Consultation Document

Process for independent review of the scientific evidence supporting a draft Import Health Standard under section 22A of the Biosecurity Act 1993

May 2008
Purpose

The purpose of this document is to outline the Ministry of Agriculture and Forestry's (MAF's) proposal for establishing an independent review process under section 22A of the Biosecurity Act 1993. This document seeks feedback on the proposal from key stakeholders.

Background

In April 2008, Parliament passed the Biosecurity Amendment Act (No 2) 2008 and the Hazardous Substances and New Organisms Amendment Act 2008. The amendments were required to resolve issues about the relationship between the Biosecurity and Hazardous Substances and New Organisms (HSNO) Acts concerning the importation of new organisms.

In response to submissions on the Bill, the Primary Production Select Committee added a new section 22A to the Biosecurity Act, to allow for an independent review to be conducted as part of the import health standard development process. The purpose of the review is to advise the Director-General of MAF on whether, in developing an import health standard, MAF has had sufficient regard to the scientific evidence about which a person consulted on the draft standard has raised a significant concern.

The Director-General of MAF must set out the process by which independent review panels are to be established by notice in the Gazette. The Gazette notice must be in place by 1 July 2008.

Submissions invited

MAF is calling for submissions on its proposed process for a section 22A review.

Written submissions must be made by 13 June 2008 and can be made by post or email to:

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Wellington
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MAF’s Proposal

Section 22A of the Biosecurity Act (see Appendix) requires the Director-General of MAF to set out the process for establishing an independent review panel by notice in the Gazette.

As required by section 22A, MAF has developed a proposal covering the following:

a) the criteria for setting up an independent review panel; and

b) how the Director-General will appoint an independent review panel, including the knowledge and experience required for appointees; and

c) the procedures to be followed by –
   i) a person eligible to seek a review; and
   ii) an independent review panel, in undertaking its review; and

d) the reporting requirements for an independent review panel.

This document sets out the proposal and provides explanatory notes which describe the rationale for particular proposals.

(a) the criteria for setting up an independent review panel

An independent review is initiated by the Director-General of MAF, either directly or following an application by a person who has raised a “significant concern” during consultation on a draft import health standard under section 22(6) of the Biosecurity Act. Applications to the Director-General must be in writing.

MAF expects that an independent review will normally be initiated through a person applying to the Director-General. However, the Director-General can initiate a review without receiving an application.

Under section 22(7) of the Biosecurity Act, consultation about an import health standard can be conducted at either the risk analysis or draft import health standard stage. Therefore, a review may be initiated based on concerns raised during consultation on either a draft risk analysis or a draft import health standard.

It is intended that, to the maximum extent possible, there will be only one review during each import health standard development process. This review will deal with all issues where significant concern exists. It is considered likely that any review will occur after consultation on the draft import health standard is complete, and before the Director-General issues a final standard.

In cases where consultation under section 22(6) does not occur, because an import health standard needs to be issued or amended urgently or the amendment is considered minor, an independent review will not be available.
The Director-General will determine whether the concern is “significant”, taking into account:

- the extent to which the scientific evidence in question is or may be material to the measures proposed in the draft Import Health Standard;
- the number of persons registering the concern;
- whether the case for review is scientifically credible;
- whether the matters have been the subject of a previous review; and
- any other matters he/she considers relevant.

(b) how the Director-General will appoint an independent review panel, including the knowledge and experience required for appointees

To strengthen the independence of the review process from the parts of MAF involved in developing the import health standard, the Director-General may delegate any of the powers or functions relating to the review to an appropriate MAF employee. While powers such as the power to appoint a panel and oversee its operation are likely to be delegated, it is not envisaged that the final decision on the dispute would be.

The Director-General will seek to appoint a panel with:
- sound judgement skills, ideally with experience in conducting a review function in the context of a statutory process;
- risk analysis experience; and
- subject matter expertise.

The panel will be provided with a secretariat to assist it to meet its terms of reference and reporting requirements.

Potential panel members must declare any conflicts of interest (including commercial, personal or political interest in the outcome) and will be eligible only if the Director-General considers any declared conflicts are manageable. To the extent possible, panel members will have had no previous involvement in the issue.

The panel will have at least two members, but the number of panel members will otherwise be at the Director-General’s discretion. A panel with three members is ideal, however, this may not always be possible due to the specific issues raised and potential conflicts of interest.
(c) the procedures to be followed by:

(i) a person eligible to seek a review

A person consulted under section 22(6) on a risk analysis or draft import health standard is eligible to seek a review. Such a person must apply in writing to the Director-General re-iterating a concern previously raised and specifying:

- the part(s) of his or her previous submission that sets out the relevant “significant concern”;
- how the concern meets the criteria for “significant”;
- the areas of MAF’s interpretation of the science disputed; and
- any additional scientific information about the significant concern that was omitted from his or her earlier submission.

An application for an independent review must be submitted to the Director-General within four weeks of a provisional version of the import health standard being made available.

MAF intends to alter its processes to release a provisional import health standard following consultation and consideration of the submissions on the draft import health standard. If the Director-General does not receive any applications for an independent review of the standard within four weeks, the provisional standard will be finalised. In cases where an import health standard must be issued or amended urgently, MAF will finalise the standard without the provisional step.

(ii) an independent review panel, in undertaking its review

A specific terms of reference will be developed for each panel established, based on the specifics of the case and taking into account the following guidelines. The applicant and/or interested parties will be provided with an opportunity to comment on the draft terms of reference prior to the Director-General finalising them.

Terms of Reference

The terms of reference will typically cover the following.

1. The independent panel is to review whether, in developing an import health standard, MAF has given sufficient regard to the scientific evidence about which a person consulted under section 22(6) has raised a significant concern.
2. The review will consider:
   − the application that triggered the review;
   − the scientific information and analysis underlying MAF’s import risk analysis and the draft import health standard;
   − any additional relevant scientific information or analysis provided by MAF
   − scientific evidence from all existing submissions relating to the “significant concern”;
   − the panel members’ own expert knowledge of the field.

3. To determine whether sufficient regard has been given, the panel will address the following questions:
   − whether MAF considered the relevant evidence;
   − whether MAF considered any irrelevant matters;
   − whether MAF addressed differences in evidence during its assessment; and
   − whether MAF reached conclusions that could reasonably be drawn based on the scientific evidence.

4. The Biosecurity Act requires the panel to be established to determine whether MAF has given sufficient regard to scientific evidence in developing an import health standard. The panel will not consider matters outside of this scope, such as whether the measures included in the import health standard achieve an appropriate level of protection for New Zealand or whether measures within a standard should be replaced or amended.

5. The Director-General will supply to the panel, all relevant material received from others and prepared by MAF related to the matters under dispute, including relevant submissions and the application/s that triggered the review. The applicant will receive a copy of all written material provided to the panel.

6. The panel may seek advice from whomever it sees fit, with the prior approval of the Director-General, to assist it in meeting the terms of reference.

7. Neither MAF nor interested parties will have direct correspondence with the panel in relation to the matters under dispute unless the panel seeks it.

8. The Panel may carry out its review by meetings, or communicating with each other by whatever means promotes the efficient completion of the Panel’s function.

9. Remuneration for the Panel members, and other terms and conditions such as reimbursement of expenses, will be set out in each member’s letter of appointment.

10. The panel will be given an indicative timeframe for the review, based on the scope. It is likely that this will be a maximum of 90 days, with the option of an extension if agreed by both the Director-General and the panel.
(d) the reporting requirements for an independent review panel

The panel will provide a written report that sets out:
- The significant concern that interested parties have raised.
- Its findings on how the scientific evidence in question was addressed in the process.
- Advice to the Director-General on whether, in the development of the import health standard, MAF has given sufficient regard to the scientific evidence concerned and, if not, what additional work is necessary before the import health standard can be finalised.

The panel will report back to the Director-General within the timeframe agreed in the Terms of Reference, unless an alternative timeframe is agreed to by the Director-General and the panel.

Additional matters

Section 22A(3) requires that the Director-General must receive a report from the independent review panel and, as soon as is reasonably practicable, determine the issue in dispute after taking into account the findings and recommendations of the independent review panel, giving reasons for that determination.

The Director-General is required to respond formally to the recommendations of the review panel and to have regard to those recommendations when making a final decision on the import health standard.

The report and determination will be notified to the applicant and will be subsequently released publicly.
Section 22A of the Biosecurity Act

Process for independent review panel to be established

(1) The Director-General must, by notice in the Gazette, set out the process by which an independent review panel is to be established to review whether, in developing an import health standard, there has been sufficient regard to the scientific evidence about which a person consulted under section 22(6) has raised a significant concern.

(2) The notice required by subsection (1) must cover the following matters:

(a) the criteria for setting up an independent review panel; and
(b) how the Director-General will appoint an independent review panel, including the knowledge and experience required for appointees; and
(c) the procedures to be followed by—
   (i) a person eligible to seek a review under subsection (1); and
   (ii) an independent review panel, in undertaking its review; and
(d) the reporting requirements for an independent review panel.

(3) The Director-General must receive any report from an independent review panel and, as soon as is reasonably practicable, determine the issue in dispute after taking into account the findings and recommendations of the independent review panel, giving reasons for that determination.

(4) The Director-General must issue a notice under subsection (1) not later than 1 July 2008.