IN THE HIGH COURT OF NEW ZEALAND
AUCKLAND REGISTRY

CIV-2016-404-2318
[2017] NZHC 1150

BETWEEN	THE UNIVERSITY OF AUCKLAND Appellant
AND	AUCKLAND COUNCIL Respondent
	FEDERATED FARMERS OF NEW ZEALAND INCORPORATED
	SOIL AND HEALTH ASSOCIATION OF NZ LIMITED
	WHANGAREI DISTRICT COUNCIL Section 301 parties

Hearing:	On the papers
Counsel:	R Brabant for Appellant M G Wakefield for Respondent R Gardner for Federated Farmers of New Zealand Inc R Makgill for Soil and Health Association of NZ Limited G Mathias for Whangarei District Council
Judgment:	30 May 2017

JUDGMENT OF WHATA J

This judgment was delivered by me on 30 May 2017 at 4.00 pm, pursuant to Rule 11.5 of the High Court Rules.

Registrar/Deputy Registrar

Date: .....

Solicitors: Auckland Council, Auckland

[1] The University of Auckland (the University) appeals against the decision of the Auckland Council (the Council) to accept the recommendations of the Independent Hearings Panel (IHP) in relation to the use of genetically modified organisms (GMOs). The University claims that Chapter E37 of the Auckland Unitary Plan (Unitary Plan) dealing with GMOs irrationally prohibits the use of viable GMO medical vaccines. By contrast the Council submits that Activity Table E37.4.1 permits medical applications.

[2] Relevantly, Table E37.4.1 provides the following activity statuses to various GMO activities:

> (A1) Genetically modified organism activities not specifically provided for or prohibited, including research within contained laboratories and medical or veterinary applications involving use of non-viable genetically modified products [permitted]
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> (A2) Genetically modified organism field trials on land and within the coastal marine area and any structure intended to house, or otherwise contain, plants and animals which are associated with the conducting of genetically modified organism field trials [discretionary]
>
> (A3) The use of any viable genetically modified veterinary vaccine of a specific dose supervised by a veterinarian [permitted]
>
> (A4) The use of any viable genetically modified veterinary vaccine not otherwise provided for [discretionary]
>
> (A5) Genetically modified organism releases – non food-related on land and within the coastal marine area and any structure intended to house or otherwise contain plants and animals which are associated with outdoor genetically modified organism release, except as specifically provided for [prohibited]
>
> (A6) Genetically modified organism releases – non food-related on land and within the coastal marine area and any structure intended to house or otherwise contain plants and animals which are associated with outdoor genetically modified organism releases, except as specifically provided for [prohibited]

[3] The Council submits that the use of viable GMO medical vaccines is permitted by A1 (as a GMO activity not specifically provided for), and that there is therefore no material error of law. But it accepts that the current version of Table E37.4.1 gives rise to an issue of interpretation.

[4] The parties agree that the appeal may be resolved by consent on the basis of the relief set out in Appendix A.

[5] I must resolve whether there is an error to correct, and if so whether I should grant the relief as sought or otherwise.

Jurisdiction

[6] The statutory frame is canvassed in detail in my judgments in *Albany North Landowners v Auckland Council*[1] and *Ancona Properties Ltd v Auckland Council*,[2] together with the judgment of Wylie J in *Transpower New Zealand Ltd v Auckland Council*.[3] It is unnecessary to repeat the dicta in those judgments. In short, I must be satisfied that the IHP erred in law in order to allow the appeal, even by consent. I must also be satisfied that if I allow the appeal, referral back to the Council and a further appeal to the Environment Court would be futile.

Assessment

[7] I do not accept that a decision to prohibit medical applications using viable GMOs is irrational in the sense that this term is used in public law; that is, testing the legality of an exercise of statutory power.[4] On the information available to me, it was available to the IHP to prefer a precautionary approach to the release of viable GMOs via medical applications, including medical vaccines.

[8] But the current version of Table E37.4.1 is ambiguous on its face. To elaborate, two interpretations of table E37.4.1 are reasonably available on the basis that medical vaccines using viable GMOs are, or are not, 'specifically provided for or prohibited': one that includes viable GMO medical vaccines within the scope of A1 and outside the scope of A6, and one in which they are outside the scope of A1, instead falling within A6. One the one hand, it could be said that discharges of viable GMOs following medical vaccine via human waste are literally "releases" to land

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1 *Albany North Landowners v Auckland Council* [2017] NZHC 138.
2 *Ancona Properties Ltd v Auckland Council* [2017] NZHC 594.
3 *Transpower New Zealand Ltd v Auckland Council* [2017] NZHC 281.
4 *Wellington City Council v Woolworths New Zealand Ltd (No 2)* [1996] 2 NZLR 537 (CA) at 545; citing *Council of Civil Service Unions v Minister for the Civil Service* [1985] AC 374 (HL) at 410.

triggering A6.[5] On the other hand, the administration of a medical vaccine to a person is not commonly considered a release to land.

[9] A contextual reading does not bring full clarity. As to context, helpfully the parties have produced a detailed statement of agreed facts.

[10] The following is clear:

(a) The s 32 report was primarily focused on the management of the outdoor use of and potential effects of GMO activities, noting:[6]

> Potential GMO activities of relevance include GM food crops, trees, grasses, animals and pharma crops, but exclude research within contained laboratories involving GMOs, medical applications involving the manufacture and use of GM products, and food containing GM products that are not viable. **Field trials and outdoor releases to the environment are the focus of the Plan Change.**
>
> (emphasis added)

(b) And further:[7]

> Inserting provisions into the **Unitary Plan to manage the outdoor use of, and potential effects of, GMO activities is considered to be the most appropriate way of achieving the purpose of the Act for this type of activity**. The Objectives clearly state the desired outcome of providing for outdoor use of GMOs while ensuring potential adverse environmental effects are avoided, or mitigated. Both the Regional Policy Statement policy and Auckland Wide Policy 1, state that this will be achieved through adopting a precautionary approach.
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> (emphasis added)

(c) GMO research in contained facilities was not considered to present risks or costs to the environment, including but not limited to the

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5 Dr Anthony Masamu Poole, Professor in the School of Biological Sciences at the University of Auckland provided evidence that medical vaccines using viable GMO's may result in GMOs being discharged to the environment via human waste.

6 Auckland Council *Section 32 Report Part 2.49 Genetically modified organisms* (30 September 2013) at 2.

7 At 8.

manufacture and use of non-viable GM products, the s 32 report stating:[8]

> Benefits
>
> The permitted activity rule would apply, **but not be limited** to research within contained laboratories involving GMOs and **medical applications involving the manufacture and use of non-viable GM products**. There are no costs identified with this rule.
>
> Efficiency and Effectiveness
>
> This rule is considered to be efficient as the absence of a permitted activity rule would mean all GMO activities would require a consent. **This rule is efficient and effective as it permits medical applications involving the manufacture and use of non-viable GM products, and vaccines that tend not to persist in the environment, appear to be low risk and are difficult to monitor.** This rule is efficient and effective in achieving the Objectives.
>
> (emphasis added)

(d) This report was based on a draft report of the Inter-Council Working Party prepared in 2013. That report states:[9]

> **The Plan Change permits GMO activities that are not classified as field trials and releases, and are not specifically addressed by the Plan Change**. This includes (but is not limited to) research within contained laboratories involving GMOs, medical applications (using GM products) and food containing GM products that are not viable.
>
> All veterinary vaccines are listed as a Permitted Activity in the Plan Change and are exempt from the need to obtain a resource consent. This is because they do not tend to persist in the environment, appear to be low risk and are difficult to monitor.
>
> (emphasis added)

[11] The notified Proposed Auckland Unitary Plan (PAUP) adopted the focus of the s 32 report on outdoor use of and potential effects of GMO activities. It:

(a) Included the following issue of regional significance:[10]

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8 At 11.

9 Auckland Council *Section 32 Report Appendix 3.49.1 – Managing Risks Associated with Outdoor Use of GMOs – Draft report* (January 2013) at 19.

10 Auckland Council *Proposed Auckland Unitary Plan Chapter B1.5 Sustainably managing our natural resources* (30 September 2013).

The outdoor use of genetically modified organisms could adversely affect our environment, economy and social and cultural resources and values. There is a lack of information, including scientific uncertainty, concerning the effects of GMOs in the environment and risks of irreversible adverse effects which could be substantial. We need to adopt a precautionary approach to managing the risks associated with the outdoor use of GMOs.

(b) Included the following in the Background text to the Regional and District Objectives and Policies regarding GMOs:[11]

Pastoral farming, dairying, horticulture and forestry are important land uses in Auckland and are significant contributors to the local and regional economy. Aquaculture is also a growing primary industry in New Zealand. Therefore there are a range of outdoor GMOs that GMO developers could consider using in Auckland, including GM food crops, trees, animals, aquaculture products and pharma crops. The potential for adverse effects, including accidental contamination, resulting from the outdoor use of GMOs poses a risk to the community and environment. By specifying classes of GMOs and applying standards to the outdoor use of GMOs, the risks associated with their use, storage, cultivation, harvesting, processing or transportation can be reduced.

Within Auckland, this will involve managing and limiting the outdoor use of GMOs. Further, rules and controls will be used to mitigate any adverse effects associated with contamination by GMOs beyond the subject site, thereby reducing the risks to the community, environment and economy. Accidental or unintentional migration of GMOs that result in GMO contamination and subsequent clean up and remediation can be expensive. The council therefore requires a GMO operator to meet all potential costs associated with the activity and will secure long term financial accountability through appropriate standards and bonding requirements.

(c) Regulated the use of GMOs by classifying:[12]

(i) two types of GMO activity as Permitted, being:

Veterinary Vaccines

And:

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11 Auckland Council *Proposed Auckland Unitary Plan Chapter C5.17 – Genetically modified organisms* (30 September 2013).

12 Auckland Council *Proposed Auckland Unitary Plan Chapter H4.19 – Genetically modified organisms – Genetically modified organisms- Activity table* (30 September 2013).

GMO activities not specifically provided for or prohibited, including research within contained laboratories and medical applications involving use of non-viable GM products.

(ii) "GMO Field Trials" (on land and within the coastal and marine area) as Discretionary activities; and

(iii) "GMO Releases" (Food-Related and Non Food-Related on land and within the coastal and marine area) as Prohibited activities.

[12] Finally:

(a) There were no submissions specifically relating to the medical application of GMOs;

(b) The relevant Council evidence included a statement that uses of GMOs in non-viable medical vaccines were not controversial, but recommended that medical vaccines (without qualification) be permitted; and

(c) The IHP's recommendations essentially adopted the PAUP approach to classification.

[13] Against this background, it appears a distinction between viable and non-viable GMOs was present throughout the plan promulgation process, but the clear focus of the controls was outdoor releases, including field trials, rather than regulating the use of approved veterinary or medical vaccines.

The error

[14] It is trite that regulation may be invalid for ambiguity.[13] The public should not be left unsure about whether they comply with the law, particularly where prosecution for non-compliance might follow.

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13 *Transport Ministry v Alexander* [1978] 1 NZLR 306 (CA) at 311 per Cooke J; citing *McEldowney v Forde* [1971] AC 632 (HL); *Official Assignee v Chief Executive of the Ministry of Fisheries* [2002] 2 NZLR 722 (CA) at [82] per Thomas J.

[15] If this matter came before me as a matter purely of interpretation (for example by way of judicial review or declaratory relief), then I would be prepared to make a definitive finding. My tentative view is that discharges via human waste were not the type of release specifically intended to be caught by A6, particularly given the overall focus on outdoor use of GMOs. But this matter has come to me on appeal as part of the plan promulgation process. The IHP and then the Council is reposed by Parliament with the responsibility for settling the provisions of the Unitary Plan. The orthodox course then is to refer the matter back to them for reconsideration in light of my judgment.

[16] It transpires that the Council and the University are prepared to consent to the amendments stated in Appendix A. The amendments bring the requisite clarity, assuming that the intention of the decisions version of the Unitary Plan was to provide for the use of viable GMO medical vaccines as a permitted activity, outside of the ambit of A6.

[17] The remaining question therefore is whether I should simply endorse this outcome or refer the relevant provisions back to the Council.

[18] In *Ancona* I signalled that agreed changes should trigger a right of appeal to the Environment Court unless such a course would be futile.[14] This is because approval of the agreed outcome is tantamount to the Council rejecting the IHP's decision. On matters of substance where an interested party might be genuinely interested in challenging this outcome, the statutory right of appeal to the Environment Court comes into frame.

[19] In the present case there were no submissions on medical vaccines. This underscores in my view that medical vaccines were not a matter of public concern. But, as noted, from my reading of the s 32 report and the other information supplied to me by the parties, a distinction was made between viable and non-viable GMO medical vaccines. While notification of the appeal occurred in accordance with my orders, I am not satisfied that legitimately affected persons with rights of appeal should be deprived of the opportunity to test the correctness of the amended position

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14 *Ancona Properties Ltd v Auckland Council*, above n 2, at [4]-[5].

in relation to use of viable GMOs in medical applications, particularly where it is not abundantly clear on the IHP's reasoning or from the s 32 report that this was the intended position.

[20] Given this, I consider that the preferable course is to allow the appeal and grant the relief sought by consent but require the Council to serve notice on all affected submitters of my decision. They will then have the opportunity to appeal the amendment as if it is a decision of the Council pursuant to s 156(1) of the Local Government (Auckland Transitional Provisions) Act 2010.

[21] I am mindful that this creates another level of cost and delay, but on a matter as wide-reaching as the release of viable GMOs (assuming there is jurisdiction to control them, which is not before me), the full ventilation of appeal rights is not futile.

Orders

[22] The appeal and relief sought is allowed by consent.

[23] The Council shall serve notice on all affected submitters on this part of the PAUP.

[24] Submitters shall have the right to appeal the amendment as if it is a decision of the Council pursuant to s 156(1) of the Local Government (Auckland Transitional Provisions) Act 2010.

E37. Genetically modified organisms

E37.1. Background

The outdoor use of genetically modified organisms ~~(GMOs)~~ has the potential to cause adverse effects on the environment, the economy and social and cultural wellbeing. The objectives and policies seek to protect the community and receiving environment from risks associated with ~~any~~ genetically modified organisms ~~activity~~. The application of a precautionary approach to the outdoor use, storage, cultivation, harvesting, processing or transportation of genetically modified organisms in Auckland means that:

- the outdoor release of a genetically modified organism is prohibited (this is to avoid the risk that significant adverse environmental effects will arise, including adverse effects on the economy, community and/or Mana Whenua resources and cultural heritage values); and
- outdoor field trialling of a genetically modified organism (with prior approval of the Environmental Protection Authority (EPA)) is a discretionary activity.

Pastoral farming, dairying, horticulture and forestry are important land uses in Auckland and are significant contributors to the local and regional economy. Aquaculture is also a growing primary industry in New Zealand. Therefore there is ~~are~~ a range of outdoor genetically modified organisms that genetically modified organism developers could consider using in Auckland, including genetically modified food crops, trees, animals, aquaculture products and pharmaceutical crops. The potential for adverse effects, including accidental contamination, resulting from the outdoor use of genetically modified organisms poses a risk to the community and environment. By specifying classes of genetically modified organisms and applying standards to the outdoor use of genetically modified organisms, the risks associated with their use, storage, cultivation, harvesting, processing or transportation can be reduced.

Within Auckland, this will involve managing and limiting the outdoor use of genetically modified organisms. Further, rules and controls will be used to mitigate any adverse effects associated with contamination by genetically modified organisms beyond the subject site, thereby reducing the risks to the community, environment and economy. Accidental or unintentional migration of genetically modified organisms that result in genetically modified organism contamination and subsequent clean up and remediation can be expensive. The Council therefore requires a genetically modified organism

consent holder to meet all potential costs associated with the activity and will secure long term financial accountability through appropriate standards and bonding requirements.

The Environmental Protection Authority is not obliged to set monitoring requirements as ~~a~~ part of its approval process, and can only require monitoring where it is relevant to assessing environmental risk. Under section 35 of the Resource Management Act 1991, the Council has a duty to monitor, which can be expensive. Requiring a genetically modified organism consent holder to meet the costs of monitoring, via consent conditions, ensures the costs are met by the consent holder, rather than the community. The resource consent status indicates the levels of risk considered acceptable by the community for that particular genetically modified organism activity and class.

Genetically modified medical applications involving the use of viable and/or non-viable genetically modified organisms (including EPA approved releases, vaccines and medical research) are permitted under this Plan. Genetically modified medical applications are also regulated by other legislation, including the Hazardous Substances and New Organisms Act 1996 (HSNO), the Medicines Act 1981 and by the Ministry of Health.

The use of genetically modified veterinary vaccines is a permitted activity where the vaccines ~~they~~ are ~~not~~ non-viable, or if viable, ~~and~~ their administration is a specific delivery dose supervised by a veterinarian. Any other use of viable genetically modified veterinary vaccines is a discretionary activity. Non-viable genetically modified veterinary vaccines tend not to persist in the environment, appear to be low risk and are difficult to monitor, making control by the Plan less appropriate. Viable genetically modified veterinary vaccines can have higher risks if their administration is not supervised or controlled by a veterinarian. An example is a viable genetically modified veterinary vaccine distributed by way of edible food or edible plants, which cannot be supervised by a veterinarian, and which may present higher risks to the environment and to the health and safety of people. In this circumstance the Council will have the discretion to require controls or to decline an application. The Council will also be able to respond quickly if there are compelling reasons for its use to benefit human or animal health and welfare. It is generally expected that if a discretionary activity consent is granted, it would apply as a consent for the use of the viable genetically modified veterinary vaccine on any land in the region, noting that specific conditions such as exclusions of specified areas may apply.

Approval from the ~~relevant~~ Environmental Protection Authority ~~approval~~ is required as a precondition for all applications for resource consent. The duration of any consent granted will be aligned with the Environmental Protection Authority approval terms.

E37.2. Objective [rcp/dp]

(1) The environment, including people and communities and their social, economic and cultural well-being and health and safety, is protected from potential adverse effects associated with the outdoor use, storage, cultivation, harvesting, processing or transportation of genetically modified organisms.

E37.3. Policies [rcp/dp]

(1) Adopt a precautionary approach by prohibiting the outdoor ~~general~~ release of a genetically modified organism, and by making outdoor field trialling of a

genetically modified organism and the use of viable genetically modified veterinary vaccines not of a specific dose and supervised by a veterinarian a discretionary activity.

(2) Provide for the use of Environmental Protection Authority approved non-viable and/or viable genetically modified medical applications (including genetically modified vaccines) as a permitted activity.

(3) Require that the holder of a resource consent granted for the outdoor field trialling of a genetically modified organism is financially accountable (to the extent possible) for any adverse effects associated with the activity, including clean-up costs and remediation, including through the use of bonds.

(4) Require outdoor field trialling of genetically modified organisms to avoid, as far as can reasonably be achieved, risks to the environment or to the mauri of flora and fauna or to the relationship of Mana Whenua with flora and fauna from the use, storage, cultivation, harvesting, processing or transportation of a genetically modified organism.

(5) Require all monitoring costs to be met by the consent holder.

(6) Require that the outdoor use of genetically modified organisms does not result in migration of genetically modified organisms beyond the area designated by:

(a) ensuring adequate site design, construction and management techniques;

(b) preventing the escape of genetically modified organisms from transporting vehicles or vessels; and

(c) ensuring all heritable material is removed upon the conclusion of the activity.

(7) Adopt an adaptive approach to the management of the outdoor use, storage, cultivation, harvesting, processing or transportation of a genetically modified organism through periodic reviews of these plan provisions, particularly if new information on the benefits and/or adverse effects of a genetically modified organism activity becomes available.

(8) Require, where appropriate, more stringent measures than those required under the provisions of the Hazardous Substances and New Organisms Act 1996 to manage potential risks.

E37.4. Activity table

Table E37.4.1 Activity table specifies the activity status of the use of genetically modified organisms on land pursuant to section 9(3) of the Resource Management Act 1991 and the activity status of works, occupation and activity in the coastal marine area pursuant to sections 12(1), 12(2) and 12(3) of the Resource Management Act 1991.

Table E37.4.1 Activity table

Activity		Activity status
(A1)	~~Genetically modified organism activities not specifically provided for or prohibited, including research within contained laboratories and medical or veterinary applications involving use of non-viable genetically modified products.~~ Research and trials within contained laboratories involving the use of genetically modified organisms, medical applications involving the use of viable and/or non-viable genetically modified organisms (including genetically modified vaccines), veterinary applications involving the use of non-viable genetically modified organisms and any other genetically modified organism release or use not specifically provided for or prohibited	P
(A2)	Genetically modified organism field trials on land and within the coastal marine area and any structure intended to house, or otherwise contain, plants and animals which are associated with the conducting of genetically modified organism field trials	D
(A3)	The use of any viable genetically modified veterinary vaccine of a specific dose supervised by a veterinarian	P
(A4)	The use of any viable genetically modified veterinary vaccine not otherwise provided for	D
(A5)	Genetically modified organism releases – food-related on land and within the coastal marine area and any structure intended to house or otherwise contain plants and animals which are associated with outdoor genetically modified organisms releases, except as specifically provided for	Pr
(A6)	Genetically modified organism releases – non food-related on land and within the coastal marine area and any structure intended to house or otherwise contain plants and animals which are associated with outdoor genetically modified organism releases, except as specifically provided for	Pr

E37.5. Notification

(1) Any application for resource consent for the following activities must be publicly notified:

(a) genetically modified organism field trials on land and within the coastal marine area and any structure intended to house or otherwise contain plants and animals which are associated with the conducting of genetically modified organism field trials; or

(b) the use of any viable genetically modified veterinary vaccine not

otherwise provided for.

(2) Any application for resource consent for an activity listed in Table E37.4.1 Activity table and which is not listed in E37.5(1) above will be subject to the normal tests for notification under the relevant sections of the Resource Management Act 1991.

(3) When deciding who is an affected person in relation to any activity for the purposes of section 95E of the Resource Management Act 1991 the Council will give specific consideration to those persons listed in Rule C1.13(4).

E37.6. Standards

All activities listed as a discretionary activity in Table E37.4.1 Activity table must comply with the following discretionary activity standards. These standards are in addition to any controls/conditions imposed by the Environmental Protection Authority.

E37.6.1. Approvals

(1) All genetically modified organism discretionary activities must:

(a) have the relevant approval from the Environmental Protection Authority; and

(b) be undertaken in accordance with Environmental Protection Authority approval conditions for the activity.

E37.6.2. Bond requirements

(1) The Council requires the holder of a resource consent for an activity involving the use of a genetically modified organism to provide a bond in respect of the performance of any one or more conditions of the consent, including conditions relating to monitoring required of the genetically modified organism activity (prior to, during and after the activity), and that this bond be available to pay or reimburse any costs incurred by, or on behalf of, the Council to avoid, remedy or mitigate any adverse environmental effects and any other adverse effects to, or on, third parties (including economic effects), that become apparent during the exercise or after the expiry of the consent.

(2) The exact time and manner of implementing and discharging the bond will be decided by, and be executed to the satisfaction of, the Council.

(3) All of the following matters will be considered when determining the amount and type of the bond:

(a) what adverse effects could occur and the potential significance, scale and nature of those effects, notwithstanding any measures taken to avoid those effects;

(b) the degree to which the consent holder for the activity has sought to avoid those adverse effects, and the certainty associated with whether the measures taken will avoid those effects:

(c) the level of risk associated with any unexpected adverse effects from the activity;

(d) the likely scale of costs associated with remediating any adverse effects that may occur;

(e) the timescale over which effects are likely to occur or arise; and

(f) the extent of monitoring that may be required in order to establish whether an adverse effect has occurred or whether any adverse effect has been appropriately remedied.

E37.6.3. Monitoring

(1) A discretionary activity for a genetically modified organism may require monitoring during, and beyond, the duration of consent. Monitoring is to be carried out by either the Council, or the consent holder, with appropriate reporting procedures to the relevant regulatory authority.

(2) A monitoring strategy for a discretionary activity for a genetically modified organism can include all of the following matters:

(a) inspection schedules for the site, storage areas and equipment (daily, weekly, monthly, events based);

(b) testing of procedures (e.g. accidental release response);

(c) training programmes for new staff, and updates for existing staff;

(d) audits of sites and site management systems; and

(e) sample testing of plants, soils and water in neighbouring properties or localities for the presence of migrated genetically modified organisms.

E37.6.4. Reporting

(1) Reporting requirements by the consent holder must be stipulated in the consent conditions.

E37.7. Assessment – controlled activities

There are no controlled activities in this section.

E37.8. Assessment – restricted discretionary activities

There are no restricted discretionary activities in this section.

E37.9. Special information requirements

(1) An application for:

(a) the use of any viable genetically modified veterinary vaccine not otherwise provided for; or

(b) for genetically modified organism field trials on land and within the coastal marine area and any structure intended to house or otherwise contain plants and animals which are associated with the conducting of genetically modified organism field trials

must be accompanied by all of the following:

(i) evidence of approval from the Environmental Protection Authority for the

specific genetically modified organism for which consent is sought;

(ii) details of the proposed containment measures for the commencement, duration and completion of the proposed activity;

(iii) details of the species, its characteristics and lifecycle, to which the genetically modified organism activities will relate;

(iv) research on adverse effects to the environment and economy associated with the activity should genetically modified organisms escape from the activity area, and measures that will be taken to avoid, remedy or mitigate such effects;

(v) evidence of research undertaken that characterises and tests the genetically modified organisms, and the certainty associated with the accuracy of that information;

(vi) a management plan outlining on-going research and how monitoring will be undertaken during, and potentially beyond, the duration of consent;

(vii) details of areas in which the activity is to be confined; and

(viii) a description of contingency and risk management plans and measures.

J.1. Definitions

[New definition to be included]

Genetically modified medical applications

The manufacture, trialling or use of viable and/or non-viable genetically modified organisms for medical purposes recognised as medicines under the Medicines Act 1981 and approved as safe to use by the Ministry of Health, including EPA approved releases, except for the outdoor cultivation of pharmaceutical producing organisms.