Citizens' Arrest

Accounting for GM Foods' Arrested Development

Sustainability Council

Contents

Researched by

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Summary

- GM crops are not in New Zealand fields because developers cannot get sufficient support from food producers and consumers, not because the law is holding them back.

- State-funded developers have nonetheless been pushing for a change of law to make it easier to get GM crops beyond the lab and into the environment.

- GMO developers and the Treasury often point to the law when seeking to explain the arrested development of GM agriculture in New Zealand. The fall off in field trial activity post the introduction of the Hazardous Substances and New Organisms (HSNO) Act is presented as proof.

- Yet the pattern of field trial activity in New Zealand over the last decade roughly tracks that in Europe. Even in the home of GM agriculture, the US, the same pattern is evident beyond the four commodity crops that dominate GM commercial production (soy, canola, maize and cotton). That is important as three of these big four are not grown in any commercial quantity in New Zealand and maize is a minor crop. When these varieties are removed from the data, just as in New Zealand, field trialling of the other crops has declined in the US. Other explanations are therefore required for the failure of GM agricultural R+D to deliver as promised in New Zealand.

- Developers claim that the regulatory regime is slow, costly and places unreasonable information requirements on developers. These are broadly without substance. For three field trial applications since 2001 for which figures are readily available, developers have been required to meet on average just 12% of the total costs of assessing outdoor GMO activities, with this decision-making largely covered by the taxpayer. Information requirements, meanwhile, are no more demanding than developers should be addressing throughout their R+D process in any event.

- Stand back analysis shows that other challenges have proven far more crippling than any regulatory requirements. These include: public unease about GMOs in the environment, consumer resistance in key export markets, lack of agricultural industry support for moving beyond the laboratory, and technical barriers.

- The Ministry for the Environment and the Environmental Protection Authority (EPA) have begun to push back against the misdirected campaign to weaken HSNO. The Ministry has stated that there is no evidence to support the claim that the law is paralysing GM agriculture. The Minister, meanwhile, has described the regulatory process as "rational and balanced".

- Not all industry players agree that the law should be weakened. NZBio, the main biotechnology industry association, has argued that New Zealand benefits from its strong regulatory regime. This NZBio says is good for the country's reputation and is necessary for activities that carry acknowledged risks.

- The association representing New Zealand's vegetable and horticultural industry has clearly signalled that it is not interested in GM crop development. This has led Plant and Food – a CRI that previously ran one of the largest domestic GM R+D programmes – to largely abandon research into GM food crops. In 2009, it recognised that grower support would be required before it could hope to secure regulatory approval and such support has not been available.

- Nevertheless, attention continues to be diverted away from the commercial and societal hurdles that beleaguer GM food propositions towards a law change as a circuit breaker.

- Lobbying by the Pastoral Genomics consortium to remove its GM grasses from having to obtain any regulatory approval was rebuffed by government, and the consortium was warned that any tinkering with the law to exclude its GM products would likely backfire.

- Tellingly, what ultimately prevented Pastoral Genomics from filing the application it had prepared for the EPA in 2010 was not a regulatory hurdle: it was an inability to convince the home team that the commercial risks of even a trial were warranted. A key section of pastoral agriculture would not support such a trial in New Zealand.

- Internationally, the introduction of GM food crops was met by one of the most profound challenges to commercialised science in recent years. At the root of this was the public sentiment that GM was entering the food chain by stealth. Moves to make outdoor GMO activities less accountable would likely rekindle those sentiments in New Zealand.

- The license to operate that developers seek must ultimately be obtained from the wider community. The HSNO legislation is simply a reflection of the level of community interest in, and concern over, GM food production. Regulatory processes that recognise this are not an aberration or something that can be successfully waved away by a ministerial 'fix'.

- Developers have been in denial for too long about the real extent of the challenges they face to commercialise GMOs in the outdoors. It is time to leave behind the myth that the HSNO Act is a barrier to worthy innovation and to face the significance of sustained community opinion.

- Prior to the election, then Minister for the Environment Nick Smith ruled out any weakening of the GM regulatory regime. Despite this, the Ministry for the Environment is going ahead with a study on whether HSNO is holding back innovation in both GM and non-GM organisms.

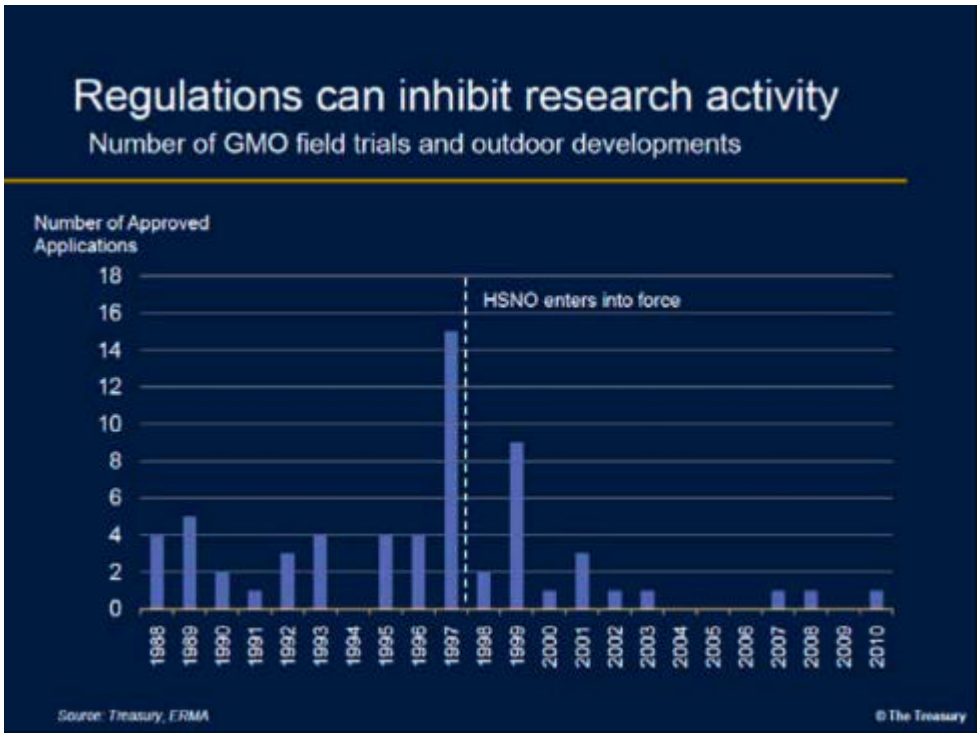
- Instead of weakening the law, the continued inability of state funded GMO developers to meet performance targets for delivery of their products to market should prompt review in a quite different direction: the value of continuing to direct investment in agricultural innovation towards GMOs instead of funding non-GM opportunities.

1. Graphic Evidence

One image has acquired near logo status in the long-running bid by GM developers to relax laws governing the outdoor use of GMOs.

A graph generated by the Treasury charts the number of GM field trials each year and shows a peak prior to, and a sudden plateau after, the new GM laws came into force. The graph is presented as clear evidence of a problem and, for the removal of any doubt, is assisted by headers that point to one possible interpretation: that regulation is responsible for the decline in GM field trial activity in New Zealand soils.

Treasury's "Strangulation by Regulation" Graph[1]

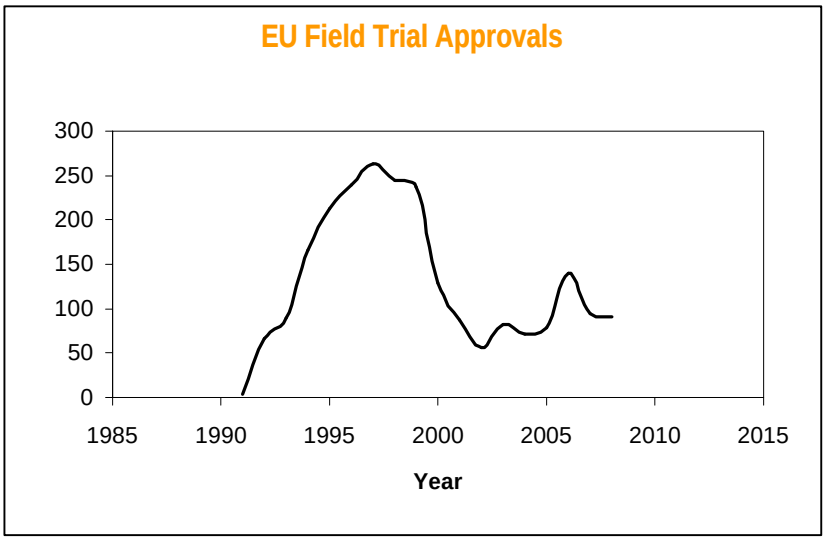


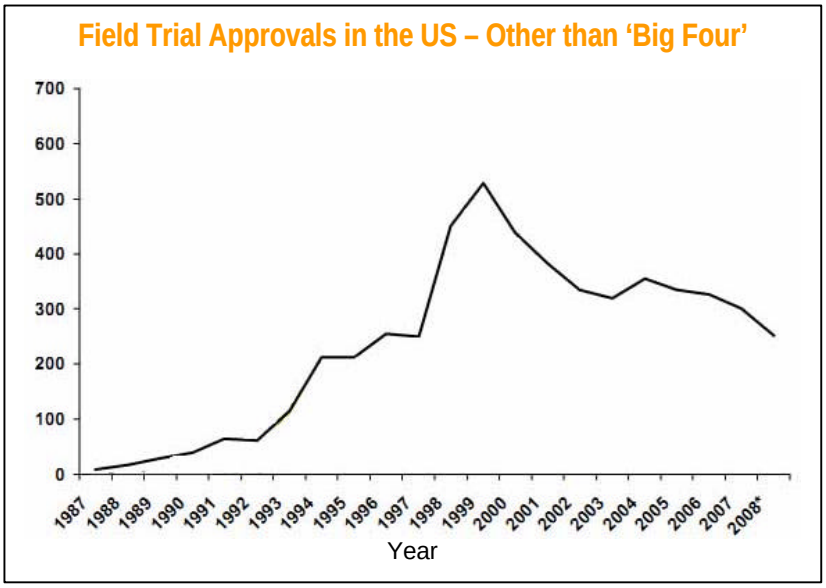
While background Treasury papers exhibit more caution in interpreting the data, when presenting to its minister and other audiences during 2009 and 2010, the Treasury left little doubt what it thought as it made the case for a weakening of the Hazardous Substances and New Organisms Act (HSNO). "HSNO is a barrier to adopting technologies that could lift productivity and improve environmental performance" reads the sentence above this graph in a condensed brief to the Finance Minister. Three sentences down it states: "Where we want to be: Rebalanced Act with stronger focus on economic growth and opportunities and more tolerance of risk".[2] The wider conclusion the Treasury implies is that regulation has arrested development of agricultural GMOs in New Zealand.[3] The Treasury did not respond to a request for an update on its position but it is understood that this remains much the same.

The bigger picture

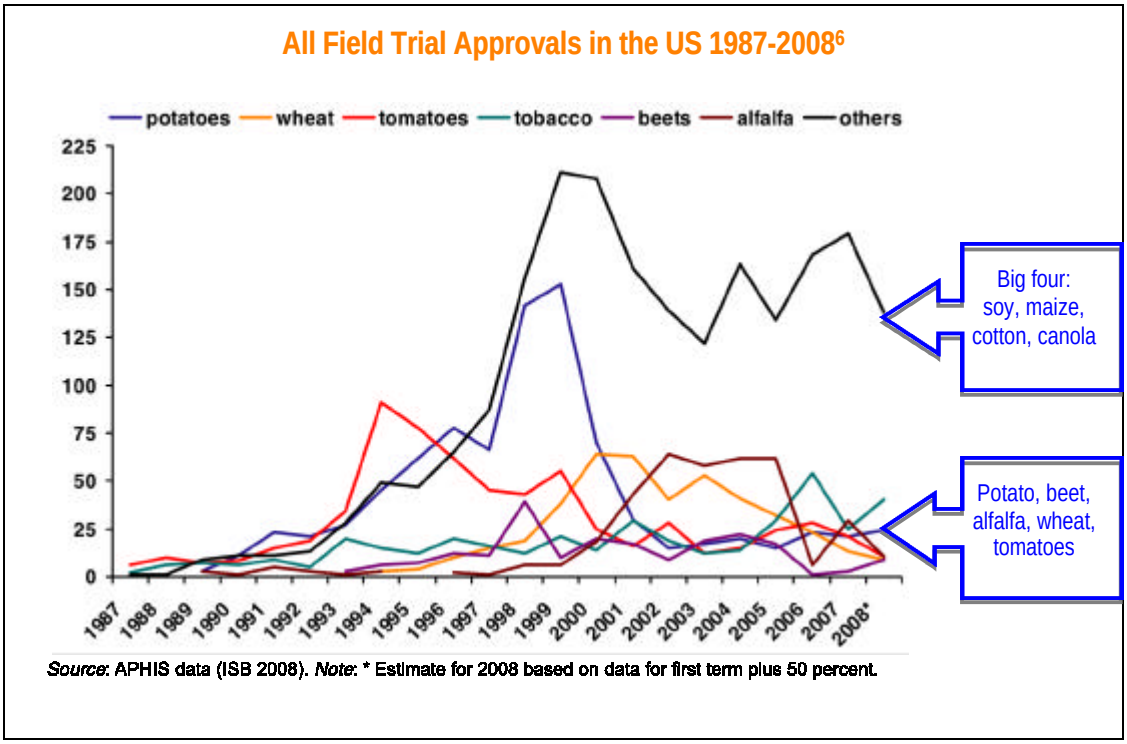
The timing of the new GM regulatory regime and the drop in the number of field trial approvals certainly invites questions. Yet a little digging reveals the story is not one of "strangulation by regulation", nor one that is confined to New Zealand shores.

Step back from the local scene and it is apparent that New Zealand is not the only country to experience a sudden decline in field trial activity around 1998. On the contrary, field activity trends in two major jurisdictions track a similar path to New Zealand. In the EU, for example, field trial approvals reached an all-time high around 1998-2000, before slumping.[4]



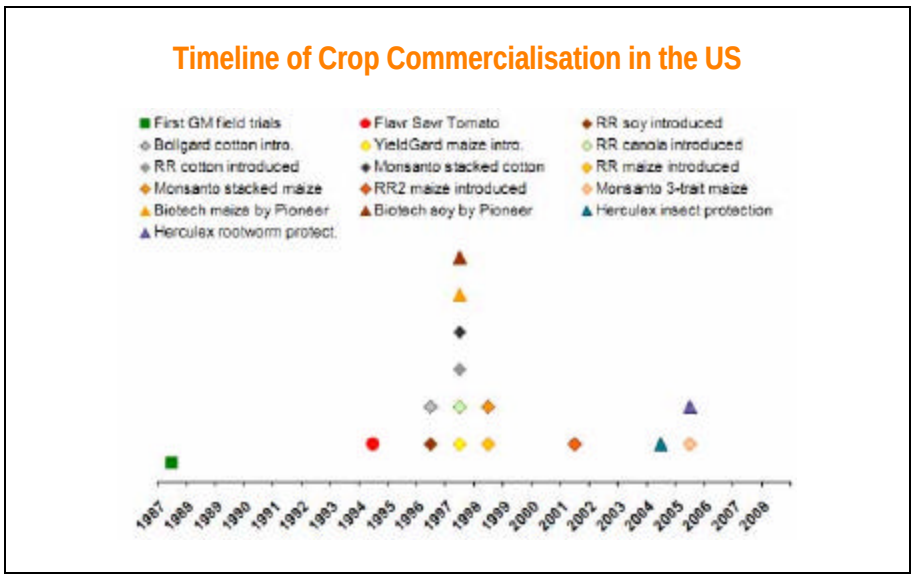


A further test of the Treasury's analysis comes from the US, which is widely agreed to be a much 'lighter regulatory touch' than New Zealand and where nearly two-thirds of field trial activity in the world takes place. Commercial GM crop production in the US is dominated by commodity crops, principally soy and maize. Field trial activity is no different. So while the volume of outdoor experiments involving GM soybean and maize is still comparatively high, field experimentation with other crops has waivered and/or stagnated (see graph immediately above). This includes crops that New Zealand developers have been seeking to field trial or conditionally release – such as the potato. For such crops, US field trial activity also surged and fell dramatically around the same time. Collapse of market prospects – such as the withdrawal of insect resistant potatoes – is considered to be the reason for this.[5]



Part of the reason for the two different trajectories for field trialling of the big four and other crops in the US is that the big four generally service animal feed markets or products that do not require labeling for GM content, while crops such as potatoes, wheat and tomatoes (see graph above) are destined for direct human consumption and are thus much more exposed to consumer preferences. That is significant to New Zealand, because it does not grow two of the big four (canola, and cotton) and soy production remains insignificant. While some maize is grown, MAF and major corn seed suppliers have both observed that the GMOs commercially available globally are not considered suitable or necessary for New Zealand conditions.[7]

A further indication that field trial experience in New Zealand is an industry phenomenon rather than a regulatory one comes from the following graph. It shows the timing of commercialisation of major crop varieties in the US, and again there is a distinct peak and fall off around the time that HSNO came into force.



Commenting on this graph, the European Commission notes that: "most new GM crops were marketed when the number of field trials reached a peak after a dynamic increase in the preceding years". In other words, trials peak just before a new product is launched. However, in this case there was a strong peak of new products in the late 1990s – followed by rather little since.[8]

The most recent industry survey of GM plantings confirms a pattern of continued narrow technology application and limited real innovation. Behind the headline of "8% growth in the area under GM crops" is the statistic that the big four crops continue to account for 99% of acreage under GM. In a decade and half since commercialisation, GM developers have not found anything to tempt meaningful numbers of growers of other crop varieties.[9]

It is also narrow geographically and really a story of the Americas - with the US, Brazil, Argentina and Canada accounting for 83% of acreage – where the bulk of production outside the Americas is cotton, not food. In Europe, just 115,000 acres is in GM crops and virtually all of this (99.9%) is one variety of corn - 85% of which is grown in Spain. This is less than 0.1% of the GM global acreage.

Overall, the technology continues to struggle to move beyond limiting harvest losses - beyond providing a different way to kill insects or weeds that compete for the crop. A technology that originally boasted an ability to transform agriculture remains narrowly confined.

Back to the drawing board

The international picture should take proponents of a law change back to the drawing board – at least to review whether the law is even a significant culprit. For if field trial activity similarly drops in other major regions with different regulatory regimes in the same period, then other causes must be found to account for what appear to be much wider trends.[10]

When the notion of 'strangulation by regulation' was again proffered recently in a renewed deregulation push,[11] the analysis was not accepted uncritically.

The EPA has disputed Treasury's interpretation of what field trial data say about HSNO. According to the regulator, the Treasury's account fails to recognize that there has been a shift from applications to trial single species to project-style applications which encompass more than one species or GM trait and that contained activity (which tends to precede field trialling) has remained "constant". Anecdotally, the EPA says, there appears to be the same level of GM R+D now as there was prior to HSNO.[12]

The Ministry for the Environment (MfE) too has concluded that there is actually "no substantive evidence" to support the oft-repeated claim that HSNO has strangled GM development.[13]

Nevertheless, MfE has decided that further investigation is required and has engaged a consultant to prepare an "initial exploratory piece" that focuses on "the scale of plausible additional benefits that could be gained in the next 20 to 30 years from increased release of new organisms".[14]

Invitations to tender for this study were originally sent out a few weeks before the general election and without the knowledge of then Environment Minister Nick Smith. While his reaction to news of this was that he was not about to tell his ministry how to think, he made clear that with respect to the GMO component of the new organisms study, HSNO would not be weakened. "The National Party is ruling out any changes in relation to genetic modification. We think the regime is working adequately in that area" Smith stated.[15]

While the study was delayed two months from the original timetable, the objectives remain the same and it is due to be completed in May 2012. The ministry maintains that there is still no substantive evidence to suggest the regulations governing GMOs are a problem but that it nonetheless wants to obtain "quantitative evidence" (as described in the tender document) to help further inform its judgement.[16]

The New Zealand market for innovation in agricultural GMOs is so small and overwhelmingly dominated by state sponsored research that obtaining meaningful sample sizes, let alone meaningful "quantitative evidence", presents a daunting challenge. The Sustainability Council believes that under such conditions, there is much to be learned by examining what has actually happened in the last decade to GMO development projects and whether the HSNO act has had a significant role in their unfolding histories. The following sections pursue this approach. The related question of what reforms would improve the HSNO Act is separate to the focus of this document and is not addressed here.

2. Charges Against the GM Regulatory Regime

There was a time when state funded R+D programmes promised to bring genetically modified fruit, vegetables, pasture grasses and livestock to New Zealand fields and tables and to fill export containers. By 2001, there had been 48 field trials of 15 different species.[17] Today GM pine trees and a GM livestock programme are the only projects being field trialled.

Developers tend to favour the 'strangulation by regulation' account to explain this. Indeed, their discontent with the regulatory regime has been a repeated feature of public debate about the role of GM in New Zealand fields and has provided a dawn chorus to incoming governments and a constant refrain in legislative reviews and regulatory decisions. Emotive imagery flows: regulation has spawned a "silent crisis in our country"[18], where GMOs sit "behind the alarmed, double high fences, in the locked laboratories or secure field plots"[19] and GM Royal Gala apples languish in glasshouses.[20] New Zealand is the land where GM is "the science that dare not speak its name"[21]. And as the country is left behind, the world ploughs ahead with GM food production – or so we are told.[22]

The HSNO Act, developers claim, strangles GM crop R+D with lengthy and costly approval processes, demands unreasonable levels of information, and carries the risk of regulatory decisions being subjected to judicial review – complaints that are discussed below.

Box 1

Pastoral Lament

Among those currently eyeing conditional release in New Zealand, the Pastoral Genomics consortium has made known in Government circles that it sees the HSNO regime as an undue obstacle to its ambitions. The consortium has lobbied ministers on more than one occasion for a "relaxation of the HSNO requirements" for experimental release of its cisgenic ryegrass lines[23], saying that "New Zealand's regulatory requirements do not favour progressing their work in this country"[24] and that the level of precaution would impose a significant delay in bringing the grasses to market. This, it was argued, would result in "a potential multibillion dollar opportunity cost to the environment and the economy."[25] More recently, the consortium told Treasury that "HSNO is restricting and delaying their work in forages that are genetically modified."[26]

Reportedly, the then Minister for the Environment did not share the consortium's view of the Act. In a meeting with the consortium, he conceded that while the regime could be "a bit slow", he considered the regulator to be "rational and balanced in its considerations". He refused to intervene "without clear evidence that the current system was not working and could not be made to work". Any attempt to make regulatory concessions to waive the GM grasses through, he warned, would backfire for both the government and the consortium.[27]

Tellingly, what ultimately prevented Pastoral Genomics from filing the application it had prepared for the EPA in 2010 was not a regulatory hurdle: it was an inability to convince the home team that the commercial risks of even a trial were warranted. A key section of pastoral agriculture would not support such a trial in New Zealand.

2.1 Timeframes for Decision-making

By law, the EPA must make a decision within 100 days of accepting an application to field trial a GMO. The regulator may extend the time needed to determine an application, for example, if further information is required to properly risk assess the proposed activity.[28] The regulator is nevertheless required to come to a conclusion as promptly as possible (s 59(5)).

Some developers argue that the "stop the clock" provisions add uncertainty and costs to the application process. Yet the time required to review an application largely depends on the applicant - the more comprehensive the application, the less likely delays will occur. Thus far, however, applicants have frequently not supplied the level of information required, leading to procedural delays as the EPA requests further information from the applicant or third parties.

In general, GM developers' public statements about the information requirements have been strategic, and dependent on the context. Crown research institute Agresearch – one of the most frequent applicants for outdoor GMO activities that require an EPA approval - has defended the time extension provisions before the courts, acknowledging that during consideration of an application, the regulator may need further information.[29]

Box 2

A "general paucity of information"[30]

The most spectacular instance of failure to provide sufficient information concerned the set of applications AgResearch filed in 2008. These sought approval in perpetuity to experiment with an almost boundless array of modifications in nine livestock species, at unspecified locations around the country. The application covered laboratory exploration through to commercial production of GM food products and biopharmaceutical products. The CRI's attempt to secure a one-stop approval for all GM livestock activities into the future was, however, self-defeating. The "general paucity of information" that MAF observed, combined with the breadth of approvals sought led the EPA to recommend that the applications be declined.[31]

The CRI withdrew these applications before they were to be heard by the Committee, but not before the regulator had spent around $56,000 processing them.

2.2 Regulatory Costs

The costs of applying to field trial or release GMOs are cited as a further, unreasonable burden on agricultural GM. Plant and Food has reportedly paid $197,598 in application fees for six field trials approved over a decade, covering GM petunia, potatoes, onion and other allium crops, and a range of GM brassica.[32] Application costs for AgResearch over the period 1999-2011 were reportedly $400,463.[33]

Originally, the HSNO regime was to recover all the costs of processing applications. In 2003, however, Government introduced a new pricing policy under which GM developers were to pay just 17% on average of the regulatory assessment costs.[34] For

three applications since 2001 that costs are readily available for, applicants have met an average of just 12% of the direct regulatory costs (see details below). For the 2008 year, when there was a significant new organisms application, 1% of the EPA $10 million budget was obtained from application fees for new organisms and less than 5% from hazardous substances fees.[35] The government carried over 94% of the cost of maintaining the regulator that year.

Share of application costs for three GM contained outdoor activities[36]

GMO	Year Approved	Cost to applicant	Cost to EPA	% of costs carried by applicant
Plant and Food GM Brassica	2001	$39,375	$389,000	9%
Plant and Food GM Allium	2008	$39,375	$400,641.23	9%
AgResearch GM livestock	2010	$67,500	$266,173.95	20%
Total		**$146,250**	**$1,055,815**	**12%**

Some developers have intimated that the state should fully cover the regulatory costs associated with outdoor GMO activities. They have pointed to Australia as a more user-friendly regime, in which applicants face no bill for regulatory assessment and where the state pays for any controls required of outdoor GMO activities.[37]

Yet the taxpayer is already shouldering the lion's share of regulatory costs for outdoor GM activities, in addition to sponsoring the R+D itself. It is also a class of technological products for which there are almost invariably alternatives that do not carry risk. Unless the expected advantages of the GM options can carry the full costs of both risk assessment (regulatory inspection) and liability claims, then there is no net economic gain for society in their deployment.

Box 3

Potatoes Off The Boil

Plant and Food has fingered application costs as preventing further development of GM potatoes. In 2003, the scientist leading the R+D predicted that it would cost up to $1 million for a larger-scale field trial (an experimental conditional release) and as much as $10 million for a commercial release.[38] No breakdown of these estimates was given and certainly under the current fee schedule, it is difficult to see how such a bill could be amassed.

When the CRI failed to secure further government funding for the GM potato R+D, it was left without the means to progress field trialling as the New Zealand potato industry did not come forward with the needed funds, whether because these were not at hand or because GM potato development was not a priority is unclear.[39]

In absence of strict liability provisions that encompass unexpected effects, the minimal contribution by way of application fees should be regarded as providing a low hurdle for the applicant to show that the activity has worthwhile benefits and is not unreasonably drawing on the EPA's thin resources. It requires developers to be convinced of the value of proceeding with outdoor GM activities as compared to alternatives, in light of the 'community of support' they can bring forward. Where there is not sufficient support – in the form of funding to meet the small portion of

regulatory costs that developers must pay – then there must be questions about the value of the GMOs in question.

Further, since field trialling began under HSNO, applications have come predominantly from specific crown research institute programmes that have been funded by the Government. The Sustainability Council has not been able to ascertain to what extent the Foundation for Research Science and Technology (FRST) or the new Ministry for Science and Innovation has been willing to meet application costs in the past. Theoretically, however, there should be no difficulty with these grants funding the full cost of a HSNO application. Indeed, to the extent that Government has been a GMO developer by virtue of its science funding policy, then one would expect that regulatory costs would be an accepted component of any GMO R+D investment.

Box 4

'Aussie Rules'

The push for NZ to adopt Australian regs

In the push to weaken regulation of GMO release and outdoor experimentation, developers have frequently advocated "harmonizing" New Zealand's regime with Australia's. While little detail is offered in documents the Sustainability Council has obtained, this would appear to mean New Zealand surrendering its GM regulation and replacing this with Aussie rules.[40]

Pastoral Genomics, CRIs and industry lobby association NZBio are among those who have at various times lobbied Government for this move. The attraction of the Australian regime, as presented to ministers, is that it provides an easier path to move GMOs from the laboratory into the field. Developers cite lower application costs, shorter timeframes and greater predictability in the regulatory assessment process as evidence of Australian superiority.[41]

A further virtue of 'harmonization' identified by MAF officials is that it could open up a common, TransTasman GM field experimentation and commercialization zone, allowing New Zealand developers to more easily expand their R+D and commercial products into Australia.[42] Clearly, such an arrangement would also allow Australian GMO developers easier access to New Zealand pastures for experimentation and commercialisation.

A fundamental difference between the two regimes is the recognition given to the weighty question of the economic implications of GMO release. In Australia, the economic risks and benefits of GMO field experimentation or release cannot be considered by the federal regulator, only by states.[43] Thus, even were a GM field trial or release likely to impose significant economic costs on non-GM producers and the wider agricultural economy, these costs would have no bearing on the regulator's assessment and a release could still be approved. Indeed, the regulator might be required to approve it even were the economic costs to the wider agricultural community likely to outweigh benefits to the developer/adopters.

Under New Zealand law, the economic risks and costs must be considered by the EPA in determining the overall desirability of allowing a GM release. For a nation that relies heavily on agriculture to make its way in the world and supplies to markets with high sensitivity to even trace GM content, consideration of the economic and market implications of GM release is essential.

It was on this basis that Fonterra informed the regulator of its concerns about a proposed field

trial of GM pine trees. There, Fonterra stressed that consideration of the implications to the country brand was essential and the overall economic impact:

> It is important that a decision to proceed with field testing is based on a clear understanding of the risk-benefit implications of any change to perceptions of New Zealand's GM status for the country as a whole.[44]

2.3 Information Requirements

Developers have also suggested that the information requirements are onerous and discourage applications being made. For example, Plant and Food's GM potato project leader has stated that his team did not have the necessary resources to compile an application for a larger scale field trial.[45]

Reasonably, developers are expected to account for the potential benefits and risks of their proposed activities. As is to be expected, the information required from applicants increases as the level of containment decreases for the proposed outdoor activities. This is because the potential impacts of outdoor activities on third parties and the environment grow with the potential for gene flow and the spread of GM crops beyond the trial site.

The information requirements are an important discipline on GMO developers. They are signalled well in advance and provide a framework for considering the implications of their projects for the wider community and specific groups within it. Arguably, the analysis and impact assessments that developers are required to submit should be addressed throughout the R+D process. As such, filing an application with the regulator should not be the first time that developers have had to critically assess the ecological, agronomic or economic implications of their GM lines.

Box 5

Regulatory Questions on the Button

The Pastoral Genomics consortium's experience of preparing an application to conditionally release GM ryegrass suggests that the questions HSNO requires developers to address are those developers must in any case address to determine the commercial viability of GM projects. That experience also confirms that such analysis is required "up-front", well before commercialisation approaches.

Initially, Pastoral Genomics expressed great frustration with the HSNO regime. Subsequently, the consortium and other developers with state-funded GM pasture grass programmes came to agree that "*significant analysis and up-front work* needs to be done to ascertain the benefits and value of the new products" (emphasis added).[46] That work programme includes the agronomic performance, economic analysis and the wider market conditions. For the time being, Pastoral Genomics has suspended plans to apply for conditional release approval and is continuing field trialling in Australia as it has been unable to gain the support of all the pastoral industry bodies it wants to secure before applying locally to the EPA.

2.4 Judicial Review

The prospect of judicial review is also cited by developers as a major disincentive for moving into the field because a legal challenge of an EPA decision can create delays, while the resources necessary to participate in such court cases, it is claimed, make field activity uneconomic.

Most law evolves through case law that helps regulators refine interpretation and implementation. Judicial review is particularly common in the early years of new legislation, or in response to contentious decisions.

It should not come as a surprise, then, that EPA decisions on outdoor GMO activities have been subject to legal challenge. The HSNO Act is relatively young and regulates activities that are acknowledged in law to carry risks. Further, the issue of outdoor GMO activities has continued to be highly controversial in New Zealand.

The right to appeal EPA decisions is part of the public process expressly built into this statute. That appeal is limited to points of law – that is, how the regulator has made its decision. Parliament has noted that decisions on acceptable levels of risk are not the exclusive terrain of expert bodies such as the EPA, but are "social, political and cultural judgement[s]".[47] In the final reading of the HSNO Bill, then Minister for the Environment Simon Upton made explicit that while Parliament provided clear purpose and principles to guide EPA's decision-making, "it is expecting the actual weightings and the actual level of risk aversion to be governed by a methodology that will be subject to public process".[48] Especially when the methodology is a pale version of what Upton envisaged, judicial review is a fundamental instrument of public process. Without it, there is little means of ensuring that the regulator remains accountable to the wider community it was established to serve.

Box 6

Appeals thus far

Since the HSNO Act came into force in 1998, six appeals involving outdoor GM activities have been taken to the High Court. One application has gone through to the Court of Appeal.

Four of these concern various applications and/or approvals for AgResearch's GM livestock R+D. Of the remaining two, one concerned a Plant and Food GM brassica field trial, and the other an abandoned GM sheep trial by Scottish company, PPL Therapeutics.

The appeals that have been taken have raised substantive matters. These include:

- What level of information needs to be provided in order for the regulator to assess an application (AgResearch, GM livestock);
- The appropriate parameters of approvals, such as whether applications for a wide range of unspecified engineered traits should be allowed (so-called generic or project-level approvals) (AgResearch, GM livestock);
- Whether developers should be required to monitor for environmental effects of the GM experiment as a condition of HSNO approval (Plant and Food GM brassica trial);
- Whether monitoring of the site of a trial involving sheep containing human genes

should be required (PPL Therapeutics trial site); and

- Whether ethical, spiritual and cultural concerns about particular applications were properly taken into account, (AgResearch, GM cattle).

In essence, two of the six cases led to fundamentally different outcomes as a consequence of the legal action. In one, the Court agreed that the EPA had not properly followed its methodology and set aside the 2001 approval for AgResearch to [field trial] GM cattle and required the regulator to reconsider and redetermine the application.[49]

A further challenge was upheld in the High Court in 2009, but later overturned in the Court of Appeal. This, too, concerned an application by AgResearch for a wide-ranging licence to experiment, discussed above. At issue was whether the applicant had provided sufficient information for the regulator to consider the application. Ultimately, the regulator recommended that the application be declined and the CRI withdrew it before it was considered by a specially appointed committee.

Elective surgery

The costs of court involvement can be significant and are cited by developers as another deterrent to moving into the field with GMOs. Yet judicial reviews concern only the decisions of the regulator. Any court costs incurred by CRIs in relation to judicial reviews are voluntarily adopted, and it is by choice that CRIs have joined the EPA as defendants. That is elective surgery for experimental gain, not in defence of existing income streams or sole solutions to an identified need. Indeed, CRI decisions to join the defense for judicial reviews of EPA decisions suggest a lack of trust that the regulator can successfully defend its decision to approve an application. More importantly, perhaps, it shows a questionable judgment about use of what is often state funding as the state is effectively paying for two teams to defend a regulatory decision.

3. A Case of Wishful Thinking?

Explanation for the lack of commercial success from New Zealand's state-funded agricultural GM R+D effort is certainly needed. Since the 1980s, tens of millions of dollars of public science funding has been invested in the development of GMOs - most of this to crown research institutes. Yet despite promises of major economic returns and imminent or certain commercialisation, not a single GM crop variety has reached the market or is likely to do so within the next decade.

Developers may wish regulation were the cause of arrested development of GM agricultural in NZ, but if it has played any role it is a minor one. Indeed, it would be much easier for developers were regulation the major obstacle to successful commercialization of GM R&D. Deeper, interrelated factors at play include:

- Technical challenges that have proven more difficult than expected;
- Partial or full loss of public funding;
- Public opinion in New Zealand about outdoor GM activities and GM food production;
- Consumer resistance to GM foods in key export markets; and
- Low levels of support from New Zealand food producers for outdoor experimentation and/or commercial GM food production.

As the Ministry for the Environment observes:

> The claim that HSNO is a regulatory barrier ignores the possibility that innovation may be inhibited by many other factors than HSNO, these include market factors (e.g,. size of the relevant market, prices of substitute goods, transition costs), capacity (levels of science and technology education, need for critical mass), funding issues (uncertainty inherent in new technology increases cost of capital, other research and development opportunities may be more attractive) and other regulation (competition, labour, company law).[50]

Some of these present complex, steep challenges for those committed to the agri-GM proposition. Some, such as consumer disquiet about GMOs, may have some bearing on regulatory settings, but overwhelm the latter in terms of their impact on the commercial viability of GM food production.

The role of these wider factors in shaping the course of two prominent CRI GMO research projects are apparent in the brief case studies that follow.

Case study 1: Plant and Food's GM Potatoes

GM potatoes are the most field trialled food crop in New Zealand. Outdoor trials began in the late 1980s with the then DSIR and were continued by the crown research institute now known as Plant and Food.

Over that time, the R+D programme has sought to produce potatoes resistant to soft-rot and the potato tuber moth.

The last field trial ended in 2003.[51] That year, the GM insect-resistant potato lines were said to be the homegrown GMO closest to commercialisation and the CRI predicted that these would be the first candidates for larger scale field trialling, with GM stock commercially available in 2013.[52] At that time, the CRI described the regulatory regime as entirely consistent with "keeping our options open".[53]

An application to conditionally release the potatoes never eventuated, however, and Plant and Food later blamed the "overly risk-averse" regulations and HSNO information requirements for the stalled R+D. The rest of the world was growing these crops, the CRI said, whereas "we just cannot seem to move beyond field trials".[54]

Loss of state funding appears to have contributed to the decision to abandon plans to conditionally release the experimental lines. In 2003, the programme failed to secure ongoing support from the Foundation for Science, Research and Technology (FRST) and the CRI acknowledged that without assistance from the state, larger-scale trials would not occur as the New Zealand potato industry was not large enough to underwrite such activity.[55]

Subsequently, the lead Plant and Food scientist acknowledged that GM may have been a "step too far" and set the CRI on a course to develop potato lines with a new type of GM that he forecast would avoid the market response that met earlier GM techniques.[56] The prospects of those being field trialled in the near term appear dim, particularly given that CRI's policy of not moving into the field without the support of the industry (see below).

Poor commercial prospects are also likely to have been a consideration for government and industry investors. "Public acceptability", the EPA noted as early as 1998, "is likely to determine commercial success of these lines".[57] This is certainly the case in the US, where the market for commercialized GM potatoes collapsed after major food processors such as MacDonalds, Frito-Lay and McCains declared they would not use GM potatoes in their product lines.[58] In turn, investment in GM potato field trialling in the US shrank abruptly.[59] The market wariness about GM potatoes persists. Just one GM potato line has been approved for release in the EU, yet this is not for human consumption, but for industrial starch production. Not all EU countries have allowed this GM variety to be grown and in 2011, just 17 hectares were grown in two member states.[60]

Case study 2: AgResearch's GM livestock

State-funded field trialling of GM cattle began in 1999. Since then, AgResearch has received five approvals to conduct outdoor experiments involving GM livestock. Currently, this R+D and Scion's experiments with GM trees are the only outdoor activities underway in New Zealand.

AgResearch has claimed a number of commercial outcomes for the R+D, including precursor biopharmaceuticals for human therapeutics, as well as food and fibre products. Recombinant human myelin basic protein (hMBP) produced in cow's milk was described in 2007 as "[t]he most promising candidates for commercialization"[61] but a product has yet to materialize and the horizons for commercialization of any products from this research continue to shift out in time.

Funding cuts may have added to the uphill gradient for the R+D[62]. Technological impasses, however, have proved more intractable. After thirteen years of R+D and at least $24 million in public science funding, the CRI announced in early 2011 that the cloning programme had reached a dead end. Cloning is considered the best if not the only means to allow GM livestock to be farmed in commercially viable numbers as it is through cloning that the GM traits are thought to be passed more reliably from one generation to the next. However the programme was to be canned as routine deformities and premature deaths of 90% of cloned offspring could not be overcome.[63] The CRI announced it would continue its transgenic work and explore new methods of cloning (such as using embryonic stem cells).

Four of the regulatory approvals for the AgResearch GM livestock R+D have been the subject of judicial review (see Box 6). This, however, is not surprising. First, the R+D has been highly controversial. While some patient interest groups hold out hope that the biopharmaceutical lines may lead to medical breakthroughs, the programme raises significant ethical issues, including the use of human genes in livestock and animal welfare concerns.

Secondly, AgResearch has typically sought blanket approvals that would confer a licence to explore modifications that are not specified in advance to the regulator (see Box 2). As such, the applications have proven legally contentious, challenging understandings about the regulatory regime, its scope, and the level of precaution required.

Despite these challenges to the approvals it has sought, the CRI has little to complain about. The regulator has given AgResearch great freedom for its outdoor experiments. The most recent approval effectively gives the CRI free range in terms of the types of GM traits it can introduce to livestock and a twenty-five year timeframe for these experiments, more than twice as long as earlier approvals for the R+D allowed. Further, in addition to public funding of the research through FRST, the taxpayer met 80% (ca $260,000) of the regulatory assessment costs arising from the application.

4. The "Crucible of Public Opinion"

It is sixteen years since GM crop production in the US began in earnest. Over that time, public opinion - far more than regulation – has steered the course of GM foods.

Globally, GM food crops have been one of the most contentious new technologies in recent decades. In some of New Zealand's key export markets, consumer resistance to GMOs in food products has persisted well beyond the recovery period predicted by the industry. In 2010, European Commission surveys across the EU-27 found that support for GM continues to decline in many member states, with opponents outnumbering supporters three to one in many nations, and supporters are in the minority across the EU. "GM food", it concludes, "is still the Achilles' heel of biotechnology".[64]

Against this background, major food processors and retailers in many countries have assumed gatekeeping roles that include ensuring that foods they make or stock are GM free. In response, one of the major multinational GM seed companies, BASF, this year announced it was closing down its European GM plant science division, explaining:

> there is still a lack of acceptance for this technology in many parts of Europe – from the majority of consumers, farmers and politicians. Therefore, it does not make business sense to continue investing in products exclusively for cultivation in this market.[65]

Difficulties also remain for GM food exports for direct human consumption in high-value Asian markets.[66]

Such market resistance has shaped the rollout of GM agriculture globally: commercial production has been restricted to crops that are primarily destined for animal feed or use in highly processed food products (such as oils) that tend to go unlabelled for GM content due to regulatory exemptions in most countries. Hence, while global production of soy, maize, canola and cotton has grown considerably since the mid-1990s in the Americas[67], other GM crops have not survived the market storm (including wheat, potatoes, tomatoes and flaxseed). Overall, the technology has stagnated in terms of the scope of crops cultivated (four crops - soy, maize, canola and cotton - account for 99% of all GM acreage) and the trait varieties employed.

As a food-exporting nation, New Zealand has not been immune to the consumer response to GM foods. Domestic concerns about GM food crops have also played their part and the "crucible of public opinion" identified by Pastoral Genomics has reportedly proved a greater deterrent to developers than the regulatory regime.[68] Zespri has predicted that this will continue for some time: "consumer opinion and perceptions will limit the acceptability of GMOs in New Zealand in the foreseeable future"[69].

The attitudes of the wider community, the Ministry for the Environment has recently noted, influence not only how demanding and precautionary regulation is, but also commercial decisions about use of the technology, "even where regulation is comparatively permissive".[70]

Industry lobby association, NZBio attributes sluggish development of GMOs beyond the laboratory "not [to] the regulatory agency or the regulatory process per se" but to "the amount of public debate and sensitivity to each individual application, the emotive, non-evidence based arguments that are often used by anti-genetic-technologies groups, and the resulting prolonged timeframes and high cost of trial approval".[71]

Support to go into the field not there

The 'resistant public' that GM developers must contend with is not just end-consumers, but farmers, growers and food processors as they respond to consumer demands/market signals. "Farmers," Dairy NZ observes, "are very cautious about consumer acceptance"[72].

In New Zealand, that has seen the horticultural and pastoral sectors broadly supportive of lab-based research, but reject outdoor use of GM crops to date.

The primary industry association for the vegetable and fruit growing industry, Horticulture New Zealand, has spelt out its position on GM to New Zealand public and researchers: a 'yes' to lab-based R+D, but a clear 'no' to GM crops:

> What we want to do is focus on some of the things that are going to align with the image that people have of New Zealand about being clean and green, and we believe we can still use some technology in the lab, no problem at all, getting some of the benefits of innovation without actually producing the genetically modified crops.
>
> There's a clear message to the researchers that they can't be genetically modified crops, but we're happy for technologies to be used in the lab that might speed up the breeding programs.[73]

Plant and Food, the main developer of GM horticultural crops has begun to acknowledge this. After more than two decades of field trialling a range of GM crops and vigorous advocacy for New Zealand becoming a GM food producer, Plant and Food affirmed in 2009 that more important than regulatory approval was a need for a "go ahead" from the agricultural community for outdoor GM activities. That signal has not been given:

> While there is broad acceptance in New Zealand of the value of genetic modification as a research tool within containment, discussion continues in industry and society as to whether New Zealand should employ genetic modification as a technology in the field at this time[74]

Without that endorsement, the CRI pledged it would not seek to develop GMOs for commercial purposes or to field trial these in New Zealand:

> Plant & Food Research will not seek to develop genetically modified cultivars for commercial release without the clear public support of the relevant New Zealand industry sectors, as well as commercial or research relationships with a clear net benefit to New Zealand.[75]

Since then, the CEO of Plant and Food has reportedly stated that "there were no plans for further field trials".[76]

It is a similar story in the pastoral sector, where commercial sensitivity to GMOs in the food chain outweighs any perceived regulatory constraints. AgResearch has acknowledged that farming industry support has become a necessary condition for even filing an application for field activities. "The agricultural sector, indeed the people of New Zealand, need to want GE", stated the CRI's then General Science Manager. The CRI recognised that without a "fully supportive" industry, the regulator would be unlikely to accept an application.[77] For that reason, AgResearch had decided not to lodge an application to field trial GM clover until there was a "conducive environment".[78]

The sector's response to proposals by the Pastoral Genomics consortium and AgResearch to move into the field with GM ryegrasses were also halted after producer consultation. In 2009, both programmes were poised to take experimental GM pasture grass lines into the field in New Zealand. However, while producer boards such as Beef and Lamb NZ, Deer Industry New Zealand and Fonterra have given significant financial support to the Pastoral Genomics GM pasture R+D, there was not sufficient industry support to take the GM lines into the field in New Zealand, as AgResearch describes:

> the sector generally continues to take a market-led stance on field trial releases of GM forages, holding the view that **the potential value of GM technology is currently outweighed by the potential negative responses of their consumers and markets**[79] (emphasis added)

As a result, plans to file an application to the regulator were shelved, and field trialling is continuing in Australia.[80]

5. The Case for Good Law

New Zealand's primary lobby association for biotechnology industries, NZBio argues that having "one of the world's most respected and robust regulatory regimes"[81] is an advantage for New Zealand. In media statements welcoming approvals of outdoor GM tree and cattle experiments, NZ Bio has argued that "New Zealand's regulatory environment provides certainty in the safety and quality of any new products."[82] It goes further, noting that "significant consumer risk may result"[83] from conducting the type of GM livestock research elsewhere. For that reason, it has argued that New Zealand is the best place to undertake high risk research:

> we are very pleased that, under this application, the proposed work will be done under the close watch of New Zealand's regulatory system and not elsewhere in the world, where regulations in some areas have proven to be insufficient to appropriately manage such research.[84]

MfE also recognizes that good regulation is required to manage activities that carry risks:

> there is a legitimate concern over the risks posed by biotechnology and the introduction of new organisms. HSNO is about managing risk. […] By definition HSNO provides a brake on innovation. The costs of foregoing some benefits from innovation are, however, legitimately traded off against the costs of damage that may arise if risk is not effectively managed.[85]

Not only does the HSNO Act provide a level of safety assurance that even the biotech industry association deems useful and appropriate, it recognises the importance of spillover effects and provides a net benefit test that encompasses this and other costs and benefits. Under these provisions, an application must not only be tested for safety, but whether it can be expected to provide a gain to society overall, not just a private gain.

Accordingly, when Scion sought approval for a large field trial of GM pine trees, Fonterra raised concerns with the EPA about the potential damage even field trialling of GM pine trees could have on market perceptions of New Zealand food products. In a submission commenting the application, Fonterra noted that:

> Any field testing of GM organisms in containment may result in release of the organism into the New Zealand environment, with the possibility of technical challenges to its complete removal in the future. In this context it is important that a decision to proceed with field testing is based on a clear understanding of the risk-benefit implications of any change to perceptions of New Zealand's GM status for the country as a whole.[86]

Fonterra also noted there was little benefit to advancing such research in New Zealand without community and consumer acceptance:

> a positive return for advancing the research in New Zealand, for both the industry involved and New Zealand as a whole, will only be achieved where it occurs in the context of consumer, customer, community and market acceptability.[87]

Ultimately, the difficulties GMO developers are facing in getting GMOs into the field is the result of their efforts being out of step with – and, in cases, hostile to - the wider community from whom it must gain it license to operate. The "crisis" GMO

developers perceive themselves to be in is not of regulatory origin, but largely societal – a failure to win hearts and minds.

No amount of regulatory discount will generate public support. On the contrary, the short history of GMOs to date tells us that attempts to foist GMOs on the public heavy handedly leads to backlashes – politically and commerically. This was the warning from the then Minister for the Environment when Pastoral Genomics lobbied for the government to weaken regulation and so smooth the way for GM grasses. That path, he warned, would "backfire" politically both on them and government.[88] The industry, he stated, must go through the front door, rather than try to find other ways through that avoided regulation.

GM scientists in New Zealand are heavily dependent on state funding. They are insulated from the direct political effects of this via science funding procedures that operate largely independently of day-to-day politics. But there is no escaping community attitudes in the end. Even if the developer's dream of regulatory approval being no more than a safety check were realised, the CRIs fronting the work must now face the fact that without public acceptance, there is no win in sight. And even where that door is open, a number of major food producers, councils, business groups and other heavy weight interests are concerned enough to provide a next line of resistance before the developer has even got to its target user, let alone the gatekeeper retailers in distant markets or the consumers they serve.

It's time to leave behind the myth that the HSNO Act is a barrier to worthy innovation and to face the significance of sustained community opinion.

Instead of a law change, the continued inability of state funded GMO developers to meet performance targets for delivery of their products to market should prompt review in a quite different direction: the value of continuing to direct agricultural innovation investment to GMOs instead of funding non-GM opportunities.

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[2] Treasury. 2009. *Natural resources: How to make the most of New Zealand's key comparative advantage*.

[3] According to Treasury, the graph "highlights the impact of HSNO on innovation". See for example: Treasury. 2010. *Industry Policy and Innovation: Supporting the Narrative.* Paper for the Economic Forum. September 15, p. 15. Internal Treasury working document obtained under the Official Information Act.

[4] In 1997, field trial activity in the EU peaked with 264 notifications, fell suddenly in 2000 to 129 approvals and, from then averaged around 86 applications per year until 2008, the last year for which data is available. European Commission Joint Research Centre. [No date]. List of SNIFs [Summary of Notifications] circulated under Article 9 of Directive 90/220/EEC *From 21 October 1991 to 08/09/2008.* Institute for Health and Consumer Protection. http://mbg.jrc.ec.europa.eu/deliberate/doc/snifs.pdf

[5] Stein A J and E Rodríguez-Cerezo. 2009. *What can data on GMO field release applications in the USA tell us about the commercialisation of new GM crops?* JRC Technical Notes, European Commission Joint Research Centre, p. 11.

[6] Ibid., p. 9.

[7] MAF notes that "the GM crops that are available globally do not offer significant advantages to the New Zealand industry". MAF. 2008. *Perceptions of MAF's Regulatory Impact on the Grain and Seed Industry.* Outside-In Review 2007/2008, p. 39

[8] Stein A J and E Rodríguez-Cerezo. 2009. *What can data on GMO field release applications in the USA tell us about the commercialisation of new GM crops?* JRC Technical Notes, European Commission Joint Research Centre, p. 10.

[9] James C. 2011. *Global status of Commercialized biotech/GM Crops: 2011*

[10] New regulations for GM field trials and commercial releases were introduced into the EU in 2001 (the so-called Deliberate Release Directive (2001/18/EC)). Field trialling peaked four years before this and had more than halved by 2000, a year before the directive was introduced (unlike the New Zealand picture which saw a peak immediately before stricter regulation). As such, the change of EU regulations does not appear to have been the driver. Further, the similar pattern in field trial activity peaking and falling off that occurred in the US was not accompanied by any significant regulatory changes during this period.

[11] In 2008, the Ministry for the Environment put the graph before the incoming Minister, to show that there has been "a dramatic decline in the number of GM approvals since the HSNO regime began and since the RCGM enquiry commenced in 2000". Ministry for the Environment. 2008. Background on Genetic Modification Issues. December 23. Obtained under the Official Information Act.

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[24] Ministry for the Environment, Meeting with Pastoral Genomics: Tuesday March 29 2009. Briefing for the Minister, March 19 2009
[25] Pastoral Genomics. [February 2009]. Briefing for the Minister. Obtained under the Official Information Act.
[26] Treasury. 2010. *Industry Policy and Innovation: Supporting the Narrative.* Paper for the Economic Forum. September 15, p. 15. Internal Treasury working document obtained under the Official Information Act.
[27] Ministry for the Environment. 2009. Email from MfE official to the Minister of Agriculture's office summarising the outcomes of the meeting with Pastoral Genomics and Nick Smith, March 25. Obtained under the Official Information Act.
[28] Section 52 of the HSNO Act allows the EPA to require further information from the application, and must request this no later than 10 working days after receiving the application. Under section 58, the EPA may also commission further analysis or seek advice regarding an application. Section 59(5) allows the regulator to extend the time required to make a decision. In 2006/07, it took ERMA 91 days to determine a GM field trial or development application; 119 days to assess a field trial/outdoor development application in 2007/08, and 163 days for the same in 2008/09. In 2008, the regulator took 112 days to come to a decision on an application for conditional release of a GM vaccine. (ERMA annual reports 2006-2010).
[29] AgResearch Limited v GE Free NZ in Food and the Environment Incorporated and Anor CA CA380/2009 [23 March 2010], para 57.
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[43] MAF. 2009. Briefing on Meeting with Fonterra and Pastoral Genomics on 14 December 2009. The Australian regulatory regime is similarly blind to social, [ethical] and cultural dimensions of GMO activities.
[44] Fonterra. 2010. Submission on Application number ERMA200479 – Scion GM Pine.
[45] Hayman K. 2003. GM Potato project loses funds. *The Press,* October 15.

[46] Dunahay T G. 2010. *Is the Grass Always Greener? Issues Affecting the Adoption of Genetically Modified Pasture Grasses in New Zealand.* Ian Axford (New Zealand) Fellowships in Public Policy, p. 52.
[47] Upton S. 1996. (23 May 1996) 555 NZPD 12691. "How risk averse we are as a community is a social, political, and cultural judgment. Technical experts-the sorts of people whom we will be appointing to the Environmental Risk Management Authority-have no special wisdom when it comes to these social, political, and cultural judgments. It is in respect of this matter that the duly elected representatives of the people should have a say and, indeed, the public at large should have a say."
[48] GE Free NZ in Food and Environment Incorporated v Environmental Risk Management Authority and Ors HC WN CIV-2010-485-000823 [16 December 2010].
[49] The Court found "a complete absence of reference to the methodology, generally or by specific clauses, following and supporting the initial generalised claim of compliance" and a "total absence of any express or clear reference to the provisions of the methodology which were applicable as the decision progressed"
[50] Ministry for the Environment. 2011. [Untitled briefing], June 12. Obtained under the Official Information Act.
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