Centre for Integrated Research in Biosafety
Tel: +64 3 364 2500, Fax: + 64 3 364 2590
Email: jack.heinemann@canterbury.ac.nz

UNIVERSITY OF CANTERBURY
Te Whare Wānanga o Waitaha
CHRISTCHURCH NEW ZEALAND

BEFORE THE WHANGAREI AND FAR NORTH DISTRICT COUNCILS JOINT HEARINGS PANEL

IN THE MATTER	of the Resource Management Act 1991 **AND**
IN THE MATTER	of Plan Change 131 and Plan Change 18 - Genetically Modified Organisms
AND	
IN THE MATTER	of the submissions and further submissions on the above two plan changes

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STATEMENT OF PRIMARY EVIDENCE OF JACK HEINEMANN
ON BEHALF OF WHANGAREI AND FAR NORTH DISTRICT COUNCILS

12 May JUNE 2016

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Summary of Evidence

1. Based upon my own research and that of other scientists I can confirm that there is a diversity of scientific opinion on the significance, scale and reversibility of environmental effects of outdoor use of GMOs and potential effects on the health and safety of communities exposed to GMOs, including when used as intended (1). There is disagreement among scientists on what constitutes an appropriate level of risk. There is also active scientific debate on the benefits from the outdoor use of GMOs (2).

2. There is a lack of information needed to adequately assess some risks and benefits, including potential long-term environmental and health and safety effects, contributing to scientific uncertainty in a risk assessment of GMOs (3). As the guidance prepared for the Cartagena Protocol on Biosafety by the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management notes: "The issue of uncertainty is dealt with – sometimes differently – in each international instrument incorporating precautionary measures" (4). Uncertainty is therefore a local concept and may legitimately result in different outcomes in different places.

3. I found that the proposed Plan Change provisions and the accompanying Section 32 Report[1] comprise a reasonable response to the scientific uncertainty about the effects from outdoor use of GMOs. I believe that the precautionary approach outlined in the proposed Plan Change provisions and the Section 32 Report is based upon sound scientific principles.

    a. A precautionary approach to risk assessment and risk management of GMOs is appropriate and consistent with international frameworks including the Cartagena Protocol on Biosafety (5) and Codex Alimenatrius (6).

    b. Moreover, the proposed Plan Change provisions are adaptive. "At the point a class or set of GMOs demonstrates potential to provide *net benefits* to the district or region, a plan change can then be made under section 73(1) of the [Resource Management] Act to make these subject to the discretionary provisions. Alternatively, a proponent of a GMO release is able to request a private plan change under section 73(2) of the Act" (emphasis added).

    c. In balancing uncertainties, potential for net benefit and other factors, the proposed Plan Change provisions make field trials a discretionary activity. Along with appropriate performance standards, in my opinion it is possible to conduct safe field trials of GMOs (Appendix 1).

    d. Where an acceptable level of risk cannot be achieved by mitigation or management, the outcome of a risk assessment may be to recommend prohibition of a GMO. Based on this and other matters that may be taken into account for decision making, the proposed

[1] Proposed Plan Change 131, Proposed Plan Change 18, and related Section 32 Reports.

Plan Change provisions prohibit the outdoor releases of GMOs that are not medicines or veterinary vaccines (Appendix 2). In my opinion, this determination is consistent with recognised international standards.

4. As a genetic engineer myself, I believe that GMOs can provide benefits. It is in that spirit that I engage with the Cartagena Protocol on Biosafety because it

> ***creates an enabling environment for the environmentally sound application of biotechnology, making it possible to derive maximum benefit from the potential that biotechnology has to offer, while minimizing the possible risks to the environment and to human health.*** (5)

5. While the statements of evidence submitted in opposition to the proposed Plan Change provisions that I review here share my view that GMOs can provide benefits, we have substantially different views on the merits of the proposed plan provisions and how to estimate net benefit. In my view, the evidence of several submitters contains conclusions that are scientifically incorrect or excessively generalised beyond appropriate for risk assessments on GMOs intended for release. None of the submissions provide a comparative evaluation of the net benefits to Whangarei or Far North Districts from GMOs.

Introduction

6. My name is Jack Heinemann. I have a doctorate in Biology/Molecular Biology from the University of Oregon. I have a double BSc (with honours) in Biochemistry and Molecular Biology from the University of Wisconsin-Madison.

7. I am a Professor in the School of Biological Sciences of the University of Canterbury specialising in the field of molecular genetics. I am also the Director of the Centre for Integrated Research in Biosafety, University of Canterbury. I have previously held academic posts at GenØk-Centre for Biosafety in Norway, and the National Institute of Allergy and Infectious Diseases, Rocky Mountain Laboratories, in the United States. I have also been an adjunct professor at the University of Montana and a guest scholar at the Rockefeller University in New York.

8. Since 2009, I have served the United Nations Convention on Biological Diversity Secretariat on the Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management. In 2014 I was part of a winning bid for an internationally contested contract to design and teach a risk assessment training course to the government of Swaziland. I have provided expert advice on horizontal gene transfer to the New Zealand Environmental Risk Management Authority. I have previously held other roles in other multinational scientific bodies, such as the author representative to the intergovernmental panel of the International Assessment of Agricultural Knowledge, Science and Technology for

Development.

9. I have also advised both multinational scientific bodies, such as the United Nations Food and Agriculture Organisation, national bodies, such as the New Zealand Commerce Commission and the Biotechnology Advisory Board of Norway, and professional organisations such as the American Academy of Microbiology. I was chosen by the Commerce Commission to provide advice on the marketing claim "GM free" as applied to chickens fed GM plant material. I was chosen after the Commission did due diligence to select an expert that was clearly independent.

10. I have 68 articles in peer-reviewed publications and ~130 professional publications of all kinds. I have spoken at over 40 international conferences including being a keynote speaker on 10 occasions.

11. This statement of evidence has been prepared by me. I have included my full CV as Appendix 3 to this statement of evidence. I provided this statement of evidence as my expert opinion and not the opinion of the University of Canterbury.

Code of Conduct

12. I confirm that I have read the Code of Conduct for Expert Witness contained in the Environment Court Practise Note and that I agree to comply with it. I confirm that I have considered all the material facts that I am aware of that might alter or detract from the opinions that I express, and that this evidence is within my area of expertise, except where I state that I am relying on the evidence of another person.

Scope of Evidence

13. I have been asked by Auckland Council, Whangarei District Council and Far North District Council to prepare scientific evidence with respect to the proposed provisions in the Auckland Unitary Plan and the Whangarei and Far North District Plans concerning genetically modified organisms (GMOs).

14. The Inter-council Working Party on GMO Risk Evaluation and Management Options (the Working Party or Inter-council Working Party) produced generic draft GMO plan provisions[2] and an accompanying section 32 analysis[3] upon which the Auckland, Whangarei and Far North GMO plan provisions and section 32 reports are based.

15. I will refer to the generic documents in my evidence with references to the Whangarei and Far North District Councils as necessary. Given that the proposed GMO plan provisions and section 32 reports are the same (although formatted differently) the scientific evidence I present is equally applicable to the plan provisions and section 32 reports of all three councils.

[2] Draft Proposed Plan Change to the District/Unitary Plan, Jan 2013
[3] Generic Section 32 Report, Jan 2013, volumes 1 and 2

16. I have been asked specifically to evaluate the precautionary approach to the outdoor use of GMOs upon which the proposed Plan Change provisions and Section 32 Report rely.

17. The proposed Plan Change provisions are based upon a precautionary approach to risk management, an adaptive approach to risk management that requires decision makers to exercise caution, including the prohibition or postponement of an activity, when faced with uncertainty and/or insufficient information, particularly in situations of potentially high costs and irreversibility.

18. I have been asked to address the uncertainty (including lack of scientific consensus) and/or lack of information about the risks and benefits from outdoor use of GMOs, including long-term (potentially irreversible) environmental effects.

19. I have been provided with the proposed Plan Change provisions and accompanying Section 32 Reports. I have read these documents and will comment from a scientific perspective informed by my research and the research of other experts. In particular I will comment on the environmental effects, health and safety effects and benefits of outdoor uses of GMOs.

20. I have been provided with submissions from parties opposing the proposed Plan Change provisions and I was asked to comment on these from a scientific perspective. The submitters included Peter Shepherd of Kohimarama Rd, Elspeth MacRae for Scion, Shoshona Galbreath on behalf of Pastoral Genomics, and Will Barker for NZBIO. I was also provided with a review of the Draft Section 32 Report produced by the Inter-council Working Party by the Royal Society of New Zealand dated July 2014. This was commissioned by Federated Farmers and attached to its submissions to the Whangarei and Far North District Councils.

Risk Assessment and Precautionary Approach

21. In this part of my statement of evidence I will set out general arguments about scientific risk assessment and risk management of genetically modified/engineered organisms (GMOs/GEOs) and the difference between risk assessment and decision-making. I will then comment on how well the proposed Plan Change provisions prepared under the Resource Management Act (RMA) align with these concepts.

22. Here and elsewhere in my statement I will refer to the products of genetic engineering as GMOs. However, I quote from sources that occasionally use similar but not identical terms such as LMOs and GEOs. LMOs are living genetically modified organisms. This term comes from the international agreement called the Cartagena Protocol on Biosafety. GEO is a genetically engineered organism, a synonym of the more common term GMO.

23. The risk assessment framework that I am most familiar with is precautionary, comparative and case-by-case. This is the prevailing

international framework as well (7). A useful description of this framework is provided in guidance developed to assist users of the Cartagena Protocol on Biosafety (8). The Protocol is an international agreement on the movement of products of modern biotechnology, including living modified organisms, across country borders.

24. A risk assessment informs decision-making but decisions can be based on more than a risk assessment. "It is important to note that risk assessor(s) are requested to recommend whether the risks are 'acceptable' or not. However, the definition of 'acceptability' may not be part of a risk assessment but could be pre-established, for example, in thresholds included in government policies or in the mandate given to the risk assessor. *Likewise, the final decision on whether to approve (with or without conditions) or prohibit the specific use of the LMO is taken during the decision-making process, which may take into account, depending of the national regulatory framework and among other things, government policies, public opinion, anticipated benefits, costs of the risk management measures and socio-economic considerations*"[4] (emphasis added).

25. The precautionary approach to risk assessment is introduced in Article 1 of the Cartagena Protocol on Biosafety. "In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary [across borders] movements."

26. The purpose of case-by-case *risk* assessment is to ensure that all potential adverse effects that might be caused by a GMO are identified, characterised, eliminated, minimised or mitigated. The Protocol and a comparative risk assessment are not designed to identify, verify or compare proposed benefits of a GMO.

27. The approach is defined this way in the training manual to the guidance:[5]

    a. "The case-by-case approach in risk assessment is based on the premise that risks that may arise from the release of an LMO depend on three main elements: (i) the LMO itself; (ii) the likely potential receiving environment; and (iii) the intended use of the LMO in question. In order to identify and assess risks, each of these elements needs to be characterized in a concerted manner and as appropriate

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4 http://bch.cbd.int/cpb_art15/training/module3.shtml#Recommendationsastowhetherornottherisksareacceptableormanageable

5 http://bch.cbd.int/cpb_art15/training/module3.shtml#Step1IdentificationofanynovelgenotypicandphenotypiccharacteristicsassociatedwiththeLMOthatmayhaveadverseeffects

for the specific risk assessment. Moreover, it is important to note that while these three elements may be sufficient to establish the boundaries of a risk assessment, potential adverse effects may extend past these elements, for instance, beyond the likely potential receiving environment and the intended use(s) of the LMO."

b. "The information required for each of these elements in a risk assessment may vary in nature and level of detail from case to case."

Proposed Plan Change Provisions and the Section 32 Report

28. The precautionary approach adopted by the Inter-council Working Party and member councils to assess and manage *activities* appears to me to be consistent with other internationally recognised frameworks for decision-making also informed by assessing and managing the risks of GMOs, such as described by the risk assessment guidance of the Cartagena Protocol on Biosafety (4). The proposed Plan Change provisions appear to align with accepted risk assessment and decision-making frameworks, by—

    a. identifying relevant protection goals[6] (e.g. the "environment, including people and communities and their social, economic and cultural well-being and health and safety", the "sustainable management of the natural and physical resources of the district/region", long term reputation for vigilance against accidental or unintentional GMO cultivation; biological threats to biodiversity or industry; sustainable pest management tools; and mauri, whakapapa and tikanga involving kaitiakitanga).

    b. considering the GMO (e.g. whether it be a plant, viral vaccine vector or animal) and the intended receiving environment and intended use (e.g. medicine, veterinary vaccine, field testing and farming operation).

    c. establishing decision-making criteria on activities that involve GMOs. The relevant criteria include policy (e.g. Te Iwi o Ngātiwai Iwi Environmental Policy), public opinion, anticipated benefits, costs of the risk management measures and socio-economic considerations.

29. I will now reflect on the currency of the science upon which the proposed Plan Change Section 32 Report analysis relies. I will refer to the generic Section 32 Report for ease of reference. Both section 32 reports for Whangarei and Far North District Councils are the same as the generic report with minor wording differences in the case of Far North District Council.

30. The Section 32 Report[7] states under 'Environmental Risks' on page 8 that: "Research into potential environmental effects of GMOs is limited due to the relative newness of the technology, the limited range of GMOs that

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[6] http://bch.cbd.int/cpb_art15/training/module2.shtml#Nationalprotectiongoalsandassessmentendpoints

[7] Generic Section 32 Report volume 1

have gained commercial approval, and gaps in research and monitoring information."

31. My response:
    a. The most significant experience gained for any form of GMO released into the environment is from GM crops. The overwhelming majority of these crops are soybeans, maize, cotton and oilseed rape. The preponderance of experience with release is in a few countries, namely the United States, Canada, Brazil, Argentina and India (see Figure 19.1 of Ref. 9). GM cropping is conducted on only about 3% of agricultural land on a global scale (see Figure 19.2 of Ref. 9). The greatest amount of experience with GM crops comes from growing soybeans and canola, first introduced in 1996, but for most GM crops including maize, significant release was limited to ~15 or fewer years. Therefore, I agree that the time span for research into effects from large crop-scale releases of GMOs is limited.

32. The Section 32 Report[8] identifies on page 8 in the first bullet point under 'Environmental Risks' that: "Effects on non-target species (plant, animal or microbial) - either directly by harming or killing the organism, or indirectly through the food web affecting organisms that are not directly exposed to the GMO" as a risk.

33. My response:

    a. An example of non-target effects was provided for insecticidal (Bt) GM crops. This observation remains current. For example, Pires Paula et al. (2014) investigated the effects of Bt cotton (a form of genetically modified cotton) on the non-target lepidopteran *Chlosyne lacinia*. They identified conditions where the transgene product, a Bt entomotoxin, had little toxicity to adults when ingested, but was *transferred to offspring* where it caused high levels of mortality. They concluded that "a large protein can be taken up and transferred inter-generationally, and may suggest the possibility of greater interaction between environmentally available proteins and insect autecology. *Despite the hundreds of studies on the effects of Cry proteins on non-target arthropods, none have looked for effects on the F1 [the next] generation*…so it is possible that such inter-generational transfer may be underappreciated" (emphasis added to Ref 10). Therefore I agree that non-target effects are a risk of some forms of GMOs and that there are good reasons to evaluate these risks.

34. The Section 32 Report[9] identifies on page 9 in the first bullet point that: "Invasiveness - increased persistence, invasiveness and competitiveness of GMOs with existing native or exotic plant species which could alter population dynamics and ecological balances" as a risk.

35. My response:

[8] Generic Section 32 Report volume 1
[9] Generic Section 32 Report volume 1

a. There is evidence that GM plants have been invasive in both the wild environment and the agroecosystem. For example, in the wild environment: "These results support the hypothesis that roadside populations of canola in the U.S. are likely persistent from year to year, are capable of hybridizing to produce novel genotypes, and that escaped populations can contribute to the spread of transgenes outside of cultivation. Reports in Canada of feral populations of GE canola emerged soon after its commercial release there. Confirmation of GE pollen and crop movement among fields in Australia, U.K., Germany and France and Japan followed shortly thereafter. Ours is the first report of feral canola in the U.S. more than a decade after its commercial release. This delay raises questions of whether adequate oversight and monitoring protocols are in place in the U.S. to track the environmental impact of biotech products" (11). And in the agroecosystem: "Canola is both a crop plant and a weed. Its volunteers[10] are considered as 'among the 20 most common weeds in Alberta [Canada] fields, occurring as a residual weed in 11.8 and 10.5% of all wheat and barley fields surveyed in Alberta in 1997, respectively' (p. 688-689 Hall et al., 2000). Volunteers can emerge for up to four years after the last planting (Legere, 2005). Interestingly, 'a single triple-resistant individual was located more than 550 m from the putative pollen source 17 mo[nths] after seeding' (p. 694 Hall et al., 2000), a distance over 5 times the recommended buffer zone. Herbicide tolerance in *Brasscica napus* can significantly reduce options for weed control. Volunteer herbicide-tolerant crops are likely to be expensive to eradicate after harvest (Smyth et al., 2002)" (12). Moreover, other traits may lead to changes in plant characteristics that may contribute to weediness, such as abiotic stress tolerance traits (4, 13). Therefore I agree that invasiveness is a risk of releasing some GMOs.

36. The Section 32 Report[11] identifies on page 9 in the third bullet point that: "Development of herbicide or pesticide resistance creating 'super-weeds' or 'super-pests'" as a risk.

37. My response:

a. The editor of the premier science journal *Nature* said of this: "by 2012, glyphosate-resistant weeds had infested 25 million hectares of US cropland. They have also appeared in other countries that have embraced glyphosate-tolerant [GM] crops, including Australia, Brazil and Argentina. Blanketing crops year after year in the same herbicide is the perfect way to foster resistant weeds. Chemical companies have come up with a solution: crops engineered to tolerate multiple herbicides. The likelihood of a weed becoming resistant to more than

[10] Volunteer plants grow from seed or vegetative propagules left in fields post-harvest, but which were not deliberately planted.
[11] Generic Section 32 Report volume 1

one chemical, they claim, is very small. And, in an eerie echo of the 1990s discussion around glyphosate tolerance, some even point out that one of the other herbicides being targeted — the choline salt of an old chemical called 2,4-D — has been used for decades with little sign of resistance. It is a flawed argument" (14). I agree that pest resistance resulting in so-called superweeds is an issue of special importance in GM cropping systems.

38. In summary, I find that the environmental risks listed by the Section 32 Report[12] are valid and supported by current research.

Uncertainty and Lack of Consensus

39. In this next part of my statement of evidence I will make general comments about the Section 32 Report statements on uncertainty in assessing the risks of GMOs, the diversity of scientific opinion on the safety of GMOs, difficulty in containing them or difficulty in reversing potential adverse effects. I will also comment on uncertainty in determination of environmental or agricultural benefits.

40. The Section 32 Report[13] in 2.2.2 Risks on page 7 says that: "GM is one of a number of applied biotechnology techniques that together are forecast to offer benefits in many sectors (as outlined above). However, there are risks (both known and unknown) and scientific uncertainty with respect to GM techniques. These risks could be substantial and certain consequences irreversible. GM is a relatively new and fast developing technology and its effects, particularly over the long term, are not completely understood. There is a lack of scientific certainty and/or agreement over many issues relating to GMOs ranging from the safety of GM food products to long term environmental effects and effects on ecosystems and ecological processes from releases of GMOs into the environment."

41. The largest and most comprehensive attempt to achieve a consensus on the science of GMO safety and benefits was conducted by the International Assessment of Agricultural Knowledge, Science and Technology for Development (commonly abbreviated as IAASTD). The international report was prepared over a period of five years, involved 400 researchers from all over the world and was adopted by an intergovernmental panel convened by the United Nations (15). The conclusions were not in line with a simple single scientific perspective as the quotes that follow illustrate (16).

    a. "The three most discussed issues on biotechnology in the IAASTD [concerned]:

        i. • Lingering doubts about the adequacy of efficacy and safety testing, or regulatory frameworks for testing GMOs [e.g., CWANA Chapter 5; ESAP Chapter 5; Global Chapter 3, 6; SSA 3];

[12] Generic Section 32 Report volume 1
[13] Generic Section 32 Report volume 1

ii. • Suitability of GMOs for addressing the needs of most farmers while not harming others, at least within some existing IPR [intellectual property rights] and liability frameworks [e.g., Global Chapter 3, 6];

iii. • Ability of modern biotechnology to make significant contributions to the resilience of small and subsistence agricultural systems [e.g., Global Chapter 2, 6]" (2).

b. "The pool of evidence of the sustainability and productivity of GMOs in different settings is relatively anecdotal, and the findings from different contexts are variable [Global Chapter 3, 6], allowing proponents and critics to hold entrenched positions about their present and potential value. Some regions report increases in some crops [ESAP Chapter 5] and positive financial returns have been reported for GM cotton in studies including South Africa, Argentina, China, India and Mexico [Global Chapter 3; SSA Chapter 3]. In contrast, the US and Argentina may have slight yield declines in soybeans, and also for maize in the US [references in Global Chapter 3]. Studies on GMOs have also shown the potential for decreased insecticide use, while others show increasing herbicide use. It is unclear whether detected benefits will extend to most agroecosystems or be sustained" (2).

c. "Other products of modern biotechnology, for example GMOs made from plants that are part of the human food supply but developed for animal feed or to produce pharmaceuticals that would be unsafe as food, might threaten human health [Global Chapters 3, 6]. Moreover, the larger the scale of bio/nanotechnology or product distribution, the more challenging containment of harm can become [Global Chapter 6]" (2).

d. "Thus, whatever choices are made, the integration of biotechnology [including GM] must be within an enabling environment supported by local research [Global Chapter 6] and education that empower local communities [CWANA Chapter 1]" (2).

e. "No regional long-term environmental and health monitoring programs exist to date in the countries with the most concentrated GM crop production [Global Chapter 3]. Hence, long-term data on environmental implications of GM crop production are at best deductive or simply missing and speculative" (2).

42. Difficulties in containing GMOs and possible irreversibility of any potential adverse effects are matters of concern to scientists, as the following quotes illustrate.

a. "Other potential environmental problems of transgenic crops…may stem, in part, from the fact that the movement of unwanted crop genes into the environment poses more of a management dilemma than unwanted nonliving 'pollutants.' For example, a single molecule

of DDT remains a single molecule or degrades. But a single crop allele occurs within an organism that may have the opportunity to multiply itself — and that allele — repeatedly through reproduction. *The fact that unwanted genes can increase their numbers could frustrate attempts at recall or containment*" (emphasis added to Ref 17).

b. "Here the authors [representing the Ecological Society of America] make the often overlooked point that some releases of GEOs [genetically engineered organisms] may be irreversible, and that *this potential for irreversibility should invoke a precautionary approach*. All too often, the release of GEOs has been compared to the release of an agrichemical. In fact, GEOs and agrichemicals are fundamentally different - chemicals eventually degrade and become diluted as they spread, whereas transgenes have the potential to persist indefinitely and to spread without dilution. Certainly, we should proceed more cautiously when we may not be able to return the environment to its original state" (emphasis added to 18).

43. Prominent groups of scientists do not believe that there are adequate *frameworks* for risk assessment of some GM crops (19). As I describe below, this includes some GMOs based on using ribonucleic acid (RNA) molecules to cause an insecticidal gene silencing activity. In the case where a proper framework for risk assessment did not exist, there could be no opportunity for scientists to have access to data that could lead to agreement on the safety of such products. When there are entire classes of GMOs for which there is disagreement between scientists that adequate risk assessments can be done, then there can be no general certainty about human health and environmental safety of all GMOs.

44. This point was articulated by the Scientific Advisory Panel convened under the United States Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). "The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) provides independent scientific advice to the EPA on health and safety issues related to pesticides. The FIFRA SAP is comprised of biologists, statisticians, toxicologists and other experts and is augmented by members of the Food Quality Protection Act (FQPA) Science Review Board (SRB)."[14]

45. "EPA consulted with the SAP [Scientific Advisory Panel] on scientific issues that might be unique to RNAi and how they could fit under the existing risk assessment framework" (19). RNAi is a form of gene silencing. It can be induced in insects that eat GM crops that are being developed to produce a form of RNA called double-stranded (ds)RNA that can kill insect pests (20).

46. "Overall, the Panel agreed with the concerns raised by the EPA regarding inadequacies of the current environmental fate and non-target effects testing frameworks for dsRNA PIPs [plant incorporated protectants] and

[14] https://www.epa.gov/sap

exogenously applied dsRNA products. Uncertainties in the potential modes of action in non-target species, potential for chronic and sublethal effects, and potential unintended consequences in the various life stages of non-target organisms are sufficient justification to question whether the current Agency framework for ecological effects testing is applicable to dsRNA PIPs or exogenously applied non-PIP end-use products…*The classic approach of developing and assembling effects data for a standard set of test species will likely not work well for this technology*" (emphasis added to 19).

47. In summary, I concur with the findings of Prof Sheldon Krimsky who wrote that one "cannot read these systematic reviews [of the scientific literature] and conclude that the science on health effects of GMOs has been resolved within the scientific community. The eight reviewers made different choices about the endpoints they evaluated, the journal articles selected in their review (although there was considerable overlap), how they weighted the importance of individual studies, and how they interpreted the weight of evidence on the findings of health effects. These differences in methodology help to account for the variation in their findings" (21). As has Prof Krimsky, I have illustrated that there is no scientific consensus on the safety of GMOs released into the environment, reversibility of potential adverse effects, potential benefits or even ability to assess risks of some kinds of GMOs.

Response to Submissions

48. In this next part of my statement of evidence I will reply to issues of science in the materials listed below. I may not repeat material covered in several submissions if I feel that I have covered the topic in replying to any one of them. My focus is on issues of science and scientific risk assessment.

49. The materials I was provided with were:

    a. The submission by Peter Shepherd to the Far North District Council (PC18-194).

    b. The submission from Scion (The New Zealand Forest Research Institute) by Elspeth MacRae. The same submission to Whangarei and Far North District Councils (PC 131-217; PC-302).

    c. The submission from Pastoral Genomics by Shoshona Galbreath to Far North District Council (PC-14).

    d. The submission from NZBIO by Will Barker to the Far North District Council (PC18-303). I did not identify any issues of science not already raised in the other submissions and so do not make specific reference to it.

50. I have also been provided with a review of the generic Working Party Section 32 Report[15] that was carried out by two Fellows from the Royal Society of New Zealand. This Review was attached to the submissions to both Far North and Whangarei District Councils by Federated Farmers (PC18-301; PC131-188). It was also specifically mentioned in the submission from Scion. This Review raises scientific issues that are relevant to both Councils' proposed plan provisions and section 32 analyses. It is attached in Appendix 4 of my evidence.

Submission from Peter Shepherd

51. Professor Shepherd states that: "A number of technologies have now been in constant use for [20 or so years]…In that time no serious adverse effects have been reported, either to the environment or on human health."

52. Contrary to Prof. Shepherd's account, there are peer-reviewed reports of animal studies that find adverse effects that could also be caused in people, and studies finding adverse effects on animal health and the environment. Health effects remain to be confirmed, but this does not mean that there is scientific certainty of safety (1, 9).

53. The absence of post-release monitoring programs for human health effects prevents concluding that there are no adverse human health effects (22).

54. There are organisations that have attested to the human health and safety of existing commercialised GM plants (1). I am unaware of any reputable scientific, government or intergovernmental organisation in the world that has suggested that GMOs, even GM crops, still to be made, approved or commercialised necessarily will be safe. Organisations such as the US National Research Council of the National Academies of Science endorse ongoing risk assessment of GMOs in a way that is consistent with the proposed Plan Change provisions: "The committee recommends that compositional changes that result from all genetic modification in food, including genetic engineering, undergo an appropriate safety assessment" and "the committee recommends that a safety assessment should be conducted prior to commercialization and continued evaluation postmarket where safety concerns are present" (23). The Ecological Society of American has said that "risk assessment studies should be made more rigorous, but also that no matter how rigorous these pre-release studies become, they will always fall short when it comes to detecting certain low probability or low magnitude effects" (18). While there are organisations that attest to safety of existing commercialised GM crops, many of these organisations also advocate for continued risk assessment. If these organisations believed that GM crops were inherently safe, there would be no need to suggest that GMOs be routinely subject to risk

[15] Managing Risks Associated with Outdoor Use of GMOs Section 32 Report volumes 1 and 2 and Draft Proposed Plan Change to the District/Unitary Plan

assessment.

55. Prof Shepherd also states that: "The rules should be modified to allow GM species which have already proven to be safe overseas to bypass the filed [sic] trials process."

56. However, that would not be consistent with international standards of environmental risk assessment. A case-by-case approach requires the risk assessment to be informed by the potential receiving environment.[16] Overseas experience may be useful to inform the risk assessment, especially when it reveals unexpected adverse effects, but is not sufficient to exclude risks in particular districts.

57. Requiring routine and location-specific risk assessment is justified on the evidence and found in international risk assessment guidance. For example, the World Health Organisation says: "At present, ***no conclusive evidence on environmental advantages or costs can be generalized from the use of GM crops****. Consequences may vary significantly between different GM traits, crop types and different local conditions including ecological and agro-ecological characteristics*" (emphasis added to reference 3).

58. **In summary**, I disagree with Prof Shepherd's submission on the proposed Plan Change because I found evidence that the proposed Plan Change provisions and the Section 32 Report recognise a range of risks, not just those someone may categorise as serious adverse effects. I also found that there are a variety of scientific views about the potential for adverse human health effects and problems with using unverified exposure assumptions to draw conclusions relevant to human health. But more to the point, believing that GMOs cause no more harm than non-GMOs or even provide benefit is still no reason for them to avoid a process through which they may be required to demonstrate a *net* benefit to a decision-maker representing the people of that area.

Submission by Elspeth MacRae on behalf of Scion (The New Zealand Forest Research Institute)

59. In the Summary section the broad claim is made that "Billions and billions of GM meals have been eaten without a single incidence of harm."

60. However, this assertion cannot be verified and no supporting evidence was cited.

    a. it is unknown how much material from GM crops people have consumed because the vast majority is used for animal feed, biofuel or fibre (e.g. soybeans, cotton, maize, canola), not food, and GM cultivars of these crops have been in the food supply at scale for a limited time, and there is no post-market adverse effects monitoring

16 http://bch.cbd.int/cpb_art15/training/module3.shtml#Step1IdentificationofanynovelgenotypicandphenotypiccharacteristicsassociatedwiththeLMOthatmayhaveadverseeffects

(1, 22).

b. there are peer-reviewed reports of animal studies that find adverse effects that could also be caused in people, and studies finding adverse effects on animal health and the environment. Human health effects remain to be confirmed, but this does not mean that there is scientific certainty of safety (1, 9).

c. the absence of post-release monitoring programs for human health effects prevents concluding that there are no adverse human health effects (22).

61. Scion also makes the broad claim that "Species threatened with extinction have been saved." Again, this claim is made without any corroborating evidence or references. I am unaware of threatened species that have been saved by GMOs or genetic engineering.

62. Scion claims that the New Zealand GM regulatory framework is "extremely onerous" and implies that it is unique, being "out of line with our trading partners". A further claim is made that "It has resulted in no commercial releases of GMOs even though there are millions of hectares of crops grown without harm internationally."

63. I have tried to but cannot verify these claims.

a. Claim that regulatory framework is 'onerous'.

i. New Zealand is not alone in regulating GMOs. There is substantial evidence of international agreement on the need to assess the risks of GMOs. The World Health Organisation estimates that internationally there are 15 legally binding instruments and non-binding codes of practice that address some aspect of GMO regulation or trade (3). These are harmonised through domestic legislation of member countries. These member countries include New Zealand's trading partners.

ii. Among the 15 legally binding instruments is the international treaty called the Cartagena Protocol on Biosafety, which exists for the purpose of assessing the risk of living GMOs (called products of modern biotechnology in Article 3 of the Protocol) released into the environment. Three of New Zealand's top 5 trading partners belong to the Cartagena Protocol (European Union, China, and Japan) (24). Moreover, New Zealand belongs to the Codex Alimentarius - a joint body of the World Health Organisation and the United Nations Food and Agriculture Organisation – that issues science-based specialist risk assessment guidance on GM microorganisms, GM plants and GM animals (also called products of modern biotechnology in the Codex) for use in food. All of New Zealand's top 5 trading partners (including Australia and the United States) belong to Codex.

iii. If New Zealand's regulation is onerous, it seems unlikely to be extreme or alone.

b. Many countries have no (legal) commercial releases of GMOs, including countries with no legislative framework. Likewise, I know of countries that have allowed legal releases but have no commercial GMOs. There are many reasons why a company or a country does or does not commercialise a particular product. For example, in 2006-7 the United States, Japan and Canada authorised the commercial production of a GM maize that produces high amounts of lysine, but it was never commercialised (25).

c. By the year 2005, over 1,000 applications were approved to field trial stress-tolerant GM plants in the United States. None of these GMOs ever progressed out of the testing phase (26, 27). Even in the home of the largest and longest commercial releases of GM crops, more GM products are probably not commercialised than are. There can be many reasons for not commercialising different products.

d. I am not aware of any research-based evidence that shows that New Zealand's legislation is the reason for no commercial releases here.

64. Scion further argues that "Scientifically, the logical regulation of new organisms is regulation which regulates organisms by their individual traits and the risk of harm of their new traits."

65. It is scientifically valid and indeed essential to consider the novel traits in organisms when conducting a risk assessment. However, it is neither unscientific nor illogical to make use of all available information when conducting a risk assessment. Taking into account the process of genetic engineering is consistent with the guidance issued by the Cartagena Protocol on Biosafety and Codex Alimentarius. The National Research Council of the US National Academies of Science specifically refers to the process, not just the trait, as a source of risk in GMOs. They say that: "While there are a variety of methods for identifying and measuring specific changes that result from genetic engineering, as well as from conventional breeding techniques, such changes are not always easily discernible—particularly when they are *unexpected outcomes of the process* or when they result from latent expression of the genetic change or accumulated changes in functional effects in the modified organism" (emphasis added to 23).

66. The National Research Council also says that: "Introduction of novel components into food through *genetic engineering can pose unique problems* in the selection of suitable comparators for the analytical procedures that are crucial to the identification of unintended compositional changes" (emphasis added to Ref 23). This statement recognises that the standard comparative approach to risk assessment has a particular weak spot for products of genetic engineering. A comparative risk assessment looks for changes between the product and a reference, usually a near-isogenic parent, of the GMO (28). Because of either the

process or the source of the genetic material used to create some GMOs, there may not be a suitable reference ('comparator') (4). This is not considered to be the case for products of other breeding techniques.

67. Other international bodies specialising in the risk assessment of GMOs have drawn similar conclusions about how important the comparator is for accurate risk assessment. The guidance developed by the Secretariat to the Convention on Biodiversity reaches similar conclusions about the critical issue of the comparator for GMO risk assessment: "A comparative approach aims at identifying changes between an LMO [living modified organism] and its *comparator(s)* that may lead to adverse effects. *The choice of comparators can have large effects on the relevance, interpretation and conclusions drawn from the risk assessment process*" (emphasis added to Ref 4). The guidance also says that: "In some cases, the non-modified recipient organisms or the parental organisms alone may not be sufficient to establish an adequate basis for a comparative assessment" (4). These views make clear that GMO risk assessment does have special challenges that arise from the process as well as the trait. Furthermore, the prevailing comparative approach to risk assessment may be particularly weak at compensating for these challenges.

68. Scion argues that "There is an overplaying of harm and risk."

69. On the contrary, I believe that the Section 32 Report and the Draft Proposed Plan Change include several passages that indicate the Councils' awareness of the framework for assessing benefits and risks. The passages I reproduce below provide support of my interpretation and make clear that the Councils have qualitative and quantitative risk assessment and adaptive benefit frameworks for considering activities in which GMOs may be used. For example—

    a. "The *absolute and relative* benefits associated with the development and use of GMOs is continually being redefined as this and other forms of applied biotechnology advance" (emphasis added).[17]

    b. "To avoid foreclosure of potential opportunities associated with a GMO development that could benefit the district or region, there is the ability to review a particular GMO activity if it were to become evident during the field trial stage or in light of other new information that a particular GMO activity would be of *net benefit* to the district or region and that potential risks can be managed to the satisfaction of Council. A council or a GMO developer can initiate a plan change to change the status of a GMO activity" (emphasis added).[18]

    c. "The potential benefits and adverse effects associated with GMO activities in the CMA are constantly evolving with changes in techniques and the underlying science, and changes in consumer markets. Therefore, classes of GMOs will be periodically reviewed at

[17] Draft Proposed Plan Change to the District/Unitary Plan 2013, page 1.
[18] Draft Proposed Plan Change to the District/Unitary Plan 2013, page 16.

> the discretion of the respective council that will make use of this additional information. At the point a class or set of GMOs demonstrates potential to provide *net benefits* to the district or region, a plan change can then be made under section 73(1) of the Act to make these subject to the discretionary provisions. Alternatively, a proponent of a GMO release is able to request a private plan change under section 73(2) of the Act" (emphasis added).[19]

70. Moreover, the section 32 Report is congruent with others of significant scientific standing that are observing the clash over evaluations of benefits and potential harms. The science journal *Nature* said: "In the pitched debate over genetically modified (GM) foods and crops, it can be hard to see where scientific evidence ends and dogma and speculation begin…Researchers, farmers, activists and GM seed companies all stridently promote their views, but ***the scientific data are often inconclusive or contradictory***" (emphasis added to reference 29).

71. Scion suggests that in its subjective view harm is overplayed by the Councils. In the subjective view of others benefit might be thought to be overplayed. Accordingly, there is no scientific test for diagnosing an 'overplay' of harm or benefit. The proposed Plan Change provisions thus provide for a local decision-maker to determine if there is a net benefit of any particular activity involving the release of a GMO.

72. Scion then lists a number of "benefits or potential of GMOs", inter alia that existing or near commercial GM crops "greatly reduce application of toxic agrichemicals"; can be grown on marginal lands leading to reductions in famine and starvation; and include vitamin enhanced food products that prevent blindness.

73. Do existing GM crops reduce agrichemical use? No. The use of herbicides has not decreased in the major agroecosystems that have adopted GM crops (30-32). Some analyses that are based on a series of short-term experiments of limited geographic range have reported declines. However, analyses that have focused on long-term studies generally report the opposite. "It appears that [GM herbicide tolerant] HT soybean crops use more herbicide than conventional soybean, and this gap increases over time. Soybean GM crops use on average 4% more herbicide in 1998, 16% more from 1999–2002, 30% more from 2003–2009. For HT soybean, herbicide applications increased from 1999 to 2009, particularly in the past few years; on the contrary, for conventional soybean weedkiller applications remained rather stable beyond annual variations. Finally, the herbicide use of HT soybean appears higher than that of conventional soybean" (31). In contrast, herbicide use is declining in highly productive countries that do not use GM crops (30).

[19] Draft Proposed Plan Change to the District /Unitary Plan 2013, page 16.

74. Herbicide use is increasing in the US whereas it is decreasing in non-GM Western European countries. While chemical insecticide use has decreased to 85% of that used before the introduction of GM crops in the US in 1996, it is not clear that the reduction is due to, or dependent upon, their use. *In the non-GM countries France, Switzerland and Germany, chemical insecticide use is down to 15% of 1996 levels* (30).

75. Have existing GM crops reduced use of more toxic pesticides? Sometimes. A case can be made for GM cotton that produces a protein insecticide. However, even in that case the benefit appears short lived as resistance to the insecticide develops (33, 34). The vast majority of all other existing GM crops, and the vast majority of acreage used to grow GM crops in general, are treated with herbicides, particularly the herbicides based on the active ingredient glyphosate. There is accumulating evidence that the adverse health effects of these herbicides have been under estimated.

    a. Glyphosate was recently reclassified by the International Agency for Research on Cancer of the World Health Organisation from 'probably not a human carcinogen' to "'probably carcinogenic to humans' (Group 2A)" (35).

    b. The Brazilian National Institute of Cancer José Alencar Gomes da Silva (INCA), a body of Brazil's Ministry of Health, explicitly linked the use of GM crops and the intended agronomic management of them with public health consequences (36). In a translation of the Portuguese, INCA said: "It is important to highlight that the release of transgenic [GM] seeds in Brazil was one of the facts that has contributed to putting the country in the first place in the ranking of pesticide consumption. This is because the cultivation of these genetically modified seeds requires the use of large amounts of these products. The cultivation model with intensive use of pesticides generates great harm, such as environmental pollution and intoxication of workers and population in general…Among the adverse effects associated with chronic exposure to active ingredients of pesticides we can mention infertility, impotency, miscarriages, malformations, neurotoxicity, hormonal disruption, effects on the immune system and cancer."

    c. "With the emergence of glyphosate-resistant ''superweeds,'' [GM soybean] producers have resorted to increasingly higher doses and more toxic formulations, including some with globally banned agro-chemicals, such as atrazine, endosulfan, and 2,4-D. In labs, studies have shown that in vertebrate embryos glyphosate and Roundup formulations are endocrine disruptors, meaning that they interfere with normal hormone and enzyme functioning, impeding normal development and causing malformations. A report by Argentine physicians link increasing cases of cancer, miscarriages, and birth defects with the spraying of agro-chemicals, especially glyphosate. Similar findings are presented in a report commissioned by the provincial government of Chaco" (37).

76. It is too early in the debate on glyphosate herbicide toxicity and carcinogenicity to humans, much less the debate on adverse effects to the environment, to know how it will resolve. Equally, though, it is too early to conclude that the shift in use to this herbicide has been in all ways more benign to human health and the environment.

77. Can GMOs be grown on marginal lands leading to reductions in famine and starvation? Yes and no. There is evidence supporting the first part of this claim. In particular, the Pampas of Argentina have become a case study where the coupling of herbicide and herbicide resistant GM crops has lead to the expansion of soybean agriculture (38, 39).

78. However, I am unaware of substantial evidence for the claim that GM cultivation per se has reduced starvation. The overwhelming majority of GM production is for biofuel and animal feed rather than direct human consumption (37). Via conversion in livestock, though, it can contribute to the human food supply.

    a. In addition to causing the well researched pesticide "transgenic treadmill' in the Pampas (38), the expansion into marginal lands accelerated by the use of GM soybeans has caused serious problems. "The ever-expanding production of GM soy has pushed past the agricultural frontier of the Pampas region into the northern provinces of Chaco, Santiago del Estero, and Salta. This is where the monocultures of GM soy have taken their heaviest toll…The expansion of the agricultural frontier threatens highly sensitive biodiverse ecoregions, including the Yungas, the Great Chaco, and the Mesopotamian forest. It also threatens the livelihood of many northern rural inhabitants, who are mostly indigenous and peasant campesinos" (37).

    b. "The environmental impact of large scale GM soy monocropping is felt all throughout the country. As monocrops expand natural habitats disappear, thus endangering plant and animal biodiversity. Large scale mechanized GM soy monocropping in the Pampas has also resulted in nutrient depletion and soil structure degradation" (37).

    c. "The GM soy-based agrarian transformation has implied radical changes in socio-ecological dynamics in Argentina: increased inequality due to concentration of landholdings and agribusinesses, rural displacement through a violent politics of dispossession, the loss of food security, and health hazards due to agrochemical exposure add to the disruptions at the ecosystem level, including deforestation, loss of biodiversity, emergence of glyphosate-resistant superweeds, nutrient depletion, and air pollution. Economic gains thus create socio-ecological unsustainability, threatening the continuity of the model itself" (37).

79. Thus, the most up to date peer reviewed research paints a far more complex and nuanced picture of the effects of GM crop adoption, especially via the conversion of 'marginal' lands to cultivation, that at least

in some large scale cases exacerbates rather than ameliorates malnutrition and poverty.

80. Do existing or near-to-release GM crops include vitamin enhanced food products that prevent blindness? No. The only product that resembles this description is the well-known β-carotene enriched rice. This is a promising product, but so far it is not available for release because of technical issues. Most importantly, the developers have not been able to breed the GM trait into varieties of rice that are suited to the countries that might benefit from the increase in β-carotene intake. This technical difficulty has also prevented field demonstrations that the rice produces adequate amounts of the vitamin A precursor under actual field conditions. Finally, unless the technical problems are solved, it will not be possible to test whether the rice does result in improved health outcomes dependent on bioavailability of β-carotene when delivered in rice-based meals.

81. It is thus inaccurate in my view to imply that this singular product has or is near to delivering the particular benefit of saving "millions of people in the third world from blindness caused by malnutrition."

82. Scion also mentions cleaner clothes and pharmaceuticals as evident benefits. These products which are derived from organisms grown in containment are, to my understanding, unaffected by the proposed Plan Change provisions. Moreover the benefits of clothing per se are not special to GM cotton. The hypothetical benefits of faster growing trees may be demonstrated in permitted field trials under the proposed Plan Change provisions.

83. Scion also makes the statement that "there are millions of hectares of GMOs in commercial production and it has been shown that GMOs and non-GMO plants and GMOs and organic farming can co-exist without…regulation."

84. Co-existence and co-existence without adverse effect are different things. Examples of where damage has occurred include—

    a. a genetically modified wheat grown to field trial stage and then discontinued was rediscovered in fields in the US state of Oregon eight years after field trials ended, and again in Montana over 10 years from the end of testing. This lead to trade disruptions and arguably reputation damage (40).

    b. a form of genetically modified rice that was grown on less then one acre of land for field testing between only 2001 and 2003 was discovered in the US rice supply in 2006 (41). This lead to lawsuits, trade disruptions and arguably reputational damage. Estimated costs to producers were up to US$1.2 billion (42). The United States has the longest history of commercial release of GM crops and still finds it challenging to maintain separation between them and non-GM cropping systems.

    c. an Australian organic farmer sued his neighbour over loss of income

because of gene flow from a GM crop (43). The organic farmer was not awarded damages but the contamination was not disputed.

d. There are many more examples of gene flow (44). In March this year the United States General Accounting Office issued a new report title: "Genetically engineered crops. USDA needs to enhance oversight and better understand impacts of unintended mixing with other crops" (45). The central conclusion of the report was that United States Department of Agriculture has failed in its duties to measure the costs of admixture, so it is not possible to conclude, as Scion has, that adverse effects can be avoided without regulation (45).

85. Finally, Scion draws attention to a 2014 Review from the New Zealand Royal Society. I address that Review below.

Review by Royal Society of New Zealand.

86. The Royal Society review was provided on a "request from Federated Farmers to review the validity of scientific conclusions" in the generic Section 32 Report produced by the Inter-council Working Party[20]. I will refer to the Commissioned Review as the "Review" and have adopted the term "Report" for the Section 32 Report to be consistent with the terminology used by the Review.

87. The Royal Society Review has six sections: Benefits and risks, Environmental Risks, Non-target effects, Invasiveness, Horizontal gene transfer, Concerns over antibiotic resistance. I respond to the content in each of these sections below.

88. In the section titled "Benefits and risks", the Royal Society Review authors stated that in "assessing benefits and risks, both the magnitude and the likelihood of each need to be taken into account" (46). The Review stated that the "Report's section on benefits and risks, however, does not include these considerations in the issues it raises."

89. In contrast, I believe that the Report did include several passages that indicated the Councils' awareness of the framework for assessing benefits and risks. The Section 32 report lists various applications and their proposed benefits in section 2.2 "Benefits and Risks". Furthermore, quantitative considerations such as 'likelihood' and 'magnitude' are inherent in the concept of 'net benefit' which the Councils use as the basis for reconsideration. In the Section 32 report it says that: "At the point a set of GMOs demonstrates the potential to provide net benefits, a change to the specific District / Unitary Plan can then make these subject to discretionary provisions. An application requirement is that the EPA has already approved such a release. Council's role is limited to determining whether there are additional conditions that would make release in the district or region permissible, or whether to decline the application."

90. Moreover, the Draft Proposed Plan Change to the District/Unitary Plan

[20] Generic Section 32 Report volume 1 and 2(Draft Proposed Plan Change to the District/Unitary Plan)

further reveals the Councils' thinking and makes clear that the Councils have qualitative and quantitative risk assessment and adaptive benefit frameworks for considering activities in which GMOs may be used (see quotes in paragraph 69, above).

91. Furthermore, the Royal Society Review provided no unqualified appraisal of actual or potential benefits arising from GMOs already in use. I could not find anything in the Review that would contradict the Councils finding that the uncertainty of proposed benefits from some GMOs is greater than the possibility of harm from releasing them.

92. In the section titled "Environmental Risks", the Review authors criticised the Councils for citing only one source about the potential harm of releasing some GMOs into the environment. The source used by the Councils' Report was an article called *GMO Myths and Truths*. It is a synopsis and analysis article for general readers[21]. The article makes reference to over 80 sources, many of which were peer-reviewed scientific papers and other quality sources that allow more detailed inspection by specialist readers. The authors of the Royal Society Review suggested that the article *GMO Myths and Truths* was "largely opinion-based and" "very selective in the arguments it makes." They select two quotes from the reference to serve as examples.

93. The Review authors highlight this quote that they say is from the article *GMO Myths and Truths*: "plants created by conventional plant breeding are not hazardous". While I could not find this quote in *GMO Myths and Truths*, I was able to find a similar phrase in the article which reads: "plants created by conventional breeding are not hazardous". This phrase differs by just one word, the use of the word 'plant' as an adjective of breeding. I assume that this is the phrase to which the Royal Society authors were referring.[22]

94. This is one example of what the Royal Society authors call "certain errors of fact" in the article used by the Councils. The Royal Society Review implies that the quote expressed erroneous beliefs held by the article authors. The Royal Society Review authors seek to demonstrate the erroneousness of the beliefs by providing examples of hazards in non-GM plants to contradict the quote. However, **the Royal Society authors have misrepresented the quote by taking it out of context**. If one reads the context of the quote in *GMO Myths and Truths* it is clear that *the article authors are presenting the argument that* "plants created by conventional plant breeding are not hazardous" *is a belief held by others* (and not the authors of *GMO Myths and Truths*). The excerpted statement that "plants created by conventional plant breeding are not hazardous" is presented by the authors of *GMO Myths and Truths* as a paraphrase of a part of an

[21] The Royal Society authors cite version 1.3b written by Associate Professor Michael Antoniou of Kings College London, and Claire Robinson and Dr. John Fagan of Earth Open Source.
[22] This same evidence was submitted to the Auckland Unitary Plans Hearings in September 2015 and the authors of the Royal Society Review did not contest it.

argument put by those arguing for less regulation of GMOs. Both the authors of *GMO Myths and Truths* and the authors of the Royal Society Review then go on to refute arguments based on a belief that "plants created by conventional plant breeding are not hazardous."

95. In context, the *GMO Myths and Truths* authors are claiming that proponents of genetic engineering "argue that if we expect GM crops to be tested extensively because of risks resulting from mutations, then governments should require conventionally bred plants to be tested in the same way. But they do not, and experience shows that plants created by conventional breeding are not hazardous. Therefore crops generated by conventional breeding and by genetic engineering present no special risks and do not require special testing. This argument [by proponents of genetic engineering] is based on what appears to be an intentional misrepresentation of the studies of Batista and Ahloowalia. These studies did not compare conventional breeding with GM, but gamma-ray-induced mutation breeding with GM. The research of Batista and colleagues and Ahloowalia and colleagues actually *provides strong evidence consistent with [*GMO Myths and Truths *authors] arguments, above, indicating that mutation breeding is highly disruptive – even more so than genetic modification*" (emphasis added).

96. The 'error of fact' was instead made by the authors of the Royal Society Report in characterising the statement as the conclusion of the *GMO Myths and Truths* authors when it was not.[23]

97. The Royal Society Review authors highlight another quote that they say is from the article *GMO Myths and Truths*: "Techniques so far do not allow for site-specific insertion."

98. I could not find this quote in the 2012 publication of *GMO Myths and Truths*[24] cited by the Royal Society Report or in a 2nd Edition of *GMO Myths and Truths* published in 2014, nor in a general Google search. By contrast and to confirm the capacity of the search tool to find similar sized phrases, a general Google search did return the article *GMO Myths and Truths* when I search for the phrase "plants created by conventional breeding are not hazardous". The phrase "Techniques so far do not allow for site-specific insertion" to my knowledge did not come from the article *GMO Myths and Truths* and appears to have been crafted by the Royal Society authors.

99. The 'error of fact' appears to be made by the Royal Society authors in attributing the phrase to *GMO Myths and Truths*.[25]

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[23] This same evidence was submitted to the Auckland Unitary Plans Hearings in September 2015 and the authors of the Royal Society Review did not contest it.

[24] I found two versions on the internet, version 1.2 and version 1.3b. Both were 123 pages and neither had the quote.

[25] This same evidence was submitted to the Auckland Unitary Plans Hearings in September 2015 and the authors of the Royal Society Review did not contest it.

100. The Royal Society authors' response to the statement "Techniques so far do not allow for site-specific insertion" was that "methods [are] now available to allow the insertion of genes at specific sites in a genome, including zinc finger nucleases (ZFNs), transcription activator-like effector nucleases (TALENs) and clustered regularly interspaced short palindromic repeats (CRISPR)/Cas9 technologies." Although this response by the Royal Society authors was to a phrase that did not exist in the article they were purporting to be responding to, I will evaluate it from a scientific perspective.

101. There is much interest in this suite of techniques frequently also referred to as new breeding technologies and genome editing techniques. The potential to reduce unintended genetic changes would be relevant to the first step of a risk assessment, the hazard identification step (4). This alone does not determine the outcome of step four, the risk characterisation, which combines the likelihood of a hazard and the magnitude of adverse effects should they arise (4). Therefore, the potential precision of these new techniques is not enough to determine that products of these new techniques will be less likely to cause significant adverse effects.

102. Moreover, these new techniques may not be as precise as implied. Unintended changes also arise from these techniques (47-49). These "emerging technologies have dramatically expanded the ability to manipulate and study model organisms, and support the promise of correcting the genetic causes behind many diseases. However, in order to achieve the full potential of this technology, many important questions and challenges must be addressed. Chief among these is the relative specificity of each nuclease platform" (47). "The issue of specificity is paramount for all the targetable nucleases, particularly in applications to human therapy and to food sources" and "What lessons can be learned from these studies? The Cas9 nuclease is less sensitive to mismatches between the sgRNA and target than we might wish" (50). What these technical quotes from the science literature demonstrate is that it would be premature to assume confidence in the safety of GMOs produced using these techniques on the argument that they only have the expected changes.

103. Much of the remainder of the Review was not directed at *GMO Myths and Truths*, but directly to the Report and to other sources of evidence cited by the Report.

104. In the section titled "Non-target effects", the Royal Society Review stated that the: "Report highlights the potential non-target effects of GMOs. For example, GMO crops that produce Bt insecticide can negatively impact non-target insect populations. However, field studies have shown that these negative impacts are markedly lower than those that occur with conventionally managed crops."

105. My response to this statement in the Review is that international risk assessment guidelines recognise the validity of *routinely* considering non-

target effects of GMOs (4). There are scientifically valid reasons for doing so (e.g. see these references and references therein: 19, 51). There remain uncertainties about non-target effects even for GM plants that have the longest history of release in other countries both because of the limited range of studies and the limited range of animals on which studies have been conducted (10). Whether there will be a net benefit, as in fewer negative effects, is a determination of the decision-maker using information from the actual intended receiving environment.

106. The Royal Society Review authors state that Bt crops have less impact than "those that occur with conventionally managed crops." However, the Review authors do not define the conditions that constitute 'conventional' and how well the research in other countries to which their reference alludes would apply to the conventions in use in Auckland and Northland. Moreover, they do not indicate if these putative benefits would accrue in the kinds of plants that might actually be used in these regions. Given that only four or five kinds of plants have GM cultivars used at major scales somewhere in the world (maize, soybeans, oilseed rape, cotton and possibly sugar beet), and none of them to my knowledge are major crops in Auckland and Northland, it is difficult to assess how applicable is the review article cited by the Royal Society authors. It is for these and other reasons that international guidance on risk assessment advocates for assessment in the intended receiving environment rather than any environment (4). Furthermore, even if the statement made by the Royal Society Review authors could be shown to be true and valid for Auckland and Northland regions, it might not be true for other 'nonconventional' practices, e.g., agroecological agriculture, organic certified agriculture or others.

107. In arguing that Bt crops have less impact, the Royal Society authors imply that there are benefits of Bt crops. However, benefits may also vary from environment to environment and the Review authors do not establish that the environments from which they draw their generalisations match Auckland and Northland. Moreover, there is not general agreement among scientists that the evidence of benefits is robust. The Ecological Society of America also reflected on different standards of evidence for making claims of benefit as compared to making claims of harm or risk. "It is worth reiterating here the authors' point that the presumed benefits of GEOs [genetically engineered organisms] are often taken for granted, *but that these benefits (especially the environmental benefits) have not been well documented*. To actually test whether the anticipated benefits are materializing will require much better data on the geographic patterns of GEO implementation than are currently available. But it is not only the benefits that have been poorly quantified. The risk assessment studies used to support decisions for deregulation suffer almost universally from poor replication, short duration, small scale, and other design flaws that greatly reduce their chance of detecting an existing problem" (18). The environmental risks of non-target effects cannot be dismissed by

reference to putative benefits seen in other environments especially when the standard of evidence for those benefits has not been confirmed to be adequate.

108. In the section titled "Invasiveness", the Royal Society Review authors describe a scenario where a GM trait could result in plants becoming weeds and expanding outside of their intended temporal or geographic boundaries. The example is consistent with the Councils' reasonable inclusion of invasiveness as a potential adverse effect. The Review authors criticise the references used in *Community Management of GMOs: Issues, Options and Partnership with Government* provided to the Councils by Simon Terry Associates[26]. Nevertheless, they neither provide contrary evidence nor dispute the conclusions. In the section "Proposed Plan Change Provisions and Section 32 Report" I have provided examples that further support the inclusion of invasiveness as a risk in the Section 32 Report.

109. In the section titled "Horizontal gene transfer (HGT)", the Royal Society Review authors provide a generally valid overview of HGT. The authors correctly stated that "HGT has long been recognised as a major force in microbial evolution."

110. However, the Review authors incorrectly define horizontal gene transfer. The majority of microbes reproduce by forms of cell division or mitosis, that is, asexually. Therefore, to define HGT as "other than by vertical transmission (normal sexual reproduction)" is nonsensical *because normal vertical transmission for microbes is* ***asexual***. The more accurate and properly inclusive definition used by the New Zealand Environmental Protection Authority (formerly ERMANZ) is: "HGT is defined as the transfer of genetic material from one organism to another organism outside the context of parent to offspring (i.e., vertical) reproduction" (52). This definition captures all HGT phenomena and therefore all pathways through which HGT might contribute to an adverse effect.[27]

111. The Royal Society Review authors again criticise the Report for drawing upon the article *GMO Myths and Truths* as a source for the analysis on horizontal gene transfer. Here the quotes attributed to *GMO Myths and Truths* are accurate.

112. The Review authors indicate that there is more than one scientific opinion on whether or not horizontal gene transfer is a risk special to GMOs, because they say: "This statement from GMO Compass [referred to in *GMO Myths and Truths*] is an accurate reflection of the *majority* scientific opinion as expressed in the peer-reviewed scientific literature" (emphasis added). The Review authors do not dispute that there are risks of adverse effects from horizontal gene transfer, but they do dispute that they would be serious.

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[26] Volume 2 Supporting Documentation to the Section 32 Report

[27] This same evidence was submitted to the Auckland Unitary Plans Hearings in September 2015 and the authors of the Royal Society Review did not contest it.

113. In the section titled "Concerns over antibiotic resistance", the Royal Society Review authors' statement that: "With respect to GM plants, there is no evidence of HGT of antibiotic resistance genes from plants to bacteria" is mainly consistent[28] with my knowledge of the existing literature describing limited scale attempts to observe transfer of antibiotic resistance genes or parts thereof from GM plants to GM microorganisms in soil (53, 54). However, there have been few if any studies of appropriate design, relevant scale and comprehensiveness for type of microbes to discount the possibility at relevant scales (54). A critical flaw in most studies has been to ignore testing in environments where there is a fitness cost that can be countered by acquisition of the transferred gene. When such factors are combined, low initial HGT frequencies result in population changes and amplification of rare gene transfers (55). The combined effect is so strong as to be able to counter other traits that otherwise reduce fitness but increase baseline levels of DNA recombination between species.

114. Horizontal gene transfer in general is probably underestimated because of the prevailing bias in how gene ancestries are determined (56). "Because the prevailing paradigm is to assume vertical inheritance when other evidence is lacking, HGT in eukaryotes will continue to be overlooked and underestimated. This is necessary to avoid HGT being described inappropriately. However, this notion, as well as high profile erroneous reports of HGT in humans and other animals, has probably had a chilling effect on the field" (57).

115. There is evidence of gene transfer in nature from multicellular organisms such as plants and animals to bacteria (57). HGT between eukaryotes has also been observed. Aphids have acquired the ability to synthesise their own carotenoids due to acquisition of the genes from a fungus (58).

116. Importantly, *there is some evidence that gene transfers from GM plants to bacteria* has occurred. In a study of microorganisms isolated from the colostomy bags of human ileostomists, the authors found evidence of bacteria carrying DNA sourced from a GM plant. "There was some indication of low-frequency gene transfer from GM soya to the microflora of the small bowel before but not during the subjects' participation in these experiments" (59).

117. The Royal Society Review also errs in my view because it confuses the frequency of a thing happening with the determination of the overall probability of an adverse effect arising. However, the frequency of a thing is not the only characteristic that matters for a risk assessment. The Review authors seem to appreciate this, but do not consistently apply it in their analysis. For the risk assessment the Review authors noted that "both the magnitude and the likelihood" (46) of an event matter. When the authors later concluded that "there is no evidence of HGT of antibiotic resistance genes from plants to bacteria. If it does occur, it would be at

[28] For an exception, see paragraph 116.

such a vanishingly small frequency that it would have no impact on the overall frequency of HGT of such genes in the environment" they only consider frequency, not magnitude of the harm.[29]

a. For example, if there were only a few automobiles in the world, the potential for a collision with a child also would be vanishingly small. Nevertheless, a robust risk assessment would consider the magnitude of harm from a collision between an automobile and a child if playgrounds were to be built on roads even if most roads were never used. The magnitude of the potential adverse effect of a child's collision with an automobile would be taken into consideration in the overall hazard characterisation step of a risk assessment (4).

b. An overall risk characterisation of horizontal gene transfer of antibiotic resistance genes could take into account both the frequency of gene transfer and the magnitude of the adverse effect if an antibiotic resistance gene were to be taken up by a disease-causing bacterium in a person or animal, especially those already taking antibiotics. The gut environment has also been shown to be conducive to gene transfer events. For example, a line of gut bacteria special to Japanese people was found to contain genes from marine bacteria enriched in the Japanese diet, strongly suggesting that the transfer of genes occurred in the human gastrointestinal tract (60).

c. The magnitude of harm from a disease-causing bacterium acquiring an antibiotic resistance gene in a particular environment (from mouth to intestine) cannot be extrapolated from the overall average contribution resistance genes in plants make to antibiotic resistant bacteria worldwide.

118. While there are many reasons why horizontal gene transfer may not result in harm, none of those reasons precludes the potential for it to cause a harm (61). Horizontal gene transfer might not result in harm because the DNA transferred from the GMO to another organism may not change the recipient into a harmful organism (61). The recipient might be able to cause harm as a result of acquiring a new gene or gene fragment, but the organism may not survive. The recipient might be able to cause harm, but might take many years to reach a population size or encounter the right conditions for it to cause harm (62). This latter limitation is lag time. The inescapable difficulty in predicting lag time is consistent with the Councils' precautionary approach to assessing GMOs.

119. Finally, the Royal Society Review only considers the limited case of horizontal gene transfer where the gene of origin is a GM plant and the recipient of it is a bacterium. The proposed Plan Changes are not specific to GM plants. The proposed Plan Changes cover the release of any kind of GMO, including among others GM bacteria. It would not be defensible to exclude plausible and significant risks of gene transfer from all GMOs

[29] This same evidence was submitted to the Auckland Unitary Plans Hearings in September 2015 and the authors of the Royal Society Review did not contest it.

based on the knowledge we have from some GM plants.[30]

120. **In summary**, the Royal Society Review was critical of the section 32 analysis. However, I found that in many places the Royal Society Review lacked scientific detail as to why the section 32 analysis or its underlying evidence was incorrect. Where details were provided, there were often some significant errors of fact or interpretation. Most importantly, in key sections the Royal Society Review took quotes out of context, or from what I could tell actually manufactured quotes. These errors in places undermined what the Royal Society authors were saying. I believe that this made the Royal Society Review unreliable.[31]

121. Moreover, the Royal Society Review did not adequately distinguish between risk characterisation and the likelihood of a hazard or adverse effect occurring, such as in the discussion on the use of new breeding technologies. The analysis on horizontal gene transfer also demonstrated this limitation. This section of the Royal Society Review also confirms that a variety of views on the risks of horizontal gene transfer are held by the scientific community. The criticism of one article used in the generic Section 32 Report[32], i.e. *Community Management of GMOs: Issues, Options, and Partnership with Government*, amounted to only a comment about references it used. The Royal Society Review did not contradict that evidence.

Submission by Shoshona Galbreath on behalf of Pastoral Genomics

122. Much of this submission is outside my area of expertise. Paragraphs 18, 21, 29, 33.3 and 47.1 have been addressed in my responses to other submissions, above. I will therefore focus here on parts of paragraph 17 (specifically 17.1 and 17.4) that have issues of science and have not been addressed above.

123. In paragraph 17.1 Pastoral Genomics says that the scientific basis for the proposed plan changes "is not supported by the international scientific consensus regarding risks posed by GM crops."

124. I have already and thoroughly evaluated statements about scientific consensus above in the section "Uncertainty and Lack of Consensus". Nevertheless, a few additional comments may assist the Hearings Panel.

125. Intense feelings are held by people on the topic of GMOs. The ferocity and variety of feelings held in the scientific community are no different, as I think the Panel will sense from various statements that were submitted to it. Dr Ulrich Loening reflected on this, saying "scientists who have published provocative results about GM crops have been vilified beyond any scientific justification" (63). *Nature* magazine concluded along similar

[30] This same evidence was submitted to the Auckland Unitary Plans Hearings in September 2015 and the authors of the Royal Society Review did not contest it.
[31] This same evidence was submitted to the Auckland Unitary Plans Hearings in September 2015 and the authors of the Royal Society Review did not contest it.
[32] Section 32 Report volume 2 Supporting Documentation to the Section 32 Report

lines, saying: “Tidy stories, in favour of or against GM crops, will always miss the bigger picture, which is nuanced, equivocal and undeniably messy” (29).

126. Tidy stories about consensus have become normal in the debate on GMOs. While normal, they are not nuanced and they seek a simplicity that is not true to the undeniable complexity of views held by the scientific community. For example:

    a. The British Medical Association said: “A great deal of research, of varying quality, has been conducted since 1999 in the arena of genetic modification of food. However, many unanswered questions remain, particularly with regard to the potential long-term impact of GM foods on human health and on the environment. The few robust studies that have looked for health effects have been short-term and specific. There is a lack of evidence-based research with regard to medium and long-term effects on health and the environment. In our view, the *potential* for GM foods to cause harmful health effects is very small and many of the concerns expressed apply with equal vigour to conventionally derived foods. However, safety concerns cannot, as yet, be dismissed completely on the basis of information currently available” (64).

    b. The World Health Organisation said that: “For an analysis of the costs and benefits of GM food, the costs to be taken into account and the intended scope of beneficiaries should be defined. Cost–benefit ratios can relatively easily be estimated for manufacturers and farmers (who may benefit from certain GM products in the short term). But of more interest are the costs and benefits for society as a whole and in the long term. This includes aspects such as sustainability of agricultural production systems, *and the cost of mitigating potential effects on health and the environment*. Such estimates require a complex form of analysis” (emphasis added to reference 3).

    c. The science journal *Nature* said: “In the pitched debate over genetically modified (GM) foods and crops, it can be hard to see where scientific evidence ends and dogma and speculation begin…Researchers, farmers, activists and GM seed companies all stridently promote their views, but ***the scientific data are often inconclusive or contradictory***” (emphasis added to reference 29).

127. In paragraph 17.4 of the Pastoral Genomics submission, it says that scientific basis for the proposed plan changes “is based on incorrect assumptions, and outdated information without regard to advancements in GM science.”

128. Without knowing the specific advancements or the assumptions, it is difficult to reply in the concrete. However, what is sure is that there will always be assumptions proven to be incorrect in the future. These may be assumptions about potential for harm and potential to derive benefit.

What is also a near certainty is that the science of genetic engineering will continue to change.

129. There is no evidence that I can find that suggests that many scientists hold firm opinions about GMOs of the future, that those so far not commercialised are and will be safe or necessarily will provide net benefits, or that they should be unregulated. Indeed, the World Health Organisation says that: “Continuous application of safety assessments based on the Codex Alimentarius principles and, where appropriate, adequate post market monitoring, should form the basis for ensuring the safety of GM foods” (65).

130. But more to the point, believing that GMOs cause no more harm than non-GMOs or even provide benefit is still no reason for them to avoid a process through which they may be required to demonstrate a *net* benefit to a decision-maker representing the people of the relevant receiving environment. It is for precisely these reasons that risk assessment guidance and legislation are in place. Those GMOs to come cannot be assumed to be identical to those GMOs that are already released, and neither can the receiving environments be assumed to be the same. Ongoing regulation and risk assessment is the status quo.

Conclusion

131. For these reasons, from a scientific perspective, I support the inclusion of the GMO provisions in the Proposed Whangarei District Plan Change and the Proposed Far North District Plan Change.

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Appendix 1: Advice Relating to GMO Field Trials

Should field trials be classified as discretionary activities?

At present, field trials are designated as discretionary activities. The reasons for this given in the plan provisions are as follows:

Field trials of GMOs under New Zealand law are designed with the objective of ensuring that no altered genetic material leaves the test site during the trial and that all heritable material is removed upon its conclusion. While this greatly reduces the prospect for adverse effects arising, breaches of trial conditions that could lead to GMOs escaping the trial site have already occurred internationally, and breaches of field trial conditions have occurred in New Zealand. These breaches illustrate the potential for field trials to result in unintended consequences that could impose costs on the community and/or adversely affect the environment. The requirement for monitoring at the operator's cost, and trigger conditions for financial liability and bonds are important additional safeguards for the community.

The classification of activities in the Working Party councils' planning documents is based on a hierarchy of risks, from negligible for permitted activities, moderate for discretionary activities and higher risk for prohibited activities.

Are field trials appropriately categorised as activities of moderate risk to human health or the environment?

International guidance on risk assessment and risk management of genetically modified organisms (GMOs) recognises the relevance of scales and types of releases[33]. Therefore, it is reasonable to consider that field trials of GMOs may have a different risk than full releases or laboratory contained work.

There are definitions of field trials in the Proposed Auckland Unitary Plan, Whangarei and Far North District Plans. They are all based on the definition of field tests in the Hazardous Substances and New Organisms Act (HSNO Act). The HSNO Act says that:

"field test means, in relation to an organism, the carrying on of trials on the effects of the organism under conditions similar to those of the environment into which the organism is likely to be released, but from which the organism, or any heritable material arising from it, could be retrieved or destroyed at the end of the trials"

For the purposes of my advice, I define a field trial as:

- a field test according to the HSNO Act
    - where the party licensed to conduct the testing (the operator) will be financially accountable for adverse effects associated with the activity and can meet those costs
        - and will prevent escape of the GMO by any means
        - and remove all heritable material upon conclusion of the activity
    - where the test has an approved monitoring plan that is sufficiently long in duration to likely detect any escaped organisms.

[33] http://www.cbd.int/doc/meetings/bs/mop-06/official/mop-06-13-add1-en.pdf

No form of containment is perfect. The highest levels of containment are achieved using laboratories. Laboratory breaches do occur, but the frequency is extremely low given the amount of work being done in these facilities worldwide. The success of laboratory-containment is due to a combination of physical barriers and management.

Similar principles are applied to field testing. These organisms are contained by generally less reliable physical barriers and are often at larger scales than laboratory work. Confidence in GMO field trial containment measures has been undermined by some high profile local and international failures. Even some GM pharma plants have escaped containment. This is especially disappointing because they may not be of low risk to human or animal health.

So far, the harm from these failures has been mainly reputational and economic. However, it can take many years for the effects of an escaped organism to become apparent, just as it can take many years for the escape to be detected. For example, a genetically modified wheat grown to field trial stage and then discontinued was rediscovered in open fields in the US state of Oregon eight years after field trials ended, and again in Montana over 10 years from the end of testing.

Similarly, a form of genetically modified rice that was grown on less than one acre of land for field testing between 2001 and 2003 was discovered in the US rice supply in 2006. It took another eight years to clear it from rice consignments. How such small field test amounts stopped many years before detection could have contaminated such a large commercial crop was described by the company as “an act of God”.[34]

Seeds of some plants can persist and remain viable for a decade or more in the soil.

Plant gene flow from test sites can also be greater than anticipated and/or arise from a failure to properly adhere to containment controls during the testing or monitoring period. This can be because seed transport by animals or machinery is underestimated, or pollen viability and mobility is underestimated, or because of incremental transfers from the original test site. In a study following up on a test field of GM bentgrass, escapees were found up to 21km from the original site, with the surrounding landscape an archepelgo of individual stands.

Field trials as I have defined them, which is consistent to how they are described by the Plan, are some of the most stringent that I have seen. They are likely to compensate for weaknesses in the design of failed field tests that have gone before. The risks are not socialised (except where the operator is a public entity).

In my view, the risk of adverse effects from field trials is adequately balanced by the performance standards assigned to them as discretionary activities. However, I recommend that the Councils, when setting resource consent conditions, consider setting explicit minimum conditions for post trial monitoring for testing of some organisms, especially those that would produce pollen or set seed, or for which there is a high probability of some individuals producing pollen or seed[35].

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[34] Reported in Ledford, H. Out of bounds. *Nature* **445**, 132-133 (2007).

[35] For example, in ERMA decision 200479 approval for GM tree testing was approved provided that trees did not produce pollen or release seed. Under these conditions, monitoring was required for only 12 months after the end of testing, provided that no trees emerged during that

I recommend that the Council -

- factor in the potentially long time lag between the cessation of field testing and detection of escaped organisms when setting monitoring requirements and terms of a bond guarantee.
- take into consideration the possibly long distances of gene flow by different routes.
- require monitoring paid for by the operator to be conducted by a party that is, and is seen to be, independent of the operator and competent in the art.

On this basis I believe that the discretionary status for field trials in the proposed plan provisions is appropriate.

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time. Where the potential for pollen or seed production is more likely to occur because of operator error or other reasons, monitoring should be of term long enough to exclude unobserved escape.

Appendix 2: Advice Relating to GM Veterinary Vaccines

I was asked to provide scientific advice "on whether or not GM veterinary vaccines should be treated differently to what the present provisions prescribe (i.e. as a permitted activity) given the difficulties that this would entail for councils to both regulate and monitor."

To provide this advice, I sought a definition of a 'veterinary vaccine'. I could not find one in either the current Auckland Council Regional or District Plans or PAUP. The definition offered by the Agricultural Compounds and Veterinary Medicines Act is that they are "biological compounds", which in my view is vague.

The lack of a definition presents a challenge, because many different products might be called vaccines depending on how they work or how they are used. In which case, my advice might vary depending on how the term 'veterinary vaccines' was interpreted.

Therefore for the purposes of this advice, I define a veterinary vaccine as a biological compound:

- controlled by the Agricultural Compounds and Veterinary Medicines Act
- that is used to produce or artificially increase immunity to a particular disease
- and has been tested and approved as safe to use by a process similar to that conducted for medical vaccines[36].

A GM veterinary vaccine is a veterinary vaccine that is a genetically modified organism (GMO) as defined by the Hazardous Substances and New Organisms Act and its Regulations.

In contrast, growing a plant (or other organism) that is genetically modified to produce proteins or other material to develop into a vaccine would be different from a plant being administered as a vaccine. This would instead be an example of a pharma crop which is a 'non-food-related GMO'. So while this product may be a GM veterinary vaccine in its final application, growing it in the district is clearly prohibited by the Draft Proposed Plan Change.

I will concentrate on GM veterinary vaccines but will make reference to other kinds of vaccines in offering my advice. I also consider differences in how a GM vaccine might be considered by a national and a local regulator guided by the GMO provisions of the PAUP.

[36] For guidelines, see http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/10/WC500004598.pdf.

Medical vaccines

There appears to be no controversy over permitting the use of nonviable GM materials in medicine. I think that there are indisputable scientific reasons for these products to be permitted.

Nonviable vaccines

I could find no definition of nonviable. I consider nonviable any GMO unlikely to survive or replicate in the environment. For the purposes of my advice, the GM veterinary vaccine would unlikely live separately from the inoculated recipient or be transmitted from the inoculated recipient.

I interpret "medical applications involving use of nonviable GM products" to include nonviable medical vaccines.

I am unaware of any evidence that a nonviable veterinary vaccine would have a different risk to human health or the environment than a nonviable medical vaccine. I also cannot conceive of a situation where it would, *provided that a nonviable GMO used as an animal vaccine benefited from a similar testing and development process and risk assessment approval process as a medical vaccine*.

Viable vaccines

I could find no definition of viable. At a minimum, viable should be living. The Cartagena Protocol on Biosafety (which was ratified by New Zealand) says that a "'Living organism' means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids." This would include genetically modified bacteria that are used as vaccines. For the purposes of my advice, a viable GM veterinary vaccine could live separately from the inoculated recipient or be transmitted from the inoculated recipient.

GMOs that are viable vaccines generally have the same potential to cause adverse effects as other GMOs. Whether or not they do so will depend on the receiving environment as well as the characteristics of the GMO.

The Plan initially sought to permit veterinary vaccines

…"because they **tend not to persist** in the environment, appear to be low risk and are **difficult to monitor**, making control by the District / Unitary Plan less appropriate" (emphasis added).

Persistence and difficulty in monitoring could be characteristics of some vaccines. Persistence will be a function of the form of the GM vaccine. For example, if the vaccine is produced by a plant, its persistence will be determined by the persistence of the plant. If the vaccine is a virus, then persistence outside of a target host might be extremely limited, depending on the virus.

In addition, on the face of it the difficulty to monitor the vaccine after release would seem to be consistent with prohibiting it, or requiring a consent. This is because the Plan states that "We need to adopt a precautionary approach to managing the risks associated with the outdoor use of GMOs." Being unable to monitor would remove options to address residual uncertainties in a risk assessment.

However, prohibiting the use of all vaccines also is not warranted. Provided that the vaccines have demonstrated efficacy and have been cleared by processes similar to medical vaccines, then to not use them might cause an increase in suffering, mortality or morbidity.

I also have looked to the Environmental Risk Management Authority (ERMA, now called the Environmental Protection Authority, EPA) decision on the equine influenza vaccine to inform my advice. In that case, the ERMA imposed six additional controls on the approval of the live vaccine. ERMA concluded that this vaccine was unlikely to be transmitted from the horse or live separately from the horse[37]. Therefore I would consider it to be nonviable. Nevertheless, the controls ERMA adopted also could be useful for applying to viable vaccines.

1. "**Control 1**: Any person using these vaccines must ensure that these vaccines are only administered to equine animals such as horses, donkeys, and zebras, and only by a veterinarian who has been trained, specifically on the controls placed on the use of this vaccine by MAF BNZ."

   The control limits the type of animal that might receive the vaccine and specifies that the vaccine may only be administered by a veterinarian.

2. "**Control 2**: Any registrant of the vaccine must maintain records of vaccine stocks and must make those records available to MAF BNZ for auditing.

   "Control 3: Any MAF BNZ approved person storing these vaccines must ensure that the vaccines are stored in a secure location and ensure that the expired vaccines are disposed of as hazardous waste. Also, that person must ensure that a record is kept of all the vaccine stock coming into and going out of such a location and must make those records available to MAF BNZ for audit.

   "**Control 4**: Any person storing, transporting or using these vaccines must ensure that any spills including storage facility and one-off spills of the vaccine are disinfected by treating with the best available and most appropriate disinfectant (eg, 70% ethanol). In addition, any spills should be recorded and notified to MAF BNZ and to ERMA New Zealand.

   "**Control 5**: Any person using these vaccines must ensure that contaminated waste from the genetically modified vaccines (including syringes, needles, disposable overalls, gloves, masks and any other material exposed to the genetically modified product) must be collected, treated and disposed of as hazardous waste. Disposal of expired vaccines must be in accord with the requirements of MAF/ERMA New Zealand Standard *Facilities for Microorganisms and Cell Cultures: 2007a3.*"

132. These controls establish conditions for storage and prevention of escape, and ensure record keeping for accountability and tracking.

3. "**Control 6**: The vaccines can only be used in New Zealand for export in

[37] "3.9.10 The Committee notes that the ALVAC® strain of Canarypox virus has been attenuated to the level that it has lost the ability to produce infectious progeny".

accordance with Overseas Market Access Requirements to a country that requires equine animals to be vaccinated using Proteqflu or Proteqflu Te; or in an Equine Influenza outbreak as defined by MAF BNZ."

133. The final control specifies the limited number of circumstances under which use is allowed.

Summary

I was asked the question: "Should veterinary vaccines that are considered to be genetically modified organisms be exempted from the need to obtain resource consent or comply with the performance standards applicable to discretionary activities?"

I found the question challenging because veterinary vaccines were not defined. I therefore have provided a definition.

Making the use of products that conform to the definition of a nonviable veterinary vaccine a permitted activity is reasonable in my view.

The question was also challenging because some viable GM veterinary vaccines may have the same potential as other GMOs to cause adverse effects in the environment or on human health. While I am not aware of evidence that demonstrates a significant environmental or human health harm from previous releases of GM vaccines for animals thus far, there is scientific uncertainty especially about large scale releases.

On the other hand, vaccines have demonstrated benefit to human and animal health. There can be serious consequences from not vaccinating animals against some diseases. When the best or only vaccine is a GM veterinary vaccine, then there are compelling reasons to allow its use.

It is reasonable for future EPA approved viable GM veterinary vaccines under the control of a veterinarian to be a permitted activity. Provided that the veterinarian would remain responsible for EPA imposed controls, record keeping and proper disposal of unused vaccine, and have a general duty to monitor for adverse effects, specific district-level concerns likely would be addressed.

It might be necessary to make use of EPA approved viable GM veterinary vaccines not administered by a veterinarian discretionary activities that must comply with performance standards. The standards would allow case-by-case decision making guided by clear rules. This process, however, would need to be able to work very quickly in situations where animal or public health were threatened.

In the table below I summarise my advice.

Table 1. Definitions or standards applying to GM veterinary vaccines that might be used in the Plan

Type of Vaccine	Performance Standards	Proposed Regulatory Status
Medical Vaccine	Not applicable.	Permitted
Nonviable GM Veterinary Vaccine	Not applicable.	Permitted
Viable GM Veterinary Vaccine that is supervised by a veterinarian[38]	Not applicable. (EPA approved with controls and there is a party responsible for demonstrating compliance with those controls, expected that veterinarians would keep immunisation, storage and disposal of unused vaccine records, and accept a general duty to report adverse effects.[39])	Permitted
Viable GM Veterinary Vaccine that is not supervised by a veterinarian	Provided that EPA approved with controls and there is a party responsible for demonstrating compliance with those controls, and that release, storage and disposal of unused vaccine records were available to the Council.	Discretionary

[38] Meaning a specific delivery dose controlled by the veterinarian.

[39] For guidelines, see http://www.nzva.org.nz/policies/9a-vaccine-use-companion-animals-new-zealand?destination=node%2F2212.

Appendix 3: Professor Jack Heinemann's CV

current June 2015

CURRICULUM VITAE

JACK A. HEINEMANN

CURRENT POSITION	Professor
ADDRESS	School of Biological Sciences University of Canterbury, Christchurch, New Zealand
EMAIL ADDRESS	jack.heinemann@canterbury.ac.nz
TELEPHONE/FAX	64 03 364-2500
CITIZENSHIP	U.S.A. and New Zealand
EDUCATION	
1985-1989	Ph.D. in Biology/Molecular Biology University of Oregon, Eugene, OR, USA
1980-1985	B.Sc(Honours) in Biochemistry B.Sc(Honours) in Molecular Biology University of Wisconsin, Madison, WI, USA

PROFESSIONAL EXPERIENCE

2007-present	Professor, School of Biological Sciences, University of Canterbury
2003-2007	Associate Professor
1994-2002	Senior Lecturer
2001-present	Director, Centre for Integrated Research in Biosafety, University of Canterbury Member, Biomathematics Research Centre (2001) University of Canterbury
2001-2012	Adjunct Professor/Senior Fellow, GenØk-Centre for Biosafety, Tromsø, Norway
1997-2000	Biochemistry Programme Coordinator (managed 5 undergraduate courses, ~ 20 postgraduate (PhD and MSc) students and 10 academic and technical staff)
1992-1994	Staff Fellow, National Institutes of Health, NIAID, Laboratory of Microbial Structure and Function
1989-1992	Intramural Research Training Award Fellow NIAID, NIH, Laboratory of Microbial Structure and Function

1985-1989	Graduate student, University of Oregon, Institute of Molecular Biology
1983-1984	Undergraduate Research Assistant, University of Wisconsin-Madison, Department of Biochemistry

INTERESTS AND EXPERTISE

Genetics and molecular biology of prokaryotic and eukaryotic microorganisms; horizontal gene transfer, particularly conjugation; effects of stress, particularly induced by antibiotics; evolution and biosafety risk assessment; eugenics (historical); influence of language on science.

HONORS AND SPECIAL RECOGNITION

2015	Recipient of the inaugural University of Canterbury Teaching Innovation Award
2014	Recipient of the Tertiary Education Union National Excellence Award in the category of Academic Freedom
2012-	Chosen by the (United Nations) Convention on Biological Diversity Secretariat to serve on the Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management
2012	Special guest speaker University of Hohenheim Centre for Tropical Agriculture 30th Anniversary, Germany
	Keynote Speaker Postgrad Research Showcase, Christchurch
2011	Keynote Speaker, ETH Monte Verita Conference: Understanding and managing ecological novelty, Switzerland
2010	Keynote Speaker, Tropentag Conference: World Food System: A contribution from Europe, ETH Zurich, Switzerland
2009-2012	Chosen by the (United Nations) Convention on Biological Diversity Secretariat to serve on the Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management
2008	Chosen by the (World Bank and UN agencies) IAASTD Secretariat as author representative to the intergovernmental meeting on the IAASTD Report
	Keynote Speaker, Feed the World Conference, London, UK
2007	Selected by the IAASTD Advisory Bureau to serve as an author on the Biotechnology theme of the Synthesis Report
2006	Appointed Lead Author in the IAASTD Global Assessment Report (nominated by Norway)
2005-9	UN Roster of Experts (Biosafety Protocol)
	Distinguished Lecture in Microbiology, University of Wisconsin-Madison
2004	Speaker in the New Zealand Royal Society's Science for Parliament Series

2002 Recipient, New Zealand Association of Scientists Research Medal (The Association's Research Medal is awarded each year to a single scientist aged under 40 for outstanding research work, principally undertaken in New Zealand during the three preceding years.)

2001 Visiting Professor, Norwegian Institute for Gene Ecology and the University of Tromsø (with Prof. T. Traavik), Tromsø, Norway

Visiting Scholar, The Rockefeller University (with Nobel Laureate Prof. J. Lederberg), New York, USA

1993 Young Investigator Award from the American Society for Microbiology Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) [one of four awarded in an international competition]

1989-2003 Various recognition: *National Business Review* Achiever of the Week (14 Feb. 2003); featured in Saunders, J. 2003. Multiple Drug Resistant Bacteria. Microbiology Today (http://www.socgenmicrobiol.org.uk/pubs/micro_today/book_reviews/MTNOV03/MTN03_24.cfm); featured in: Delwiche, C.F. 2000. Griffins and Chimeras: Evolution and Horizontal Gene Transfer. BioScience 50, 85-87; featured in: Ankenbauer, R.G. 1997. Reassessing Forty Years of Genetic Doctrine: Retrotransfer and Conjugation. Genetics 145, 543-549; **keynote addresses**, The Norwegian Biotechnology Advisory Board Meeting (Oslo, Norway, 1997) and International Conference on Gene Transfer Mediated by Bacterial Plasmids (Banff, Alberta, Canada, 1990); invited speaker, "Microbial Stress Response" Gordon Conference, 1994. 1989-1992 **Intramural Research Training Award** (National Institutes of Health); 1980-1989 Undergraduate and graduate school awards include: 1984, **Outstanding Senior** (final year) **Student Award** (University of Wisconsin-Madison Alumni Association); 1983, **Mary Shine Peterson Award** (Department of Biochemistry, University of Wisconsin); University of Wisconsin Forensics Team Scholarship; 1981, Phi Eta Sigma, the Freshman's Honor Society, MACE, the Chancellor's Men's Honor Society; 1986-1986 NIH Molecular Biology Predoctoral Traineeship (University of Oregon).

GRANTS Total value since 1995 ~NZ $3.9 million

2015 Brian Mason Trust ($12,072).

2014- Donations to UC Foundation for pesticide project (~$150,000)

2013-2014 Safe Food Institute ($64,000)

2010-2012 Marsden Fund (Primary Investigator) (NZ $620,000)

2009-2012 GE Biosafety Forecast Service (NZ $492,000)

2008 GE Biosafety Forecast Service (NZ $123,000)

2006-07 Constructive Conversations (subcontract FRST) (NZ$35,000)

2005-07 GE Biosafety Forecast Service (NZ $767,000)

University of Canterbury (NZ $30,000)

United Nations Food and Agriculture Organisation (FAO) report on Gene Flow (NZ $50,000)

Erskine Fund Teaching Fellowship (NZ $20,000)

2004 GE Biosafety Forecast Service (NZ $324,000)

2003 GE Biosafety Forecast Service (NZ $31,000)

2002 FRST: Postdoctoral fellowship (to RJ Weld to work in my laboratory for 3 years)

OECD Fellowship (~NZ $40,000 for RJ Weld to work in Norway for 6 months)

Brian Mason Trust: NZ $15,000 for research on GMOs

2001 Miscellaneous: GENØK (US $10,000); Rockefeller University (US $6,000); University of Canterbury (US $3,000); US-New Zealand ISAT Bi-lateral Relations Grant ($3,200)

2000 Marsden Fund (Associate Investigator) (NZ $447,000)

Ministry of Health (NZ $3,000)

1999 Marsden Fund (Primary Investigator) (NZ $528,000)

Joint U. Canterbury/Crop & Food Res. (NZ $171,000)

Ministry of Health (NZ $8,000)

1995-1998 (1998) Lotteries Health Research Grant (NZ $71,350), University of Canterbury Research Award (NZ $45,000); (1997) Christchurch School of Medicine Summer Studentship Award (to sponsor an undergraduate researcher), Don Beaven Trust Travelling Fellowship (NZ $3,000), University of Canterbury Research Award ($20,000); (1996) Lotteries Science Research Grant (NZ $35,000), (1995) University of Canterbury Research Award (NZ $25,000), University of Canterbury Equipment Award (NZ $90,000)

CONSULTATIONS, SYMPOSIA and PROFESSIONAL ACTIVITIES

Spoken at **over 50 international conferences** (~85% at invitation), presented **>10 keynote addresses** and **chaired over a dozen sessions**. Served on the organising committees of 5 international meetings. ***Referee*** on occasion for **Applied and Environmental Microbiology, Bioessays, Biology Letters Review, Current Microbiology, Drug Discovery Today, Environmental Biosafety Research, Environmental Monitoring and Assessment, Environmental Pollution, Environmental Science and Technology, FEMS Microbiology, FEMS Microbiology Ecology, Entropy, Food and Chemical Toxicology, Food Chemistry, Future Virology, International Journal of Antimicrobial Agents, Journal of Applied Microbiology, Journal of Bacteriology, Journal of Organic Systems, Microbiological Research, Microbiology, Microbiology Indonesia, Molecular Biology and Evolution, Molecular Ecology**, **Molecular Microbiology, Nature Biotechnology, Nature Genetics, New Zealand Journal of Zoology, Pharmacological Research, Plasmid**, **Proceedings of the National Academies of Science USA (PNAS), RNA Biology**, **RNA Journal**, **Royal Society Proceedings B**, **Science**, **Science of the Total Environment, Scientific Reports, World Journal of Microbiology and Biotechnology**, and ten granting agencies (NSF, USA; FRST, Marsden, HRC and Lotteries Grants Board, Auckland Medical Research Foundation, New Zealand; MacQuarie, Australia; NERC and Wellcome Trust, UK, Alzheimer's Foundation, Danish National Research Foundation, Denmark, Slovak Research and Development Agency, Slovak Republic, Beef Cattle Research Council, Canada). Chief organiser of the 1999 International Osmoregulation Conference, Christchurch, New Zealand and the 2009 Hazard ID and Risk Assessment of (Trans)gene Flow, Tromsø, Norway. ***Organiser and Instructor*** of two prominent international courses:

School of Bioinformatics and Genomics Summer Course in Phylogenomics (2003, Sweden) and International Biosafety Course (2003-continuing, Norway).

2015 Graduating Year Review of Massey University's Bachelor of Natural Sciences
Invited speaker, New Zealand Association of Scientists conference *Going Public: Scientists speaking out on difficult issues* Wellington
Invited speaker, University of Otago Christchurch School of Medicine *Antibiotic resistance by stealth* Christchurch

2014 Invited speaker Lincoln University
Invited speaker, Miriam College, Quezon City, Philippines

2013 Invited speaker, Understanding Biosafety: Regulation of Genetic Engineering and Genetically Modified Organisms in Agriculture, Hyderabad, India
Invited speaker, Safety Issues in Application of Food- and Biological Technologies, Kunming, China
Invited speaker, UC Teaching Week, Christchurch
Professorial promotions referee, University of California Santa Barbara

2012 Master of Ceremonies International Scientific Conference Can GM Crops Meet India's Food Security and Export Markets?, New Delhi
Invited Speaker, Can GM crops meet India's food security and export markets?, Hyderabad, India
Invited Speaker, GMO Risk Assessment, Independent Biosafety Research and Holistic Analysis, Hyderabad, India
Invited Speaker, Meeting of the Parties (MOP6) side event 1: talk titled "AHTEG on risk assessment and risk management Process and Outcome", Hyderabad, India
Invited Speaker, MOP6 side event 2: talk titled "Horizontal Gene Transfer Field Trials", Hyderabad, India
Invited Speaker, Regional and Stakeholder Forum on Genetic Modification, Hastings, New Zealand

2011 Editorial Board of **DNA and Cell Biology** (http://www.liebertpub.com/products/product.aspx?pid=13)

2010 Invited Speaker, Advancing the Understanding of Biosafety Conference, Nagoya, Japan

Invited Speaker, Third World Network Side Event at the 5th Meeting of the Parties of the Cartagena Protocol, Nagoya, Japan

2009 Invited Speaker Food Markets and Society II: National Symposium on Future Food Technologies, Auckland, New Zealand
Invited speaker: Evolution: the experience, Melbourne, Australia

2008 Expert witness to Tasmanian Joint Select Committee on Gene Technology in Primary Industries (nominated by Hon David Llewellyn, Chair)

2006 Invited speaker, International Biosafety Symposium Meeting of the Parties (MOP3) of the Cartegena Protocol on Biosafety, Curitiba, Brazil

Expert reviewer, Denmark Centre of Excellence Programme.

2005 Expert reviewer on New Zealand Environmental Risk Management Authority's policy paper: Horizontal Gene Transfer
Keynote Speaker, UNEP/GEF National Biosafety Framework Initiative, Dominican Republic

2004 Invited speaker, International Biosafety Symposium Meeting of the Parties (MOP1) of the Cartegena Protocol on Biosafety, Kuala Lumpur, Malaysia
Invited speaker, School of Bioinformatics and Genomics Summer Course in Phylogenomics, Göteborg University, Sweden

2004-2005 Executive Committee, United Nations Environment Programme and GENØK Biosafety Capacity Building Partnership

2003 Scientific consultant to the New Zealand Parliamentary Local Government and Environment Select Committee on "Corngate".
Invited Speaker, American Society for Microbiology ICAAC conference.

2002 Speaker: ERMANZ conference on Horizontal Gene Transfer
Microbial Genetics Conference, Bergen, Norway
New Zealand Microbiology Society Meeting

2001 Advisor to New Zealand Minister of Science in the "Horizontal Gene Transfer Round Table Meeting"

2000 Expert panel New Zealand Ministry of Health
New Zealand PGSF Biotechnology Tender Panel

University of Canterbury Representative to the NZ Royal Commission on Genetic Engineering

1999 Expert Panel on Antibiotic Residues for the New Zealand Ministry of Health

1997 Keynote speaker, The Norwegian Biotechnology Advisory Board Meeting, Oslo, Norway

1993 Advisor to the United States Department of Energy, under the auspices of the American Academy of Microbiology, for genetic modification of bacteria

2002-2004 **Editorial Board** of Targets (Elsevier "Trends" series journal); 1999-2004 **Editorial Board** of Drug Discovery Today (Elsevier "Trends" series).

POSTGRADUATE TEACHING (1995-present)

Experience: Primary supervisor of 13 completed MSc theses, 12 BSc (Hons) theses and 7 PhD theses, and associate or co-supervisor for more than 20 BSc (Hons), MSc and PhD students since joining the University of Canterbury (1994). My research laboratory presently has 3 PhD and 1 MSc student and 1 postdoctoral scholar.

Achievements: My research students received 5 of the 6 poster awards in the 1996 Queenstown International Molecular Biology Meeting attended by researchers from all over the world and uniformly represented by New Zealand and Australian universities. Joanne Kingsbury and Tim Cooper, while PhD students in my laboratory, won the first and second prizes, respectively, for best research talks at the 1998 national meeting of the Microbiology and Biochemical Societies of New Zealand. Tim was a postdoctoral scholar at Michigan State University and is now at Auckland University. Joanne is a postdoctoral scholar at Duke University. Tim was subsequently nominated for the American Society of Microbiology Sternberg Thesis Award. Gayle Ferguson, another of my PhD students, won first prize for her talk at the Microbiology Society national meeting in 2001 and was a postdoctoral scholar at Columbia University, New York.

EXTERNAL TEACHING ACTIVITIES

2014 Faculty and textbook developer for Government of Swaziland short professional course on Biosafety (under contract to Third World Network)

2009 Faculty and Coordinator for the Gateways Partners Symposia Course and Conference on (trans)gene Flow, Tromsø, Norway

2005 Faculty and organiser of the Solomon Islands Biosafety Course

2003-2011 Faculty and instructor International Biosafety Course

2003-4 Principal Organiser and Instructor (2003), Göteborg University's Bioinformatics summer graduate course, Sweden

2000-present PhD examiner: 2 x University of Malay; 5 x University of Otago; 3 x Massey; 2 x Lincoln; 1 x Macquarie University; 1 x Dartmouth University; 1 x University of Sydney
MSc. examiner: 1 x Massey University, 3 x Otago University; 1 x Macquarie University
Assessor (MSc proposals): 3 x Auckland University

Teaching experience during NIH (1990-1994), under- and post-graduate years (1980-1989): 1990-1994 Supervisor, NIH Summer Student Program, Rocky Mountain Laboratories, USA (resulting in a research paper in the journal **Genetics**

by an undergraduate student in 1996); 1992-2000, University of Montana USA affiliate faculty; Guest lecturer, University of Montana, 1992-1994 "Advanced Topics in Microbiology", (course 595) University of Montana, Department of Biology; Teaching Assistant for Core Biology Lecture and Laboratory, Department of Biology, University of Oregon, Eugene, OR, USA; Presenter, Special Project Course in Bioethics, Department of Botany, University of Wisconsin, Madison, WI, USA.

STAFF LEADERSHIP ROLES

Serving the University of Canterbury on 12 *ad hoc* committees in addition to standing committees (listed below): chair of the College of Science Biosecurity Programme Committee (2004); Science Faculty Working Committee evaluating proposals for establishing a Department of Biochemistry (1995-6); the AUS Workloads Committee (1996); lead workshops at the Canterbury-hosted Education Forum (1999); and served on the AAC Subcommittee on Appeals Procedures (2000). Presentation to New Zealand Academic Quality Agency for UC audit 2014. Since 1995, I have served on 6 and chaired an additional 6 Search Committees (total of 12) for new academics. Participating in the staff mentorship and buddy programme.

2015- Elected University Academic Representative to the Council of the Tertiary Education Union
Acting Head of School (ad hoc)
President, Tertiary Education Union (TEU) Canterbury Branch
Appointed to the Board of the New Zealand Academic Qualifications Authority

2014- Chair, School of Biological Sciences Teaching and Learning Committee
Executive Committee, School of Biological Sciences
College of Science Strategic Academic Advisory Committee
President, Tertiary Education Union (TEU) Canterbury Branch

2013- Co-chair Academic Freedom Aotearoa

2013 President, Tertiary Education Union (TEU) Canterbury Branch
Acting Chair, Teaching and Learning Committee of the School of Biological Sciences
Observer, UC Promotions Round Associate Professor and Professor

2009 UC Academic Audit Working Group on the role of critic and conscience of society

2007-2008 President, Association of University Staff (AUS) Canterbury Branch

2006-2007 Canterbury representative AUS National Council

2006 AUS National Bargaining Team

2005-2006 Academic Representative (elected) on the Canterbury Branch AUS

2005-2006 School of Biological Sciences Research Committee

2002-2003 Chair, University Institutional Biosafety Committee

2001-2003 Departmental Supervisor of Postgraduate Studies

2002 University Teaching and Learning Committee

2000-2001 Department HSNO-Biology Officer and University representative to the HSNO Consultative Group

2002-2004 Department Safety Committee

1996-2005 Chair (2000), University Joint Academic Student Grievance Committee

1998-2001 Plant and Microbial Sciences Workload Committee

1996-1998 Branch Committee of the Association of University Staff (AUS)

1994-1998 Plant and Microbial Sciences Curriculum Committee

1994-1998 Academic Supervisor of the Graduate Seminar Series

PROFESSIONAL ORGANIZATIONS

1989-continuing	American Society for Microbiology
1994-continuing	New Zealand Microbiology Society
1995-2002	New Zealand Molecular Biology Society
1998-continuing	New Zealand Society for Biochemistry and Molecular Biology
2002-2004	New Zealand Association of Scientists
2015-	New Zealand Association of Scientists
2014-	Australian Society for Antimicrobials
2014-	Alliance for the Prudent Use of Antibiotics

SCIENCE and COMMUNITY

2015: What Do We Really Know About Roundup Weed Killer? National Geographic 23.04.15 http://news.nationalgeographic.com/2015/04/150422-glyphosate-roundup-herbicide-weeds/; Scientists keep quiet on controversial subjects fearing backlash from peers. nzDoctor 15.04.15 http://www.nzdoctor.co.nz/news/2015/april-2015/14/scientists-keep-quiet-on-controversial-subjects-fearing-backlash-from-peers.aspx; Common pesticides linked to antibiotic resistance. Guardian 24.3.15 http://www.theguardian.com/lifeandstyle/2015/mar/24/pesticides-antibiotic-resistance-study; Study links widely used pesticides to antibiotic resistance. Civil Eats 24.3.15 http://civileats.com/2015/03/24/study-links-widely-used-pesticides-to-antibiotic-resistance/; Popular weedkiller tied to antibiotic resistance. Rodale News 24.3.15 http://www.rodalenews.com/roundup-antibiotic-resistance; Herbicides raise resistance to medical antibiotics. Times of India 24.3.15 http://timesofindia.indiatimes.com/life-style/health-fitness/health/Herbicides-raise-resistance-to-medical-antibiotics/articleshow/46676730.cms; Herbicides may hurt antibiotics. Radio New Zealand 25.3.15 http://www.radionz.co.nz/news/national/269603/herbicides-may-hurt-antibiotics; Study Links Widely Used Pesticides to Antibiotic Resistance. Time Magazine 24.3.15 http://time.com/3756870/pesticides-antibiotic-resistance/?xid=tcoshare; Est-ce que le glyphosate favorise la résistance aux antibiotiques? Amis del Latterre. 24.3.15 http://www.amisdelaterre.org/Nouvel-article,1878.html;

2014: Degrees of usefulness. New Zealand Herald 12.4.14 http://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=11236723; How can we help feed the world. Waikato Times 4.11.14; Technologie n'est pas magie. Le Monde 28.10.14.

2013: Lead Opinion: Keep the pause button on GM pressed. The Hindu 7.9.13. Genetically engineered foods: myths and truths. Organic NZ 1.2.13. Scientists at odds over GM fungi. NZ Farmers Weekly

25.3.13. Lax GM rules may bite back- scientists. The Press 25.3.12. New GM technology under fire. New Zealand Farmers Weekly. 27.3.13. Scientist warned agency of GM danger. The Press 28.3.13. Claims of lax food safety regulations for GM molecules. Radio New Zealand Nine to Noon. 28.3.13.

2012: GM crops may not resolve food crisis, scientists say. Times of India. 25.9.12. Scientist warns against genetically modified wheat. TV3 News. 12.9.12 http://www.3news.co.nz/Scientist-warns-against-genetically-modified-wheat/tabid/1160/articleID/269009/Default.aspx; GM crop link to liver failure. New Zealand Herald, 12.9.12; GM crop could cause liver failure: scientist. The West Australian, 11.9.12; Scientists wary of CSIRO GM crop. The Australian, 11.9.12; The worm in Bt brinjal. Business Standard (India), 25.3.12; 'Proper risk assessment a must for adopting safe biotech' Times of India. 6.10.12.

2010-2011: Bt. Brinial: Note by Ministry of Environment and Forests, The Hindu, 10.2.10, Rural Report Radio New Zealand, 9.05.11; AgResearch stalls "damaging" report, Dominion Post, 23.6.11; AgResearch tried to block report, The Press, 23.6.11; Signals of gene transfer risk "not adequately tested", The Press, 23.6.11; AgResearch academic in row over GE report, Southland Times, 23.6.11; Radio New Zealand Checkpoint, 23.6.11. Quoted in The Atlantic http://www.theatlantic.com/health/archive/2011/03/the-battle-for-biodiversity-monsanto-and-farmers-clash/73117/, 28.03.11.

2008: Call for Government to invest more in agricultural research, Radio New Zealand, 16.4.08. Arts to get the chop, The Dominion Post, 30.4.08. Executions and amputations as staff protest job cuts, Westport News, 29.4.08. Restructuring goes ahead, Westport News, 30.4.08. Plans for restructuring go ahead, Gisborne Herald, 30.4.08. Claims that GM foods are needed to avert a food crisis are rubbished, Radio New Zealand, 9.6.08; Claims that GM crops are needed to prevent food shortages are disputed by experts, Radio New Zealand, 9.6.08.

2007: GM Corn, 30 minute interview on RNZ Nine to Noon programme 19.7.07; Discussion as to whether new type of genetically modified corn safe for human consumption, RNZ (Morning Report), 7.2.07; Food safety minister asked to reject new type of genetically modified corn, RNZ (6.00am news), 7.2.07; Minister asked to reject GM animal feed, New Zealand Herald, 7.2.07; Lobby tries to halt feed imports, Marlborough Express, 7.2.07; GM maize fears raised, Bay of Plenty Times, 7.2.07; Food lobbyists: Govt must act fast to stop GE corn, Northern Advocate, 8.2.07; Academic research under pressure, Gulf News, 15.2.07; Review of approval of genetically modified corn for animal feed, RNZ (Checkpoint), 21.2.07

2006: The Press (Christchurch) "Gene claims a rationale for abuse" (15 August, p. A8); ABC Science Online "Food Regulator Criticised over new GM corn" (4 August); Interview National Radio's Morning Report (6 June on High Lysine Corn); Interview National Radio's Checkpoint (5 June on Corn Food Safety); The Press (Christchurch) Heinemann, J.A. 5 May 2006 Perspectives article "Alarm bells over GM food approval: part 2. Featured in New Zealand Herald 24.03.06 Company wants stockfeed GE corn approved for people; TVNZ and TV3 interview on Frank Sin's "gay gene", 6 and 10 pm news 13.03.06; Christchurch Press interview on Frank Sin's "gay gene".

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on horizontal gene transfer to Canterbury Botanical Society; Featured in news article by Pockley, P. 2000. New law threatens to undermine genetics in New Zealand. **Nature** *406*, 8; Letter to the Editor of the Christchurch **Press**: "Genetic Engineering"; Interviewed by Paul Holmes (Auckland radio) for NewstalkZB (27 June); Radio New Zealand News interviews (30 June and 20 July); Featured in 4 news articles by the Christchurch **Press** on genetic engineering regulations; Heinemann, J.A. June 2000. Open letter to Helen Clark. **The Best Underground Press – Critical Review** (6), *9*, 2; University of Canterbury student newspaper **CANTA** articles: "Why do students but not academics have to be world-class?" (10 May 2000) and "Teaching is as teachers do" (17 May 2000); Heinemann, J.A. 2000. Research hazards. **New Zealand Education Review** (Sept. 8, 2000, p. 9); Heinemann, J.A. 2000. National security risk. NZ Listener (Jul 7), 7-8; interview on horizontal gene transfer by CHTV (1 Nov.); interview National Programme **Eureka!** (Nov. 26-27, 2000); Heinemann, J.A. 2001. The fate of students within our hands. **New Zealand Education Review** (Jan. 12, 2001, p. 7).

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1999: Talk on Genetically Modified Food to the Canterbury WEA; Talk on Genetically Modified Food to the Probus Club; Article to University of Canterbury public relations magazine, **Canterbury Research**, entitled: Are all Genes made of DNA?

1998: Talk on Genetically Modified Food to the WEA Bishopdale Community Centre; Article to community magazine, **City Habitat**, entitled "What is a University?"; Article to community magazine, **City Habitat**, entitled "Why You Don't Want to be my Client".

1997: Interview National Programme, New Zealand Public Radio: "Superbugs"; Article to University of Canterbury public relations magazine, **Canterbury Research**, entitled: "The Life and Times of the Undead"; Debate Plains FM, Christchurch, New Zealand: "Risk and Ethics of Genetic Engineering".

1995: Interview National Programme, New Zealand Public Radio: "Antibiotic Resistance"; Advisor for a nationally ranked high school student science project competition.

TOTAL PROFESSIONAL PUBLICATIONS 129

Peer-Reviewed Publications **(*invited)** Total: 68

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*Heinemann, J.A. and Wickson, F. 2011. Why would Australia want to grow genetically modified wheat? http://theconversation.edu.au/why-would-australia-want-to-grow-genetically-modified-wheat-3755. 3,861 readers (to April 2013).

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2015 Submission on Application A1097 Food Derived From Herbicide-Tolerant And Insect-Protected Corn Line MON87411 Assessment Report
Submission on Executive Council decision on Application for general release of genetically modified maize containing MON87460, reference number Monsanto-14/1474 (South Africa)

2011 Submission on the Assessment Report for Application A1063 - Food Derived from Herbicide Tolerant Soybean Line MON87708 by Monsanto Europe S.A. Submitted to Food Standards Australia/New Zealand

2011 Assessment of the technical dossier submitted under EFSA/GMO/NL/2011/93 for approval of transgenic soya event MON 87708 by Monsanto Europe S.A. Report No. Genøk/raad/jul2011/93 http://www.genok.no/filarkiv/File/Hoeringer/genok_raad_jul2011_h93.pdf

2011 Assessment of the technical dossier submitted under EFSA/GMO/NL/2011/69 for approval of transgenic potato event AV43-6-G7 by AVEBE U.A. Report Genøk/raad/mar2011http://www.genok.no/filarkiv/File/Hoeringer/genok_raad_mar2011_h69.pdf

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2010 Assessment of the technical dossier of EFSA/GMO/UK/2009/76 submitted by the applicant for genetically modfiied soybean MON 87769. Report No. Genøk/raad/may2010/h76 http://www.genok.no/filarkiv/File/Hoeringer/DN_inspill_H76_MON87769_forweb.pdf

2010 Assessment of the technical dossier related to EFSA/GMO/NL/2010/78. Report No. Genøk/raad/sept2010/h78

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2010 Submission on the 1st Assessment Report for Application A1029 Food Derived from Drought Tolerant Corn Line MON87460 Assessment Report. Submitted to Food Standards Australia/New Zealand

2009 Submission II on the Assessment Report for Application A1018 Food Derived from High Oleic Acid Soybean DP-305423-1. Submitted to Food Standards Australia/New Zealand

2009 Submission I on the Assessment Report for Application A1018 Food Derived from High Oleic Acid Soybean DP-305423-1. Submitted to Food Standards Australia/New Zealand

2006 Submission to Codex Alimentarius Commission on Recombinant DNA Plants Modified for Nutritional or Health Benefits

2006 Submission to Food Standards Australia/New Zealand on A580 Food Derived From Amylase-Modified Corn Line 3272 Initial Assessment Recommendation

2006 Submission to Food Standards Australia/New Zealand on A549 High Lysine Corn Draft Assessment Recommendation

2005 Submission to Food Standards Australia/New Zealand on A549 High Lysine Corn Initial Assessment Recommendation

2005 Submission to the Food Regulation Standing Committee on Review of FSANZ assessment and approval processes and treatment of confidential commercial information

*2004 Submission to the Ministry of Foreign Affairs and Trade on the question of ratifying the Cartagena Protocol on Biosafety

2004 Submission to Food Standards Australia New Zealand on application A524 Food Derived from Herbicide-Tolerant Wheat MON 71800.

*2003 To the Education and Science Committee call for submissions on the New Organisms and Other Matters Bill.

2002 To the Ministry of Science Research and Technology on the Public Discussion Paper “New Zealand Biotechnology Strategy”.

*2002 To the Finance Select Committee on the Hazardous Substances and New Organisms (Genetically Modified Organisms) Amendment Bill/Inquiry.

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Appendix 4: Royal Society of New Zealand Review of the Section 32 Report

Commissioned Review | July 2014

Managing Risks Associated with Outdoor Use of Genetically Modified Organisms

Professor Barry Scott FRSNZ
Professor Clive Ronson FRSNZ

Foreword

In February 2014 the Council of the Royal Society of New Zealand considered a request from Federated Farmers to review the validity of scientific conclusions underpinning Auckland Council, Far North District Council, Kaipara District Council and Whangarei District Council Draft Proposed Plan Change to the District /Unitary Plan for Managing Risks Associated with Outdoor Use of Genetically Modified Organisms (GMO) Draft Section 32 Report (January 2013). Professor Barry Scott FRSNZ and Professor Clive Ronson FRSNZ are the authors of this focused review of scientific and technical assertions in that Report, on behalf of the Royal Society of New Zealand. Economic and cultural aspects relating to the outdoor use of GMOs were outside the scope of this review. We thank the authors and peer reviewer Dr Tony Conner FRSNZ for undertaking this work.

Sir David Skegg FRSNZ, President, Royal Society of New Zealand

Benefits and risks

In assessing benefits and risks, both the magnitude and the likelihood of each need to be taken into account; this is the approach taken in New Zealand by agencies such as the Environmental Protection Authority[1] and Food Standards Australia New Zealand[2]. There is an element of risk associated with most human activities but it is the weighing up of magnitude and likelihood that is important in the decision making process. The Report's section on benefits and risks, however, does not include these considerations in the issues it raises.

In considering the risks, the Report highlights the impact of rare events and uses the emergence of bovine spongiform encephalopathy (BSE) in United Kingdom cattle as the example. It is important to point out that the BSE outbreak in the UK was a consequence of food manufacturing practices and had nothing to do with Genetic Modification (GM). In fact, current scientific evidence strongly supports the opinion that GMOs do not impose any greater risks as a result of their genetically modified status[3]. Any risks imposed are a result of the host organism and the trait it expresses, and are the same for an organism expressing a particular trait created by GM or by conventional means[4].

1 http://www.epa.govt.nz

2 http://www.foodsafety.govt.nz/science-risk/risk-assessment/overview.htm

3 Conner A. J., Glare T. R. and Nap J-P. (2003) The release of genetically modified crops into the environment - Part II. Overview of ecological risk assessment. Plant J. 33, 19–46

4 Leyser O. (2014). Moving beyond the GM Debate. PLOS Biol. 12, e1001887

Environmental Risks

The Report highlights a number of potential risk areas associated with the outdoor use of GMOs, but only one supporting reference is supplied in relation to these assertions[5]. The reference[5] is largely opinion-based and is very selective in the arguments it makes. Furthermore, certain errors of fact are made, which might have been avoided had the publication been subjected to scientific peer review. For example:

- " … *plants created by conventional plant breeding are not hazardous*". While this is likely to be true if the starting material has already been selected over many years and has been shown to be safe, there are many scenarios where this will not be the case. For example: kiwifruit are allergenic to certain individuals[6]; crossing a commercial tomato cultivar with a wild relative to introduce disease resistance has the potential to introduce a range of of traits that could be undesirable for some consumers[7]; and the potato cultivars 'Lenape' (USA and Canada) and 'Magnum Bonum' (Sweden) were both withdrawn due to excessive glycoalkaloid content in their tubers following successful breeding for pest and disease resistance[8].

- "*Techniques so far do not allow for site-specific insertion*". This may have been true in 2005, but is certainly not so now, with a variety of methods now available to allow the insertion of genes at specific sites in a genome, including zinc finger nucleases (ZFNs), transcription activator-like effector nucleases (TALENs) and clustered regularly interspaced short palindromic repeats (CRISPR)/Cas9 technologies[9].

The specific areas highlighted in the Report as environmental risks are addressed below:

Non-target effects

The Report highlights the potential non-target effects of GMOs. For example, GMO crops that produce Bt insecticide can negatively impact non-target insect populations. However, field studies have shown that these negative impacts are markedly lower than those that occur with conventionally managed crops. The scientific consensus is that the use of insect-resistant biotech crops constitutes a major advance over the use of broad-spectrum synthetic insecticides for control of insect pests since they are environmentally more benign[10]. A well-publicised case in New Zealand involved the purportedly significant detrimental effect of Bt-expressing maize pollen on the monarch butterfly. This concern arose from laboratory studies in which the pollen was fed to the butterfly. However, subsequent large-scale field trials demonstrated no detrimental effects; for example, it was noted that when the maize was in flower the monarchs were not present. Thus, in this instance, while the potential hazard was high, exposure was negligible resulting in effectively zero risk[11].

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5 Antoniou M., Robinson C., and Fagan J. (2012) GMO Myths and Truths: An evidence-based examination of the claims made for the safety and efficacy of genetically modified crops. Earth Open Source, UK. 123 pp.

6 Bublin M., Mari A., Ebner C., Knulst A., Scheiner O., Hoffmann-Sommergruber K., Breiteneder H., Radauer C. (2004) IgE sensitization profiles toward green and gold kiwifruits differ among patients allergic to kiwifruit from 3 European countries. J. Allergy Clin. Immunol. 114, 1169–1175.

7 Labate J. A. and Robertson L. D. (2012) Evidence of cryptic introgression in tomato (*Solanum lycopersicum* L.) based on wild tomato species alleles. BMC Plant Biol. 12:133.

8 Zitnak A. & Johnston G. R., (1970) Glycoalkaloid content of B5141–6 potatoes. Am. Potato J. 47, 256–260.

9 Voytas D. F. and Gao C. (2014) Precision genome engineering and agriculture: opportunities and regulatory challenges. PLOS Biol.12, e1001877.

10 Gatehouse A. M. R., Ferry N., Edwards M. G. and Bell H. A. (2011) Insect-resistant biotech crops and their impacts on beneficial arthropods. Phil. Trans. R. Soc. B 366, 1438–1452; Yu H-L, Li Y-H; Wu K-M (2011) Risk assessment and ecological effects of transgenic *Bacillus thuringiensis* crops on non-target organisms. J. Integr. Plant Biol. 53, 520–538.

11 Sears M. K., Hellmich R. L., Stanley-Horn D. E., Oberhauser K. S., Pleasants J. M., Mattila H. R., Siegfriedi B. D., and Dively G. P. (2001) Impact of *Bt* corn pollen on monarch butterfly populations: A risk assessment. Proc. Natl. Acad. Sci. U. S. A. 98, 11937–11942.

Invasiveness

Plant 'weediness' or 'invasiveness' is an inherent property of the plant:

- Old Man's Beard is highly invasive because of its vigorous scrambling properties[12].
- Clover is weedy because its seeds are long lived and can be widely dispersed. As a legume, it can grow on nitrogen poor soils[13].
- By contrast, domesticated crops such as potatoes and maize are not invasive[14].

In making a risk assessment of the potential invasiveness of a GMO or a naturally occurring plant species, the most important consideration is the inherent biological properties of the starting organism[15]. Single GM changes are very unlikely to change the persistence of a crop species, unless it involves the introduction of herbicide resistance genes, used in an environment with increased use of herbicide. The 'weediness' of the plant then becomes linked to the general agricultural practice that the plant is used in[16].

The bullet points on effects on non-target species, invasiveness and rare events given in the Report are taken directly from *Community Management of GMOs: Issues, Options and Partnership with Government*. (Simon Terry Associates, March 2004). However, we note that the references given in the source publication in support of these concerns are largely opinion pieces, rather than evidence based articles.

Horizontal gene transfer

Horizontal gene transfer (HGT) refers to any process in which a recipient organism acquires genetic material from a donor organism other than by vertical transmission (normal sexual reproduction). It is not restricted by species boundaries and HGT has been shown between organisms as diverse as bacteria and plants and animals[17].

HGT has long been recognised as a major force in microbial evolution and, with advances in large-scale sequencing technologies, it is also being recognized as a significant contributor to the evolution of eukaryotic genomes, with most transferred genes coming from bacteria[18]. Evidence for HGT is most often seen between organisms that are intimately associated (e.g., in mutualistic or parasitic relationships)[19]. For example, it is likely that there has been frequent transfer of genes from bacterial endosymbionts to their invertebrate hosts over an evolutionary time scale[20]. Such large evolutionary timescales make it impossible to observe HGT involving plants and animals in real time.

Statements in the Report relating to horizontal gene transfer are largely based on the publication *GMO Myths and Truths: An evidence-based examination of the claims made for the safety and efficacy of*

12 Ogle C. C., La Cock G. D., Arnold G. and Mickleson N. (2000) Impact of an exotic vine *Clematis vitalba* (F. Ranunculaceae) and of control measures on plant biodiversity in indigenous forest, Taihape, New Zealand. Austral Ecol. 25, 539–551.

13 Baker M.J . and Williams W. M. (Eds) 1987. White clover. CABI, UK. 534 pp.

14 Conner A. J., Glare T. R and Nap J-P. (2003) The release of genetically modified crops into the environment - Part II. Overview of ecological risk assessment. Plant J. 33, 19–46

15 Warwick S. I., Beckie H .J., and Hall L. M. (2009) Gene flow, invasiveness, and ecological impact of genetically modified crops. The year in evolutionary biology 2009: Ann. N.Y. Acad. Sci. 1168: 72–99.

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17 Bock R. (2010) The give-and-take of DNA: horizontal gene transfer in plants. Trends Plant Sci. 15, 11–22.

18 Keeling P. J. (2009) Functional and ecological impacts of horizontal gene transfer in eukaryotes. Curr. Opin. Genet. Dev. 19, 613–619.

19 Bock R. (2010) The give-and-take of DNA: horizontal gene transfer in plants. Trends Plant Sci. 15, 11–22; Dunning Hotopp, J. C. (2011) Horizontal gene transfer between bacteria and animals. Trends Genet. 27, 157–163.

20 Dunning Hotopp J. C. (2011) Horizontal gene transfer between bacteria and animals. Trends Genet. 27, 157–163.

genetically modified crops[21]. In the introduction to the publication's section on HGT, it is stated that "*The EU-supported website GMO Compass states, "So far, horizontal gene transfer can only be demonstrated under optimised laboratory conditions." Alternatively, they argue that if it does happen, it does not matter, as GM DNA is no more dangerous than non-GM DNA*." This statement from GMO Compass is an accurate reflection of the majority scientific opinion as expressed in the peer-reviewed scientific literature[22]. However the *GMO Myths and Truths* article then goes on to claim that "*The consequences of HGT from GM crops are potentially serious, yet have not been adequately taken into account by regulators*." We contend that the arguments used to support this claim in the body of the section do not stand up to scientific scrutiny.

Concerns over antibiotic resistance

HGT among bacteria is a major contributor to microbial evolution including to the emergence of new strains of pathogens and to antibiotic resistant strains. The recent emergence of Gram-negative pathogens expressing New Delhi Metallo-beta-lactamase-1 (NDM-1) is one example of the profound effect of HGT. The associated carbapenemase enzyme makes bacteria resistant to carbapenem antibiotics, which are a mainstay for the treatment of Gram-negative antibiotic-resistant bacterial infections. Bacteria that produce carbapenemases are very difficult to treat. Other recent studies using next generation sequencing (NGS) have indicated that antibiotic resistance has been acquired by *Streptococcus pneumoniae* by genetic transformation within patients. These examples show that HGT of antibiotic resistance genes can occur rapidly. A major factor thought to contribute to this spread is the misuse of antibiotics. The message is that, where selective pressure occurs, traits that allow adaptation to that pressure can be acquired by bacteria through HGT.

With respect to GM plants, there is no evidence of HGT of antibiotic resistance genes from plants to bacteria[23]. If it does occur, it would be at such a vanishingly small frequency that it would have no impact on the overall frequency of HGT of such genes in the environment. It should also be noted that new-generation transgenic plants often do not contain antibiotic-resistance genes.

21 Antoniou M., Robinson C., and Fagan J. (2012) GMO Myths and Truths: An evidence-based examination of the claims made for the safety and efficacy of genetically modified crops. June 2012, Earth Open Source, UK. 123 pp.

22 Brigulla M. and Wackernagel W. (2010) Molecular aspects of gene transfer and foreign DNA acquisition in prokaryotes with regard to safety issues. Appl. Microbiol. Biotechnol. 86, 1027–1041.

23 Brigulla M. and Wackernagel W. (2010) Molecular aspects of gene transfer and foreign DNA acquisition in prokaryotes with regard to safety issues. Appl. Microbiol. Biotechnol. 86, 1027–1041.