SUBMISSION ON LEGAL ISSUES TO THE ROYAL COMMISSION OF INQUIRY INTO GENETIC MODIFICATION

With respect to: Relevant matters (e) & (n) in the terms of reference of the warrant to the Royal Commission

Prepared For and on behalf of:

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Contents

Executive Summary

The Environmental Risk Management Authority (ERMA), in a decision of 20 December 2000, ruled on a definition of *"field test"* and *"heritable material"* which enables applications, that arguably should be for *"release"*, to be approved as *"field tests".* This is a significant legal precedent that we seek the Royal Commission to disregard in its interpretation of *"field tests".* We further seek the Royal Commission to recommend the removal of the *"field test"* category from the Hazardous Substances and New Organisms Act 1996 s.2.

Applicants to import or develop genetically engineered organisms should be liable for *"a duty of care"* against control failures, at common law, especially when its actions are within the scope of conditions set in any ERMA approval.

1 Introduction

These submissions on behalf of GE Free New Zealand (GE Free) address two issues:

(i) The legal definition of *"field test",* including the term *"heritable material",* as described, in the Hazardous Substances and New Organisms Act 1996 (HSNO) s.2, and

(ii) The liability, under common law for control failure, of applicants to import or develop genetically engineered organisms

This submission describes the ERMA decision, and includes extracts from:

- HSNO Act,
- ERMA's Protocol Document Interpretation of and Explanations of Key Concepts,
- ERMA's Annotated Methodology,
- The submission to this Royal Commission by the Ministry for the Environment,
- Transcripts of the cross-examination witnesses for the Ministry for the Environment, and ERMA, before this Royal Commission.

We include bold type for key points.

2 The legal definition of *"field test"*

GE Free seeks that the Royal Commission recommend the removal of the *"field test"* category. We aim to illustrate the difficulties in differentiating between *"field test"* and *"release".* We submit that the interpretation, the Environmental Risk Management Authority (ERMA), applied in a decision of 20 December 2000, reflects those difficulties and significantly alters the spirit of the HSNO Act.

ERMA argued in the decision that if the definition of *"field test"* precluded the possibility of an organism not being retrieved at the end of the trial, the field test category *"would be redundant"*; and ruled that was not *"what the law currently provides for"*.

The key point of contention is that the definition of *"field test"* as described in the HSNO Act, differs from the interpretation applied by ERMA to the extent, that according to the Authority's own Protocol, it amounts to a *"release"* of a modified organism. These terms are the difference between significant degrees of environmental risk, and we argue are sufficiently clear in the HSNO Act not to need redefinition.

We argue that it is impossible, to conduct a *"field test"* as envisaged by the HSNO Act. We agree with the ERMA decision that this makes the category *"redundant"*, but submit that total containment

was what Parliament intended, and that although the light of growing science has shown this to be difficult to achieve, it cannot alter the original intent of the legislation.

2.1 Relevant Content of decision – NZ FRI – *Pinus radiata* - App Code GMF99001

The decision relates to an application (attached) by the New Zealand Forest Research Institute (FRI), which states at p.1:

"To field test, in the Bay of Plenty (Rotorua), over a period of 20 years, Pinus radiata plants with genetic modifications to the genes controlling productive development. The total duration of this project including a post-trial monitoring phase is 22 years."

2.2 The ERMA jurisdiction to consider "A field test…"

According to written decision of the ERMA Special Committee at p.5:

"A field test is an intermediate stage between a development and a release. In a development, there is no requirement for environmental realism ("conditions similar to those of the environment into which the organism is likely to be released") while in a release there are no restrictions on the movement of the organism (no containment controls). The function of a field test is to study the organism in a realistic environment without committing that organism irretrievably to the environment. Hence the "clean up" limb of the field-test definition: "from which the organism or any heritable material arising from it, could be retrieved or destroyed at the end of the trials". This requirement ensures that the management of effects achieved through containment controls during the trial is not negated by after the trials by the organism remaining at the site. The emphasis here is not on escape but on what happens when the trial is over, as there would be little point in having strong containment during the trial if there were not mechanisms to also deal with the organism at the end of the trial period…"

We submit this description of the Act, and of the definition of *"field test"* is appropriate, except that we disagree the only risk is at the completion of the trial. However we suggest the ERMA Evaluation and Review Report prepared for this application, at p.3, influenced the Special Committee in its decision:

"Given current knowledge about (Horizontal Gene Transfer) HGT, ***it is considered likely that some horizontal gene transfer to soil microorganisms may occur. … There is considerable scientific uncertainty about the effects of such transfer*** *and the proposed trial offers opportunities for further research in this area."*

We suggest that the ERMA Special Committee considered any approval of the trial, as such, to be in breach of their Protocol, *Interpretations and Explanations of Key Concepts Number 3, Series 2,* and the HSNO Act s.45 (1) (a). The Protocol at p. 4 states:

"Containment - new organisms (including genetically modified organisms)
An application for approval for containment will specify the secure location or facility where the organism is to be contained. ***A secure location or facility is one that is under the supervision of the facility manager; who must be able to manage the security of the organism, and of material and people within the boundaries of the containment zone. If this is not possible, the application should be for release. For field testing of genetically modified organisms, the Authority will need to be assured that the genetically modified material will be contained."***

We suggest the Special Committee realised the trial cannot contain, by that definition, soil microorganisms infected by the genetically engineered pines; and there is no legal provision to test organisms in an uncontained field situation.

We suggest ERMA are now more aware of the consequences of cross infection to soil microorganisms from genetically engineered plants. We refer to our cross examination of Dr. Abdul Moeed, a witness for the Ministry of the Environment, and currently Senior Scientific Advisor at ERMA (Transcript p.4376, Lines 15 – 25). When questioned on whether he, as a member of the Interim Assessment Group, *"…could honestly quantify the risk"* to soil microorganisms before they approved the field trial of genetically engineered tamarillos at Kerikeri in 1998; Dr.Moeed replied, *"at the time the IAG did quantify the risk honestly and openly"*. In answer to a further question as to whether he could quantify the risk *"now"*, Dr. Moeed admitted he *"…can't sort of give an answer to it".*

The ERMA decision continues to address the legal issue, and goes further with their following interpretation of the legislation.

2.3 "… the possibility…of escape…from a field test"

The ERMA Special Committee decision describes a view of the HSNO Act as follows at p.5:

"The Act envisages the possibility, however undesirable, of an organism escaping from a field test. Section (45)(1)(a)(ii) requires the Authority to determine whether the benefits of having the organism in containment outweigh the adverse effects of the organism should it escape. In addition, the standard for containment during the trial is set at "adequate" under section 45(1)(a)(iii).

However, The HSNO Act appears to show no such a determination, and at s.45 states:

Determination of application--- (1) ***After considering any application for approval made under section 40 of this Act, the Authority (if the application is not approved under section 42 of this Act) may, in its discretion, ---***

(a) Approve the application if---

(i) The application is for one of the purposes specified in section 39 (1) of this Act; and

(ii) After taking into account all the effects of the organism and any inseparable organism, including, but not limited to, the effects on the matters in section 43 of this Act (for applications made under section 40 (1) (b) of this Act) or the matters in section 44 of this Act (for applications made under section 40 (1) (a) or (c) of this Act), ***the beneficial effects of having the organism in containment outweigh the adverse effects of the organism and any inseparable organism should the organism escape; and***

(iii) The Authority is satisfied that the organism can be adequately contained; or

(b) Decline the application in any other case.

We argue the Act does not require ERMA to do anything in this regard, but offers discretion, subject to their satisfaction the organism can be adequately contained; the alternative is to decline the application. We suggest the Special Committee considered this interpretation because of the difficulty in complying with the containment requirements for field tests.

2.4 "possibility…of an organism not being retrieved"

Further, the ERMA decision at p. 6 states what it believes the law should provide for:

"If the mere possibility, however remote, of an organism not being retrieved at the end of the trial disqualified a proposal from being a field test, the field test category would be redundant. *It would never be able to be used, as 100% guarantees are not available. Activities under the Act would be limited to developments and releases.* ***While some might argue that this is a good thing, it is clearly not what the law currently provides for."***

With this decision, ERMA are creating a significant precedent at law, and apparently incorporating what should be described as *"releases"* into *"field tests".*

The comment from ERMA *"it is clearly not what the law currently provides for"* indicates the Special Committee had considered evidence that such circumstances had not been considered by Parliament when the law was passed. However, it would appear the Government was well aware of the risks of introducing new organisms to the environment. In their submission to the Royal Commission, the Ministry for the Environment state at p.15 para. 54:

54. In the Cabinet paper presented in November 1989 it was stated that:

· new organisms were to be assessed prior to the organisms reaching the environment;

· all importations or releases carried some level of risk; and

· ***it was realistic to assume that eventually all new imported organisms would eventually escape into the wider environment.***

This submission suggests that for such an important definition it is important to establish just what the law intended; we argue that it was to the letter as it was written. On this basis we seek that the Royal Commission interpret the definition strictly as written in the HSNO Act s.2, no matter that it makes the category redundant.

2.5 The definition of *"Heritable material"*

ERMA continues to question the HSNO Act, and its definitions further on p. 6. In this instance it is the term *"heritable material"* as included in the definition of *"field test"* and is not separately defined.

"The reference to "heritable material arising from an organism" does not refer to all biological material produced or shed by the organism, but to material that could be passed on. This would usually by breeding but could include other "naturally occurring" means such as horizontal gene transfer. According to the Shorter Oxford dictionary, the basic meaning of heritable is "able to be inherited", and to inherit is to "derive or possess" (for example a characteristic) by transmission from a progenitor. "Transmit" means to pass on, especially by inheritance or heredity.

ERMA use this definition to exclude pine needles and fallen branches from the definition of heritable material; commenting:

"The Committee acknowledges that it would be difficult, if not impossible, to contain all biological material such as pine needles and fallen branches within the field test site."

We argue that ERMA is creating a new legal definition, apparently because of difficulty complying with the strict interpretation of HSNO. This submission seeks that the Royal Commission interprets the original definition strictly.

3 ERMA precedent

We refer to ERMA's Annotated Methodology of August 1998. Ch.6 P.14

6. D E C I S I O N PATH S

"In accordance with the guiding principles, decisions made by the Authority will follow a path which ensures that all relevant considerations are applied and in the right order. Decision paths ensure consistency in the Authority's approach, to help build up a history of precedents and provide some

certainty to applicants about how their applications will be treated. The appropriate decision path will also apply to decision-making under authority delegated in accordance with section 19(2) of the Act."

We suggest that the policy of precedents described in the Methodology, especially with reference to the HSNO Act s.19 (2) (Delegation by Authority), emphasise the importance of this definition of *"field test"* to future applications, because it is ERMA policy to use such precedents consistently. Arguably, to interpret the definition in such a fundamentally different way to the strict letter of the law would require policy direction from the highest level in the Authority.

We refer to the cross examination of the ERMA witnesses before this Royal Commission, Dr. Bas Walker and Dr. Oliver Sutherland (Transcript p.4503 Line 30 to p.4505 Line 25). We suggest that the evidence of Dr. Walker was unclear as to whether or not ERMA had difficulty with the strict legal definition of *"field test"*. We argue that the evidence indicates, on the balance of probability, that ERMA do have some problem with the strict interpretation, and it is timely for the issue to be resolved. Accordingly we submit that it is appropriate the Royal Commission makes a clear recommendation on the future of field trials.

4 Liability at common law.

The HSNO Act s.61 affords ERMA the immunities and privileges of a District Court Judge. We accept that parties have appeal, and reassessment, provisions in the Act, but submit there is a legal anomaly in terms of liability at common law. We seek that the Royal Commission recommend a specific provision in the HSNO Act providing for open liability, of applicants for importation or development of genetically engineered organisms, for control failure of the organism. We submit that this especially important where the applicant has met the conditions set by ERMA when granting the approval.

We argue that although any applicant for approval to import, or develop, a genetically engineered organism has a duty under the HSNO Act s. (2)(f) to:

> *" Include…*
> *(e) All the possible adverse effects of the organism on the environment;* "

there should also be liability for *"duty of care"* specified in the Act. We suggest that the economic consequences of a control failure with a genetically engineered organism could be substantial, and have been so overseas. We argue that if potential applicants had to consider the financial implications of liability for a failure, it would moderate their enthusiasm more so than the current penalties under s.114 of the Act, or the provisions of s.13, which discharges liability to any person in breach of the general duty.

We refer to:

Todd et al, 1997. The Law of Torts in NZ, 2nd edition Ch.4.3.7, p.170

Negligence: The Duty of Care - Economic implications.

"The practical implications of imposing a duty on a negligent defendant as regards considerations of economic efficiency, loss spreading, and the insurability of a risk traditionally have not featured prominently in judicial discussion in New Zealand of duty issues. Clearly, though, such considerations to some considerable extent are bound up with general arguments about floodgates and deterrence, and it is likely that an evaluation of the specific economic consequences for an industry or occupation of imposing or denying a duty will become increasingly significant…"

We suggest that such an evaluation by the Royal Commission is appropriate. We submit that it is only proper, considering the profit motive in genetic engineering, that applicants are moderated by the need to consider financial liability for loss of containment. Arguably they would need to seek commercially sourced indemnity, which if not available may stop any applications before they begin. This would provide more balance to, and increase public confidence in, the approval process.

5 Summary

This submission argues that in the decision GMF 9901 of 20 December 2000, ERMA, faced with the difficulty of ruling on inadequate containment of genetically engineered organisms that can infect soil, have interpreted definitions from the HSNO Act 1996 s.2 in a manner that creates significant legal precedent as well as illustrating the practical difficulties of conducting *"field tests"* within the law.

In making these decisions on the definition of *"field test"* and *"heritable material",* ERMA have arguably, by the terms of their own Protocol, included environmental releases in the legal description of a *"field test"*, because in their own words not to do so would make the category *"redundant".* We agree with ERMA that the *"field test "* category is redundant under the definition, and submit it should remain so.

We seek that the Royal Commission:

- Apply the definition of *"field test"* strictly as described in the HSNO Act s.2, and interpret *"heritable material"* as any biological material emanating from an organism, and therefore,
- Recommend removal of the *"field test"* category from the Act.

We also seek the Royal Commission to recommend a specific provision in the HSNO Act providing for open liability, of applicants for importation or development of genetically engineered organisms, against control failure of the organism.