

BIOSECURITY AUTHORITY POLICY STATEMENT ON CONDUCTING IMPORT RISK ANALYSES AND APPLYING THEM IN THE DEVELOPMENT OF IMPORT HEALTH STANDARDS

1 PURPOSE AND SCOPE

1.1 Purpose

This policy statement sets out the principles to which the Biosecurity Authority (MAF Biosecurity) will adhere when conducting risk analyses and applying them to effectively manage risks associated with the importation of 'risk goods'.

This policy principally covers the science-based assessment of risks ('risk analysis') and the development and issuing of import health standards under the Biosecurity Act 1993.

1.2 Background

One of MAF Biosecurity's principal functions is protecting New Zealand's biosecurity and biodiversity by administering part III of the Biosecurity Act 1993, which deals with the "effective management of risks associated with the importation of risk goods" (s 16).

'Risk goods' are defined in s 2 of the act as:

- any organism, organic material, or other thing, or substance, that (by reason of its nature, origin, or other relevant factors) it is reasonable to suspect constitutes, harbours, or contains an organism that may -
- (a) Cause unwanted harm to natural and physical resources or human health in New Zealand; or
 - (b) Interfere with the diagnosis, management, or treatment, in New Zealand, of pests or unwanted organisms.

1.3 Risk analysis

Risk analysis provides the best means of ensuring that chief technical officers (CTOs), or those acting under their delegated authority, fulfil their legal obligations under section 22 of the Biosecurity Act when developing import health standards.

Risk analysis is a management tool that incorporates scientific methods to enable regulators to gather and assess information and data in a thorough, consistent, logical and transparent way. It ensures that:

- organisms that may cause unwanted harm are identified;
- the likelihood of these organisms being introduced into New Zealand and the nature and possible effect on people, the environment and the economy is assessed;
- appropriate biosecurity measures to effectively manage the risks posed by these organisms are developed, and;
- the results, conclusions and recommendations arising from the analysis are effectively communicated amongst interested parties.

Risk analysis also allows regulators to make the best use of available resources.

MAF Biosecurity is committed to developing a high level of expertise in risk analysis, and consistently using risk analysis in the development of import health standards.

1.4 MAF Biosecurity's accountabilities

[This section will be completed when the memorandums of understanding with other departments are finalised]

1.5 Related documents

MAF Biosecurity Authority will develop import health standards under the Biosecurity Act:

- taking into account the risk analysis techniques developed by the world organisation for animal health or Office International des Epizooties (OIE), and those developed under the auspices of the Interim Commission on Phytosanitary Measures (ICPM) operating within the framework of the International Plant Protection Convention (IPPC) (see appendix A);
- in accordance with the *Biosecurity Council policy statement on interdepartmental consultation on risk analyses and import health standards under section 22 of the Biosecurity Act 1993* (17 December 1998);
- in accordance with the *MAF Biosecurity Authority policy statement on consultation* (29 February 2000);
- in accordance with the *Protocol on harmonisation of quarantine administrative procedures* (1988) to the Australia New Zealand Closer Economic Relations Trade Agreement.

Within MAF Biosecurity the Animal Biosecurity, Forest Biosecurity and Plants Biosecurity groups will develop and document their procedures for conducting risk analyses in accordance with this policy.

2 IMPORT RISK ANALYSIS

2.1 Use of risk analysis

All import health standards prepared by MAF Biosecurity under part III of the Biosecurity Act will be based on a risk analysis, which may assess a commodity or a pest/pathway combination.

MAF Biosecurity may use the risk analyses of other parties, including other countries or relevant international organisations. However, before doing this MAF Biosecurity will carefully evaluate the risk analysis and modify it, if necessary, for New Zealand circumstances.

2.2 Terminology used in risk analysis

MAF Biosecurity risk analyses will use relevant international terminology: that of the OIE when dealing with animal health or zoonoses¹, and that of the IPPC when dealing with phytosanitary matters². Each risk analysis will contain a glossary of the terms used which have a different meaning in different risk analysis lexicons.

¹ The Office International des Epizooties *International animal health code, mammals, birds and bees* (2000) defines 'Risk analysis' as "The process composed of hazard identification, risk assessment, risk management and risk communication" (terms which are themselves defined).

² The International Standard for Phytosanitary Measures number 5 (*Glossary of phytosanitary terms*, 1999) defines 'Pest risk analysis' as "The process of evaluating biological or other scientific and economic evidence to determine whether a pest should be regulated and the strength of any phytosanitary measures to be taken against it".

2.3 Key elements in risk analyses

Section 22(5) of the Biosecurity Act sets out the elements that must be considered when an import health standard (IHS) is developed. Because all MAF IHSs are to be based on a risk analysis, the obligation to have regard to certain matters is set out here. Under this policy statement, MAF risk analysts must ensure these matters are properly considered when risks are assessed and any sanitary or phytosanitary measures recommended.

Section 22(5) of the act states:

- (5) When making a recommendation to the Director-General in accordance with this section, the chief technical officer must have regard to the following matters:
- (a) The likelihood that goods of the kind or description to be specified in the import health standard may bring organisms into New Zealand;
 - (b) The nature and possible effect on people, the New Zealand environment, and the New Zealand economy of any organisms that goods of the kind or description specified in the import health standard may bring into New Zealand;
 - (c) New Zealand's international obligations;
 - (d) Such other matters as the chief technical officer considers relevant to the purpose of this Part.

The SPS agreement and related WTO jurisprudence also set out what is required in a risk analysis. A risk analysis will:

- Identify the organisms whose entry, establishment or spread New Zealand wishes to prevent.
- Identify for those organisms the associated potential biological, economic and environmental consequences of entry, establishment or spread.
- Evaluate the likelihood of the entry, establishment and spread of those organisms, and the associated potential biological, economic and environmental consequences³.
- Evaluate how the sanitary or phytosanitary measures that might be applied would affect the likelihood of the entry, establishment or spread of those organisms⁴.

The requirements of both the Biosecurity Act and the SPS agreement are reflected in sections 2.4–2.8 of this policy statement.

2.4 How things are to be considered

The act requires a decision-maker to “have regard to” the matters listed in s 22(5). This means that they must take the criteria into account and consider them when making a decision. It is up to the decision-maker to decide how much weight to give each consideration, so long as the ultimate decision is not unreasonable or irrational.

For instance, there is a procedural obligation in the Biosecurity Act to consider possible effects on social, cultural and aesthetic conditions that affect or are affected by components of the broad definition of ‘environment’. The act allows, but does not require, importation decisions to be made on the basis of such considerations.

MAF risk analysts will document how the statutory criteria were taken into account for each risk analysis.

³ It is not sufficient for a risk analysis to conclude that there is a ‘possibility’ of entry, establishment or spread of an organism (with associated potential consequences); a valid risk analysis must evaluate the likelihood (i.e. probability). The evaluation of likelihood can be expressed either quantitatively or qualitatively, and the risk evaluated must be an ascertainable risk rather than a theoretical uncertainty.

⁴ To facilitate the possible development of import health standards, any sanitary or phytosanitary measures recommended shall be justified in the risk analysis and not be more trade restrictive than required, taking into account technical and economic feasibility.

2.5 Organisms and the likelihood of introduction

The analysis may be of the risks posed by an organism or a number of organisms associated with the importation of risk goods. All organisms that are being considered must be listed in the risk analysis.

2.6 Effects on people, the economy and environment

Risk analysts must consider the potential effects on people, the economy or environment of organisms that may be introduced as a consequence of importing risk goods. The potential effects of importing the risk goods themselves (such as economic effects on domestic producers) cannot be considered in a biosecurity risk analysis.

2.6.1 People

A risk analysis for a commodity that may harbour zoonotic organisms cannot be completed until the risks associated with such organisms are addressed. In such cases risk analysts will develop and apply risk analyses in cooperation with other agencies, particularly the Ministry of Health.

2.6.2 Economy

Risk analysts must consider economic effects that could arise from the introduction, establishment or spread of organisms, including:

- the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; and
- the costs of control or eradication in New Zealand;

and should consider the relative cost-effectiveness of alternative approaches to limiting risks.

The economic analysis of possible effects on the New Zealand economy need extend only as far as is necessary for the risk analyst to reasonably establish appropriate conditions for the importation of risk goods. It does not necessarily need to extend to a precise quantification of every potential effect on the economy. If similar risks have previously been assessed in a risk analysis or in the development of an import health standard, such an analysis need be repeated only if new information has come to light or if relevant circumstances have changed.

2.6.3 Environment

Under the Biosecurity Act the New Zealand “environment” is defined as:

Environment includes:

- (a) Ecosystems and their constituent parts, including people and their communities;
and
- (b) All natural and physical resources; and
- (c) Amenity values; and
- (d) The aesthetic, cultural, economic, and social conditions that affect or are affected by any matter referred to in paragraphs (a) to (c) of this definition.

2.7 International obligations

In common with other jurisdictions, New Zealand is a party to a multitude of international agreements. As a party to a treaty, New Zealand is obliged to comply with the relevant treaty provisions and, where necessary, give full effect to them in its domestic law. Risk analysts should have regard to these obligations when conducting a risk analysis and recommending sanitary or phytosanitary measures.

International agreements of treaty status to which New Zealand is a party and which are relevant to part III of the Biosecurity Act include:

- the General Agreement on Tariffs and Trade 1994;
- the Agreement on the Application of Sanitary and Phytosanitary Measures (1994);
- the Convention on Biological Diversity (1992);
- the Australia New Zealand Closer Economic Relations Trade Agreement (1983);
- the International Plant Protection Convention (1952).

There are other relevant international agreements to which New Zealand is a party, but which are not of treaty status and thus do not create any legal obligations unless they are incorporated in other, treaty-status international instruments. These include:

- The Rio Declaration on Environment and Development (1992).

2.8 Consideration of other matters

In recommending sanitary or phytosanitary measures, a risk analyst can also consider any other matters that are relevant to the purpose of part III of the Biosecurity Act: if they relate to the “effective management of risks associated with the importation of risk goods” (s 16).

This could include the possible disease impacts or effects on the environment of the risk goods themselves, if they were an organism (e.g. a pathogen imported for diagnostic work); as these cannot be considered under paragraphs (a) and (b) of s 22(5).

The nature and possible effect on the New Zealand environment of new organisms for which approval to import for release is given under the Hazardous Substances and New Organisms Act 1996 will not be considered by MAF. That assessment is the responsibility of the Environmental Risk Management Authority (ERMA New Zealand).

2.9 Dealing with uncertainty or lack of knowledge

Uncertainty results from both variation inherent in biological systems and from lack of information. MAF Biosecurity will incorporate a level of precaution in its import risk analyses to account for uncertainty, for instance when making a professional judgement on whether available information is sufficient, when making assumptions or selecting parameters for quantitative risk analyses, and when recommending risk management decisions based on a risk analysis. What constitutes sufficient scientific evidence will need to be decided on a case-by-case basis depending on the degree of uncertainty and the severity of potential harm.

Where biosecurity risk management measures are adopted in situations where there is not sufficient scientific evidence necessary for a comprehensive analysis of risks, MAF Biosecurity Authority will take appropriate steps to seek the additional information necessary for a more objective assessment of risk and review the measure accordingly within a reasonable period of time.

2.10 Process for conducting risk analyses

When carrying out import risk analyses MAF Biosecurity will:

- Invite the participation of other departments whose biosecurity responsibilities might be affected, as outlined in the *Biosecurity Council policy statement on interdepartmental consultation on risk analyses and import health standards under section 22 of the Biosecurity Act 1993*.
- Ensure risk analyses are reviewed within MAF, prior to being peer-reviewed by appropriately-qualified experts outside MAF. Peer reviewers will be given specific terms of reference for their critique. Each critique will be, in turn, reviewed and, where

appropriate, incorporated into the analysis. If suggestions arising from the critique are not adopted the rationale for doing this must be documented.

- Undertake consultation in accordance with the *MAF Biosecurity Authority policy statement on consultation*.
- Prepare an analysis of all submissions and make this available to all those who made submissions.
- Publish the subsequent decision of a chief technical officer to issue, or not issue as the case may be, standard(s) based on the risk analysis.

2.11 Consultation

Consultation is an integral part of the risk management process. MAF Biosecurity recognises that consultation is an iterative and collaborative process involving a two-way dialogue from the very start of the risk management process. Every reasonable opportunity will be extended to stakeholders to involve them directly in the process through an appropriate forum or medium.

MAF Biosecurity undertakes to consider with an open mind all concerns raised and to provide timely feedback. To ensure that a meaningful dialogue is established all parties should acknowledge that, while they have a right to propose an alternative view, they also have an obligation to provide reasoned argument.

2.12 Work programmes

Each group in MAF Biosecurity carrying out risk analyses will develop in advance an annual work programme of risk analyses which will be discussed with consultation committees, and published.

3 CONSIDERATIONS WHEN DEVELOPING IMPORT HEALTH STANDARDS UNDER s 22 OF THE BIOSECURITY ACT

3.1 Background

Under s 22 of the Biosecurity Act 1993, the Director-General of MAF may issue an import health standard (IHS) specifying the requirements for the importation of risk goods. This authority is delegated to MAF Biosecurity Authority chief technical officers (CTOs).

Import health standards are issued following the recommendation of a CTO. Within MAF the authority to make such recommendations is delegated to those national managers and national advisers within the Animal Biosecurity, Forest Biosecurity and Plants Biosecurity groups whose duties include the development of IHSs. (The Biosecurity Policy Coordination group maintains current schedules of delegations.)

3.2 Standards to be based on a risk analysis

Under this policy the domestic and international legal obligations relating to developing an IHS are set out in sections 2.4–2.8, as they must be considered by risk analysts.

The development of an IHS is a separate process from a risk analysis, but the sanitary or phytosanitary measures applied in an IHS must be based on those recommended in a risk analysis approved by the CTO. 'Based on' means that there must be a rational relationship between the risk analysis and the IHS developed; any IHS must be reasonably supported by a risk analysis.

If there is a difference between the recommended measures in the risk analysis and those finally adopted in an IHS, the reasons justifying the differences must be detailed in a bridging document. The person recommending that an IHS be issued under section 22(5) of the Biosecurity Act is responsible for checking that the IHS meets the obligations in that section of the act (as discussed in sections 2.4—2.8 of this policy statement).

Provided the sanitary or phytosanitary measures contained in an IHS are based on a risk analysis no further consultation is required before the IHS is issued. (However, every government department with biosecurity responsibilities must still be notified as required under section 22(8) of the Biosecurity Act.) If different measures are used then a round of stakeholder consultation must be undertaken followed by a review of submissions as set out in MAF Biosecurity's consultation policy.

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APPENDIX A: RISK ANALYSIS TECHNIQUES DEVELOPED BY RELEVANT INTERNATIONAL ORGANISATIONS

Under the SPS agreement, international standards, guidelines and recommendations developed by “relevant international organisations” are defined in annex A, paragraph 3 as:

- for animal health and zoonoses, the standards, guidelines and recommendations developed under the auspices of the International Office of Epizootics;
- for plant health, the international standards, guidelines and recommendations developed under the auspices of the Secretariat of the International Plant Protection Convention in cooperation with regional organizations operating within the framework of the International Plant Protection Convention.

The relevant guidelines for risk analysis are:

- Contained in the current edition of the OIE *International animal health code, mammals, birds and bees*. In the ninth edition (2000), this is chapters 1.3.1 and 1.3.2; pp 21–28.
- IPPC (1996) *Guidelines for pest risk analysis*. International Standards for Phytosanitary Measures; ISPM Publication No. 2.