The Impact of the Hazardous Substances and New Organisms (HSNO) Act on Research in New Zealand

Summary

In response to concerns regarding the regulatory burden on New Zealand's research community, the Royal Society of New Zealand (RSNZ) consulted its Members, Fellows and Constituent Organisations on the experiences of working in fields requiring the regulatory oversight of the 1996 HSNO Act. The HSNO Act specifies the regulation of harmful substances and new organisms in New Zealand, in this paper however, only matters relating to new organism regulation are considered. The key areas of review identified by the research community include:

- **Reduction of the administrative overheads**: the administrative burden required by the Act could be reduced without any increase in risk or decrease in overall regulatory oversight.
- **Revision of the existing organisms register:** this register should be revised using the recent publications of the New Zealand Inventory of Biodiversity (Gordon, 2012) or the New Zealand Organisms Register (NZOR, 2012).
- **Treatment of low-risk organisms and practices**: should be revised, with particular attention being paid to the stringency of regulations governing the use of the *E.Coli* strain *K-12*.
- **Regulation could shift from technique-based to trait-based oversight**: to streamline administrative processes and bring New Zealand regulations in line with regulations in the rest of the world.

The Royal Society of New Zealand recommends that a review of the application of the HSNO Act be undertaken in order to address the issues described in this document.

Introduction

Almost all of this country's agricultural production is based on species which were, at one time, new to New Zealand. Continuing access to new imported or developed organisms will play an important role in helping New Zealand maintain its international agricultural competitive edge.

This paper highlights the findings from a consultation of the New Zealand research community regarding the balance of risk and regulation in the HSNO Act (see Appendix 1), with regard to the effects the HSNO Act has had, and continues to have, on research involving new organisms (including genetically modified organisms or GMOs). Overall, the perception from the research community is that the stringency of regulations on research and development involving new organisms could be significantly eased whilst maintaining the same level of regulatory oversight. Currently, this regulatory stringency leads to the possibility that the New Zealand innovation system is being prevented from realising the full benefit of research, or techniques, using new organisms.

Over the 16 years since the Act's inception, the amount of research involving new organisms, whether genetically modified *Pinus radiata* or new pest species has increased dramatically and there is concern that regulatory frameworks have not kept pace with progressing scientific knowledge. Concerning GMOs specifically, there have been a number of publications over this period that find that recombinant organisms have yielded low risk, high value organisms with benefits at both the farm and environment level (Lottmann et al., 2010, Schnitzler et al., 2010, Qaim, 2009, Walter et al., 2010). With respect to potential biosecurity responses to new pest organisms, in some cases these organisms have become widespread in the environment, but the complexity of the HSNO Act/Biosecurity Act boundary makes it difficult for researchers to act quickly to mitigate damage.

Shared academic and industrial viewpoints

Academic and industrial submissions to the RSNZ consultation share a number of concerns regarding the effects that HSNO requirements have on research with new organisms in New Zealand. These concerns relate mainly to: the incompleteness of categorization strategies within the Act and the advantages of moving towards trait-based rather than technologically-based regulation. Broadly, the amount of administrative oversight was not seen to be necessary and the same quality of risk management could be achieved with less.

In detail, the views held were:

- The classification strategy for two organism types under the HSNO framework - existing organisms and new organisms - is felt to be in need of revision. In order for an organism to be classified as new, it is assessed against a register of organisms present in New Zealand that was set in 1998. If it does not appear on this register, it is classified as new (the HSNO Act definition of 'new organism' can be referred to in Appendix 2). This is important because if the organism is new then under the classification strategy it requires EPA approval to work on, which incurs high administrative costs compared to recognised organisms. The list of existing plant, animal, fungal, and microbial organisms specified by the 1996 HSNO Act will necessarily be incomplete in an absolute sense due to the continual discovery of endemic organisms. However, researchers are concerned that the 1998 list, as it stands is, incomplete even by knowledge of present organisms at that date. Currently, there is no authoritative list of New Zealand's organisms, and classifications have depended on researchers' efforts in evaluating presence or absence in relation to the Act's specified date of implementation. An improvement would be to amend the date to a recent time, such as that of the publication of the New Zealand Inventory of Biodiversity (Gordon, 2012) for all organism types except plant species and varieties in horticulture (but including micro-organisms and marine life), or the New Zealand Organisms Register (NZOR, 2012) which is to be actively updated. It is crucial that this classification strategy is revised as, for example, there are instances of accidentally introduced, but beneficial organisms, that are quite clearly present in New Zealand yet not classified under the existing organisms list (e.g. self introduced beneficial organisms such as *Serangium maculigerum,* a coccinelid white fly predator). As these beneficial organisms have not been updated on the register, research into their efficacy for beneficial applications cannot be conducted without serious administrative and auditing oversight; this is despite the fact that these organisms are currently present in New Zealand, and are not listed in the unwanted organisms register.

- In relation to new organisms created by genetic modification, the framework of the Act is built upon the regulation of technology rather than traits. Arguments for trait-based

regulation recommend that focus should be on the risks of a trait, or phenotype, such as herbicide tolerance, rather than the technique employed to produce that trait. There are a plethora of different GM techniques that can be used to achieve the same trait outcome, adding to the complexity of regulatory oversight. While it could be argued that this is the correct approach given that these different techniques could demand a different risk assessment, recent research has shown that variation introduced into plants by traditional methods (quantitative breeding and selection) can introduce significantly more change to an organism than the same traits achieved through GM (Batista et al, 2008). Moves towards a trait based regulatory framework would bring New Zealand more in line with international partners such as the European Union, the United States, Canada and Australia.

- A corollary of the need for high compliance overhead under the HSNO Act is that institutions and companies do not necessarily then have the resources to undertake GMO field trials and so these activities are abandoned or are severely compromised in order to minimise costs. The amount of knowledge gleaned from small trials is therefore commensurably small (a history of field trials and outdoor developments of GMOs in New Zealand is detailed in Appendix 3).

- There is concern that traditional breeding programs have also been negatively impacted by the regulatory requirements of the HSNO Act. Researchers note that germplasm collections in New Zealand have been gradually depleted due to the regulatory cost and uncertainty in seeking approval for both importing exotic germplasm and refreshing stocks of germplasm through breeding. The regulatory complications regarding the importation of new species for traditional crossbreeding purposes may negatively impact the ability to develop invasive organism-resistant species as well as endangering the ability of New Zealand plant based industries to remain competitive.

Academic-specific viewpoints

Concerns specific to academic research focus on the perceived restrictive oversight of low-risk genetically modified organisms and the high administrative costs of regulatory compliance:

- Submissions universally requested that specific attention should be directed to improve regulations concerning low-risk modifications to routine laboratory organisms (the current regulations which describe the differences between low-risk and non-low risk modifications are referenced in Appendix 2). The view of many researchers is that the risk and regulation balance for low-risk modifications to routine laboratory organisms is not correct. Time delays and opportunity costs involved in preparing applications are necessary even for research with extremely low or zero risk; for example, the requirement to track commercially purchased *E. coli* competent cells is taking an extremely risk averse approach to managing what are considered as extremely low risk organisms i.e. organisms which do not have the ability to live outside of specific conditions provided by the laboratory. International developments have seen decisions by UK and US agencies exempting the *E . coli* strain *K-12* from review (HSE 2001 , USEPA 2011). A particular concern is that although herbarium specimens (preserved plant species) are dried and frozen, resulting in low viability and a correspondingly low biosecurity risk, they still require time consuming administrative requirements to be met under the HSNO Act. The permitting and auditing practices for transporting plant and fungal specimens, both domestically and internationally, is seen to be too time consuming given the low-risk nature of the samples.

- At Massey University an estimate of the costs for each MAF audit to the institution is, on average, almost $3000 with two audits required annually. A breakdown of the costs relating to the application of HSNO legislation to field testing in containment for Scion projects recently totalled 32% of total expenditure of the annual research budget for all plant gene discovery and laboratory/field containment. Of this, 60% was solely due to administration costs. These costs represent a large portion of institutions' operating budgets and relate only to the administrative side of compliance within the Act. Submissions see a need to streamline the audit process and to revisit the administrative requirements in order to remove some of these time and financial burdens. This is thought to be possible without compromising regulatory oversight.

Industrial-specific viewpoints

There is a perceived regulatory risk from the HSNO Act in New Zealand. ArborGen, for example, has no plans at this time to invest in, or further develop biotech trees for the New Zealand market beyond its existing investment and research programmes over the next five years. While technical challenges; the risk associated with product launches; and market size and attractiveness are important to AborGen, the implementation of the HSNO Act in New Zealand acts as a major barrier to committing to this market. Specific concerns relate to the time, costs and low comparative advantage of doing this research in New Zealand against doing the research overseas:

- Based on the established history of commercialising biotech agricultural crops, estimates made by ArborGen of the time and cost incurred to bring a full release of a biotech product to market in the United States are currently 3-4 years and at a cost of over $1m (steps have just been taken to reduce the time for commercial approvals down to 13-15 months). As there are no commercially released GMO's in New Zealand at this time, it is difficult to estimate time to market and costs for a conditional or full release of a biotech product in New Zealand, but given the greater lack of certainty and higher perceived regulatory risk it is difficult for ArborGen to make a case for expanding biotech tree development in New Zealand.

- In comparison, overseas regulation is more streamlined, less time consuming and less of a financial burden (an international comparison of GM related fees and processes is presented in Appendix 4). Projected costs estimated at ArborGen for obtaining field test approval for key New Zealand biotech pine are $500,000 with a consenting time of over 1-2 years. As a comparison, costs in the United States are substantially less, where it can take as little as 3 months and cost less than US$10,000. Given the different operating environments and social concerns between the United States and New Zealand there will understandably be some difference in desired consenting processes and costs.

Summary

Whilst there have been changes to the Act, including the introduction of the Low-Risk Genetic Modification Regulation in 2003, there is a strong feeling that there is still scope for improvement with respect to research and innovation output. Researchers claim that our onerous regulation plays a role in the low level of new organism commercialisation and development in New Zealand.

The community also expressed concerns regarding the ability of research organisations to rapidly respond to new organism pest incursions which can spread quickly in the field and have potential for widespread impact on agricultural primary producers.

Whilst New Zealand will typically have different concerns regarding new organisms and GM modified organisms compared with other countries, all submissions consider that the administrative burden required by the Act could be streamlined without any increase in risk or loss in regulatory oversight. Examples offered by our contributors are: revision of the existing organisms register, or changes to the process of recognising endemic organisms; changes to the treatment of low-risk organisms and practices; and a shift to trait-based, rather than technique-based, regulation.

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Appendix 1 – Contributors to this paper

Industrial and academic submissions

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Landcare Research
Massey University, Institute of Molecular BioSciences
New Zealand Institute of Forestry
Plant and Food Research
Scion
University of Auckland, School of Biological Sciences
University of Otago, Department of Botany
University of Otago, Institutional Biological Safety Committee

Personal submissions

Dr Tony Conner, AgResearch
Mr Colin Eady, Plant and Food Research
Mr Dean Satchell, Sustainable Forest Solutions

Appendix 2 – Classifications for new organisms, low-risk host organisms, low risk genetic modification and non-low risk genetic modifications

The following classifications are referenced from *Hazardous Substances and New Organisms Regulations 2003*. For further information it is available at:
http://www.legislation.govt.nz/regulation/public/2003/0152/latest/whole.html
and:
http://www.mfe.govt.nz/publications/organisms/discussion-paper-sep02/section11-sep02.pdf

(1) A new organism is –

(a) An organism belonging to a species that was not present in New Zealand immediately before 29 July 1998:
(b) An organism belonging to a species, subspecies, infrasubspecies, variety, strain , or cultivar prescribed as a risk species, where that organism was not present in New Zealand at the time of promulgation of the relevant regulation:
(c) An organism for which a containment approval has been given under this Act:
(d) A genetically modified organism:
(e) An organism that belongs to a species, subspecies, infrasubspecies, variety, strain, or cultivar that has been eradicated from New Zealand.

(2) An organism ceases to be a new organism when an approval has been given in accordance with this Act for the importation for release or release from containment of an organism of the same kind as the organism.

(3) Despite the provisions of this section, an organism present in New Zealand before 29 July 1998 in contravention of the Animals Act 1967 or the Plants Act 1970 is a new organism.

(4) Subsection (3) does not apply to the organism known as rabbit haemorrhagic disease virus, or rabbit calicivirus.

(7) Low-risk host organisms

(1) A **category 1 host organism** is an organism that—
(a) is clearly identifiable and classifiable according to genus, species, and strain or other sub-specific category as appropriate; and
(b) is not normally able to cause disease in humans, animals, plants, or fungi; and
(c) does not contain infectious agents normally able to cause disease in humans, animals, plants, or fungi; and
(d) does not produce desiccation-resistant structures, such as spores or cysts, that can normally be disseminated in the air; and
(e) is characterised to the extent that its main biological characteristics are known; and
(f) does not normally infect, colonise, or establish in humans.

(2) A **category 2 host organism** is an organism that—
(a) is clearly identifiable and classifiable according to genus, species, and strain or other sub-specific category as appropriate; and
(b) is—
(i) a micro-organism of risk group 1 or risk group 2 that—
(A) is or contains an infectious agent pathogenic to humans, animals, plants, or fungi; or
(B) produces desiccation-resistant structures, such as spores or cysts, that may normally be disseminated in the air; or
(C) is not characterised to the extent that its main biological characteristics are known; or
(D) normally infects, colonises, or establishes in humans; or
(ii) a mammalian cell line containing active viruses or infectious agents normally able to cause disease in humans; or
(iii) a whole animal, vertebrate or invertebrate, including oocytes, zygotes, early embryos, and other cells able to grow without human intervention into a whole animal; or
(iv) a whole plant—

(A) with a reproductive structure and that is not kept in a closed container; or
(B) with a reproductive structure and that is kept in a closed container; or
(C) without a reproductive structure and that is not kept in a closed container.

(5) Categories of low-risk genetic modification

(1) A category A genetic modification is a modification that—
- (a) involves a category 1 host organism, as defined in regulation 7(1); and
- (b) is carried out under a minimum of PC1 containment; and
- (c) does not increase the pathogenicity, virulence, or infectivity of the host organism to laboratory personnel, the community, or the environment; and
- (d) does not result in the genetically modified organism having a greater ability to escape from containment than the unmodified host organism.

(2) A category B genetic modification is a modification that is carried out under a minimum of PC2 containment and involves either—
- (a) a category 1 host organism, as defined in regulation 7(1), that satisfies the requirements of subclause (3); or
- (b) a category 2 host organism, as defined in regulation 7(2), that satisfies the requirements of subclause (4).

(3) If a category 1 host organism is used,—
- (a) the nucleic acid that is introduced must be characterised to the extent that—
  - (i) its sequence is known; or
  - (ii) its gene function is understood; and
- (b) the modification must not—
  - (i) result in a genetically modified organism that is more pathogenic, virulent, or infectious to laboratory personnel, the community, or the environment than a category 2 host organism; and
  - (ii) result in the genetically modified organism having a greater ability to escape from containment than the unmodified host organism.

(4) If a category 2 host organism is used,—
- (a) the modification must involve either—
  - (i) a host organism that is not normally able to cause disease in humans, animals, plants, or fungi; or
  - (ii) a host organism that is normally able to cause disease in humans, animals, plants, or fungi provided that the nucleic acid that is introduced is characterised to the extent that—
    - (A) its sequence is known; and
    - (B) its gene function is understood; and
    - (C) its potential gene products are understood; and
- (b) the modification must not—
  - (i) increase the pathogenicity, virulence, or infectivity of the host organism to laboratory personnel, the community, or the environment; and
  - (ii) result in the genetically modified organism having a greater ability to escape from containment than the unmodified host organism.

Developments that are not low-risk genetic modifications

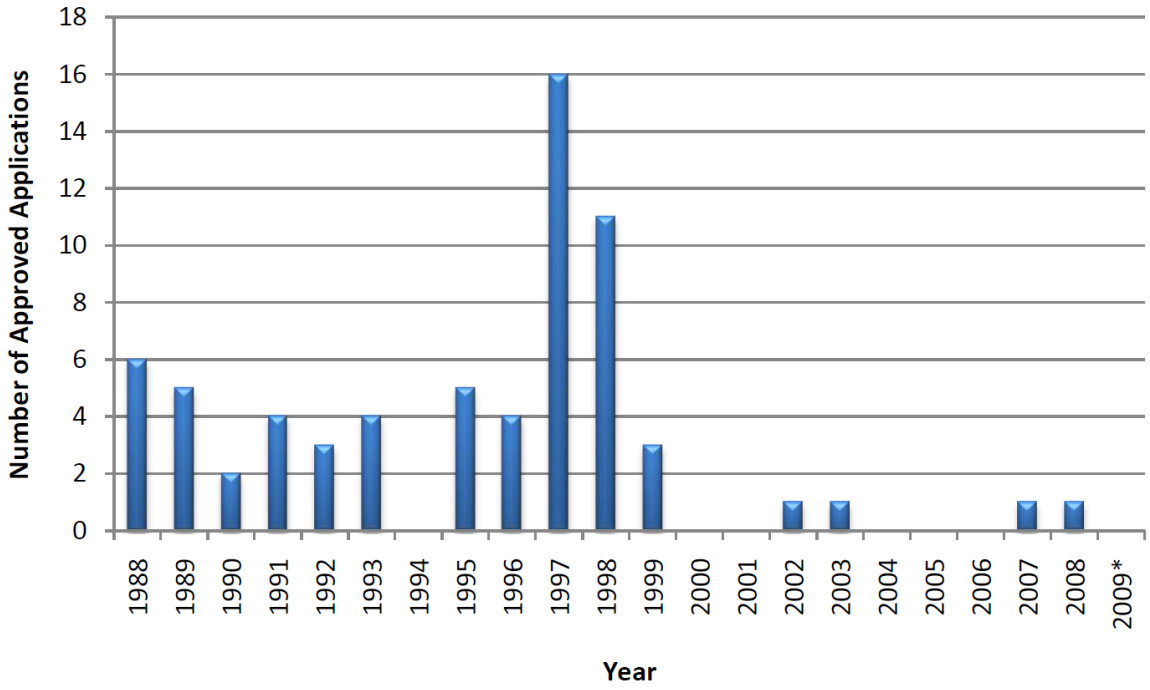
(1) The following developments are not low-risk genetic modifications:
- (a) developments involving host organisms that are micro-organisms of risk group 3 or risk group 4:
- (b) developments involving the expression of genes encoding toxins that have an oral or dermal vertebrate LD_{50} of less than 100 μg/kg:
- (c) developments involving production of pharmacologically active forms of other biologically active molecules that have an oral or dermal vertebrate LD_{50} of less than 100 μg/kg:
- (d) developments involving the expression of genes that encode a substance toxic to vertebrates at levels higher than the level occurring in the organism from which they are derived—
  - (i) including, despite paragraph (b), genes that encode a substance toxic to vertebrates that have an oral or dermal LD_{50} greater than 100 μg/kg; but
  - (ii) excluding developments involving the expression of genes that are—
    - (A) from a toxin-producing organism as donor; and
    - (B) shown not to encode a substance toxic to vertebrates:

(e) developments involving viral vectors whose host range includes human cells and that contain 1 or more inserted nucleic acid sequences coding for a product that can lead to uncontrolled mammalian cellular proliferation or be toxic to mammalian cells, or both:
(f) developments involving or resulting in viral genomes, viroids, or fragments of a genome capable, in the host/vector system used, of giving rise to particles naturally infectious and normally able to cause disease in humans, animals, plants, or fungi other than those that satisfy the requirements of a category A or category B genetic modification:
(g) developments using micro-organisms as a host or vector that are normally able to cause disease in humans, animals, plants, or fungi and that use defective vector/helper virus combinations with the potential to regenerate a non-defective recombinant virus other than those that satisfy the requirements of a category A or category B genetic modification:
(h) developments involving recombinations between whole viral genomes, viroids, or complementary fragments of these genomes, where 1 or more fragments contain 1 or more virulence determinants or pathogenic determinants, including developments that can alter the host range of a pathogen or that increase the virulence or infectivity of the virus:
(i) developments involving the introduction of genes determining pathogenicity into micro-organisms other than category 1 host organisms involved in category A genetic modification:
(j) developments involving micro-organisms that are capable of causing disease in humans, animals, plants, or fungi unless the developments only involve cloning genetic material that is well characterised and is known not to increase the virulence or infectivity of the host:
(k) developments involving modifications to pathogenic micro-organisms that result in resistance to antibiotics used for clinical or veterinary treatment of infections caused by that micro-organism.

(2) For the purposes of clause 1(a),—

- risk group 3 means micro-organisms that are pathogens—
  (a) that usually cause serious human, animal, or plant disease and may present a serious hazard to laboratory personnel; and
  (b) that could present a risk if spread in the community or the environment; and
  (c) in respect of which effective preventative measures or treatments are usually available
- risk group 4 means micro-organisms that are pathogens—
  (a) that usually cause life-threatening human or animal disease and present a serious hazard to laboratory personnel; and
  (b) that are readily transmissible from—
    (i) an individual human to another human or to an animal; or
    (ii) an individual animal to another animal or to a human; and
  (c) in respect of which effective treatment and preventive measures are not usually available.

Appendix 3 – Historic number of field trials and outdoor developments of GMOs in New Zealand



Data Source: *(NZ) ERMA/EPA 1988-2009*

Figure Source: *International Comparisons to the Hazardous Substances and New Organisms Act 1996, 2009, New Zealand treasury summer intern paper.*

This figure shows the number of approved applications for field trials and outdoor developments in New Zealand over the period 1988-2009. There is a correlation with the reduction in field trial developments and the passing of the 1998 HSNO Act, but it is important to remember the possibility of confounding data which may prevent attributing causation.

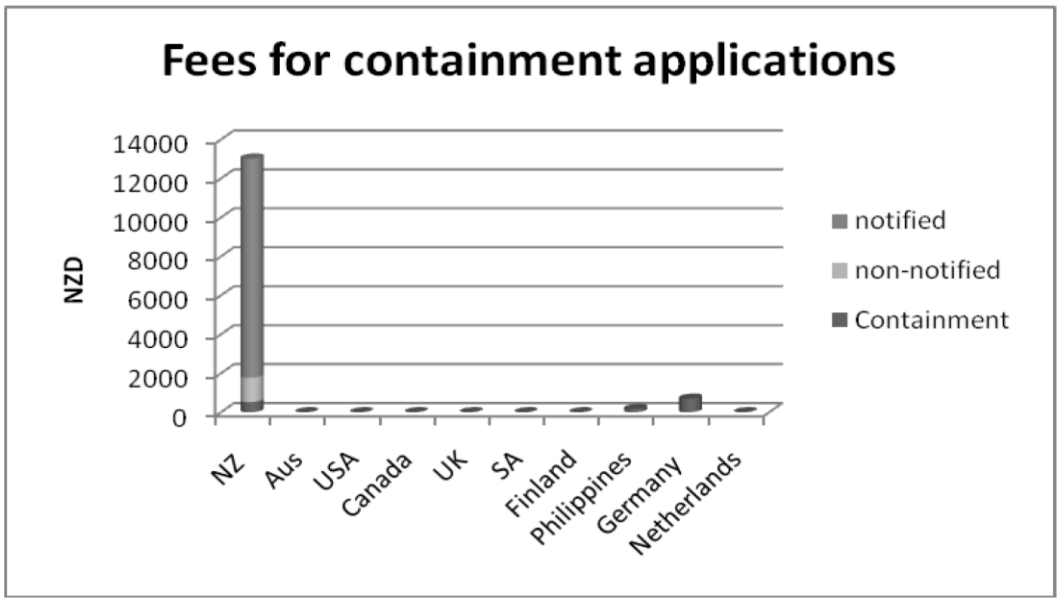
Appendix 4 – International comparison of fees

Reproduced from: *Comparisons of GM regulation in New Zealand and overseas, 2009, New Organisms Division, EPA, Report number AU.09.046*

Contained laboratory use

New Zealand	
Rapid $562.50 (NZD) Non-notified $1125 (NZD) Notified $11 250 (NZD)	Development and importation of a GMO into NZ requires ERMA approval. There are three pathways: **Low risk GMOs** A short risk assessment is performed. This assessment along with the application is then considered by the Decision-maker. **Timeframe: 10 working days.** **Non-low risk GMOs** A full risk assessment based on the work proposed in an application is performed. This assessment along with the application is then considered by the Decision-making Committee. Non-low risk applications may be publicly notified if there is likely to be significant public interest in the application. **Non-notified 70 working days** **Notified 100 working days**
Australia	
No charge	Contained research with GMOs fit under three regimes: **Exempt** dealings involve very well understood organisms and processes for creating and studying GMOs. There are no requirements to report exempt dealings to the Regulator **Notifiable low risk dealings (NLRD)** – GMOs assessed as low risk under specified containment (PC1/PC2) -assessed and recorded by Intitutional safety committees **Dealings not involving intentional release (DNIR)** –eg Oncogenic GMOs - licensed by OGTR.
European Union	
Fee set by member state: **Finland** $700-1800 (NZD) € 340-850 **UK** No Charge **Germany** Between 0.6 and 0.25% of the cost of building the facility **Netherlands** No charge	Facilities are regulated; not every organism. Application including environmental assessment is made to the member state when a facility begins doing GM. Member states decide whether to publicly notify Member states must provide the council of the European Communities an annual summary including a description, proposed uses and risks of the GMOs being used. **Germany** Registration of facilities (not specific developments) to a 'risk level' by authorities of the German federal states. There are four "risk levels" in Germany. Projects with GM plants belong to the lowest risk level (1).

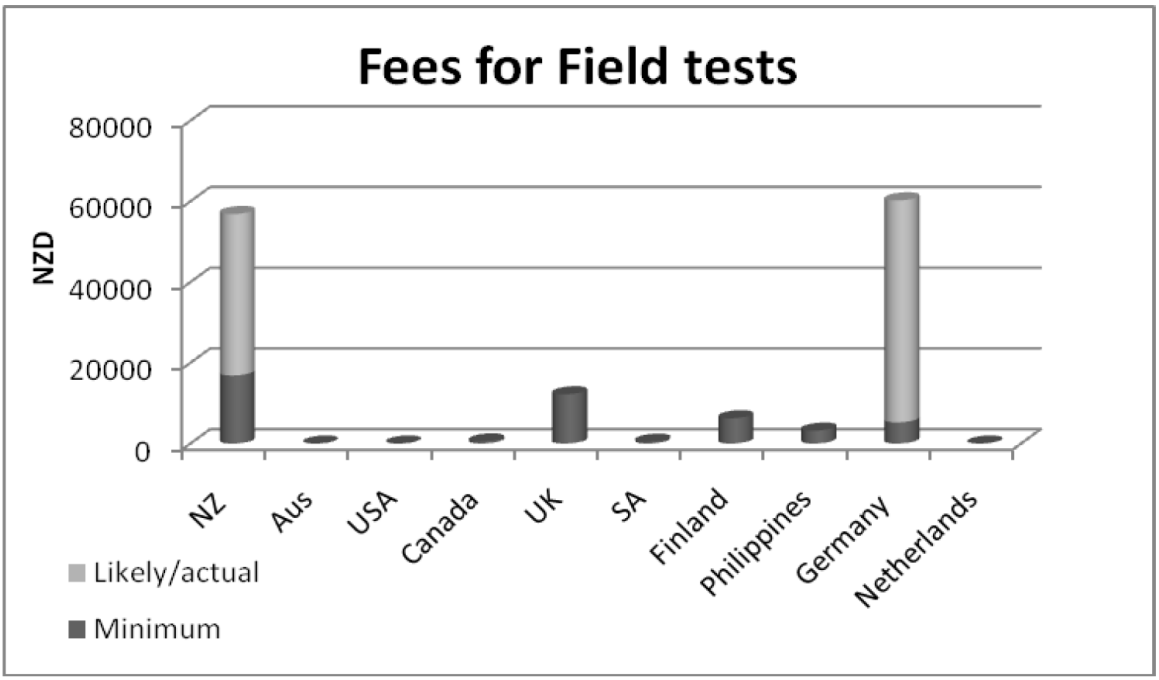
Japan	
No charge	Voluntary guidelines overseen by Science and Research Agency for work outside of a university and the Ministry of Education, Culture, Sports and Science technology for work within a university.
USA	
No Charge	Voluntary guidelines – NIH's guidelines for research involving Recombinant DNA molecules.
Canada	
Academic $20 (NZD) $15 (CAD) Business $47 (NZD) $35 CAD	Charges for import (not for development)
Malaysia	
No charge	Notification to the National biosafety board is required for contained use, import for contained use and export of LMOs.
Philippines	
No charge	
South Africa	
$170 (NZD) R910	



Field test/small scale release – not contained field tests as in NZ

New Zealand	
Negotiated, from $16 875, likely fee of $40,000 + disbursements	Unlike the other countries in this table, field tests in NZ are containment applications. Field tests are used to expose plants or animals to conditions similar to those they would experience should they be released. The plants or animals must be contained to the field test site. Field tests are considered after a full assessment of the risks and benefits to health and safety, the environment, social, cultural, ethical and economic impacts and a public notification period. The risk assessment, application and any additional information from the public is then considered by the Decision-making Committee in order for a decision to be reached. **Timeframe:100 working days**
Australia	
No charge	Application made to OGTR, staff prepare a risk assessment and management plan. Advice provided by expert body. Decision made by the Gene technology Regulator. Risk assessment considers health and safety of people and the environment. Assessments do not consider the social, cultural, ethical or economic impacts. Only risks are assessed not benefits The **time frame for assessment is 150-170 days**, and these approvals have a lifespan. Public notification is not mandatory.
European Union	
Fee set by member state **Finland** $6270 (NZD) € 3000 **Germany** **Fees** $5,250-31,500 (NZD) €2500-15000 + exp **Actual costs** $6,300-105,100 (NZD) €3,000 and 50,000 for past applications **Netherlands** No charge **UK** Initial application $12 200 (NZD) £5000 Repeat $6000 (NZD) £2500 Annual monitoring $2000 (NZD) £850	**Directive 2001/18/EC part B** Application made to the member state in which the release is to take place. This application covers information about the GMO, staff, conditions of the trial, effects on human health or environment, controls, remediation, waste management and emergency response and monitoring plans. Application is notified to other member states Decision making lies at the Member State level . There are some aspects of the authorisation procedure that are regulated differently in the Member States for example public notification. **Germany** Field tests might include trials in several consecutive years and at several trial sites. The expenses charged to the applicant include costs for notification, and consultation on applications.

Japan	
	Law concerning Securing of Biodiversity by the Regulation of the use of genetically modified organisms (known as the Cartagena law). Class 1 and Class 2 categories for plants (class 1 – release, class 2 – contained). Overseen by the Ministry of Agriculture, Forestry and Fisheries (MAFF) and the Ministry of the Environment. Public consultation is not required.
USA	
No Charge	Application made to APHIS, information requirements include weed assessment, specific information on the trait, how it differs from parental and procedures and safe guards. APHIS forward notifications to state agencies for any comments. **Two tiered system –** **Notification** for lower risk GMOs (plants altered with common traits eg herbicide resistance). **Permit** system for higher risk eg plants producing pharmaceuticals or GMOs other than plants. APHIS must be satisfied that the benefits outweigh the risk.
Canada	
Initial application $540 (NZD) $400 (CAD) Annual renewal or new site $140 (NZD) $100 (CAD)	Applications are made to the plant biosafety office (PBO). Provincial governments are notified. Standard terms and conditions are applied to trials, including reproductive isolation (through isolation distances), site monitoring and post-harvest land use restrictions. Each field trial is subject to restrictions in the size and number of sites per province Applications are not publicly notified, but PBO recommends neighbours are informed if they may be affected in the event of an isolation breakdown. **Timeframe; 30 days if not intended for food or feed, 60 days if using a plant crop usually used as food or feed.**
Malaysia	
$210-840 RM500-2000	For field release research and development applications, the larger the size of the field test the higher the application price. The maximum size allowed is 10ha per field site.
Philippines	
$3200 (NZD) P103,400	Application made to Bureau of Plant Industry (BPI). Environmental Risk assessment, and public consultation are carried out prior to a decision. **Time frame for applications is 120 days from acceptance.**
South Africa	
$460 (NZD) R2,550	


Fees for Field tests
NZD
80000
60000
40000
20000
0
NZ
Aus
USA
Canada
UK
SA
Finland
Philippines
Germany
Netherlands
Likely/actual
Minimum

Market/release a GMO

New Zealand	
Full or conditional release fee is negotiated. The minimum fee is $16875 with a likely fee of $40,000-80,000 + disbursements The fee for the release of a qualifying organism is $562.50	A full release application, if approved, allows a new organism to be released without controls. The released organism would no longer be regulated under the HSNO Act. A conditional release application, if approved, allows a new organism to be released into the New Zealand environment with controls. The released organism would still be regulated under the HSNO Act. **The timeframe for these applications is 100 working days** and they are considered after a full assessment of the risks and benefits to health and safety, the environment, society, culture and the economy and a public notification period. The risk assessment, application and any additional information from the public is then considered by the Decision-making Committee in order for a decision to be reached. A qualifying organism is a 'low risk' new organism contained within a human or animal medicine. This type of application is assessed after a short risk assessment The **time frame for a qualifying organism application is 10 working days**
Australia	
No charge	Application is made to OGTR, staff prepare a risk assessment and management plan. Expert advice provided by expert body. Decision made by the Gene technology Regulator. Risk assessment is based on the dealings with the GMO and considers health and safety of people and the environment. Assessments do not consider the social, cultural, ethical or economic impacts or benefits. **The time frame for assessment is 255 days, and these approvals tend not to have a time frame** Public notification is not mandatory.
European Union	
Member states set the fee **Finland** $12 500 (NZD) € 6000 **Germany** **Fee** $10,500-63,100 + exp € 5000-30000 + exp Est actual costs $105,100-210,300 €50,000-100,000 **no charge** for applications to market GM crops under the GM food and feed regulations **UK** $29 200 (NZD)	**Directive 2001/18/EC** Covers placing on the market of GMOs not intended for food or feed purposes, such as ornamental plants, the initial risk assessment is carried out by the Member State which the applicant selects to file the application. Information requirements include diversity of sites, effects on human health and the environment, an environmental risk assessment, conditions of use and handling of the GMO and its products. Monitoring plan, labelling and packaging plan and a proposed period for the consent (not more than 10 years). Applications are sent to all member states, the European commission and the public for comment. An assessment report, taking into account comments and expert advice is sent to the applicant indicating whether the GMO should be marketed. If the assessment is not favourable the application may be declined at this stage. If the assessment is favourable then the assessment report and application is sent to the European commission and member states for further comments. The public is also notified.

£12,000 if lead for the risk assessment, otherwise no charge. **no charge** for applications to market GM crops under the GM food and feed regulations **Netherlands** No charge	Each application is assessed in terms of potential risks it poses to human health or the environment. A collective decision is made by all Member States and the Commission acting jointly. **Release for food or feed** **Regulation EC 1829/2003** An application is made to a member state, this application is then sent to European food safety authority (EFSA). EFSA informs other member states, the European commission and the public. Information requirements include, the transformation event, compliance with Cartagena, method of production, safety research, ethical concerns, detection methods and a proposal for monitoring. EFSA forms an opinion within 6 months of receiving all information. Member state then has 3 months to comment. If the opinion is in favour then EFSA reports back to the European commission which then drafts a decision to the Committee within 3 months.
Japan	
	Law concerning Securing of Biodiversity by the Regulation of the use of genetically modified organisms (known as the Cartagena law). Class 1 and Class 2 categories for plants (class 1 – release, class 2 – contained). Overseen by the Ministry of Agriculture, Forestry and Fisheries (MAFF) and the Ministry of the Environment. Assessment covers, safety of host, genes and vectors, allergenicity (if food), toxicity, competitive superiority and cross fertility. Public consultation is not required.
USA	
No Charge	When a developer has collected enough evidence that a GMO poses no more of a risk than an equivalent non-GMO, a petition application may be made to APHIS to grant the GMO non-regulated status. If the petition is approved, the GMO may then be introduced into the United States without any further APHIS regulatory oversight. Information requirements for a petition include the biology of the plant, differences between unmodified and modified, expression of gene products, effects on non-target organisms, field test reports etc. A petition application is publicly notified for 60 days. **For release of intended food or feed** USFDA requires information on the intended use of the product, particulars of the genetic modification, the effect of the modification on the properties of the food, allergencity and toxicity, safety assessments, comparison of the composition of the bioengineered food to that derived from the parental.
Canada	
$2700 (NZD) $2000 CAD	Applications are made to the Minister. Criteria for assessment include, potential for the PNT to become a weed or plant pest, potential for gene flow, potential for effects on non target organisms including humans. Minister makes a decision taking into account all comments and advice including an environmental risk assessment.

	If the organism is deemed to be non-toxic then no conditions can be placed on the release approval. If toxic and still approved for release then conditions can be specified regarding the manufacture or import of the organism. All applications are publicly notified for 60 days. **Release for food or feed** Applications are made to the Minister and must include data about the novel trait, modification history, toxicology, dietary exposure, feeding trials and an environmental risk assessment.
Malaysia	
Commerical release $840-3350 RM2000-8000 For sale $4200 RM10,000	The larger the size of the release the higher the price, therefore for a commercial field release above 10ha per location is $3350.
Philippines	
Commercialisation $8350 (NZD) P270,000 Direct use $6650 (NZD) P215,000	Application made to Bureau of Plant Industry (BPI). Environmental Risk assessment, food safety assessment and public consultation are carried out prior to a decision. **Time frame for applications is 60 days from acceptance.**
South Africa	
$2850 (NZD) R15,600