

# **MEMORANDUM OF UNDERSTANDING BETWEEN ERMA NEW ZEALAND AND THE MINISTRY OF AGRICULTURE AND FORESTRY CONCERNING NEW ORGANISM ENFORCEMENT**

## **1 INTRODUCTION**

The Ministry of Agriculture and Forestry (MAF), primarily through the MAF Biosecurity Authority, is the lead agency for the management of biosecurity in New Zealand and the administration of the Biosecurity Act 1993. ERMA New Zealand<sup>1</sup> is the lead agency for the management of the deliberate (legal) introduction of new organisms into New Zealand and the application of the Hazardous Substances and New Organisms Act 1996 (HSNO Act). There are significant areas of overlap in the responsibilities of the two agencies. Many of the operational systems managed by MAF for the purposes of biosecurity are of direct relevance to management of the responsibilities of ERMA New Zealand.

As a consequence of the HSNO Amendment Act 2003 MAF (as the enforcement agency) has responsibility for ensuring that the provisions of the HSNO Act with respect to new organisms are enforced (Section 97A of the HSNO Act). A further description of the statutory responsibilities and authorities of each organisation in relation to new organisms is given in section 3, below.

This Memorandum of Understanding (MOU) addresses only “top level” issues and the bases for the two organisations to work together. The implementation of these provisions will be specified in joint documents (listed as Annexes to this document), which will provide more detailed bases for the enforcement of HSNO new organism regulatory requirements.

This document is intended as a statement of mutually agreed intentions in relation to an area of strong mutual interest. This document is not intended to create legally enforceable rights and/or obligations.

For the purposes of management of enforcement of provisions of the HSNO Act in respect of new organisms, this MOU replaces the version signed 27 October 1998 (which was developed to cover all HSNO Act related matters). The original MOU continues to apply in relation to other purposes, until separate new MOUs are developed.

## **2 OBJECTIVES**

The objectives of this MOU are to:

- Ensure cooperation between the parties facilitates the efficient and effective discharge of their statutory functions and duties;
- Ensure that risks associated with new organisms are adequately managed under both the Biosecurity and HSNO Acts;

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<sup>1</sup> ERMA New Zealand is made up of three components: (i) the Environmental Risk Management Authority (the Authority) - a semi-judicial decision-making body (and also the Governing Board of ERMA New Zealand), (ii) Ngā Kaihautū Tikanga Taiao - a committee to advise the Authority on Māori issues; (iii) The Agency - the administrative support organisation for the Authority.

- Clarify the responsibilities, powers, functions and duties of ERMA New Zealand and MAF in relation to new organism enforcement;
- Confirm ERMA New Zealand’s consultation responsibilities to MAF with respect to processing new organism applications under the HSNO Act;
- Specify a plan for resolution of any differences over preferred courses of enforcement action in areas where the agencies have overlapping responsibilities.

The parties also endorse the objectives of:

- Contributing to efficient and effective regulatory control consistent with statutory obligations and Government policies;
- Ensuring that regulatory intervention is limited to what is appropriate to achieve the purposes of the Acts administered by the two parties;
- Avoiding unnecessary compliance costs; and
- Establishing compatible perspectives on managing the risks posed by new organisms.

### **3 STATUTORY RESPONSIBILITIES AND AUTHORITIES**

#### **3.1 ERMA New Zealand responsibilities, powers, functions and duties**

The purpose of the HSNO Act is to protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms. ERMA New Zealand is a Crown Entity in accordance with the HSNO Act. The main function of the Authority, with respect to new organisms, is to make decisions on applications to introduce new organisms (including genetically modified organisms, GMOs) to New Zealand.

Inspection, enforcement and ancillary powers are detailed under Part VII of the HSNO Act (sections 97 – 124). In particular, the Chief Executive (CE) of the Authority (ie the CE of ERMA New Zealand), has functions, powers, duties and protections of enforcement officers under section 98A of the HSNO Act (refer to section 4.6, below, for more detail). The Authority can also appoint enforcement officers under section 99(3), and this power has been delegated to the Chief Executive of ERMA New Zealand.

The Authority has a range of reporting requirements which cover new organism activities. Section 99(1) of the HSNO Act provides that the Authority shall ensure that the provisions of the HSNO Act are enforced on all premises likely to contain a new organism. Also under section 99(1), the Authority shall advise MAF and the Minister when it considers that there is insufficient or unnecessary inspection and enforcement. In addition, the Authority may advise the Minister on the extent of compliance with, and adequacy of, new organism controls (section 11(a)); the adequacy of enforcement and the effectiveness of the Act in reducing risks posed by new organisms (section 11(b)); the number and type of incidents caused by inadequate management of new organisms (section 148); and enquire into incidents and emergencies involving new organisms (section 11(e)).

A primary mechanism enabling the review of enforcement adequacy and incidents is MAF's responsibility to report to the Authority regarding the nature and level of inspection and enforcement (by enforcement officers) under section 98(2) of the HSNO Act (refer also to section 3.2, below).

### **3.2 MAF responsibilities, powers, functions and duties**

MAF responsibilities include the administration of the Biosecurity Act 1993, which provides for the exclusion, eradication and effective management of pests and unwanted organisms. A pest is specifically an organism that is identified as a pest in an approved pest management strategy. An unwanted organism is an organism that a chief technical officer believes is capable or potentially capable of causing unwanted harm to any natural and physical resources or human health, and includes:

- Any new organism, if the Authority has declined approval to import that organism; and
- Any organism specified in the Second Schedule of the HSNO Act.

It does not include any organism approved for importation under the HSNO Act, unless:

- The organism has escaped from containment or
- A chief technical officer, after consulting the Authority and taking into account any comments made by the Authority, believes that the organism is capable or potentially capable of causing unwanted harm to any natural and physical resources or human health.

MAF is responsible for managing the risks associated with the potential for imported risk goods to bring harmful organisms into New Zealand.

Subsequent to the passage of the HSNO Amendment Act 2003, MAF, through section 97A, also has responsibilities for ensuring that the provisions of the HSNO Act with respect to new organisms are enforced. Provision is also available for MAF to appoint enforcement officers under the HSNO Act. Consequent to that, MAF has responsibilities under section 98(2) of the HSNO Act to report to ERMA New Zealand on the nature and level of inspection to be provided by those enforcement officers.

## **4 OPERATIONAL ASPECTS OF NEW ORGANISM ENFORCEMENT**

### **4.1 Provision and sharing of information**

ERMA New Zealand has requirements for an understanding of MAF Biosecurity standards and procedures, for information collected by MAF in its role as the enforcement agency and for more general information from MAF's biosecurity activities to allow assessment of the respective roles of the Biosecurity Act and the HSNO Act to allow effective reporting on the overall effectiveness of the HSNO Act (specific reporting responsibilities under the HSNO Act summarised in sections 3.1 and 3.2, above).

MAF Biosecurity Authority has requirements for a thorough understanding of the enforcement requirements of ERMA New Zealand and the basis of the decisions leading to those requirements. Apart from information directly linked to the statutory responsibilities

of the two parties to the MOU, information on wider biosecurity issues or on rationale for decision-making may be required to allow each to determine relevant information and to place the more specific information in a wider context.

There will be a general undertaking from both ERMA New Zealand and MAF to share information that is relevant to the performance, functions and duties of each party.

## **4.2 Exclusion of new organisms from New Zealand**

### **4.2.1 Prevention of introduction of new organisms**

MAF monitors New Zealand's borders to identify risk material, and to ensure that the risks of harmful organisms entering New Zealand are managed. This same activity may result in the detection of attempts to introduce, or introductions of, new organisms and/or prohibited organisms.

MAF will consult ERMA New Zealand during the development and review of procedures to manage the risk of introduction of new organisms (eg import health standards, GM-testing protocols for imports, and associated border security standards). ERMA New Zealand recognises that consultation may not take place in cases of urgency or in respect of minor amendments. MAF Biosecurity Authority will report regularly to ERMA New Zealand on relevant border activities (including prosecutions that relate to new organisms), as specified in the operational agreement on border activities (Annex to this MOU).

### **4.2.2 Determination of new organisms**

ERMA New Zealand will provide MAF Biosecurity Authority with the opportunity to comment on all applications for determination of whether or not an organism is a new organism (under section 26 of the HSNO Act). ERMA New Zealand will provide determination results to MAF Biosecurity Authority for assistance with related border activities (eg to update records such as the MAF Plants Biosecurity Index).

In cases where a species is determined not to be a new organism, there may be concerns from a risk point of view. The Authority has thus implemented a policy of briefly examining any risks associated with these organisms at the time the determination is made. This would include consideration of legislative restrictions under the HSNO Act (eg prescription of an organism as a risk species under section 140(1)(h)). The Authority may well consider that risks are best left to be managed under the Biosecurity Act (eg via unwanted organism status), since such organisms would be considered to be "present" in New Zealand. In such cases ERMA New Zealand will relay any concerns regarding risks to MAF Biosecurity Authority (prior to, or at the time that a determination is made). The Authority may record any response from MAF regarding risk management under the Biosecurity Act, in its final determination document.

### **4.2.3 Assessment of new organism applications for importation into containment, use in containment, conditional release and full release**

ERMA New Zealand will consult with MAF Biosecurity Authority as provided for in section 58(1)(c) of the HSNO Act regarding all new organism applications. ERMA New Zealand will recognise the special areas of expertise available within MAF and will give due recognition to the responsibility that MAF will have for the enforcement of any

controls for containment or conditional release. In particular, MAF will be consulted regarding inspection and/or audit frequency and control requirements, where it is proposed that these be varied from previously agreed standards (as specified in Operational Agreements, listed as Annexes to this MOU).

#### **4.2.4 Assessment of applications for use of new organisms in an emergency**

It is acknowledged that MAF might make an application for use of a new organism in a biosecurity emergency. In this event, MAF will be the applicant, but may also be consulted for additional comments in its role as a government agency. MAF acknowledges that it is the responsibility of ERMA New Zealand to make decisions on such applications under the HSNO Act.

#### **4.2.5 Transshipment of new organisms**

Transshipment of organisms through New Zealand requires approval from MAF under the Biosecurity Act. In addition, transshipment of new organisms also requires approval under the HSNO Act. ERMA New Zealand will consult with MAF Biosecurity Authority over any application for transshipment of new organisms. Similarly, MAF will refer any party to ERMA New Zealand where it is evident they require an additional HSNO Act approval for transshipment.

### **4.3 Monitoring compliance with controls in ERMA New Zealand approvals.**

MAF Biosecurity Authority will ensure that controls on approvals for new organisms in containment or for conditional release are inspected for compliance under the HSNO Act. The compliance regime will include physical inspections, system audits, and other related activities as determined by ERMA New Zealand in consultation with MAF Biosecurity Authority (recognising that more frequent inspections may be required in response to non-compliance or other factors such as quarantine requirements). “Resolution Plan B” (see section 6) may apply in the event of a disagreement over the compliance regime.

Non-compliance will be dealt with as per the requirements specified in relevant Operating Agreements (as Annexed to this MOU), including requirements for direct reports to ERMA New Zealand in the case of serious non-compliance. Refer also to section 4.5 below.

MAF Biosecurity Authority will regularly report to ERMA New Zealand on compliance and enforcement activities relating to containment and conditional release of new organisms, as specified in relevant operational agreements provided as annexes to this MOU.

The parties recognise that qualifying organisms (as defined in the HSNO Act) may be the subject of a conditional release approval, with the corresponding need to ensure that controls are complied with. The parties agree that the compliance and enforcement activities that are implemented under the Medicines Act and the Agricultural Compounds and Veterinary Medicines Act should be taken into account in determining the appropriate compliance regime for qualifying organisms.

#### **4.4 Surveillance for incursions of new organisms**

ERMA New Zealand acknowledges that the management of national surveillance programmes for incursions of new organisms is the responsibility of MAF Biosecurity Authority under the Biosecurity Act.

ERMA New Zealand has an interest in the process and results of national surveillance programmes because of their potential to lead to the recognition of the presence of new organisms in New Zealand. Such information may have value in determining the effectiveness of the HSNO Act as required by section 11.

MAF Biosecurity Authority will provide ERMA New Zealand with the opportunity to comment regarding development and review of surveillance programmes, including the priority to be afforded to particular new organisms in the design of surveillance programmes.

MAF Biosecurity Authority will provide regular reports to ERMA New Zealand on the results of their surveillance programmes, as specified in the Operational Agreement regarding Border Activities, provided as an Annex to this MOU.

#### **4.5 Responses to new organism incursions and non-compliance situations**

ERMA New Zealand acknowledges that the management of responses to incursions of new organisms is the responsibility of MAF Biosecurity Authority under the Biosecurity Act.

##### **Enforcement response to non-compliance relating to HSNO Approvals**

Where an incursion response relates directly to a HSNO Act approval (eg escape of a new organism from containment), ERMA New Zealand has a direct interest in MAF's response. Such events may be deliberate or inadvertent in nature, but might result in risks being posed to the environment or human health that need to be managed (eg sabotage of a GM field test, illegal development of a GMO, or escape of a zoo animal). In these cases, ERMA New Zealand has a direct interest in MAF's enforcement response. If ERMA New Zealand has concerns about any proposed course of action in response to non-compliance with approvals for new organisms under the HSNO Act, it will discuss those concerns with MAF Biosecurity Authority with the aim of resolving any differences. In the event of any remaining differences over proposed actions for non-compliance with HSNO Act approvals, ERMA New Zealand will assume final decision-making responsibility under the provisions of "Resolution Plan B" (refer to section 6 of this MOU).

##### **Management of response to incursions in the uncontrolled environment (for organisms without HSNO approval)**

Where an incursion relates to new organisms without HSNO Act approval (eg detection of a new pest within New Zealand and where its source cannot be determined), ERMA New Zealand has an indirect interest in MAF's response (refer to section 3 above, regarding statutory responsibilities). MAF Biosecurity Authority will provide ERMA New Zealand with the opportunity to comment regarding the development and review of incursion response procedures for exotic and/or new organisms.

In the absence of previously agreed response protocols for particular organisms, MAF Biosecurity Authority will notify ERMA New Zealand, and consult to the extent possible, in the initial response phase to any incursion (ie during the period when the following actions take place - confirmation of the identity of the organism involved, determination of the geographic extent of the incursion, assessment of the impact of the ongoing presence of the organism in New Zealand, assessment of the practicality of eradication and the making of decisions on ongoing control / eradication measures).

In the event of any differences over proposed actions relating to new organisms, final decision-making responsibility will lie with ERMA New Zealand where direct non-compliance with a HSNO Act approval has occurred (eg escape of a new organism from containment), under the provisions of “Resolution Plan B” (refer to section 6 of this MOU). For all other cases (ie where there is not a HSNO Act approval), MAF Biosecurity Authority will assume final decision-making responsibility, under the provisions of “Resolution Plan A” (refer to section 6 of this MOU). Examples of where MAF would take the lead include both deliberate and inadvertent importation and release of new organisms without HSNO Act approval.

#### **4.6 ERMA New Zealand’s Reserve Powers of Enforcement**

It is recognised that the primary role of MAF notwithstanding, the Authority and also the Chief Executive of the Authority, will retain the power to independently undertake enforcement. It would be inappropriate to give a general undertaking to resile from the exercise of those powers, in deference to decisions by MAF. However, these powers will not be exercised without first informing MAF of the intention to do so and the reasons, with sufficient notice so that MAF can comment on the expressed intentions before they are implemented.

#### **4.7 Prosecution for offences under the HSNO Act**

MAF has primary responsibility for undertaking prosecutions for conduct that is an offence against the new organism provisions of the HSNO Act. However, MAF may commonly use the provisions of the Biosecurity Act (or other Acts) as the basis for such prosecutions, as MAF deems most appropriate.

MAF Biosecurity Authority will consult with ERMA New Zealand regarding development and review of policies that relate to new organism prosecutions.

MAF will advise ERMA New Zealand of any situation which is referred to MAF’s Special Investigation Group for consideration of prosecution where the cause for that referral may be a breach of the HSNO Act, irrespective of whether it is proposed to prosecute under the Biosecurity or HSNO Act. ERMA New Zealand may choose to seek further information on such cases and may wish to be consulted over decisions whether to prosecute or on what charges.

MAF Biosecurity Authority will report regularly to ERMA New Zealand on prosecution results relating to new organisms, as specified in the various joint agreements (Annexed to this MOU).

ERMA New Zealand reserves the right to independently take a prosecution action under the HSNO Act, but will not do so without first informing MAF of the intention to do so

and the reasons, with sufficient notice so that MAF can comment on the expressed intentions before they are implemented.

## 5 Auditing

MAF will seek ERMA New Zealand participation in the development of its schedule of audits of activities carried out by, or on behalf of, MAF relevant to enforcement of HSNO Act provisions related to new organisms.

MAF will invite representation of ERMA (staff member or other representative) on teams auditing procedures relevant to enforcement of HSNO Act provisions related to new organisms. These will include inspection procedures for compliance with conditions of containment, inspection procedures for compliance with conditions of conditional release and procedures for managing incursion responses.

ERMA New Zealand undertakes to participate in audits of MAF's compliance activities as necessary to verify that HSNO Act requirements and the provisions of this MOU and related agreements (ie Performance Guidelines and Operational Agreements as Annexes to the MOU) are being effectively implemented.

## 6 Resolution of differences

MAF and ERMA New Zealand have overlapping interests in the broad area of New Zealand biosecurity. Differences in opinions over appropriate decisions or actions will arise. All reasonable efforts will be made to ensure that differences are resolved amicably through consultation and discussion.

Despite best intentions, disputes will arise over preferred courses of action in areas where the agencies have overlapping responsibilities. The positions taken may be a function of the wider (different) ranges of responsibilities of the two agencies, or may be driven by more pragmatic considerations such as the availability of resources. Two sets of actions may be activated if this happens as follows, and these are cross-referenced in the detailed text:

- **Resolution Plan A:** A final decision is taken by **MAF**, but ERMA New Zealand reserves the right to advise the Minister for the Environment of the circumstances, the implications and any action that might be taken in the future to avoid such a dispute (refer to section 4.5 above, in relation to new organisms **without** HSNO Act approval).
- **Resolution Plan B:** A final decision is made by **ERMA New Zealand**, but MAF reserves the right to charge costs to ERMA New Zealand where this is the cause of dispute and/or to advise the Minister for the Biosecurity of the circumstances, the implications and any action that might be taken in the future to avoid such a dispute (refer to sections 4.3 and 4.5 above, in relation to new organisms **with** HSNO Act approval).

## 7 Reporting

MAF generates information which is critical to ERMA New Zealand in meeting its obligations to advise the Minister for the Environment regarding the adequacy of new organism enforcement (refer to section 3 above, regarding statutory responsibilities).

The reporting requirements summarised in various sections of this MOU are defined in more detail in joint agreements between ERMA New Zealand/and MAF Biosecurity Authority, as Annexes to this MOU.

## 8 SIGN-OFF and REVIEW OF THIS MOU

The following staff are, meanwhile, designated as the co-ordinators of this agreement for each party:

Anne Rose for ERMA New Zealand

Geoff Daniels for the MAF Biosecurity Authority

These staff are responsible for keeping the agreement current, and will be the prime contacts in each organisation in connection with the implementation of the agreement. Either party may change the co-ordinator representing them and will notify the other party at the time of the change. Review of this agreement can be made at the request of the co-ordinator from either the MAF Biosecurity Authority or ERMA New Zealand.

In the event that there is any reorganisation of functions within either ERMA New Zealand or the MAF Biosecurity Authority, such that the specific references to the organisations are no longer appropriate, then this agreement will still apply in connection with those parts of the organisations that retain the relevant functions. Such re-organisation may prompt either party to request a review of this agreement.

Sign-off:

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Dr Bas Walker  
Chief Executive  
ERMA New Zealand

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Dr Barry O'Neil  
Group Director  
MAF Biosecurity Authority

Date \_\_\_\_\_

Date \_\_\_\_\_

## **ANNEXES**

Detailed operational matters have been dealt with under a range of other joint agreements. At this time (ie October 2003), agreements between ERMA New Zealand and MAF Biosecurity Authority exist for the following (development of further joint agreements and protocols over time is likely):

- Performance Guidelines for New Organism Enforcement
- Operational Agreement regarding the requirements for the containment of new organisms
- Operational Agreement: Border Activities regarding importation of New Organisms
- (draft) Operational Agreement regarding Conditional Release of New Organisms