the dynamics of managing the reputation of an industry/product or service – hence the term 'gold standard'.

40. Equally, Figure 1 proves assurance is much more than just a regulatory system and a regulatory system is much more than the legislation. Assurance may require trade-offs but may also add value, both of which must be assessed in terms of New Zealand's long term objective, being 'sustainable and equitable growth'.

[19] Biotechnology Strategy 2003, page 32

41. Key observations from Figure 1, include:

(i) Assurance is a subset of managed innovation
(ii) Managed innovations can be assessed in terms of outputs, processes and systems
(iii) Managed innovation assumes not all innovation adds to sustainable and equitable growth
(iv) Effective Assurance protects what we have and proves/records performance for stakeholders
(v) Effective assurance is only one of a number of elements necessary to manage innovation (eg. 1-5 on figure 1)
(vi) Effective assurance has a primary and a secondary focus. Firstly, that the right decision is made and that stakeholders are provided with the quality information they seek. The second and less important focus is the delivery process. In terms of field tests, if applicants are not concerned about the approval/decline aspect (as they have all been approved) but are only concerned about process/delivery issues (see figure 1, column 4)– that is less serious. [see Para 36]
(vii) There are a number of tools used to manage the biotechnology system. Any analysis of a 'whole-of-government co-ordination role for biotechnology'[20] will require consideration of the whole system.
(viii) In order to 'conduct periodic independently contracted system audits to assess whether the regulatory regime and its operation are achieving an appropriate balance between assurance and innovation'[21], MoRST must define what is measurable, what is effective and what is relevant (see figure 1, column 5).

# Conclusion

42. To conclude, as MoRST goes about assessing this regulatory regime, it must assess and develop measures for the 'whole system' in a transparent and comprehensive manner. However, before it can do this, it must clarify what level of assurance is being applied by either regulation or by delegation (eg ERMA), in order to provide an insight into whether the current level of assurance is hindering or enhancing innovation.

[20] Biotechnology Strategy 2003, page 32
[21] Biotechnology Strategy 2003, page 32

**Figure 1: Innovation and Assurance Framework**