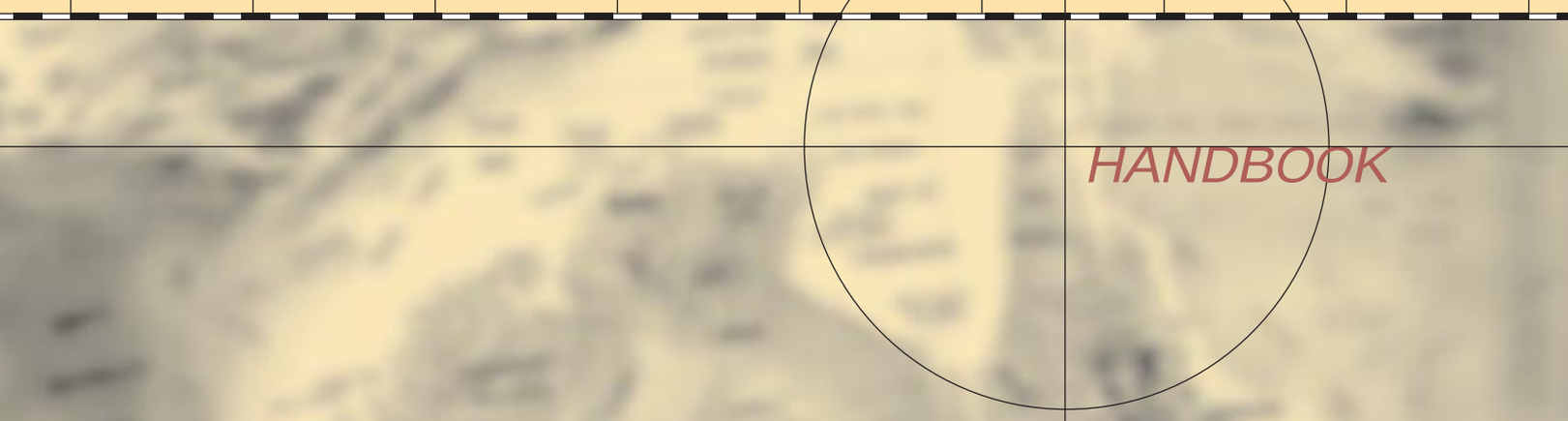
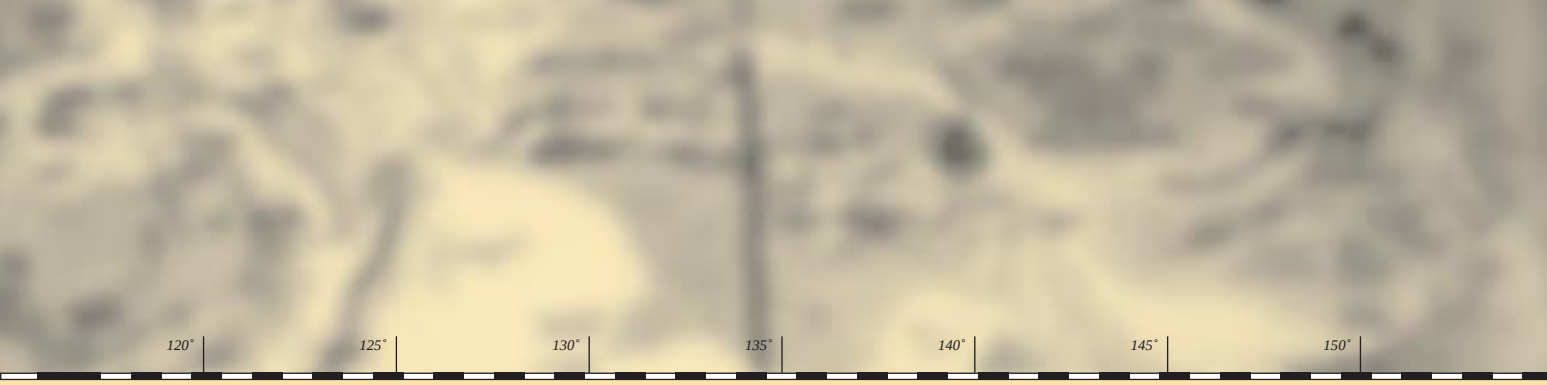
The AQIS Import Risk Analysis Process

HANDBOOK



AQIS
AUSTRALIAN QUARANTINE AND INSPECTION SERVICE



Flowchart of the Import Risk Analysis Process

stakeholder contact

INITIATION

1.1 import proposal lodged with AQIS — initiated by AQIS

1.2 proposal acknowledged

1.3 priority considered (where required)

1.4 type of risk analysis determined by AQIS program specialists

1.5 proposed IRA approach approved by ED AQIS and stakeholders advised

ROUTINE RISK ANALYSES

2.1 risk analysis conducted

2.2 draft IRA paper with recommendations published, and comment invited on technical issues

NON-ROUTINE RISK ANALYSES

3.1 after consultation with stakeholders; issues, timing, Risk Analysis Panel determined

agreed — not agreed

3.2 appeal to Director of Quarantine

3.3 appeal determined by Director of Quarantine and stakeholders advised

3.4 issues paper published and comment invited

3.5 risk analysis conducted

3.6 draft IRA paper with recommendations published, and comment invited on technical issues

DETERMINATION

4.1 comment reviewed and risk analysis recommendations finalised

4.2 risk analysis recommendations submitted to ED AQIS

4.3 import proposal determined by ED AQIS

4.4 determination and final IRA paper published and stakeholders advised

determination agreed

4.5 appeal to Director of Quarantine on the process

4.6 appeal considered by Import Risk Analysis Appeal Panel

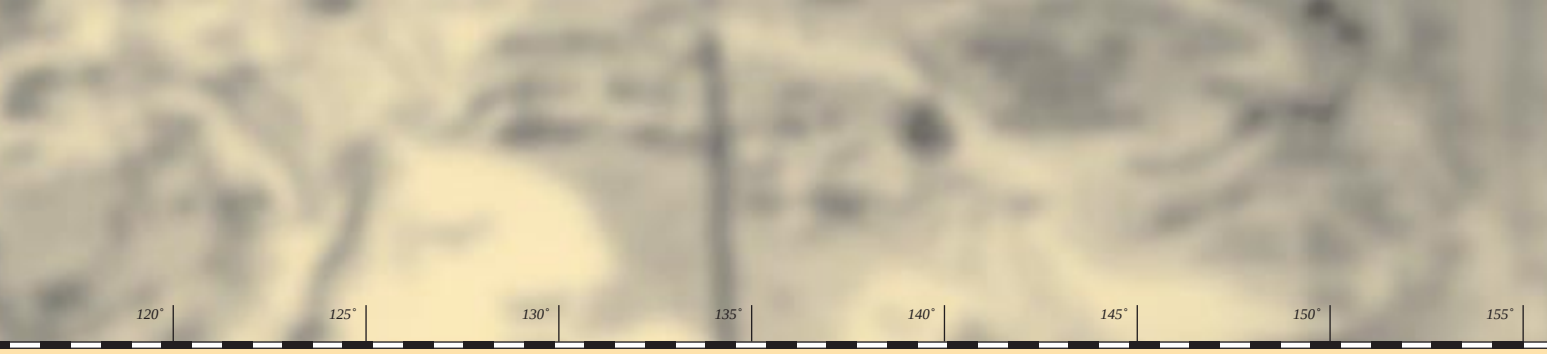
appeal rejected — appeal upheld and deficiency addressed

4.7 appellant and applicant advised

stakeholder contact

IMPORT RISK ANALYSIS POLICY APPLIED

Note: the normal provision for appeal and remedies available under the *Administrative Decisions (Judical Review) Act 1977* would apply.



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Plant Quarantine issues

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Copies of the Handbook

The Handbook is available in both hard copy and electronic forms. Hard copies are available from either of the above AQIS contact points. Electronic copies are available through the AQIS homepage: **http://www.aqis.gov.au**

Comment on the first edition

Comment on the first edition of the Handbook is welcome and will be considered in the production of the next edition. Comment may be sent in hard copy form to:

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fax (02) 6272 4568

or by email to **aqis.qdu@dpie.gov.au**

The AQIS Import Risk Analysis Process Handbook is published by the Quarantine Development Unit, which complements the activities of the Animal and Plant Quarantine Policy Branches of AQIS in conducting and co-ordinating research and development on policy, methodology and other issues relevant to protecting Australia's environment and animal, plant and human health.

The AQIS Import Risk Analysis Process

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HANDBOOK

AQIS
Protecting our way of life !

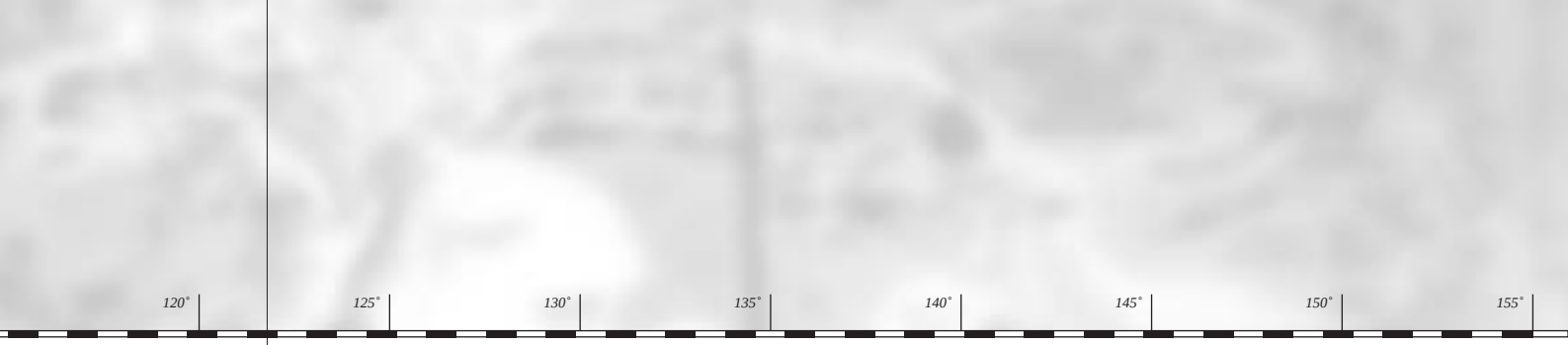


Table of Contents

Foreword 5

Acronyms and definitions 6

Introduction 7

Purpose of the Handbook 8

International Standards 9

WTO SPS Agreement 9

Office International des Epizooties (OIE) 10

International Plant Protection Convention (IPPC) 10

Quarantine Decision-Making 11

The IRA Process 12

Overview 12

Initiation 13

1.1 Import proposal lodged with AQIS 13

1.2 Proposal acknowledged 13

1.3 Priority considered (where required) 14

1.4 Type of risk analysis determined by AQIS program specialists 14

1.5 Proposed IRA approach determined by Executive Director AQIS, and stakeholders advised 14

Import Risk Analysis 15

Routine IRA pathway 15

2.1 Risk Analysis conducted 15

2.2 Draft IRA paper with recommendations published and comment invited on technical issues 15

Non-routine IRA pathway 15

3.1 After consultation with stakeholders: issues, timing, risk analysis panel determined 15

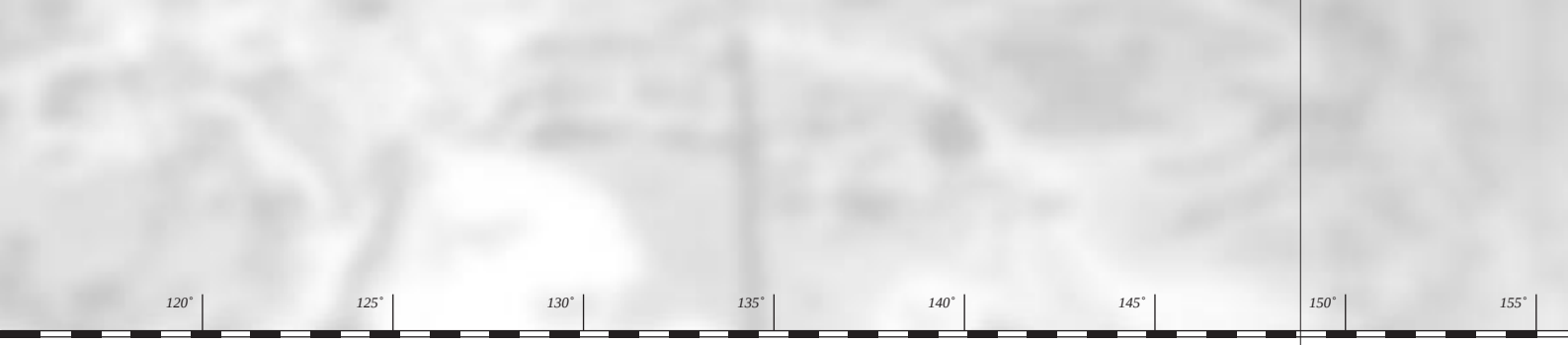
3.2 Appeal to Director of Animal and Plant Quarantine 16

3.3 Appeal determined by Director of Animal and Plant Quarantine and stakeholders advised 16

3.4 Issues paper published and comment invited 17

3.5 Risk analysis conducted by the RAP 17

3.6 Draft IRA paper with recommendations published and comment invited on technical issues 17



Determination (routine and non-routine processes) 18

4.1 Comment reviewed and risk analysis recommendations finalised 18

4.2 Risk analysis recommendations submitted to Executive Director AQIS 18

4.3 Import proposal determined by Executive Director AQIS 18

4.4 Determination and final IRA paper published, and applicant and stakeholders advised 18

4.5 Appeal to the Director of Animal and Plant Quarantine on the process 18

4.6 Appeal considered by Import Risk Analysis Appeal Panel 19

4.7 Appellant/applicant advised of outcome of appeal 19

Application of the Import Risk Analysis Policy 19

ANNEX 1 20

Agreement of the Application of Sanitary and Phytosanitary Measures (SPS Agreement)

ANNEX 2 34

PART 1

OIE International Animal Health Code—Draft Chapter on Import Risk Analysis 34

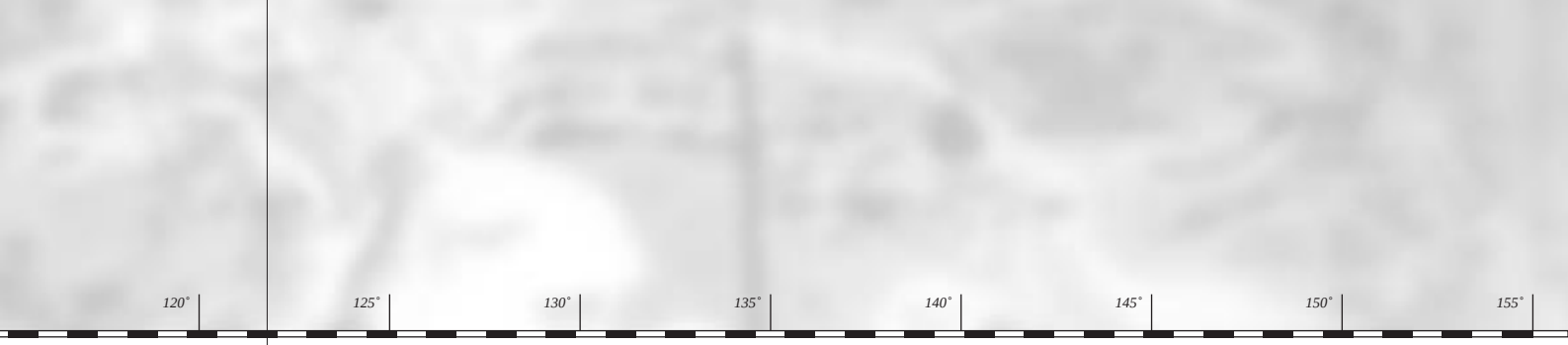
PART 2

International Standards for Phytosanitary Measures—Guidelines for Pest Risk Analysis 44

ANNEX 3 60

Summary of Procedures for Application for Access to Australia for Plants and Plant Products 60

Application for Permit to Import Quarantine Material and Application Completion Instructions 63



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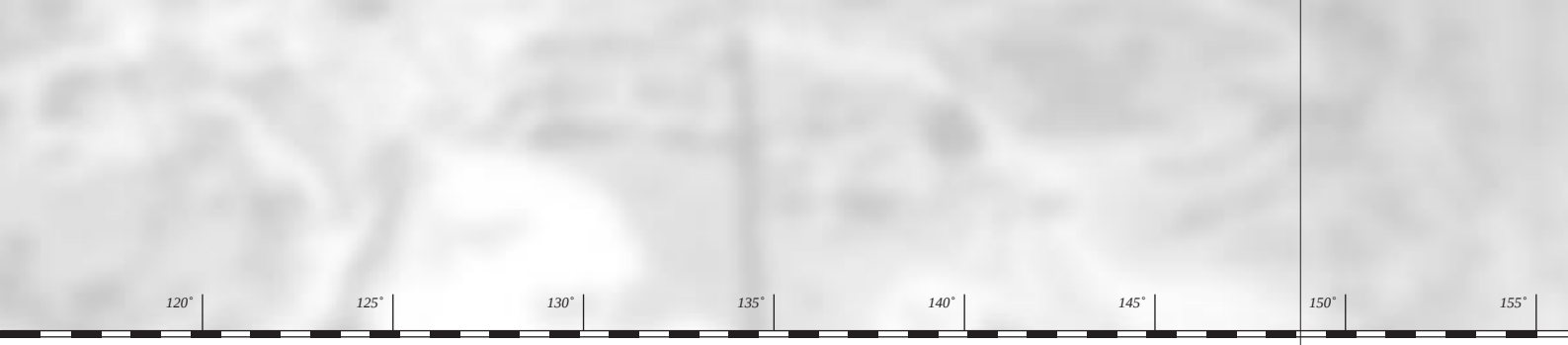


Foreword

In August 1997 the Australian Government released its response to the major review of Australian quarantine, *Australian Quarantine: a shared responsibility*[1], carried out by a committee chaired by Professor Malcolm Nairn. The review committee was established in December 1995 by the then Government to undertake an independent review of Australia's plant and animal quarantine policies and programs, and reported against its terms of reference in October 1996.

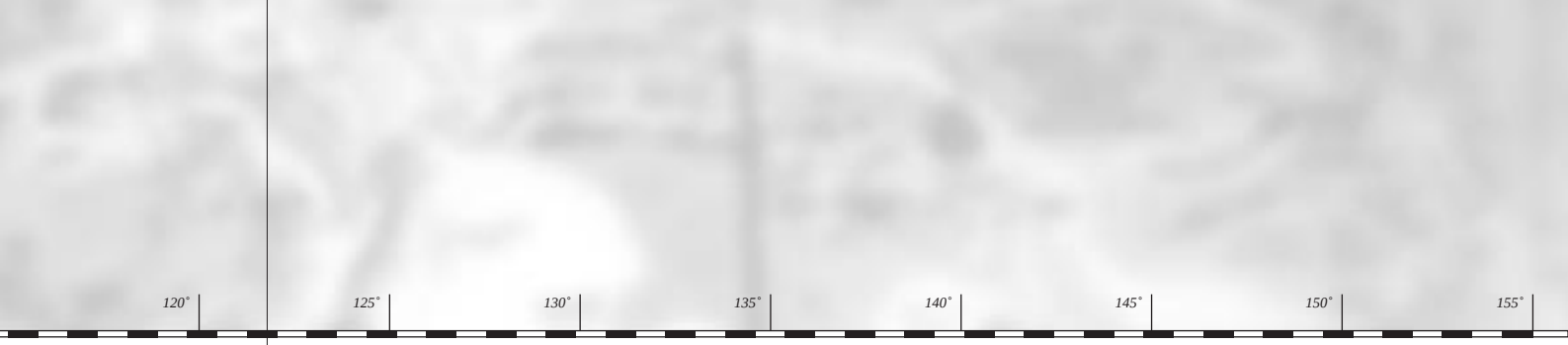
One of the areas of quarantine policy receiving wide attention in recent times has been the process for carrying out import risk analyses. The Nairn Committee made a number of recommendations to address this issue and these recommendations have been endorsed by the Australian Government. The publication of this Handbook responds to recommendations of the review committee, and of the Senate Rural and Regional Affairs and Transport Legislation Committee in its report[2] on the Australian Quarantine and Inspection Service (AQIS) that AQIS should develop improved strategies to communicate its risk analysis process.

This Handbook reflects AQIS's consideration of comment provided by stakeholders on a draft version. The Handbook and the processes it describes will be kept under review and improvements made in the light of experience.

Paul Hickey
EXECUTIVE DIRECTOR
AQIS

1 Nairn, M.E., Allen P.G., Inglis A.R. and C. Tanner (1996) *Australian Quarantine: a shared responsibility*, Department of Primary Industries and Energy, Canberra

2 Report of the Senate Rural and Regional Affairs and Transport Legislation Committee 1996



Acronyms and Definitions

AQIS . . . . . .Australian Quarantine and Inspection Service

CVO . . . . . .Chief Veterinary Officer

CPPO . . . . . .Chief Plant Protection Officer

DPIE . . . . . .Department of Primary Industries and Energy

IRA . . . . . .Import Risk Analysis

IPPC . . . . . .International Plant Protection Convention

IRAAP . . . . . .Import Risk Analysis Appeal Panel

OIE . . . . . .Office International des Epizooties

QEAC . . . . . .Quarantine and Exports Advisory Council

Quarantine Act . .*Quarantine Act 1908*

RAP . . . . . .Risk Analysis Panel

SPS Agreement . .WTO Agreement on the Application of Sanitary and Phytosanitary Measures

TBT Agreement . .WTO Agreement on Technical Barriers to Trade

WTO . . . . . .World Trade Organization

application
a formal, detailed request in writing for the importation of animals, plants or their products

appropriate level of protection / acceptable level of risk
according to Annex A of the SPS Agreement, the appropriate level of protection is the level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory. *Note: many Members otherwise refer to this concept as the 'acceptable level of risk'*

Director of Animal and Plant Quarantine
Secretary of DPIE, who has decision-making power under the Quarantine Act

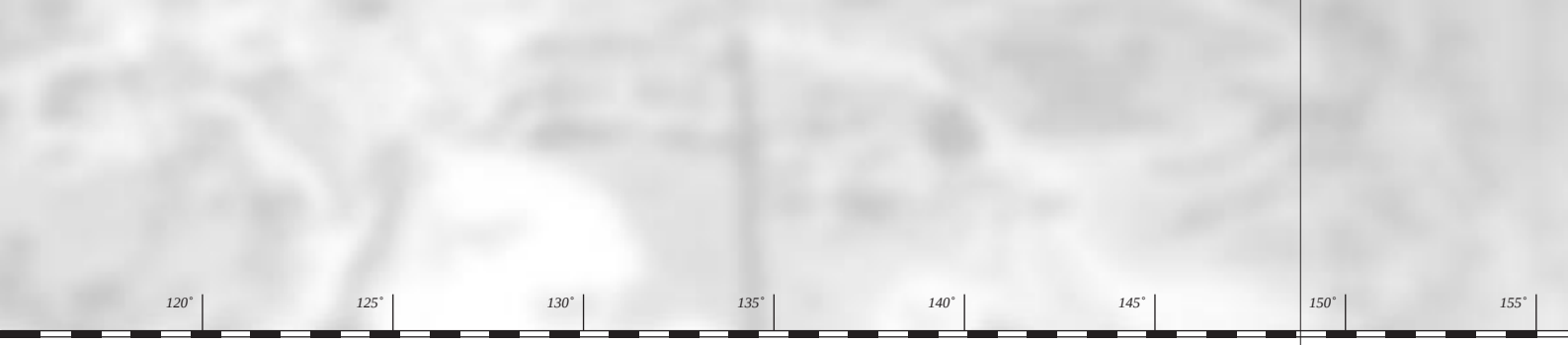
Executive Director of AQIS
Officer in charge of AQIS

import risk analysis
the process through which quarantine policy is developed or reviewed, incorporating risk assessment, risk management and risk communication

non-routine analysis
one of the pathways for conducting an IRA, involving a risk analysis panel comprised of AQIS and other experts

routine analysis
one of the pathways for conducting an IRA, involving an AQIS in-house team of experts

stakeholder
governments, individuals, community or industry groups or organisations, in Australia or overseas, that have an interest in the subject matter of an IRA



Introduction

People and goods arriving in Australia from overseas may bring diseases and pests with them. Illegal imports, either through smuggling or as undeclared items at airports and seaports, also pose risks. The primary role of quarantine policies and procedures is to keep unwanted diseases and pests out of Australia, while at the same time facilitating the international flow of people and goods.

Import risk analysis (IRA) underpins Australia's quarantine policies and procedures. The Nairn Committee identified six principles that should apply to IRA. IRA should be:

- conducted in a consultative framework;
- a scientific process and therefore politically independent;
- a transparent and open process;
- consistent with both Government policy and Australia's international obligations (under the SPS Agreement);
- harmonised, through taking account of international standards and guidelines; and
- subject to appeal on the process.

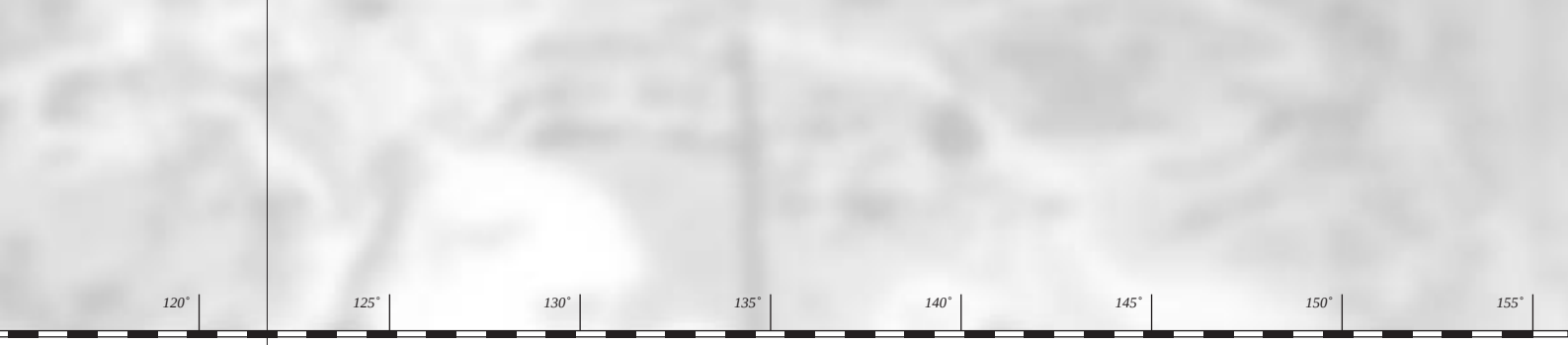
Each year AQIS receives many proposals to import agricultural commodities. These range from items from sources whose pest and disease status is similar to those for which an IRA has previously been conducted, to items where considerable scientific analysis is required to assess the risk. Most proposals fall into the first category and are usually assessed relatively quickly by AQIS, without the need for the formal IRA process described in this Handbook. AQIS is also called on to make minor adjustments to established quarantine conditions. Many of these issues arise as practical questions associated with existing trade and are not of such concern to stakeholders that a formal public comment process is warranted. In general, they would not be dealt with through the process described in this Handbook because they involve no significant new technical issues and require no new substantial risk analysis.

Proposals requiring an IRA — in other words those involving significant variations in established policy — may take some time to resolve. To accommodate the different technical demands associated with situations where significant new analysis is required, the Government decided to handle less complex changes to or reviews of established policy using a routine risk analysis process, while more complex tasks will be handled through a non-routine process. Most changes to or reviews of established policy require only a routine analysis, which will be handled in-house by AQIS, with consultation with scientists and other experts both inside and outside AQIS as required. More complex proposals (non-routine risk analyses) will involve appointment of an expert panel (called a risk analysis panel or RAP) to consider the issues. The panel will consult with scientists and other experts as appropriate.

Both types of analysis will incorporate frequent consultation and communication with stakeholders, including the applicant. The process set out in this Handbook reflects the Government's commitment to ensuring there is opportunity for contribution by all interested parties to quarantine risk analyses.

AQIS maintains a register of known stakeholders. Interested parties wishing to be included in future communications and consultation with respect to a particular proposal or generally, should contact either the Animal or Plant Quarantine Policy Branch of AQIS (see contact details) to ensure they are placed on this register.

Both types of analysis make provision for appeal on the decision-making process.



Purpose of the Handbook

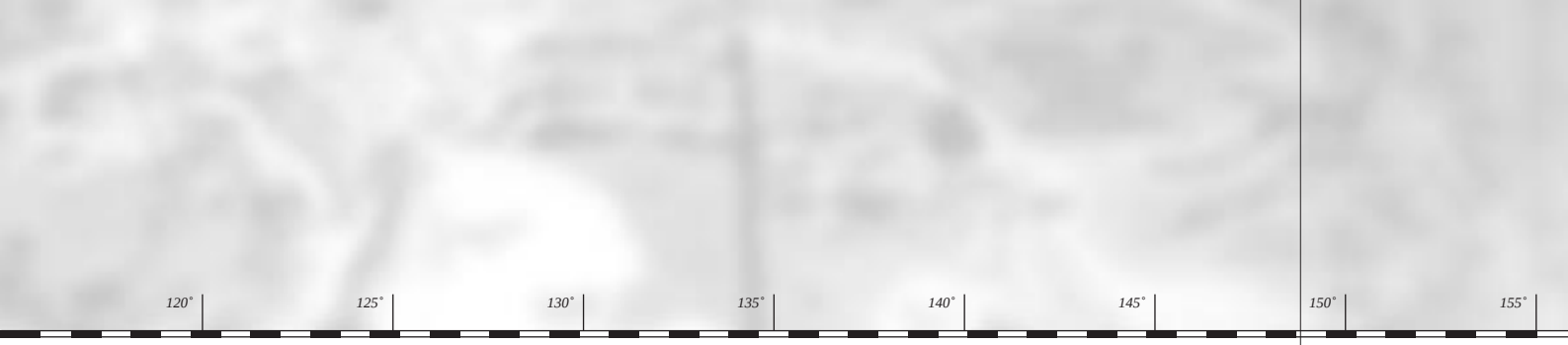
This Handbook sets out for stakeholders and other interested parties the process AQIS will follow in developing and reviewing quarantine policies for importing plants, animals and their products into Australia. The process is designed to ensure that:

- risks of entry, establishment and spread of pests and diseases, and their potential impacts are fully evaluated;
- importation is only permitted when such risks can be managed in a manner consistent with Australia's very conservative approach to acceptance of pest and disease risk; and
- stakeholders are fully informed, are satisfied with the process followed and understand the basis for decisions.

The process does not include procedures used to assess plants for weediness potential, organisms imported as biological control agents or the evaluation of traits conferred on a plant species by genetic manipulation where there are existing import conditions for that species. Information on these assessments is available from the Plant Quarantine Policy Branch of AQIS (see contact information on the inside front cover).

AQIS will use the process outlined in the Handbook when it carries out an IRA. In exceptional circumstances — for example, when there is a significant change in the basis upon which an IRA is being conducted — the Executive Director of AQIS may determine, in consultation with stakeholders, that the IRA process should be varied.

The Handbook, which will be reviewed regularly to ensure it reflects the contemporary approach, also sets out the consultation opportunities and notes the appeal procedures open to stakeholders. In this Handbook the term 'stakeholders' includes the applicant/proponent for a specific proposal and all interested parties.



International Standards

Australia's international rights and obligations have been taken into account in developing the process outlined in this Handbook. These rights and obligations derive principally from the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). Other WTO Agreements, including the Agreement on Technical Barriers to Trade (TBT Agreement), may also be relevant in certain circumstances. Specific international guidelines on risk analysis developed under the International Plant Protection Convention (IPPC) and by the Office International des Epizooties (OIE), the world organisation for animal health, are also relevant.

The process described is consistent with Australian/New Zealand Standard AS/NZS 3931:1998.

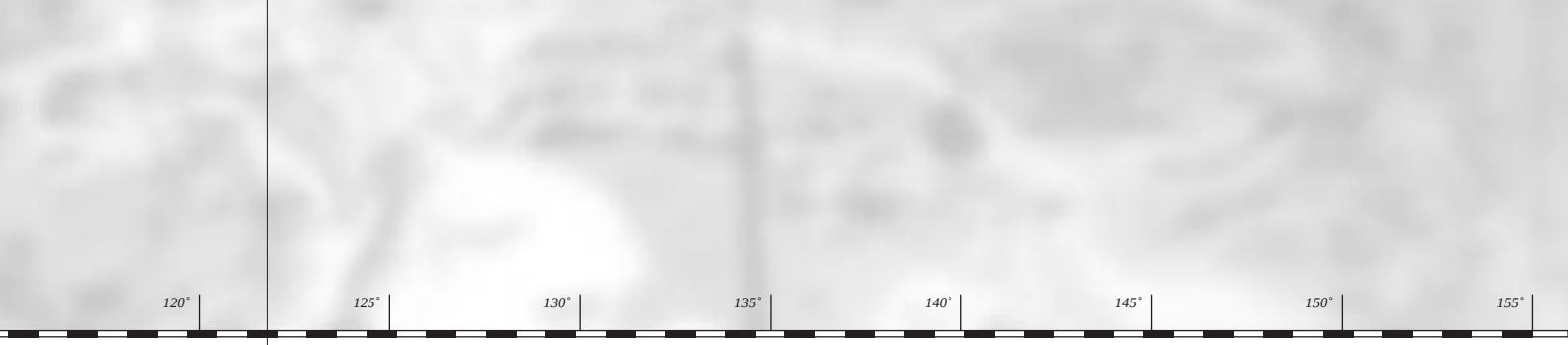
WTO SPS Agreement

The SPS Agreement defines the basic rights and obligations of WTO member countries with regard to the use of sanitary and phytosanitary (SPS) measures, which are measures necessary to protect human, animal or plant life or health, including procedures to test, diagnose, isolate, control or eradicate diseases and pests. SPS measures may directly or indirectly affect international trade and should not be used as a disguised restriction on trade. Member countries have the right to take SPS measures to the extent necessary to protect human, animal, or plant life or health provided these measures are based on scientific principles and are not maintained without sufficient scientific evidence.

The SPS Agreement encourages Members to base their national SPS measures on relevant international standards, guidelines and recommendations. Governments may choose national measures that provide a higher level of protection than relevant international standards, subject to conformity with obligations relating to risk assessment and a consistent approach to risk management.

In assessing risks, WTO Members are required to take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases and pests; existence of disease/pest free areas; relevant ecological and environmental conditions; and quarantine or other treatment.

Annex 1 contains the text of the SPS Agreement.



Office International des Epizooties (OIE)

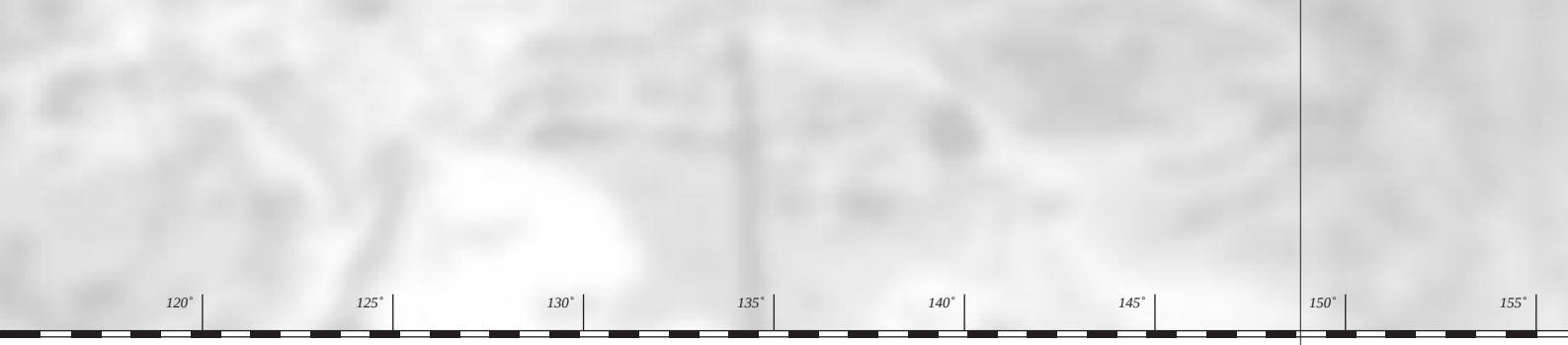
The OIE (the world organisation for animal health, recognised by the WTO SPS Agreement as the body responsible for establishing animal health standards and guidelines for international trade in animals and animal products) has broad guidelines for risk analysis which recognise that the importation of animals and animal products may involve a degree of risk to the importing country. OIE supports risk analysis as providing importing countries with an objective method of assessing risks associated with importation and determining how those risks may be managed. The analysis should be transparent so the exporting country is provided with a clear and documented decision on the conditions imposed or for the refusal for importation.

The OIE International Animal Health 1992 Code chapter on import risk analysis (as redrafted for consideration by the OIE International Committee) is at Annex 2.

International Plant Protection Convention (IPPC)

The International Plant Protection Convention (IPPC) is recognised by the WTO SPS Agreement as the convention under which international standards for phytosanitary measures are developed.

The IPPC Guidelines for Pest Risk Analysis is at Annex 2.



Quarantine Decision-Making

Under the *Quarantine Act 1908* and subordinate Regulations, AQIS, an operating group within the Department of Primary Industries and Energy, regulates animal and plant quarantine, exercising the delegations of the Director of Animal and Plant Quarantine (the Director) who is the Secretary of the Department.

AQIS is responsible for implementing Australia's very conservative approach to pest and disease risk, which reflects the high value of our agricultural industries and Australia's very favourable animal and plant health status as well as the need to protect Australia's natural fauna and flora.

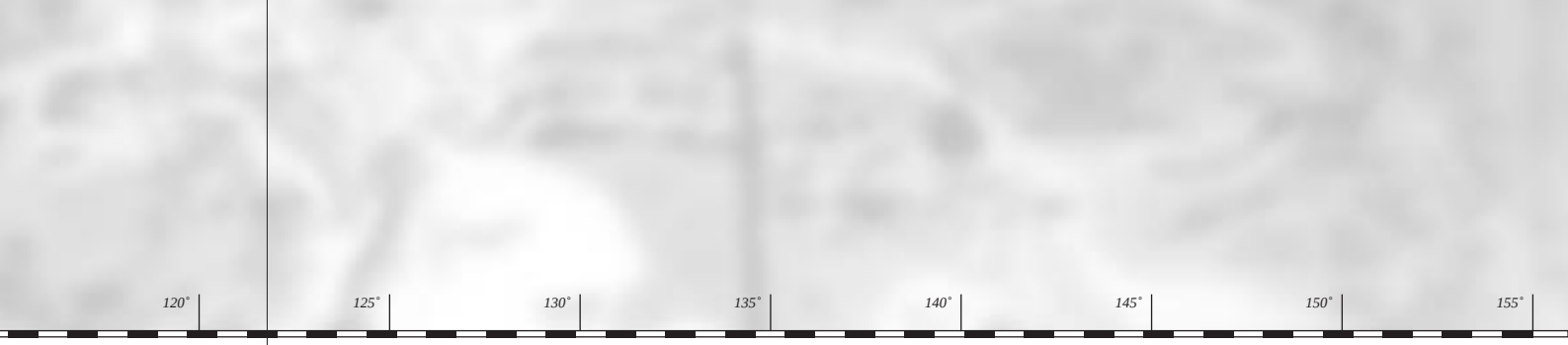
In many instances the quarantine requirements AQIS develops to protect our plant and animal health status against the entry and establishment of unwanted pests and diseases are based on the standards, guidelines and recommendations established by the relevant international organisations.

In certain instances and in conformity with rights under the WTO SPS Agreement, Australia has not adopted such international norms because to do so would result in an unacceptably high level of risk of disease or pest entry and establishment.

Australia does not, however, maintain a zero risk quarantine policy, which would be impracticable since it would imply the exclusion of all import trade and entry of international passengers. Rather, Australia's quarantine policy is based on the concept of the management of risk to an acceptably low level.

The social and economic considerations arising from the potential impact of pests and diseases that could enter and establish in Australia as a result of importation are taken into account, but the potential competitive economic impact of prospective imports on domestic industries is not within the scope of AQIS's import risk analysis. Relevant economic considerations in quarantine risk analysis include the cost of programs required to manage disease and pest outbreaks, the cost to industry of an outbreak and the cost to industry of loss of markets due to an outbreak.

The removal or reduction of quarantine restrictions on imports, when consistent with appropriate risk management, may have the effect of exposing domestic industries to substantially greater import competition and consequent structural adjustment pressure. The Government may in such circumstances seek relevant economic analysis and consider options available for an appropriate response. Such considerations may occur in parallel with, but will in no way influence, the import risk analysis performed in accordance with the procedures described in this Handbook.



The IRA Process

Overview

The flowchart on the inside back cover shows the four components of the IRA process approved by the Government for use by AQIS. The phases are:

- initiation;
- risk analysis;
- determination; and
- policy application.

Initiation is triggered by AQIS receiving an importation proposal, or by AQIS itself. This stage includes consideration of the priority of the proposal and whether the proposal warrants an IRA, whether routine or non-routine. AQIS may make minor extensions or variations to existing import conditions without the need for the formal IRA process. Proposals involving significant variations to established policy would necessitate the IRA process (via either a routine or non-routine pathway) being followed.

AQIS notifies stakeholders when a proposal necessitating an IRA has been received and gives them the opportunity to comment on AQIS's plan for handling the IRA.

A public file, containing the non-confidential stakeholder comment and technical documentation, is established at the commencement of each IRA. Public files are held at AQIS headquarters in Canberra[3] and are available to stakeholders during business hours for perusal and copying. Contact information for making appointments to gain access to a public file is listed under the relevant Quarantine Policy Branch on the inside front cover.

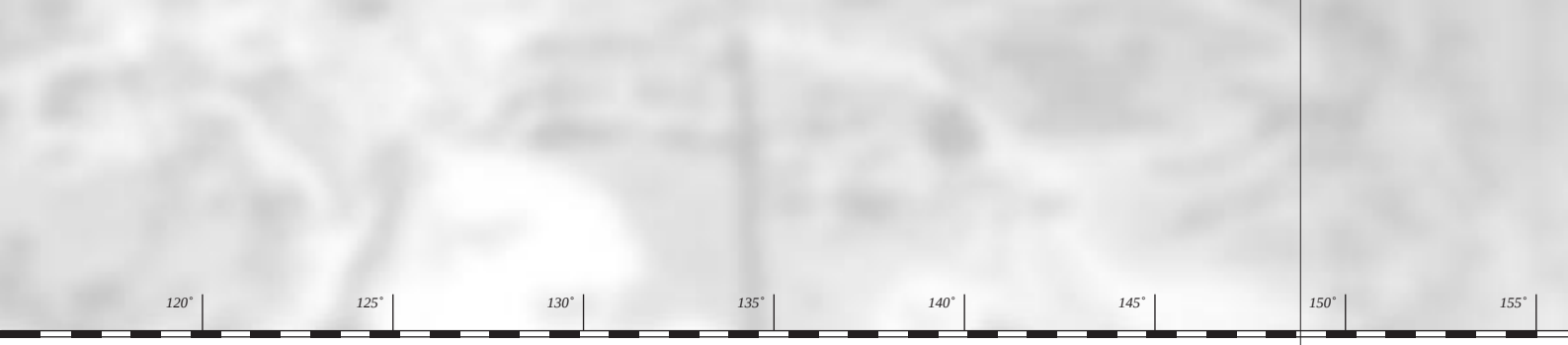
Subject to the *Freedom of Information Act 1982* and the *Privacy Act 1988*, all submissions received with respect to an import proposal will be publicly available and may be listed or referred to in papers or reports prepared on the proposal. If a request for anonymity does not accompany a submission, the respondent will be taken to have consented to the disclosure of his or her identity for the purposes of the Privacy Act. The contents of a submission will not be treated as confidential unless they are marked 'confidential' and they are capable of being classified as such in accordance with the Freedom of Information Act.

Risk analysis is the set of steps involving the conduct of an IRA by either a routine or non-routine pathway. A routine IRA is undertaken in-house by an AQIS team (with stakeholder consultation) while a non-routine IRA involves a RAP, which would typically include non-AQIS members and may utilise technical working groups (TWGs). A non-routine IRA also involves consultation with stakeholders on its conduct, including support for such matters as the scope, the issues to be resolved, and the composition of a RAP. This stage incorporates appeal provisions on a non-routine IRA. It concludes, for both types of IRA, with a recommendation to the Executive Director of AQIS.

The third component involves a determination on the matter by the Executive Director of AQIS. There is provision for stakeholder appeal on the grounds that AQIS has failed to follow due process.

Subject to the outcome of any appeal, the import policy is applied.

3 Edmund Barton Building, Blackall Street Barton ACT 2600



The procedures undertaken at each step of the IRA process as set out in the Government's response are described below. Paragraph numbers correlate with those used in the flow chart on the inside back cover.

Initiation

Current import policies for animals, plants and their products are based on an assessment of risks conducted at some time in the past and updated from time to time.

AQIS has a responsibility to keep established import conditions current and to modify them appropriately. There will be a need to review established import conditions, for example when new information on a pest or disease becomes available. A review may be prompted by interested parties presenting information that *prima facie* justifies further risk analysis or AQIS may decide to initiate an analysis on the basis of information from its own sources. AQIS may make minor changes as a matter of course but will advise stakeholders of a significant review of import conditions.

When risks change significantly and rapidly, AQIS may need to respond as a matter of urgency by applying protective measures on a precautionary basis, and there may not be an opportunity to consult with stakeholders before a decision is made. An appropriate risk analysis will be initiated as soon as practicable and every effort will be made to consult as soon as possible to ensure stakeholders are fully informed of the reasons for the action. The *Quarantine Act 1908* provides for emergency measures to be taken and the WTO SPS Agreement allows for the application of such measures without prior notification to other WTO members.

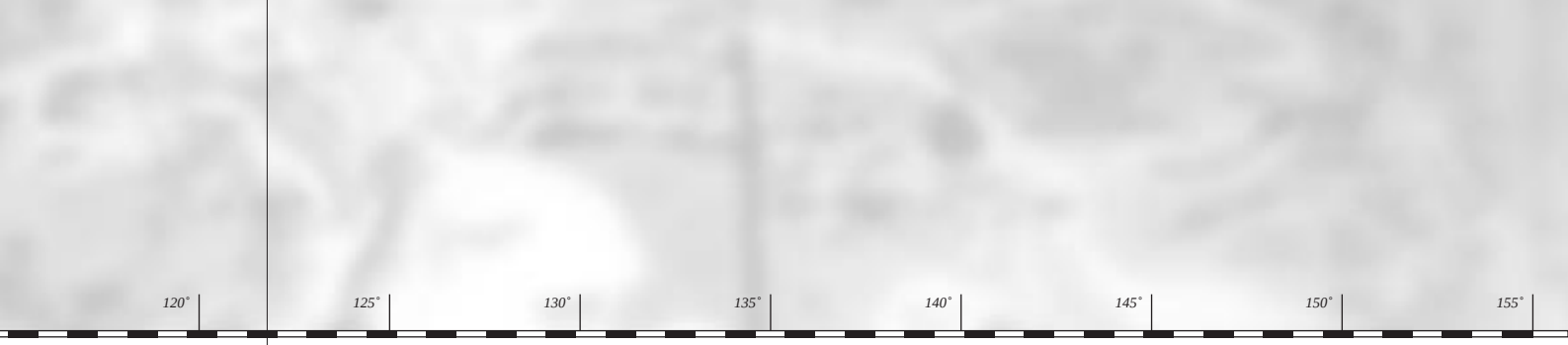
1.1 Import proposal lodged with AQIS

A proponent may request the development or review of an import policy either by asking AQIS in writing to consider a proposal to import a plant, animal, a plant/animal product, or goods associated with such commodities, or by applying to AQIS for an import permit (see Annex 3). Proposals may come from individuals, companies, industry organisations, task forces, independent reviews, State and Federal government departments, and overseas governments and their agencies.

For AQIS to be able to begin the IRA process, the proponent of an import proposal must provide AQIS with sufficient information to enable an adequate analysis of risk.

1.2 Proposal acknowledged

For proposals necessitating an IRA process, AQIS registers the proposal, acknowledges receipt and advises known stakeholders as listed in the AQIS stakeholder register. AQIS also announces receipt of the proposal in the AQIS Bulletin and on the AQIS Internet homepage. Other interested parties may indicate at this stage that they wish to be added to the list of registered stakeholders with respect to a particular application or generally.



Advice to stakeholders normally includes information on the commodity (animal or plant species) or product type, its country of origin and, subject to legal restraints with regard to any commercial-in-confidence material, its intended use.

At this stage, if they wish, stakeholders may offer information and comment on the priority they consider should be accorded by AQIS to the proposal.

1.3 Priority considered (where required)

AQIS has a responsibility under Commonwealth administrative law as well as to stakeholders and from the perspective of bilateral/multilateral relationships to consider all proposals in a timely manner, within the constraints of available resources. AQIS will prioritise proposals taking into account factors such as the availability of data, the order of receipt of proposals, the breadth and nature of interest in the establishment of new or revised conditions, the need to consider access by a particular date (for example, for the Sydney 2000 Olympic Games) as well as stakeholder comment.

The factors taken into account by AQIS in prioritising a particular proposal will be identified in a statement placed on the public file for that proposal. AQIS risk analysis resources will be assigned to work through the priority list, beginning with the highest priority analyses.

The priority assigned by AQIS to the conduct of a risk analysis on the proposal is not subject to appeal.

1.4 Type of risk analysis determined by AQIS program specialists

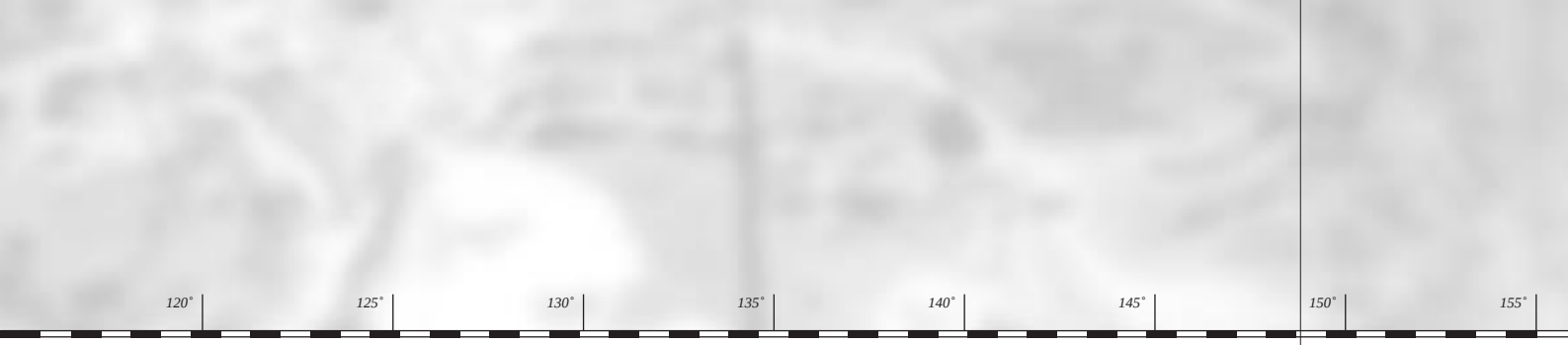
AQIS will evaluate each proposal to determine whether a routine or a non-routine analysis is warranted and circulate its evaluation to stakeholders, requesting comment within 30 days.

The routine analysis process will typically be followed when the analysis is technically less complex or the proposal appears *prima facie* not to require assessment of significantly greater or different risks than those AQIS has previously examined. In a complementary way, non-routine analyses will be required where there are potentially significant quarantine risks to be evaluated that have not previously been studied by AQIS, and where the analysis is likely to be large and technically complex.

1.5 Proposed IRA approach determined by Executive Director AQIS, and stakeholders advised

The relevant policy area of AQIS considers comments received from stakeholders on the approach and makes a recommendation to the Executive Director of AQIS for determination.

In the event of significant disagreement by stakeholders with the AQIS proposal on the approach, AQIS may consult further, including arranging a meeting or meetings to provide an opportunity for stakeholders to discuss issues raised.



When the Executive Director of AQIS is satisfied that all relevant issues have been considered, he or she approves initiation of the IRA process, via either a routine or non-routine approach.

AQIS advises stakeholders of the Executive Director's determination.

Import Risk Analysis

Routine IRA pathway

2.1 Risk analysis conducted

AQIS forms an in-house team of scientists, combining expertise in quarantine risk analysis and in the science relevant to the import proposal under consideration. The team conducts the routine IRA using procedures based on international standards. During this process, AQIS would routinely seek input from, and consult with, stakeholders and technical experts as appropriate to that analysis.

Stakeholders are informed of any significant variation to the process once it is under way.

Procedures recommended by the IPPC and OIE for conducting a risk analysis are detailed in Annex 2. In accordance with the SPS Agreement, in conducting risk analyses AQIS will take into account risk assessment procedures developed by these international organisations.

2.2 Draft IRA paper with recommendations published and comment invited on technical issues

AQIS circulates to stakeholders, for comment within 60 days, the draft IRA paper covering technical issues on disease and pest risk, risk management options and a preliminary view on which option would achieve Australia's appropriate level of protection. AQIS also announces the release of the paper in the *AQIS Bulletin*, on the AQIS Internet homepage and, in accordance with Australia's obligations as a Member, to the WTO to provide other countries with the opportunity to comment.

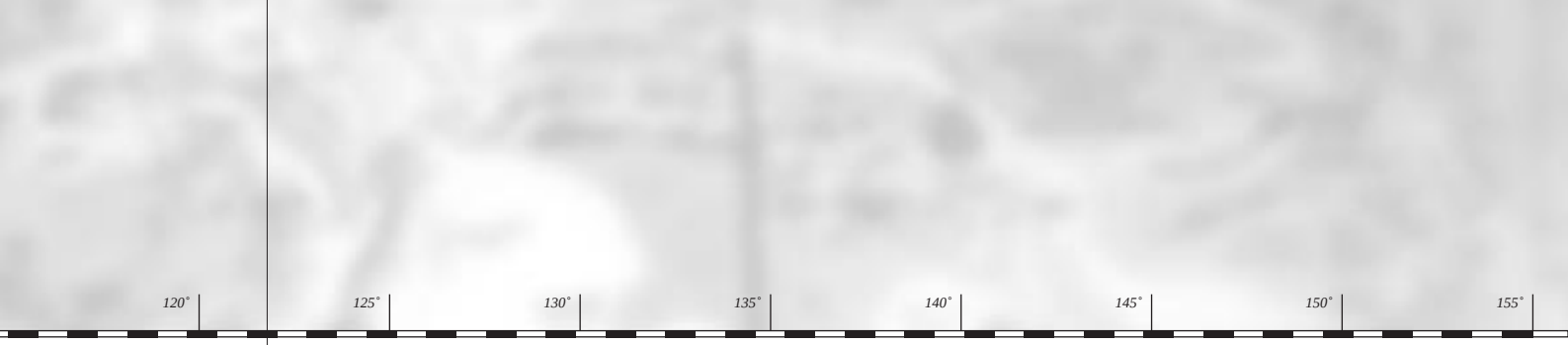
The Routine process follows the same path as the non-routine IRA process from step 4.1 of the flow chart on the inside back cover.

Non-routine IRA pathway

3.1 After consultation with stakeholders: issues, timing, risk analysis panel determined

AQIS circulates to stakeholders information addressing the scope of the IRA with regard to the commodity under assessment, a preliminary timetable and a proposed RAP membership. Stakeholders have 30 days to submit comment on these proposals.

A RAP will generally comprise three to five members, some with experience and expertise in quarantine risk analysis, and others with scientific or technical expertise in plant and animal diseases and pests relevant to the import proposal under consideration. The Chair of the panel will be a member of the relevant policy area of AQIS with experience in quarantine risk analysis,



awareness of Australia's international rights and obligations under the SPS Agreement, and an appreciation of Australia's appropriate level of protection.

Policy areas of AQIS maintain a register of individuals with expertise in these areas and any proposal on RAP membership would be on the basis of this expertise. RAP members may be drawn from AQIS, other government agencies (Federal and State), industry, scientific organisations, private consultancy firms or the general public.

Stakeholders may be asked to nominate technical experts who could be approached to participate in any TWGs established by the RAP.

Following consideration of stakeholder comments, the relevant policy area of AQIS submits to the Executive Director recommendations on the scope, timetable and RAP membership. When satisfied all processes have been completed, the Executive Director makes a determination and stakeholders are informed. Where feasible, electronic means of communication will be used.

Stakeholders are informed of any significant variation to the process once it is under way.

3.2 Appeal to Director of Animal and Plant Quarantine

Stakeholders may appeal the Executive Director's determination in relation to scope, timetable, RAP membership and approach, within 15 days from the date on which advice is sent to stakeholders. Stakeholders requiring additional time should notify AQIS.

Appeals should be sent to the Director of Animal and Plant Quarantine, who is the Secretary of the Department of Primary Industries and Energy. The address is:

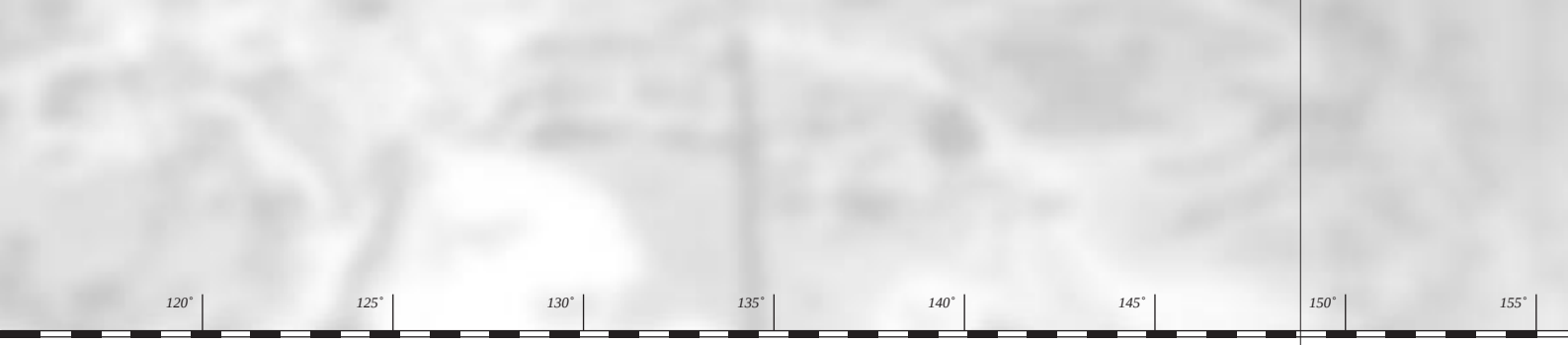
The Secretary
Department of Primary Industries and Energy
GPO Box 858
CANBERRA ACT 2601
Australia

Information on appeals is made public.

If in the course of RAP proceedings a RAP member ceases to be available, or for another reason the Executive Director believes it is necessary to vary the membership of the panel, the Executive Director may decide, in consultation with stakeholders, to make such changes as are appropriate to ensure that the work of the RAP can be satisfactorily completed. In this event, stakeholders are advised at the next consultation step.

3.3 Appeal determined by Director of Animal and Plant Quarantine and stakeholders advised

The Director of Animal and Plant Quarantine would normally consider an appeal on the process and advise stakeholders of the determination within 45 days of receipt of the appeal.



3.4 Issues paper published and comment invited

The RAP members meet to agree on the work program and to decide what, if any, TWGs are necessary to work on specific aspects of the IRA. The RAP would decide on the terms of reference and membership for any TWGs. To encourage coherence and focus on the relevant issues, and effective communication with the RAP, generally TWGs would be chaired by a member of the RAP.

The RAP prepares an issues paper, canvassing:

- the expected scope of the analysis;
- the main pest and disease risk issues;
- the need for and scope of any other assessments or investigations (for example, the economic or environmental impact of disease or pest entry);
- the prospective timetable for the IRA; and
- other matters it may need to consider.

Issues papers will vary significantly in size and content depending on the type of commodity to be imported, the complexity of the technical issues and the availability of data. An issues paper may be a brief document providing an outline of precedents for similar proposals, a list of the pest or disease issues that may be considered during the risk analysis and a brief reflection on the need for other assessments.

A panel considering a major risk analysis may decide to provide, in addition to the above, substantial information including previously compiled technical information on identified pests and diseases of concern (such as consultants' reports), and literature references. While the detail in issues papers varies, issues papers do not include estimates of quarantine risk nor risk management options.

The issues paper is distributed to stakeholders, for comment within 60 days.

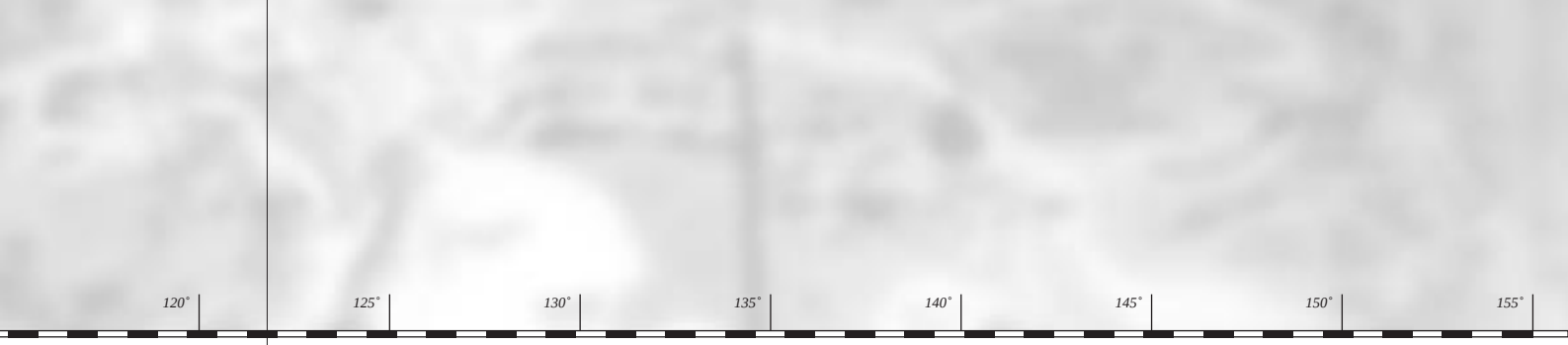
3.5 Risk analysis conducted by the RAP

The RAP, assisted by TWGs as necessary, conducts the risk analysis, taking into account comment received on the issues paper and consulting with stakeholders as appropriate.

Procedures recommended by the IPPC and OIE for conducting a risk analysis are detailed in Annex 2. In accordance with the SPS Agreement, in conducting risk analyses AQIS will take into account risk assessment procedures developed by these international organisations.

3.6 Draft IRA paper with recommendations published and comment invited on technical issues

At the completion of the RAP's deliberations, AQIS circulates to stakeholders, for comment within 60 days, a draft IRA paper covering technical issues related to disease and pest risk, risk management options and a preliminary view on which option would achieve Australia's appropriate level of protection. AQIS also announces the release of the paper in the *AQIS Bulletin*, on the AQIS Internet homepage and to the WTO.



Determination (routine and non-routine processes)

4.1 Comment reviewed and risk analysis recommendations finalised

After considering all technical issues, including comment received, the AQIS risk analysis team (for routine IRAs) or RAP (for non-routine IRAs) finalises the IRA recommendations.

In exceptional circumstances, depending on the complexity of the proposal and the range of comment received (for example, new or important information coming to light), there may be a need for more than one round of consultation. In this case a revised draft is circulated for further comment before finalisation.

4.2 Risk analysis recommendations submitted to Executive Director of AQIS

The IRA recommendations are submitted to the Executive Director for consideration.

The AQIS risk analysis team or the RAP is expected to present its recommendations on the basis of consensus. If consensus is not achievable, differences of view will be clearly identified.

4.3 Import proposal determined by Executive Director of AQIS

The Executive Director considers the recommendations of the AQIS risk analysis team or the RAP, and makes a determination. The Executive Director may seek such further advice from the AQIS risk analysis team or the RAP as he or she believes necessary to assist in making a determination.

If the RAP does not provide consensus recommendations, the Executive Director will make a determination or decide on other action as appropriate.

The Executive Director must be satisfied that the IRA has been conducted in accordance with the agreed process, and that the determination on the proposal would maintain Australia's appropriate level of protection and otherwise accord with Australia's international rights and obligations under the SPS Agreement.

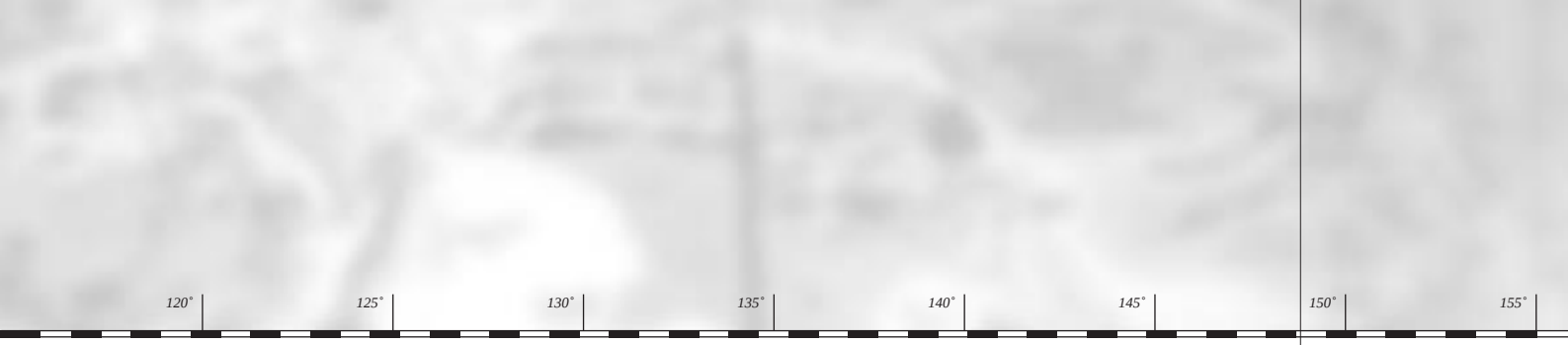
4.4 Determination and final IRA paper published, and applicant and stakeholders advised

The Executive Director's determination and the final IRA paper are published. AQIS advises the applicant and other stakeholders, and arranges notification in the *AQIS Bulletin* and on the AQIS Internet homepage.

If there are no appeals within 30 days from the date on which advice is sent to stakeholders, the policy is adopted.

4.5 Appeal to the Director of Animal and Plant Quarantine on the process

Any stakeholder of the opinion that the process outlined in this Handbook has not been properly followed, including that the risk



analysis failed to consider a significant body of relevant scientific or technical information, may appeal to the Director.

An appeal at this stage may only be on IRA processes that were not within the purview of the earlier appeal provision.

Information on appeals is made public.

4.6 Appeal considered by Import Risk Analysis Appeal Panel

An Import Risk Analysis Appeal Panel (IRAAP) considers the appeal and makes its decision within 45 days. The IRAAP routinely comprises the Chair of the Quarantine and Exports Advisory Council (QEAC) (Chair), the Director of Animal and Plant Quarantine, the Chief Plant Protection Officer (CPPO) or Chief Veterinary Officer (CVO) as appropriate, and one other member of QEAC.

The QEAC Chair, in consultation with the Director, may nominate alternatives to the CPPO/CVO to participate as a member of an appeal panel where the CPPO/CVO has been directly involved in the management of a particular IRA process.

Dismissal of an appeal by an IRAAP requires majority support.

4.7 Appellant/applicant advised of outcome of appeal

If the appeal is upheld, the IRAAP refers its conclusions to the AQIS team or the RAP for rectification of the deficiency in the process.

If the appeal is rejected, the policy is adopted.

AQIS advises the appellant and all stakeholders of the decision by the appeal panel.

Application of the Import Risk Analysis Policy

Once the IRA is complete, application of the policy can proceed. AQIS circulates any new or revised import conditions and notifies the WTO.

AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES

Members,

Reaffirming that no Member should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health, subject to the requirement that these measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members where the same conditions prevail or a disguised restriction on international trade;

Desiring to improve the human health, animal health and phytosanitary situation in all Members;

Noting that sanitary and phytosanitary measures are often applied on the basis of bilateral agreements or protocols;

Desiring the establishment of a multilateral framework of rules and disciplines to guide the development, adoption and enforcement of sanitary and phytosanitary measures in order to minimize their negative effects on trade;

Recognizing the important contribution that international standards, guidelines and recommendations can make in this regard;

Desiring to further the use of harmonized sanitary and phytosanitary measures between Members, on the basis of international standards, guidelines and recommendations developed by the relevant international organizations, including the Codex Alimentarius Commission, the International Office of Epizootics, and the relevant international and regional organizations operating within the framework of the International Plant Protection Convention, without requiring Members to change their appropriate level of protection of human, animal or plant life or health;

Recognizing that developing country Members may encounter special difficulties in complying with the sanitary or phytosanitary measures of importing Members, and as a consequence in access to markets, and also in the formulation and application of sanitary or phytosanitary measures in their own territories, and desiring to assist them in their endeavours in this regard;

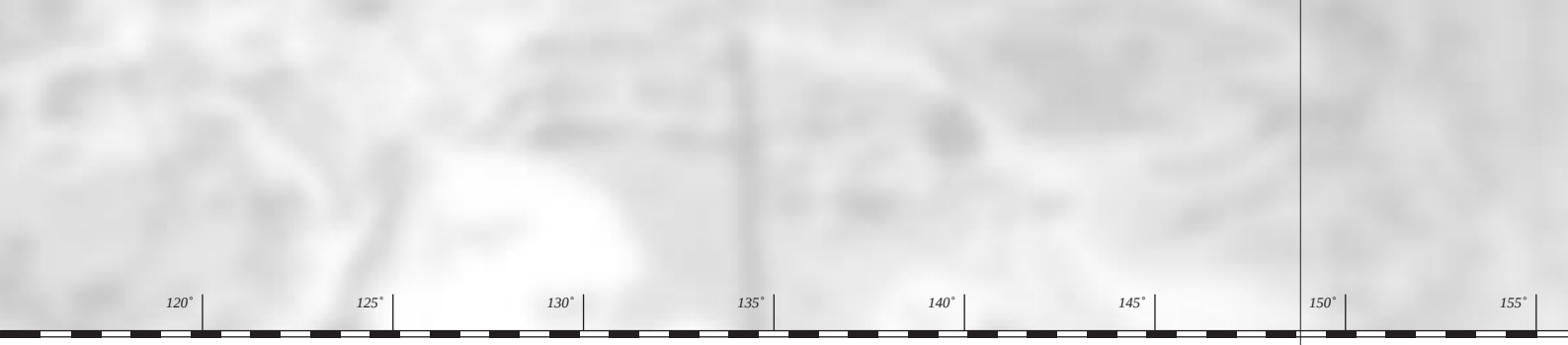
Desiring therefore to elaborate rules for the application of the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b)[1];

Hereby agree as follows:

Article 1
General Provisions

1. This Agreement applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade. Such measures shall be developed and applied in accordance with the provisions of this Agreement.
2. For the purposes of this Agreement, the definitions provided in Annex A shall apply.
3. The annexes are an integral part of this Agreement.

[1] In this Agreement, reference to Article XX(b) includes also the chapeau of that Article.



4. Nothing in this Agreement shall affect the rights of Members under the Agreement on Technical Barriers to Trade with respect to measures not within the scope of this Agreement.

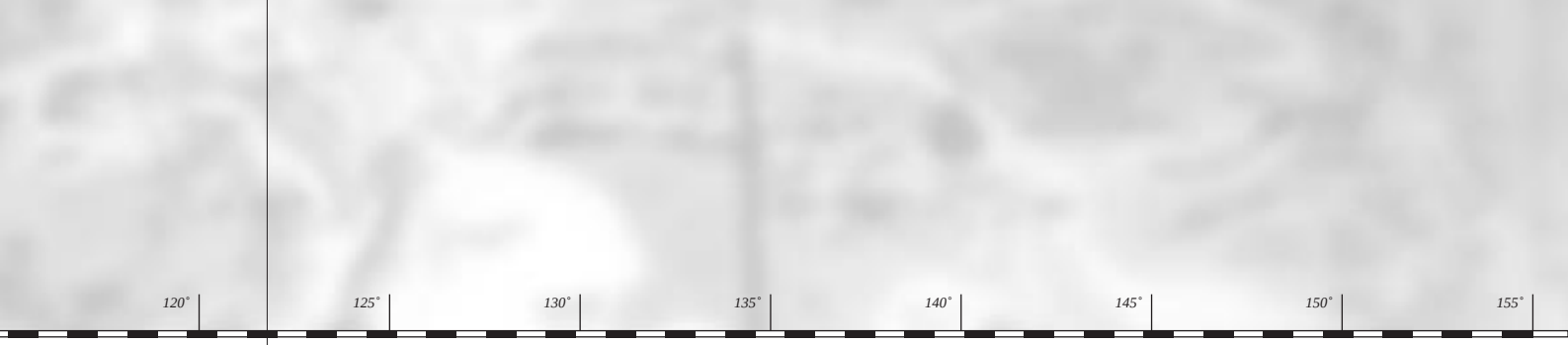
Article 2
Basic Rights and Obligations

1. Members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement.
2. Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.
3. Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade.
4. Sanitary or phytosanitary measures which conform to the relevant provisions of this Agreement shall be presumed to be in accordance with the obligations of the Members under the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b).

Article 3
Harmonization

1. To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement, and in particular in paragraph 3.
2. Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994.
3. Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5.[2] Notwithstanding the above, all measures which result in

[2] For the purposes of paragraph 3 of Article 3, there is a scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of sanitary or phytosanitary protection.



a level of sanitary or phytosanitary protection different from that which would be achieved by measures based on international standards, guidelines or recommendations shall not be inconsistent with any other provision of this Agreement.

4. Members shall play a full part, within the limits of their resources, in the relevant international organizations and their subsidiary bodies, in particular the Codex Alimentarius Commission, the International Office of Epizootics, and the international and regional organizations operating within the framework of the International Plant Protection Convention, to promote within these organizations the development and periodic review of standards, guidelines and recommendations with respect to all aspects of sanitary and phytosanitary measures.

5. The Committee on Sanitary and Phytosanitary Measures provided for in paragraphs 1 and 4 of Article 12 (referred to in this Agreement as the "Committee") shall develop a procedure to monitor the process of international harmonization and coordinate efforts in this regard with the relevant international organizations.

Article 4
Equivalence

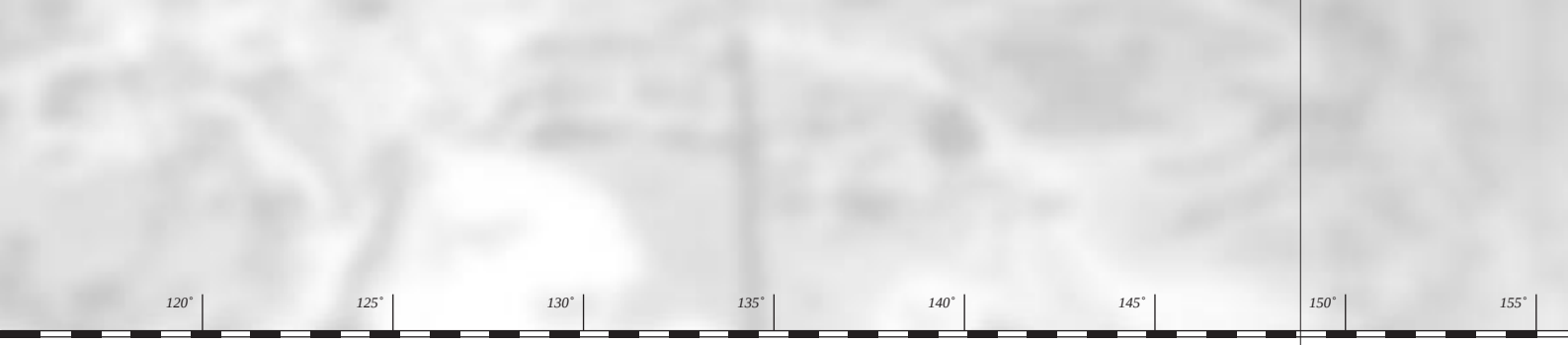
1. Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.

2. Members shall, upon request, enter into consultations with the aim of achieving bilateral and multilateral agreements on recognition of the equivalence of specified sanitary or phytosanitary measures.

Article 5
Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection

1. Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.

2. In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment.



3. In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Members shall take into account as relevant economic factors: 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; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.

4. Members should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimizing negative trade effects.

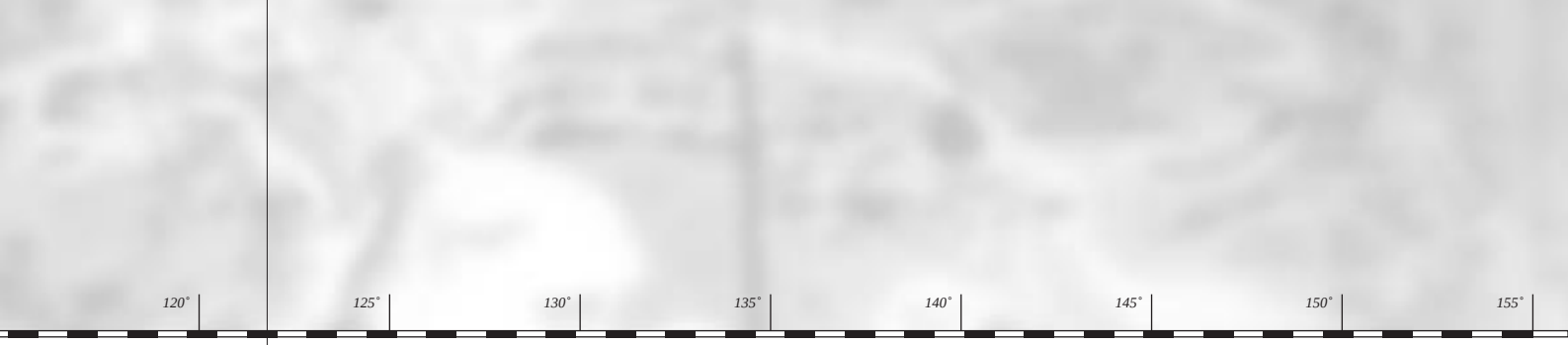
5. With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade. Members shall cooperate in the Committee, in accordance with paragraphs 1, 2 and 3 of Article 12, to develop guidelines to further the practical implementation of this provision. In developing the guidelines, the Committee shall take into account all relevant factors, including the exceptional character of human health risks to which people voluntarily expose themselves.

6. Without prejudice to paragraph 2 of Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility.[3]

7. In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.

8. When a Member has reason to believe that a specific sanitary or phytosanitary measure introduced or maintained by another Member is constraining, or has the potential to constrain, its exports and the measure is not based on the relevant international standards, guidelines or recommendations, or such standards, guidelines or recommendations do not exist, an explanation of the reasons for such sanitary or phytosanitary measure may be requested and shall be provided by the Member maintaining the measure.

3 For purposes of paragraph of Article 5, a measure is not more trade-restrictive than required unless there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of sanitary or phytosaniatary protection and is significantly less restrictive to trade.



Article 6
Adaptation to Regional Conditions, Including Pest- or Disease-Free Areas and Areas of Low Pest or Disease Prevalence

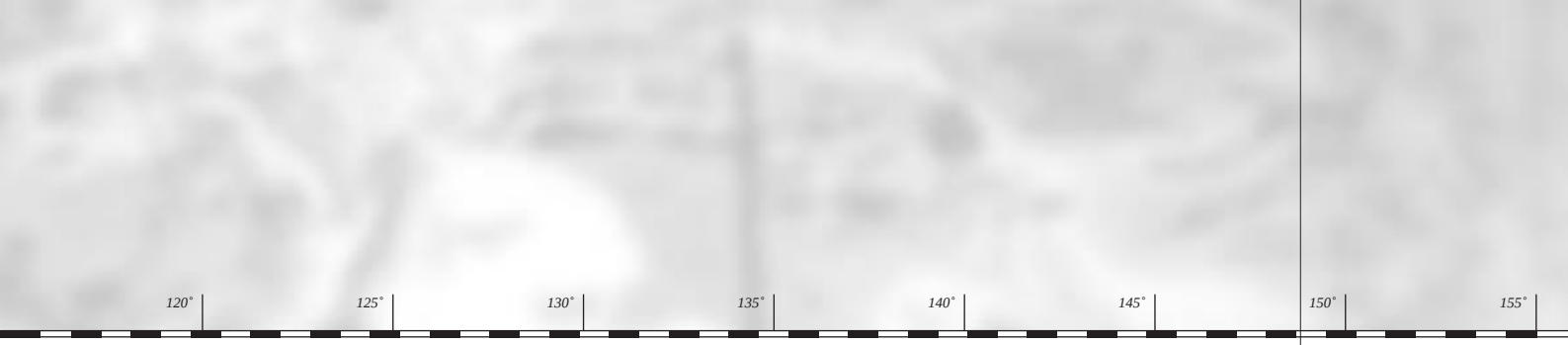
1. Members shall ensure that their sanitary or phytosanitary measures are adapted to the sanitary or phytosanitary characteristics of the area — whether all of a country, part of a country, or all or parts of several countries — from which the product originated and to which the product is destined. In assessing the sanitary or phytosanitary characteristics of a region, Members shall take into account, *inter alia*, the level of prevalence of specific diseases or pests, the existence of eradication or control programmes, and appropriate criteria or guidelines which may be developed by the relevant international organizations.
2. Members shall, in particular, recognize the concepts of pest- or disease-free areas and areas of low pest or disease prevalence. Determination of such areas shall be based on factors such as geography, ecosystems, epidemiological surveillance, and the effectiveness of sanitary or phytosanitary controls.
3. Exporting Members claiming that areas within their territories are pest- or disease-free areas or areas of low pest or disease prevalence shall provide the necessary evidence thereof in order to objectively demonstrate to the importing Member that such areas are, and are likely to remain, pest-or disease-free areas or areas of low pest or disease prevalence, respectively. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.

Article 7
Transparency

Members shall notify changes in their sanitary or phytosanitary measures and shall provide information on their sanitary or phytosanitary measures in accordance with the provisions of Annex B.

Article 8
Control, Inspection and Approval Procedures

Members shall observe the provisions of Annex C in the operation of control, inspection and approval procedures, including national systems for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs, and otherwise ensure that their procedures are not inconsistent with the provisions of this Agreement.



Article 9
Technical Assistance

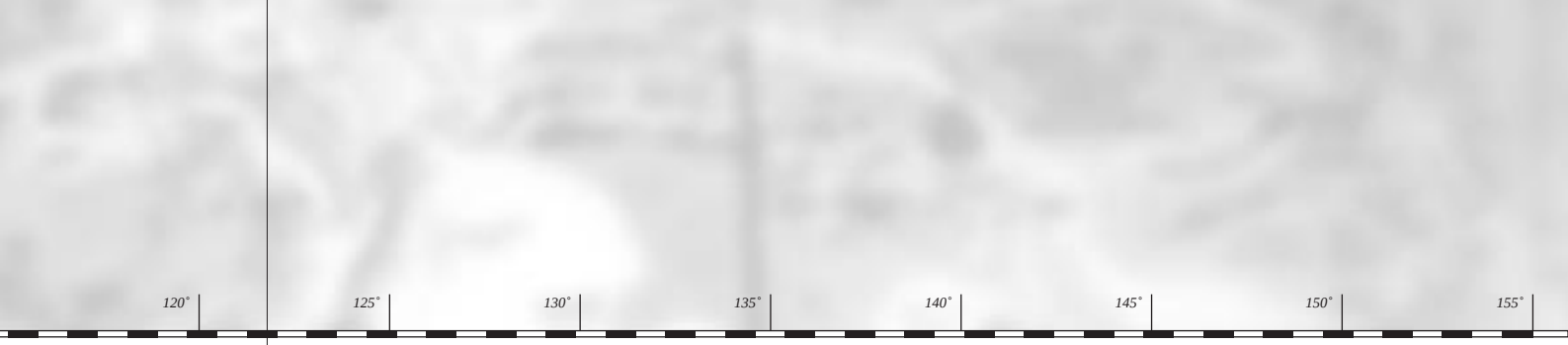
1. Members agree to facilitate the provision of technical assistance to other Members, especially developing country Members, either bilaterally or through the appropriate international organizations. Such assistance may be, *inter alia*, in the areas of processing technologies, research and infrastructure, including in the establishment of national regulatory bodies, and may take the form of advice, credits, donations and grants, including for the purpose of seeking technical expertise, training and equipment to allow such countries to adjust to, and comply with, sanitary or phytosanitary measures necessary to achieve the appropriate level of sanitary or phytosanitary protection in their export markets.
2. Where substantial investments are required in order for an exporting developing country Member to fulfil the sanitary or phytosanitary requirements of an importing Member, the latter shall consider providing such technical assistance as will permit the developing country Member to maintain and expand its market access opportunities for the product involved.

Article 10
Special and Differential Treatment

1. In the preparation and application of sanitary or phytosanitary measures, Members shall take account of the special needs of developing country Members, and in particular of the least-developed country Members.
2. Where the appropriate level of sanitary or phytosanitary protection allows scope for the phased introduction of new sanitary or phytosanitary measures, longer time-frames for compliance should be accorded on products of interest to developing country Members so as to maintain opportunities for their exports.
3. With a view to ensuring that developing country Members are able to comply with the provisions of this Agreement, the Committee is enabled to grant to such countries, upon request, specified, time-limited exceptions in whole or in part from obligations under this Agreement, taking into account their financial, trade and development needs.
4. Members should encourage and facilitate the active participation of developing country Members in the relevant international organizations.

Article 11
Consultations and Dispute Settlement

1. The provisions of Articles XXII and XXIII of GATT 1994 as elaborated and applied by the Dispute Settlement Understanding shall apply to consultations and the settlement of disputes under this Agreement, except as otherwise specifically provided herein.



2. In a dispute under this Agreement involving scientific or technical issues, a panel should seek advice from experts chosen by the panel in consultation with the parties to the dispute. To this end, the panel may, when it deems it appropriate, establish an advisory technical experts group, or consult the relevant international organizations, at the request of either party to the dispute or on its own initiative.

3. Nothing in this Agreement shall impair the rights of Members under other international agreements, including the right to resort to the good offices or dispute settlement mechanisms of other international organizations or established under any international agreement.

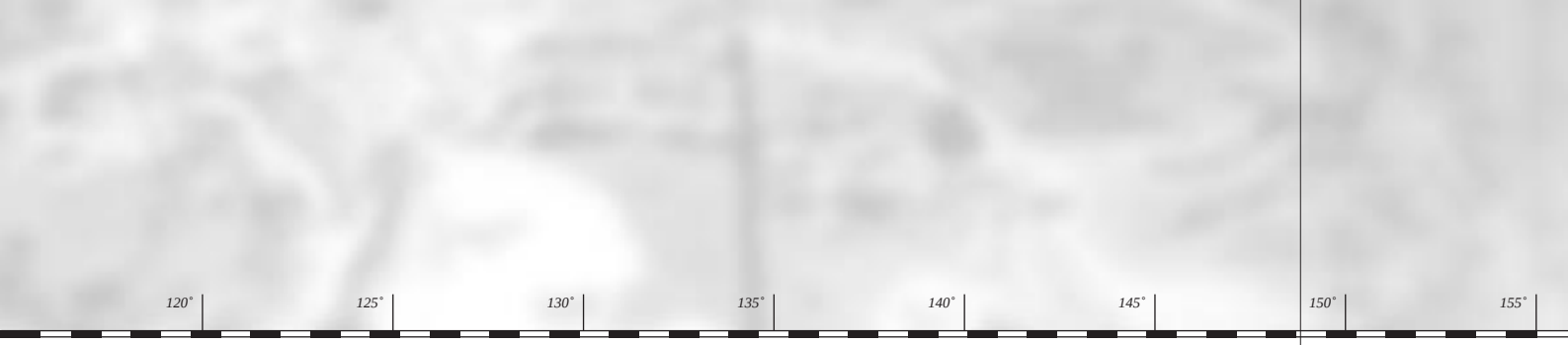
Article 12
Administration

1. A Committee on Sanitary and Phytosanitary Measures is hereby established to provide a regular forum for consultations. It shall carry out the functions necessary to implement the provisions of this Agreement and the furtherance of its objectives, in particular with respect to harmonization. The Committee shall reach its decisions by consensus.

2. The Committee shall encourage and facilitate ad hoc consultations or negotiations among Members on specific sanitary or phytosanitary issues. The Committee shall encourage the use of international standards, guidelines or recommendations by all Members and, in this regard, shall sponsor technical consultation and study with the objective of increasing coordination and integration between international and national systems and approaches for approving the use of food additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs.

3. The Committee shall maintain close contact with the relevant international organizations in the field of sanitary and phytosanitary protection, especially with the Codex Alimentarius Commission, the International Office of Epizootics, and the Secretariat of the International Plant Protection Convention, with the objective of securing the best available scientific and technical advice for the administration of this Agreement and in order to ensure that unnecessary duplication of effort is avoided.

4. The Committee shall develop a procedure to monitor the process of international harmonization and the use of international standards, guidelines or recommendations. For this purpose, the Committee should, in conjunction with the relevant international organizations, establish a list of international standards, guidelines or recommendations relating to sanitary or phytosanitary measures which the Committee determines to have a major trade impact. The list should include an indication by Members of those international standards, guidelines or recommendations which they apply as conditions for import or on the basis of which imported products conforming to these standards can enjoy access to their markets. For those cases in which a Member does not apply an international standard, guideline or recommendation as a condition for import, the Member should provide an indication of the reason therefor, and, in particular, whether it considers that the standard is



not stringent enough to provide the appropriate level of sanitary or phytosanitary protection. If a Member revises its position, following its indication of the use of a standard, guideline or recommendation as a condition for import, it should provide an explanation for its change and so inform the Secretariat as well as the relevant international organizations, unless such notification and explanation is given according to the procedures of Annex B.

5. In order to avoid unnecessary duplication, the Committee may decide, as appropriate, to use the information generated by the procedures, particularly for notification, which are in operation in the relevant international organizations.

6. The Committee may, on the basis of an initiative from one of the Members, through appropriate channels invite the relevant international organizations or their subsidiary bodies to examine specific matters with respect to a particular standard, guideline or recommendation, including the basis of explanations for non-use given according to paragraph 4.

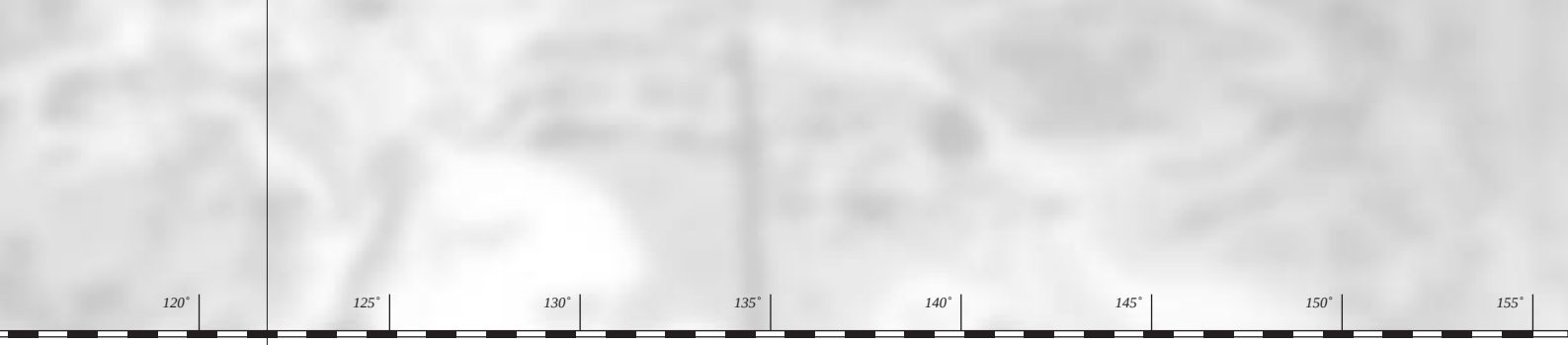
7. The Committee shall review the operation and implementation of this Agreement three years after the date of entry into force of the WTO Agreement, and thereafter as the need arises. Where appropriate, the Committee may submit to the Council for Trade in Goods proposals to amend the text of this Agreement having regard, *inter alia*, to the experience gained in its implementation.

Article 13
Implementation

Members are fully responsible under this Agreement for the observance of all obligations set forth herein. Members shall formulate and implement positive measures and mechanisms in support of the observance of the provisions of this Agreement by other than central government bodies. Members shall take such reasonable measures as may be available to them to ensure that non-governmental entities within their territories, as well as regional bodies in which relevant entities within their territories are members, comply with the relevant provisions of this Agreement. In addition, Members shall not take measures which have the effect of, directly or indirectly, requiring or encouraging such regional or non-governmental entities, or local governmental bodies, to act in a manner inconsistent with the provisions of this Agreement. Members shall ensure that they rely on the services of non-governmental entities for implementing sanitary or phytosanitary measures only if these entities comply with the provisions of this Agreement.

Article 14
Final Provisions

The least-developed country Members may delay application of the provisions of this Agreement for a period of five years following the date of entry into force of the WTO Agreement with respect to their sanitary or phytosanitary measures affecting importation or imported products. Other developing country Members may delay application of the provisions of this Agreement, other than paragraph 8 of Article 5 and Article 7, for two years following the date of entry into force of the



WTO Agreement with respect to their existing sanitary or phytosanitary measures affecting importation or imported products, where such application is prevented by a lack of technical expertise, technical infrastructure or resources.

Annex A
Definitions[4]

1. *Sanitary or phytosanitary measure* — Any measure applied:

   (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;

   (b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;

   (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or

   (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.

2. *Harmonization* — The establishment, recognition and application of common sanitary and phytosanitary measures by different Members.

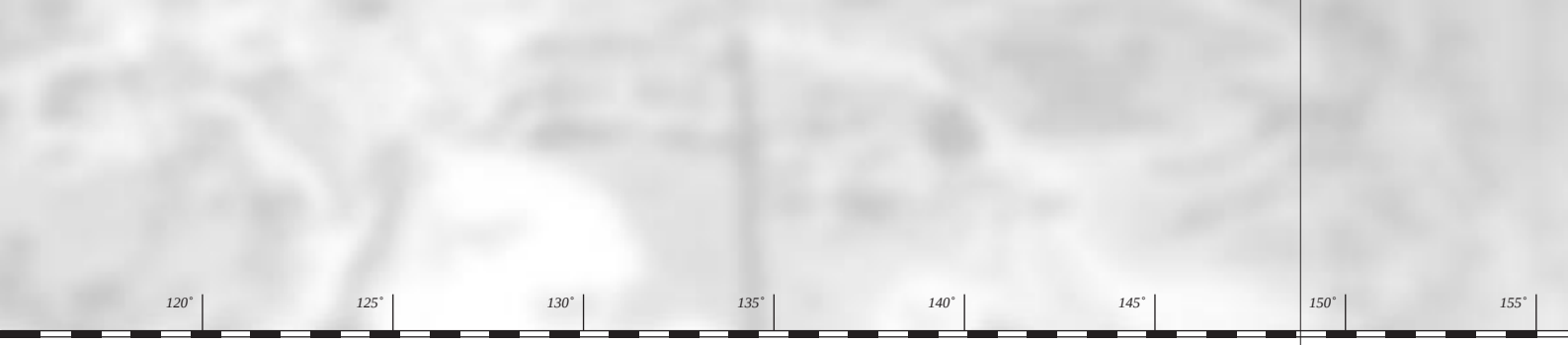
3. *International standards, guidelines and recommendations*

   (a) for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice;

   (b) for animal health and zoonoses, the standards, guidelines and recommendations developed under the auspices of the International Office of Epizootics;

   (c) 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; and

4 For the purpose of these definition, "animals" includes fish and wild fauna; "plant" includes forests and wild flora; "pests" include weeds; and "contaminants" include pesticide and veterinary drug residues and extraneous matter.



(d) for matters not covered by the above organizations, appropriate standards, guidelines and recommendations promulgated by other relevant international organizations open for membership to all Members, as identified by the Committee.

4. *Risk assessment* — The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.

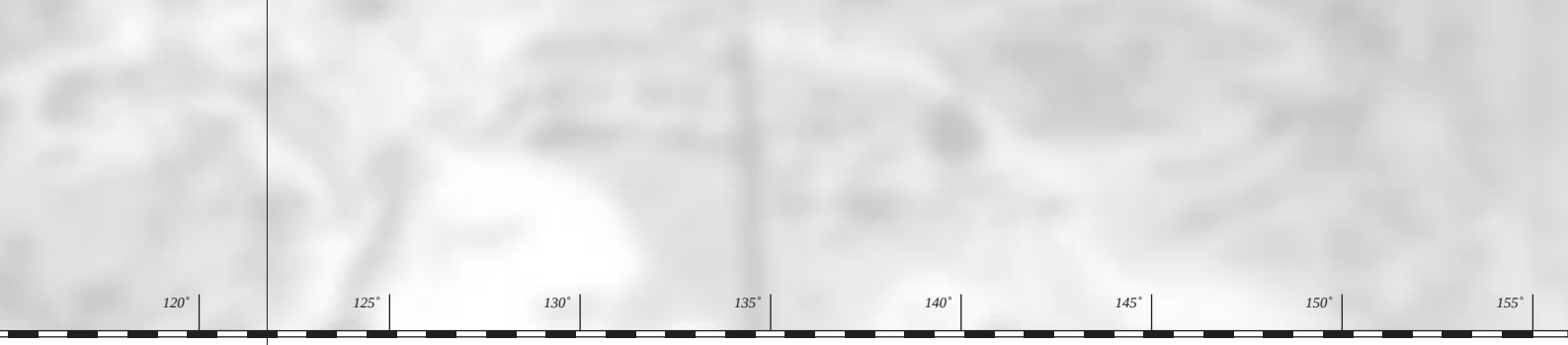
5. *Appropriate level of sanitary or phytosanitary protection* — The level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory.

   NOTE: Many Members otherwise refer to this concept as the "acceptable level of risk".

6. *Pest- or disease-free area* — An area, whether all of a country, part of a country, or all or parts of several countries, as identified by the competent authorities, in which a specific pest or disease does not occur.

   NOTE: A pest- or disease-free area may surround, be surrounded by, or be adjacent to an area — whether within part of a country or in a geographic region which includes parts of or all of several countries — in which a specific pest or disease is known to occur but is subject to regional control measures such as the establishment of protection, surveillance and buffer zones which will confine or eradicate the pest or disease in question.

7. *Area of low pest or disease prevalence* — An area, whether all of a country, part of a country, or all or parts of several countries, as identified by the competent authorities, in which a specific pest or disease occurs at low levels and which is subject to effective surveillance, control or eradication measures.



Annex B
Transparency of Sanitary and Phytosanitary Regulations

Publication of regulations

1. Members shall ensure that all sanitary and phytosanitary regulations[5] which have been adopted are published promptly in such a manner as to enable interested Members to become acquainted with them.

2. Except in urgent circumstances, Members shall allow a reasonable interval between the publication of a sanitary or phytosanitary regulation and its entry into force in order to allow time for producers in exporting Members, and particularly in developing country Members, to adapt their products and methods of production to the requirements of the importing Member.

Enquiry points

3. Each Member shall ensure that one enquiry point exists which is responsible for the provision of answers to all reasonable questions from interested Members as well as for the provision of relevant documents regarding:

   (a) any sanitary or phytosanitary regulations adopted or proposed within its territory;

   (b) any control and inspection procedures, production and quarantine treatment, pesticide tolerance and food additive approval procedures, which are operated within its territory;

   (c) risk assessment procedures, factors taken into consideration, as well as the determination of the appropriate level of sanitary or phytosanitary protection;

   (d) the membership and participation of the Member, or of relevant bodies within its territory, in international and regional sanitary and phytosanitary organizations and systems, as well as in bilateral and multilateral agreements and arrangements within the scope of this Agreement, and the texts of such agreements and arrangements.

4. Members shall ensure that where copies of documents are requested by interested Members, they are supplied at the same price (if any), apart from the cost of delivery, as to the nationals[6] of the Member concerned.

Notification procedures

5. Whenever an international standard, guideline or recommendation does not exist or the content of a proposed sanitary or phytosanitary regulation is not substantially the same as the content of an international standard, guideline or recommendation, and if the regulation may have a significant effect on trade of other Members, Members shall:

   (a) publish a notice at an early stage in such a manner as to enable interested Members to become acquainted with the proposal to introduce a particular regulation;

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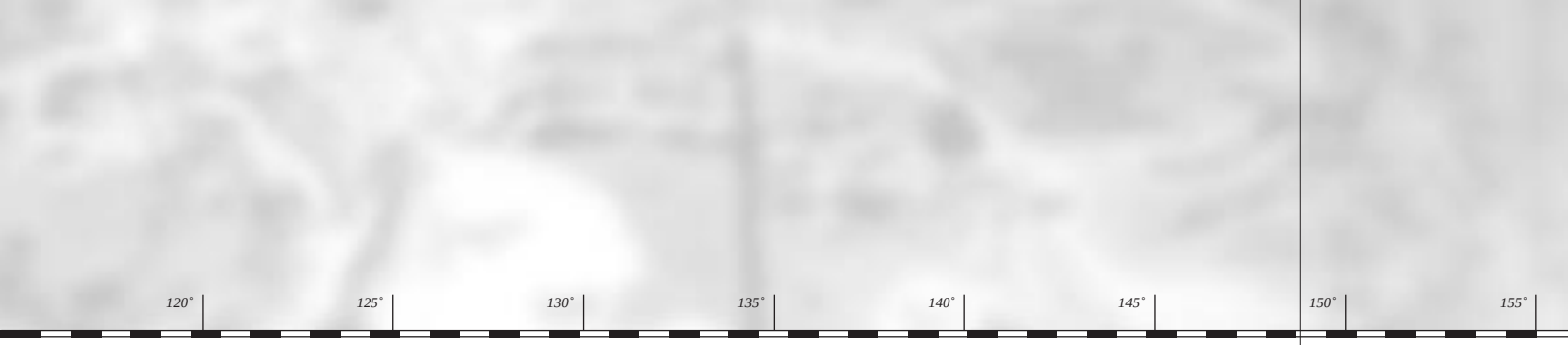
5 Sanitary and phytosanitary measures such as laws, decrees or ordinances which are applicable generally.

6 When "nationals" are referred to in this Agreement, the term shall be deemed, in the case of a separate customs territory Member of the WTO, to mean persons, natural or legal, who are domiciled or who have a real and effective industrial or commercial establishment in that customs territory.



(b) notify other Members, through the Secretariat, of the products to be covered by the regulation together with a brief indication of the objective and rationale of the proposed regulation. Such notifications shall take place at an early stage, when amendments can still be introduced and comments taken into account;

(c) provide upon request to other Members copies of the proposed regulation and, whenever possible, identify the parts which in substance deviate from international standards, guidelines or recommendations;

(d) without discrimination, allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take the comments and the results of the discussions into account.

6. However, where urgent problems of health protection arise or threaten to arise for a Member, that Member may omit such of the steps enumerated in paragraph 5 of this Annex as it finds necessary, provided that the Member:

(a) immediately notifies other Members, through the Secretariat, of the particular regulation and the products covered, with a brief indication of the objective and the rationale of the regulation, including the nature of the urgent problem(s);

(b) provides, upon request, copies of the regulation to other Members;

(c) allows other Members to make comments in writing, discusses these comments upon request, and takes the comments and the results of the discussions into account.

7. Notifications to the Secretariat shall be in English, French or Spanish.

8. Developed country Members shall, if requested by other Members, provide copies of the documents or, in case of voluminous documents, summaries of the documents covered by a specific notification in English, French or Spanish.

9. The Secretariat shall promptly circulate copies of the notification to all Members and interested international organizations and draw the attention of developing country Members to any notifications relating to products of particular interest to them.

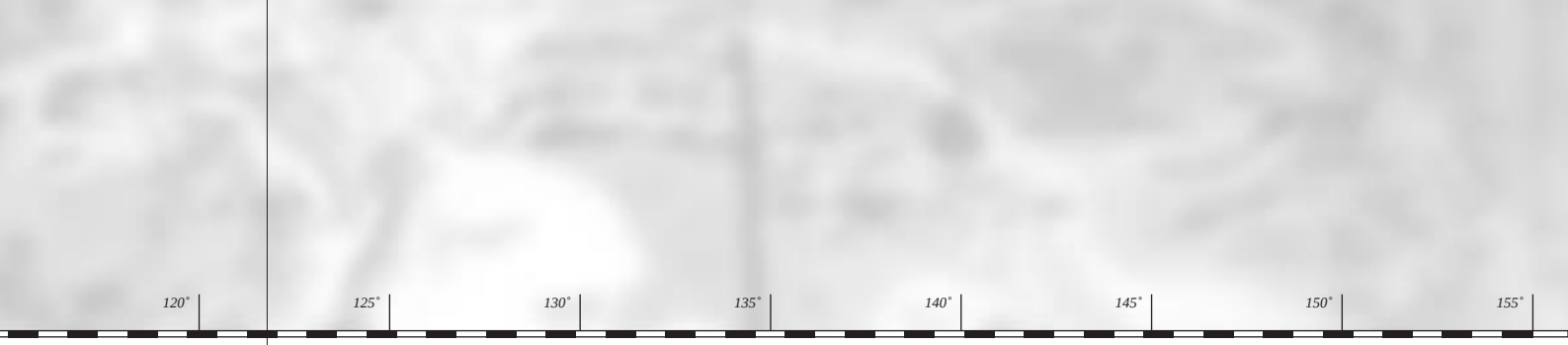
10. Members shall designate a single central government authority as responsible for the implementation, on the national level, of the provisions concerning notification procedures according to paragraphs 5, 6, 7 and 8 of this Annex.

General reservations

11. Nothing in this Agreement shall be construed as requiring:

(a) the provision of particulars or copies of drafts or the publication of texts other than in the language of the Member except as stated in paragraph 8 of this Annex; or

(b) Members to disclose confidential information which would impede enforcement of sanitary or phytosanitary legislation or which would prejudice the legitimate commercial interests of particular enterprises.



Annex C
Control, Inspection and Approval Procedures[7]

1. Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that:

   (a) such procedures are undertaken and completed without undue delay and in no less favourable manner for imported products than for like domestic products;

   (b) the standard processing period of each procedure is published or that the anticipated processing period is communicated to the applicant upon request; when receiving an application, the competent body promptly examines the completeness of the documentation and informs the applicant in a precise and complete manner of all deficiencies; the competent body transmits as soon as possible the results of the procedure in a precise and complete manner to the applicant so that corrective action may be taken if necessary; even when the application has deficiencies, the competent body proceeds as far as practicable with the procedure if the applicant so requests; and that upon request, the applicant is informed of the stage of the procedure, with any delay being explained;

   (c) information requirements are limited to what is necessary for appropriate control, inspection and approval procedures, including for approval of the use of additives or for the establishment of tolerances for contaminants in food, beverages or feedstuffs;

   (d) the confidentiality of information about imported products arising from or supplied in connection with control, inspection and approval is respected in a way no less favourable than for domestic products and in such a manner that legitimate commercial interests are protected;

   (e) any requirements for control, inspection and approval of individual specimens of a product are limited to what is reasonable and necessary;

   (f) any fees imposed for the procedures on imported products are equitable in relation to any fees charged on like domestic products or products originating in any other Member and should be no higher than the actual cost of the service;

   (g) the same criteria should be used in the siting of facilities used in the procedures and the selection of samples of imported products as for domestic products so as to minimize the inconvenience to applicants, importers, exporters or their agents;

   (h) whenever specifications of a product are changed subsequent to its control and inspection in light of the applicable regulations, the procedure for the modified product is limited to what is necessary to determine whether adequate confidence exists that the product still meets the regulations concerned; and

   (i) a procedure exists to review complaints concerning the operation of such procedures and to take corrective action when a complaint is justified.

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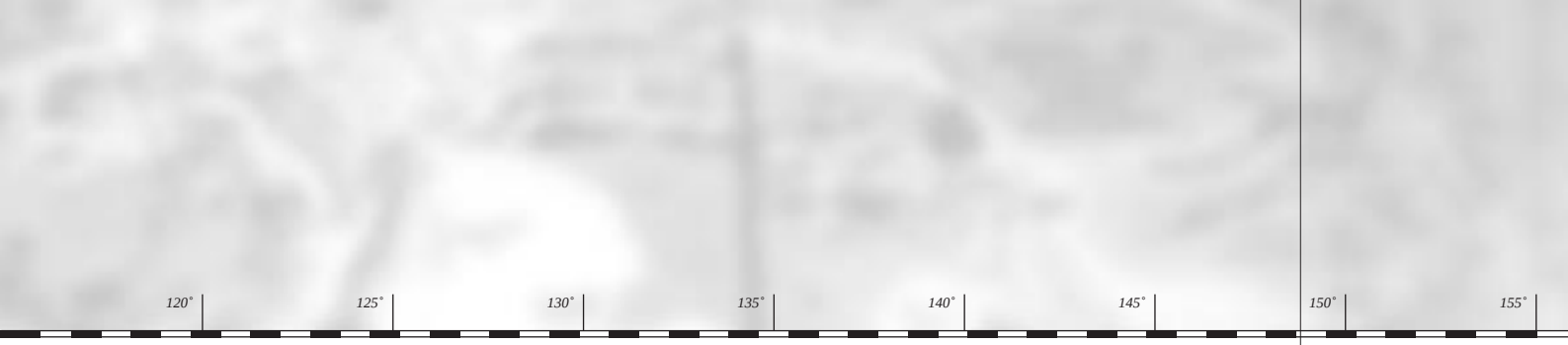
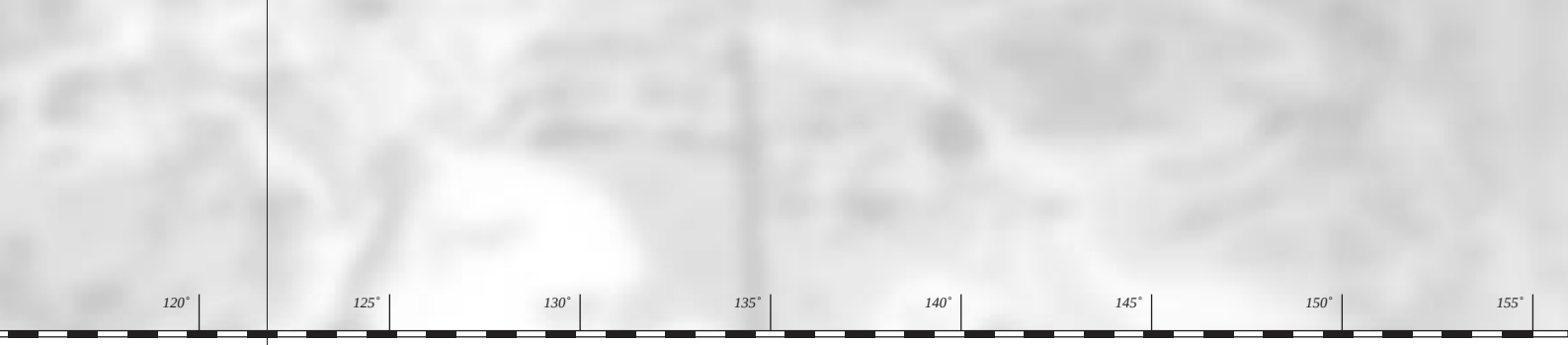
7 Control, inspection and approval procedures include, *inter alia*, procedures for sampling, testing and certification.



Where an importing Member operates a system for the approval of the use of food additives or for the establishment of tolerances for contaminants in food, beverages or feedstuffs which prohibits or restricts access to its domestic markets for products based on the absence of an approval, the importing Member shall consider the use of a relevant international standard as the basis for access until a final determination is made.

2. Where a sanitary or phytosanitary measure specifies control at the level of production, the Member in whose territory the production takes place shall provide the necessary assistance to facilitate such control and the work of the controlling authorities.

3. Nothing in this Agreement shall prevent Members from carrying out reasonable inspection within their own territories.



OIE INTERNATIONAL ANIMAL HEALTH CODE— DRAFT CHAPTER ON IMPORT RISK ANALYSIS
Appendix XX of Document 66 SG/12/CS
OIE, Paris 1988

Chapter 1.4.1.
Import Risk Analysis

Article 1.4.1.1.
Introduction

The importation of animals and animal products involves a degree of disease risk to the importing country. This risk may be represented by one or several diseases or infections.

The principal aim of import risk analysis is to provide importing countries with an objective and defensible method of assessing the disease risks associated with the importation of animals, animal products, animal genetic material, feedstuffs, biological products and pathological material. The analysis should be transparent. This is necessary so that the exporting country is provided with clear and documented reasons for the imposition of import conditions or refusal to import.

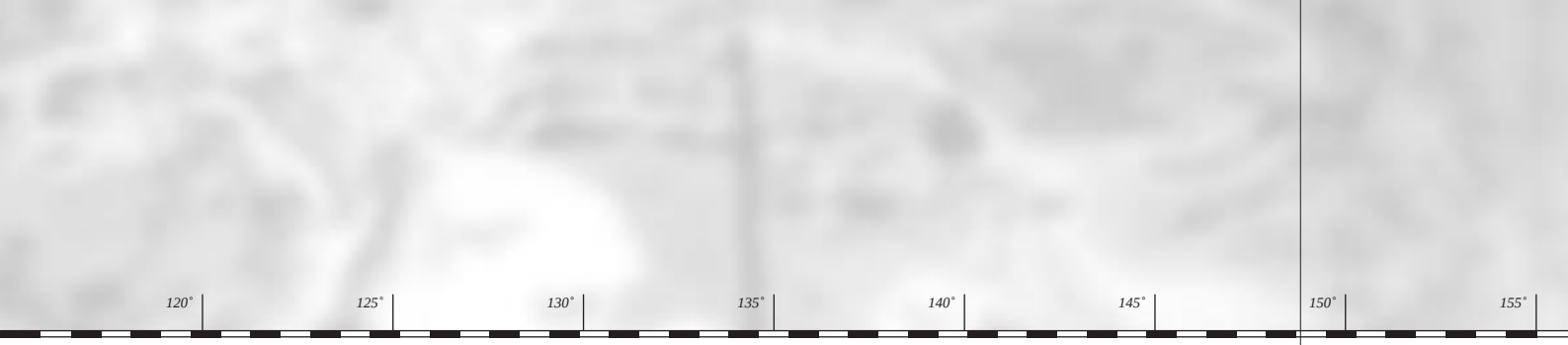
Transparency is also essential because data are often uncertain or incomplete and, without full documentation, the distinction between facts and the analyst's value judgements may blur.

This Chapter outlines OIE's role with respect to the World Trade Organization (WTO) *Agreement on the Application of Sanitary and Phytosanitary Measures* (the so-called SPS Agreement), provides definitions and describes OIE's procedure for settlement of disputes.

Chapter 1.4.2. provides guidelines and principles for conducting transparent, objective and defensible risk analyses for international trade. The components of risk analysis described in that Chapter are hazard identification, risk assessment, risk management and risk communication.

The risk assessment is the component of the analysis which evaluates the risk. Risk assessments may be non-quantitative or quantitative and in many circumstances non-quantitative assessments are appropriate. They also require less time and resource to carry out and so are often the type of assessment used for routine decision making. No single method of import risk assessment has proven applicable in all situations, and different methods may be appropriate in different circumstances.

The process of import risk analysis usually needs to take into consideration the results of an evaluation of Veterinary Services, zoning and regionalisation and surveillance systems in place for monitoring of animal health in the exporting country. These are described in separate Chapters in the *Code*.



Article 1.4.1.2.
The SPS Agreement and the OIE's Role and Responsibility

The WTO SPS Agreement binds WTO members either to base their import decisions on international standards or to conduct scientifically-based risk analysis. The SPS Agreement recognizes the OIE as the relevant international organisation responsible for the development and promotion of international animal health standards, guidelines, and recommendations affecting trade in live animals and animal products. In particular the WTO will look to the OIE to develop internationally accepted standards for conducting risk analyses and standard guidelines for ensuring the practical and safe implementation of the WTO regionalisation and equivalency concept.

Article 1.4.1.3.
Definitions

Accepted risk: . . . . . .that level of risk which it has been decided to accept in a given set of circumstances.

Commodity: . . . . . .animals, animal products, animal genetic material, feedstuffs, biological products and pathological material.

Hazard: . . . . . .in the context of import risk analysis, a biological agent which may have an adverse effect.

Hazard identification: . . . . .the process of identifying the biological agents which could potentially be introduced in the commodity considered for importation.

Risk: . . . . . .the integration of the likelihood of the occurrence and the magnitude of the consequences of an adverse event to animal or human health in the importing country.

Risk assessment: . . . . . .the process of estimating the risk presented by a hazard, in qualitative or quantitative terms.

Risk communication: . . . . . .the processes by which information and opinions regarding hazards and risks are gathered from potentially affected and interested parties prior to and during a risk assessment and the process by which the results of the risk assessment and proposed risk management measures are communicated to the decision-makers and interested parties in the importing and exporting countries. It is a two-way process and should ideally begin at the start of the risk analysis process and continue throughout.

Risk management: . . . . . .the process of selecting and implementing measures that can be applied to reduce the level of risk.

Uncertainty: . . . . . .the lack of precise knowledge of the model input values which is due to measurement error or to lack of knowledge of the steps required, and the pathways from hazard to risk, when building the model of the scenario being assessed. This is also known as epistemic uncertainty.

Variability: . . . . . .a real-world complexity in which the value of an input is not the same for each case due to a natural heterogeneity or diversity in a given population. This is also known as aleatory uncertainty.

Transparency: . . . . . .comprehensive documentation of all data and information sources used in the risk analysis, and subsequent logical analysis or arguments.

Sanitary measure: . . . . . .measures such as those described in each Chapter of the Code which are used for risk reduction and are appropriate for particular diseases.

Quantitative risk assessment: .an assessment where the outputs of the risk assessment are expressed numerically.

Qualitative risk assessment: . .an assessment where the outputs on the likelihood of the outcome or the magnitude of the consequences are expressed in qualitative terms such as high, medium, low or negligible.

Sensitivity analysis: . . . . . .the process of examining the impact of the variation in individual model inputs on the model outputs.

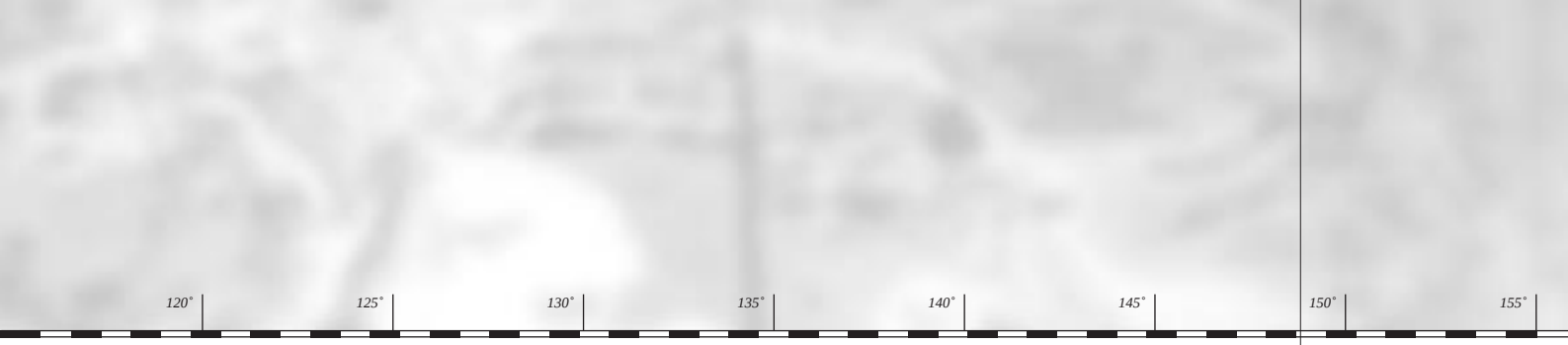
Article 1.4.1.4.
Accountability

The Head of the Veterinary Service of the exporting country is ultimately accountable for veterinary certification used in international trade.

Article 1.4.1.5.
The OIE In-house Procedure for Settlement of Disputes

OIE shall maintain its existing in-house mechanisms for assisting member organisations to resolve differences. In-house procedures which will apply are that:

1. Both parties agree to give the OIE a mandate to assist them in resolving their differences.
2. If considered appropriate, the Director General of the OIE recommends an expert, or experts, and a chairman, as requested, agreed by both parties.
3. Both parties agree on the terms of reference and working programme, and to meet all expenses incurred by the OIE.
4. The expert or experts are entitled to seek clarification of any of the information and data provided by either country in the assessment or consultation processes, or to request additional information or data from either country.



5. The expert or experts should submit a confidential report to the Director General, who will transmit it to both parties.

Chapter 1.4.2.
Guidelines for Risk Analysis

Article 1.4.2.1.
Introduction

The relationships between hazard identification, risk assessment, risk management and risk communication in import risk analysis are outlined in Figure 1.

The process of import risk analysis begins with a risk management decision to conduct a risk assessment for the importation of a commodity. The history and background, a full description of the commodity, and the volume, quantity, frequency and time-frames of the proposed importation are all documented.

The risk assessment process consists of hazard identification and four interrelated assessment steps. These steps clarify the stages of the risk assessment, describing them in terms of the events necessary for the identified potential risk(s) to occur, and facilitate understanding and evaluation of the outputs. The product is the risk assessment report which is used in further risk communication and risk management.

Article 1.4.2.2.
Hazard Identification

The hazard identification involves identifying the biological agents which could potentially produce adverse consequences associated with the importation of a commodity.

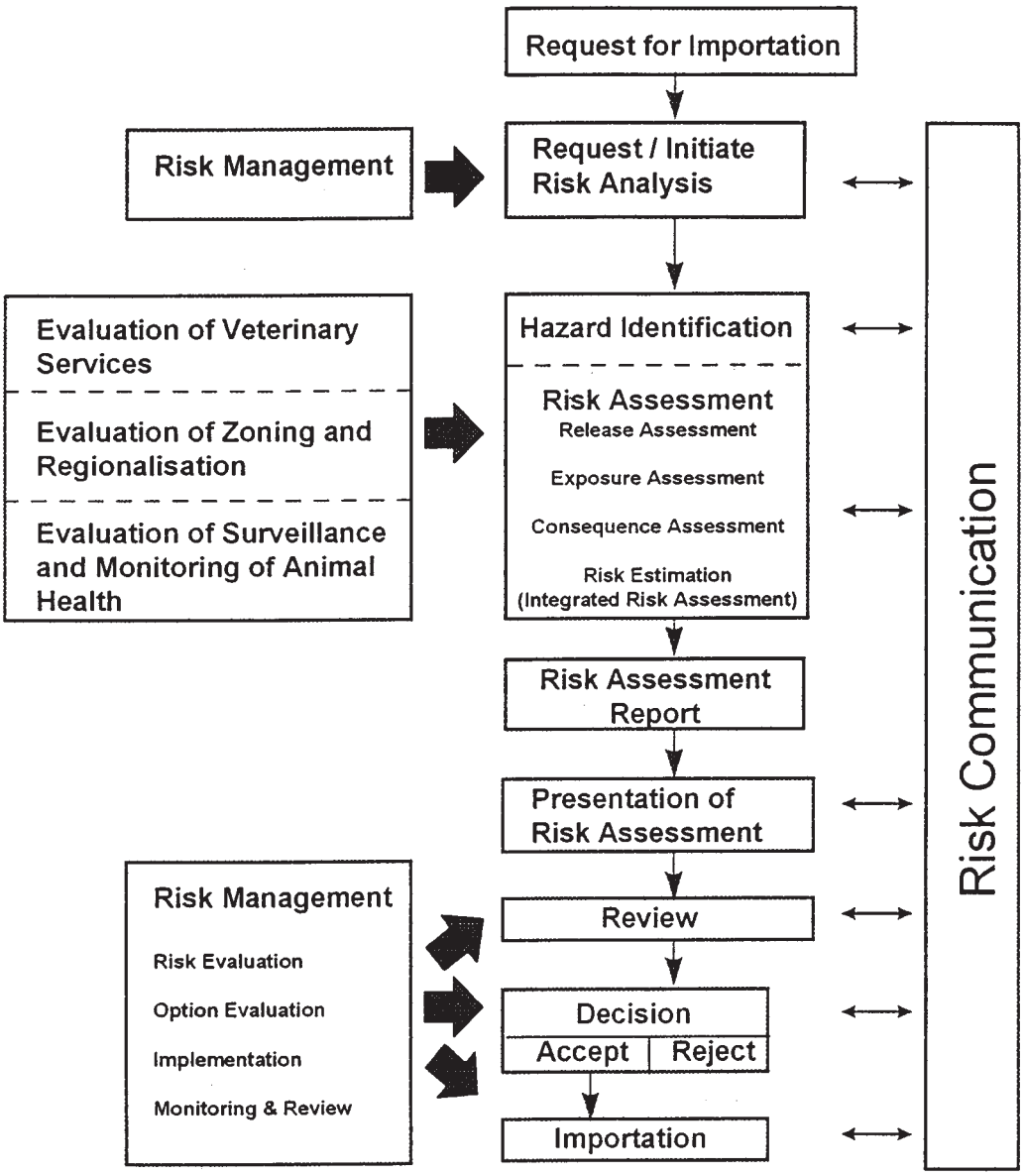
The potential hazards identified would be those appropriate to the species being imported, or from which the commodity is derived, and which may be present in the exporting country. It is then necessary to identify whether each potential hazard is already present in the importing country, and whether it is a notifiable disease or is subject to control or eradication in that country and to ensure that import measures are not more trade restrictive than those applied within the country.

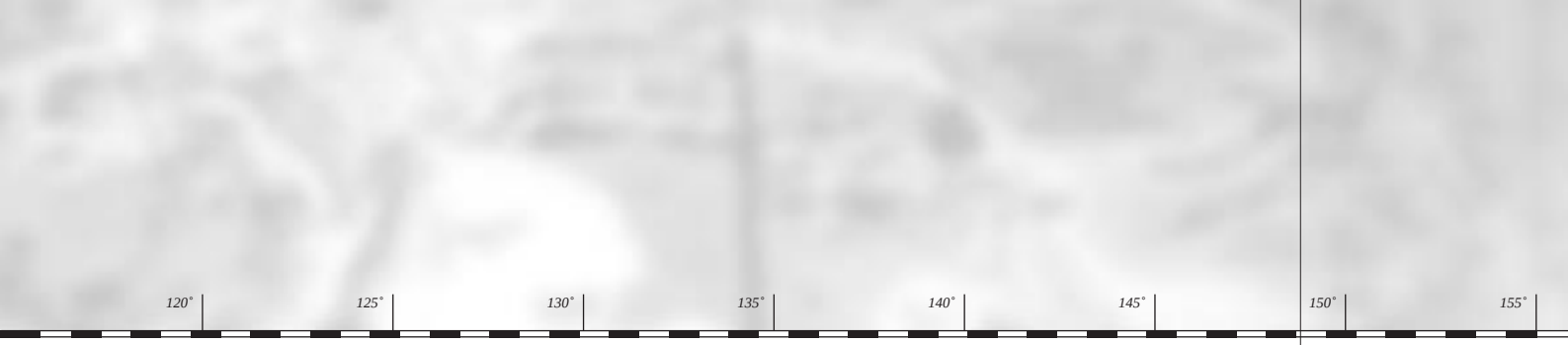
Hazard identification is a categorization step, identifying biological agents dichotomously as potential hazards or not. The risk assessment may be concluded if hazard identification fails to identify potential hazards associated with the importation.

The evaluation of the Veterinary Services, surveillance programmes and zoning and regionalisation systems may be important inputs for hazard identification with respect to the probability of the presence of a biological agent infecting an animal population in the exporting country.

An importing country may decide to permit the importation using the appropriate sanitary standards recommended in the *Code*, thus eliminating the need for a risk assessment.

Figure 1: Import Risk Analysis Process



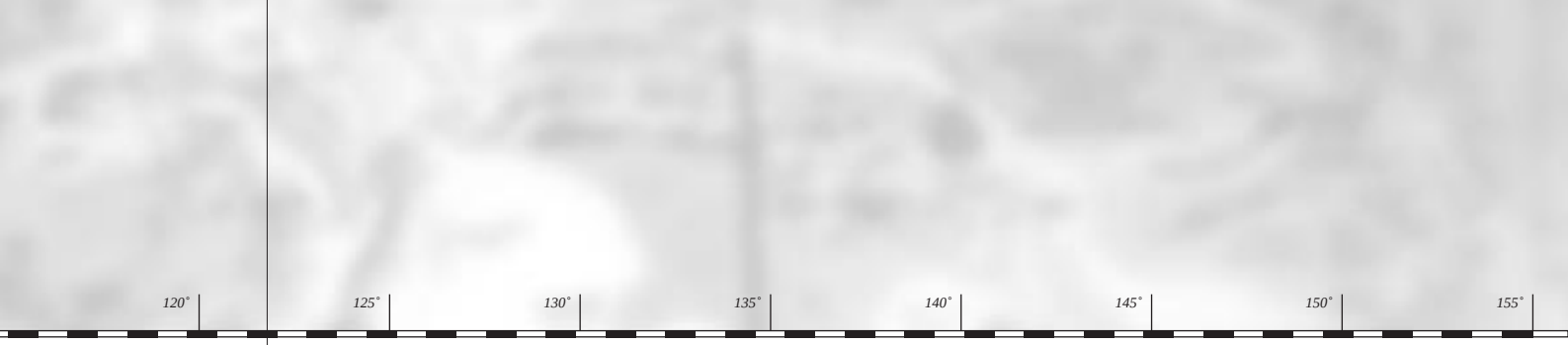


Article 1.4.2.3.
Risk Assessment Steps

1. Release assessment

   Release assessment consists of describing the biological pathway(s) necessary for a risk source to release (that is, introduce) biological agents into a particular environment, and estimating the probability of that complete process occurring, either qualitatively (in words) or quantitatively (as a numerical estimate). The risk source is the importation activity that could introduce a biological agent into an importing country. The release assessment describes the probability of the release of each of the potential hazards (the biological agents) under each specified set of conditions with respect to amounts and timing, and how these might change as a result of various actions, events or measures. Some of the inputs that may be required in the release assessment are:

   – incidence/prevalence
   – incidence/prevalence in adjoining zones or countries
   – evaluation of the Veterinary Services, surveillance programmes and zoning and regionalisation systems of the exporting country
   – species, age and breed of animals
   – agent predilection sites
   – ease of agent contamination
   – effect of processing and inactivation procedures such as freezing, heat treatment, maturation, fumigation, salting, desiccation, pasteurization, steam heat, storage, chemical and mechanical treatment, and acidification
   – effect of additives or treatments
   – animal health certification policy and practice
   – vaccination policy and practice
   – effect of diagnostic testing
   – effect of therapeutic treatment
   – effect of quarantine (pre- and post-embarkation, with or without sentinel animals)
   – effect of slaughter inspection (*ante* and *post mortem*)
   – effect of deboning of carcases
   – effect of removal of lymphatic and central nervous system tissues from carcases
   – effect of temperature and duration of storage and transit.



2. Exposure assessment

   Exposure assessment consists of describing the biological pathway(s) necessary for exposure of animals and humans in the importing country to the hazards (in this case the biological agents) released from a given risk source, and estimating the probability of the exposure(s) occurring, either qualitatively (in words) or quantitatively (as a numerical estimate).

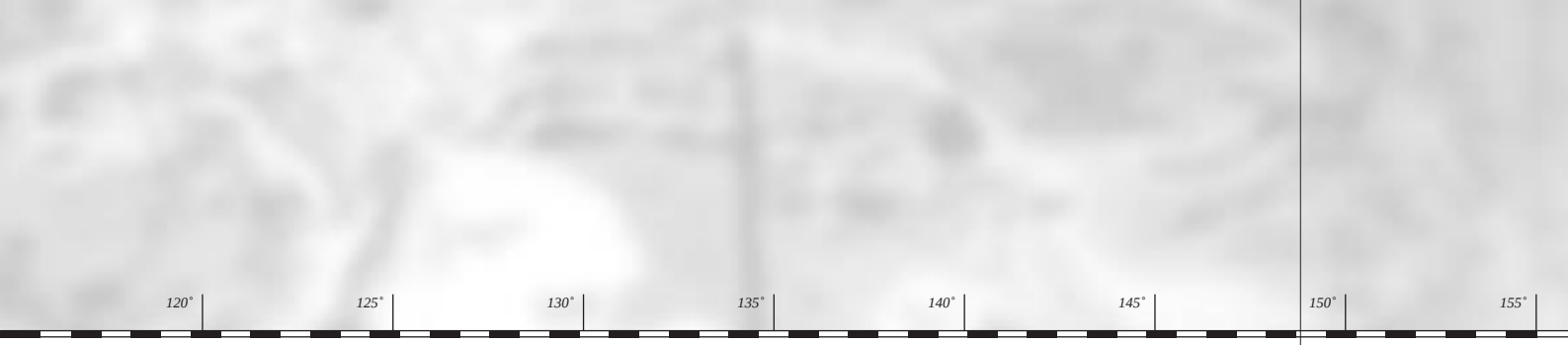
   The probability of exposure to the identified hazards is estimated for specified exposure conditions with respect to amounts, timing, frequency, duration of exposure, routes of exposure (e.g. ingestion, inhalation, or insect bite), and the number, species and other characteristics of the animal and human populations exposed. Some of the inputs that may be required in the exposure assessment are:

   – the presence of potential vectors
   – the nature and properties of the agent
   – the inherent nature and intended use of the imported animals or products
   – routes of exposure, modes of transmission and portals of entry
   – primary, secondary and intermediate hosts of the agent
   – human and animal demographics
   – customs and cultural practices
   – compliance with human and animal health legislation
   – disposal practices for unused commodity or contaminated material
   – geographical and environmental characteristics
   – the intended distribution of the imported animals or products
   – the volume of commodity to be imported
   – the distribution in the importing country of the vectors of the pathogen under consideration.

3. Consequence assessment

   Consequence assessment consists of describing the relationship between specified exposures to a biological agent and the consequences of those exposures. A causal process must exist by which exposures produce adverse health or environmental consequences, which may in turn lead to socio-economic consequences. The consequence assessment describes the potential consequences of a given exposure and estimates the probability of them occurring. This estimate may be either qualitative (in words) or quantitative (a numerical estimate). The consequences for which the probability may be estimated include:

   – transmission of infection to exposed animals or humans
   – disease or death in animals or humans caused by the transmitted infection
   – subclinical production losses caused by the transmitted infection



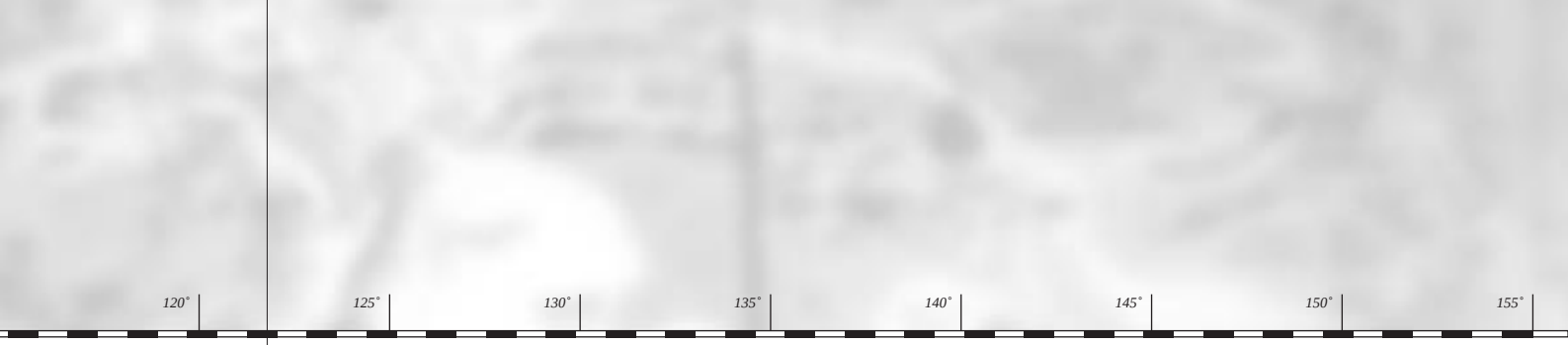
- spread of infection or disease, and epidemics
- animal losses from deaths and removal and slaughter/destruction
- production losses including abortions and infertility
- loss of gene pool
- losses from trade embargoes
- losses from domestic animal movement restrictions
- losses in domestic marketability
- control and eradication costs
- monitoring, surveillance, laboratory testing and trace back costs
- quarantine and isolation costs
- compensation costs
- cleaning and disinfection costs
- treatment costs
- vaccination costs
- human illness and deaths
- treatment and hospitalization costs for human illness
- adverse consequences to the environment.

4. Risk estimation (also known as Integrated Risk Assessment)

Risk estimation consists of integrating the results from the release assessment, exposure assessment, and consequence assessment to produce overall measures of the potential outcome from the health, environmental and economic risks, given the hazards identified at the outset. Thus risk estimation takes into account the whole of the risk pathway from hazard identified to unwanted outcome. A risk assessment is thus a summation of the findings of the release, exposure and consequence assessments.

The final outputs may include:

- estimated numbers of herds, flocks, animals or people experiencing health impacts of various severities over time
- probability distributions, confidence intervals, and other means for expressing the uncertainties in these estimates
- portrayal of the variance of all model inputs
- a sensitivity analysis to rank the inputs as to their contribution to the variance of the risk estimation output
- analysis of the dependence and correlation between model inputs.



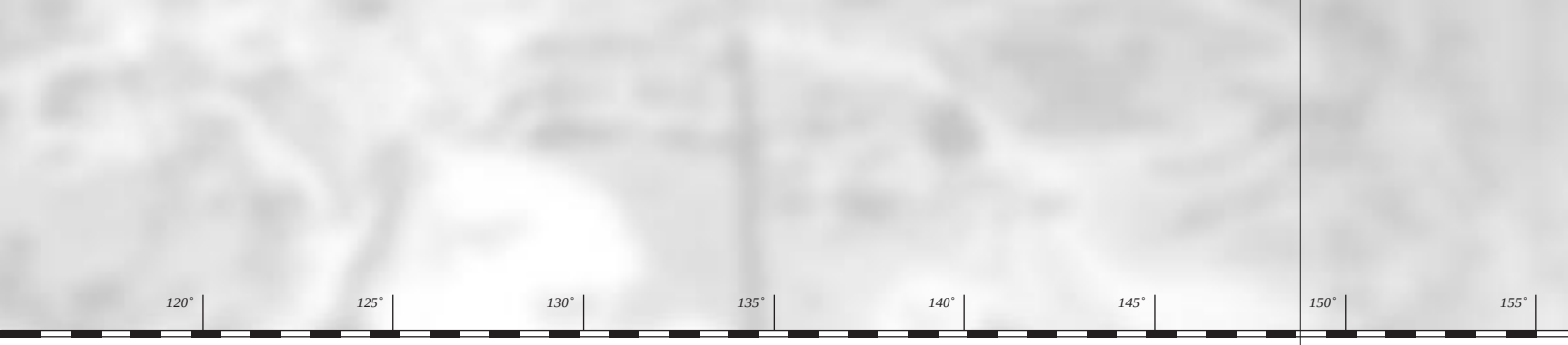
Article 1.4.2.4.
Principles of Risk Assessment

1. Risk assessment should be flexible to deal with the complexity of real life situations. No single method is applicable in all cases. Risk assessment must be able to accomodate the variety of animal commodities, the multiple hazards that may be identified with an importation and the different disease epidemiologies, detection and surveillance systems, exposure scenarios and types and amounts of data.
2. Both qualitative and quantitative risk assessments are valid.
3. The risk assessment should be based on the best, available information that is in accord with current scientific thinking. The assessment should be well-documented and supported with references to the scientific literature and other sources, including expert information elicitation.
4. Consistency in risk assessment methodology should be encouraged and transparency is essential in order to ensure fairness and rationality, consistency in decision making and ease of understanding by all the interested parties. Consistency may be limited to similar commodities and depend on the types and amount of data available.
5. Risk assessments should describe the uncertainty in the risk estimation output.
6. In general, risk increases with increasing volume of commodity imported.
7. The risk assessment should be amenable to updating when additional information becomes available.

Article 1.4.2.5.
Risk Management

While risk management comprises a number of measures, not all will necessarily be included in every risk analysis. The elements of risk management include:

1. Risk evaluation — the aspect of risk management concerned initially with the decision to request a risk assessment and secondly, interpreting, comparing, judging the significance of and deciding the tolerability of the risk as estimated in a risk assessment document.
2. Option evaluation — the process of identifying, evaluating the efficacy and feasibility of, and selecting sanitary measures, in addition to those that may have been considered in the initial risk assessment, in order to reduce the risk associated with an importation. The efficacy is the degree to which an option reduces the likelihood and magnitude of adverse biological and economic consequences. Evaluating the efficacy of the options selected is an iterative process that involves their incorporation into the initial risk assessment and then the evaluation of the degree of risk reduction achieved. The evaluation for feasibility normally focuses on technical, operational and economic factors affecting the implementation of the risk management options.



3. Implementation — the process of following through with the risk management decision on acceptance or refusal of the importation and ensuring that the risk management measures are in place for either decision.

4. Monitoring and review — the ongoing process to observe the importation and conduct a review, if necessary, of the risk assessment, the sanitary measures and the risk management decision.

Article 1.4.2.6.
Principles of Risk Management

1. The risk management decision on importation should be based on the probability of adverse health effects on animals or humans; that is the health-associated outputs of the risk assessment. These health associated outputs may (and probably will) in their turn have economic consequences, which will then also be included as risk assessment outputs. All risk management decisions should be in accordance with the WTO SPS Agreement.

2. The international standards of the OIE, as recommended in the *Code*, are the preferred choice of sanitary measures for risk management. The application of these sanitary measures should be in accordance with the intentions in the standards.

Article 1.4.2.7.
Risk Communication

Risk communication represents the interactive exchange of information on risk among risk assessors, risk managers and other interested parties. It begins when a risk analysis starts and continues after the implementation of the decision on the importation acceptance or refusal.

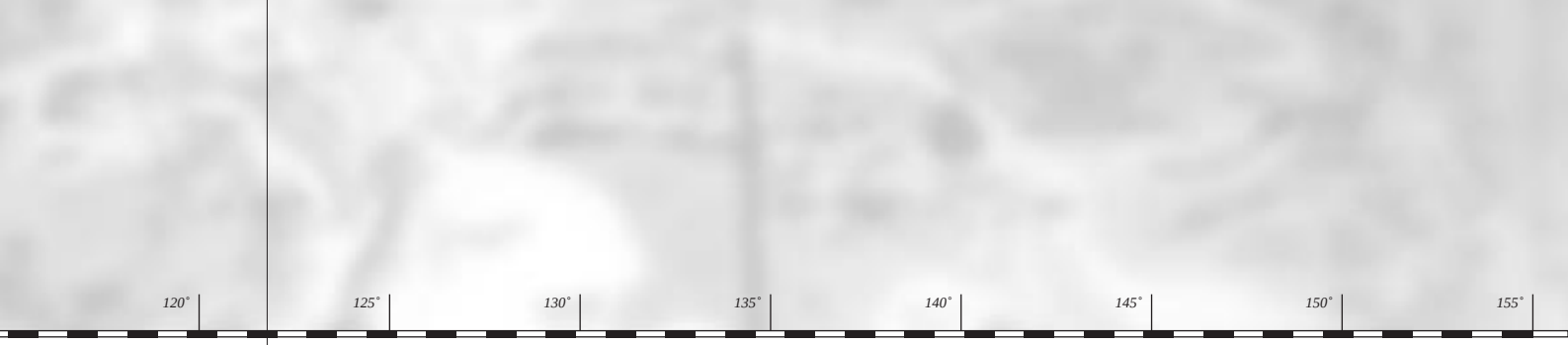
Article 1.4.2.8.
Principles of risk communication

1. The communication of risk should be an open, interactive and transparent exchange of information that may continue after the decision on importation.

2. The principal recipients of risk communication include the authorities in the exporting country and other stakeholders such as domestic and foreign industry groups, domestic livestock producers and consumer groups.

3. Peer review should represent a component of risk communication in order to obtain scientific critique and to ensure the validity of the scientific data, methods and assumptions.

4. The uncertainty in the model, model inputs and the risk estimates of the risk assessment should be communicated.



Annex 2, Part 2

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES GUIDELINES FOR PEST RISK ANALYSIS

Secretariat of the International Plant Protection Convention
Food and Agriculture Organization of the United Nations
Rome, 1996

Reprinted courtesy IPCC Secretariat, FAO, Rome

Contents

Endorsement 45

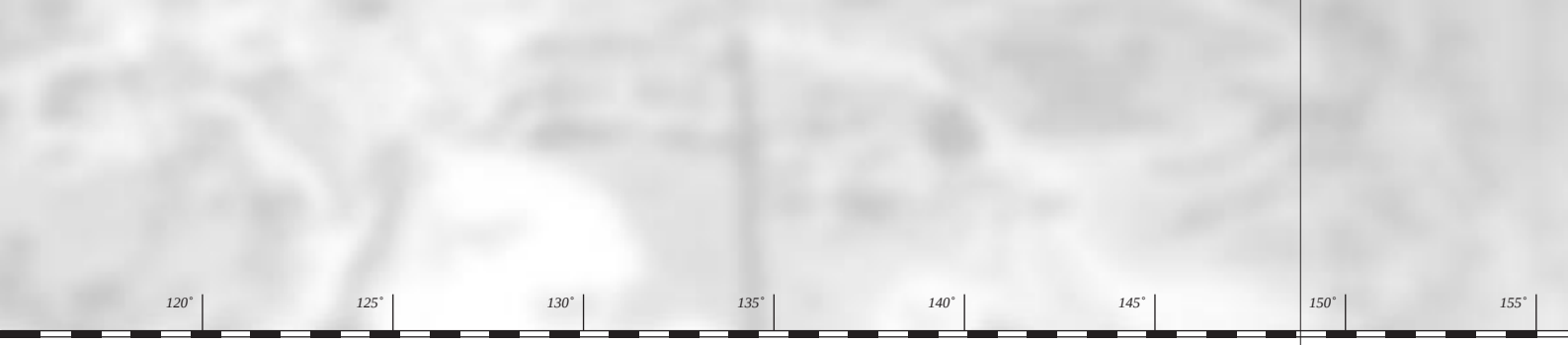
Introduction
- Scope 46
- References 46
- Definitions and Abbreviations 46
- Outline of Requirements 47

General Requirements for Pest Risk Analysis (PRA) 48

1. Stage 1: Initiating the PRA Process 48
   - 1.1 PRA Initiated by a Pathway 48
   - 1.2 PRA Initiated by a Pest 48
   - 1.3 Review of Earlier PRAs 49
   - 1.4 Conclusion for Stage 1 49
2. Stage 2: Pest Risk Assessment 51
   - 2.1 Geographical and Regulatory Criteria 51
   - 2.2 Economic Importance Criteria 52
     - 2.2.1 Establishment potential 52
     - 2.2.2 Spread potential after establishment 52
     - 2.2.3 Potential economic importance 53
   - 2.3 Introduction Potential 54
   - 2.4 Conclusion for Stage 2 54
3. Stage 3: Pest Risk Management 56
   - 3.1 Risk Management Options 56
   - 3.2 Efficacy and Impact of the Options 56
   - 3.3 Conclusion for Stage 3 57
4. Documenting the PRA Process 58

Figure 1. PRA Stage 1: Initiation 50
Figure 2. PRA Stage 2: Assessment 55
Figure 3. PRA Stage 3: Management 57

Other documents published by the IPPC Secretariat under the framework of international standards for phytosanitary measures (ISPMs) 58

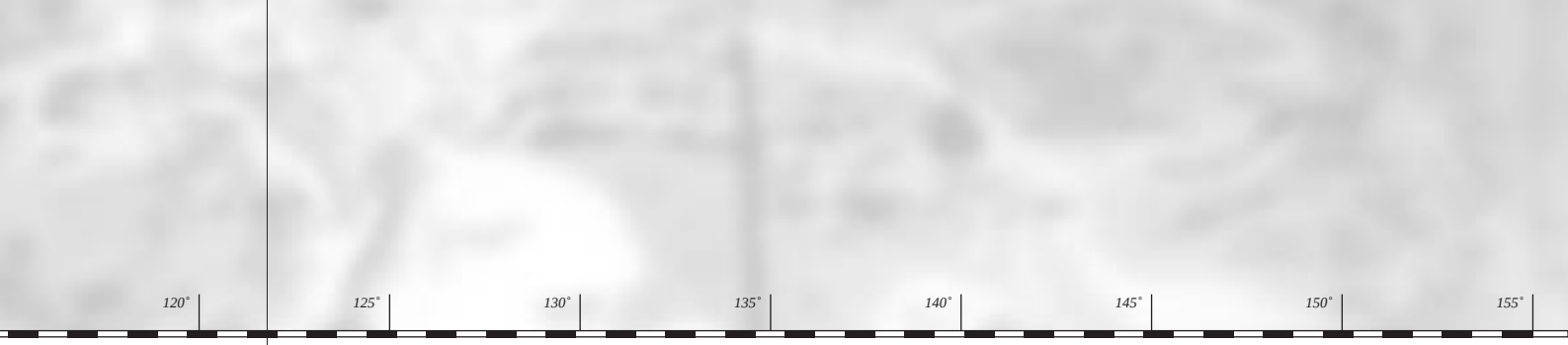


Endorsement

International standards for phytosanitary measures are prepared by the Secretariat of the International Plant Protection Convention as part of the United Nations Food and Agriculture Organization's global programme of policy and technical assistance in plant quarantine. This programme makes available to FAO Members and other interested parties guidelines to achieve international harmonization of phytosanitary measures, with the aim to facilitate trade and avoid the use of unjustifiable measures as barriers to trade. The standards are presented in a framework composed of seven parts encompassing procedures for: Import Regulations, Export Certification, Compliance Procedures, Pest Surveillance, Exotic Pest Response, Pest Management and Post-Entry Quarantine. Other standards are presented as reference documents.

The following standard was endorsed in November 1995 by the 28th Session of the FAO Conference.

Jacques Diouf
Director-General
Food and Agriculture Organization of the United Nations



Introduction

Scope

This standard describes the process of pest risk analysis for plant pests for the purpose of preparing phytosanitary regulations by National Plant Protection Organizations.

References

FAO Glossary of Phytosanitary Terms, *FAO Plant Protection Bulletin*, 38(1) 1990: 5–23.

International Plant Protection Convention, 1992. FAO, Rome.

Principles of plant quarantine as related to international trade, 1995. ISPM Pub. No. 1, FAO, Rome.

Definitions and Abbreviations

Area . . . . . .An officially defined country, part of a country or all or parts of several countries.

Endangered area . . . . . .An area where ecological factors favour the establishment of a pest whose presence in the area will result in economically important loss.

Entry (of a pest) . . . . . .Movement of a pest into an area where it is not yet present, or present but not widely distributed and being officially controlled.

Entry potential . . . . . .Likelihood of the entry of a pest.

Establishment . . . . . .The perpetuation, for the foreseeable future, of a pest within an area after entry.

Establishment potential . . . . . .Likelihood of the establishment of a pest.

Introduction . . . . . .Entry of a pest resulting in its establishment.

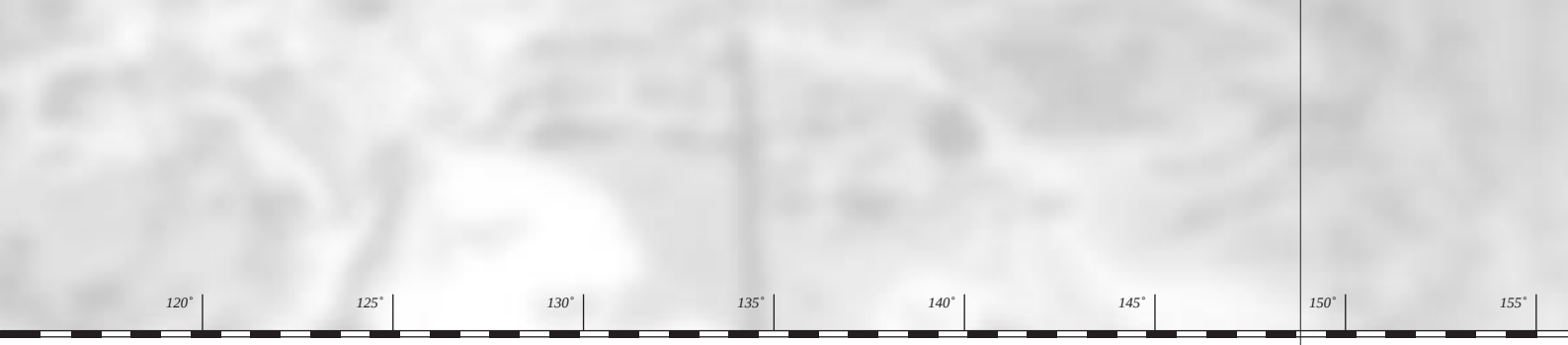
Introduction potential . . . . . .Likelihood of the introduction of a pest.

IPPC . . . . . .International Plant Protection Convention, as deposited in 1951 with FAO in Rome and as subsequently amended.

National Plant Protection Organization (NPPO) . . . . . .Official service established by a government to discharge the functions specified by the IPPC.

Official . . . . . .Established, authorized or performed by a National Plant Protection Organization.

Pest . . . . . .Any species, strain or biotype of plant or animal, or any pathogenic agent, injurious to plants or plant products. (Definition subject to formal amendment of the IPPC.)



Pest free area . . . . . .An area in which a specific pest does not occur as demonstrated by scientific evidence and in which, where appropriate, this condition is being officially maintained.

Pest risk analysis (PRA) . . . . . .Pest risk assessment and pest risk management.

Pest risk assessment . . . . . .Determination of whether a pest is a quarantine pest and evaluation of its introduction potential.

Pest risk management . . . . . .The decision-making process of reducing the risk of introduction of a quarantine pest.

Phytosanitary measure . . . . . .Any legislation, regulation or official procedure having the purpose to prevent the introduction and/or spread of quarantine pests.

Phytosanitary regulation . . . . . .Official rule to prevent the introduction and/or spread of quarantine pests, by regulating the production, movement or existence of commodities or other articles, or the normal activity of persons, and by establishing schemes for phytosanitary certification.

PRA area . . . . . Area in relation to which a pest risk analysis is conducted.

Quarantine pest . . . . . A pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled. (Definition subject to formal amendment of the IPPC.)

Spread . . . . . Expansion of the geographical distribution of a pest within an area.

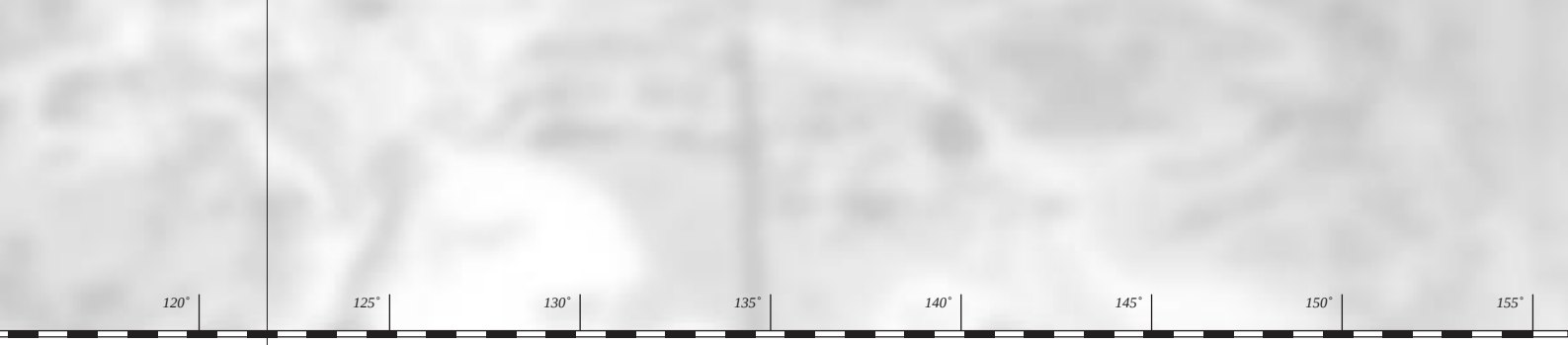
Spread potential . . . . . Likelihood of the spread of a pest.

Outline of Requirements

Pest risk analysis (PRA) consists of three stages: initiating the process for analyzing risk, assessing pest risk, and managing pest risk (See Figures 1–3).

Initiating the process involves identification of pests or pathways for which the PRA is needed. Pest risk assessment determines whether each pest identified as such, or associated with a pathway, is a quarantine pest, characterized in terms of likelihood of entry, establishment, spread and economic importance. Pest risk management involves developing, evaluating, comparing and selecting options for reducing the risk.

PRA is only meaningful in relation to a defined "PRA area" considered to be at risk. This is usually a country, but can also be an area within a country, or an area covering all or parts of several countries [e.g. the area covered by a Regional Plant Protection Organization (RPPO)].



General Requirements for Pest Risk Analysis (PRA)

1. Stage 1: Initiating the PRA Process

There are generally two initiation points for a pest risk analysis (see Figure 1):

- the identification of a pathway, usually an imported commodity, that may allow the introduction and/or spread of quarantine pests
- the identification of a pest that may qualify as a quarantine pest.

Either can involve pests already present in the PRA area but not widely distributed and being officially controlled, as well as pests absent from the PRA area, since both are covered by the quarantine pest definition.

1.1 PRA Initiated by a Pathway

A requirement for a new or revised PRA originating from a specific pathway will most frequently arise in the following situations:

- International trade is initiated in a new commodity (usually a plant or plant product) or a commodity from a new origin. The PRA may be triggered by a request for import, or by the appearance in trade of consignments of a commodity. The pathway may concern a single area of origin or several.
- New plant species are imported for selection and scientific research purposes
- A pathway other than commodity import is identified (natural spread, mail, garbage, passenger's baggage etc.)
- A policy decision is taken to establish or revise phytosanitary regulations or requirements concerning specific commodities
- A new treatment, system or process, or new information impacts on an earlier decision.

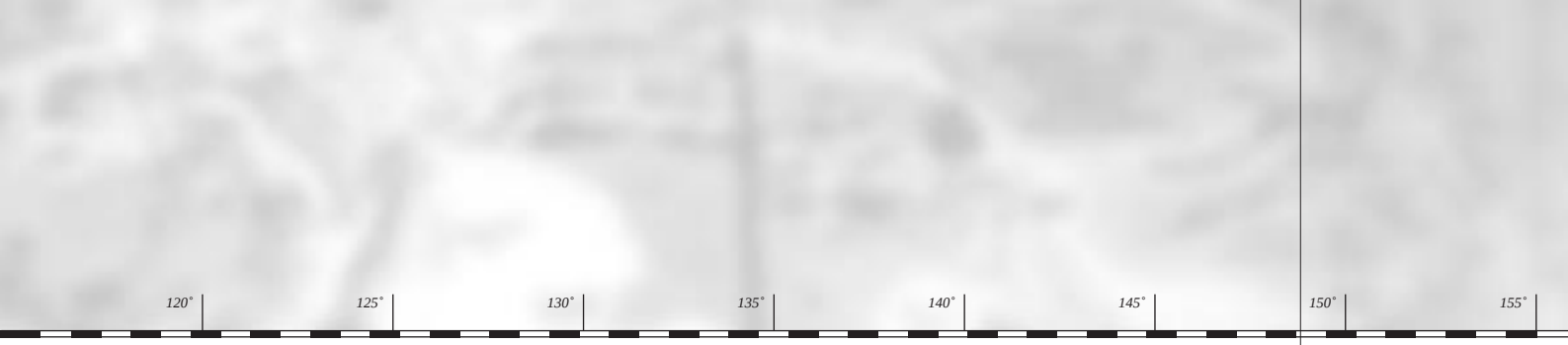
The pests which are likely to follow the pathway (e.g. be carried by the commodity) are then listed, and each is then subjected to Stage 2 in the PRA process[1]. If no potential quarantine pests are identified as likely to follow the pathway, the PRA stops at this point.

1.2 PRA Initiated by a Pest

A requirement for a new or revised PRA originating from a specific pest will most frequently arise in the following situations:

- An emergency arises on discovery of an established infestation or an outbreak of a new pest within a PRA area
- An emergency arises on interception of a new pest on an imported commodity

[1] The list of pests may be generated by any combination of databases, literature sources, or expert consultation. Once the list of pests has been established, it is preferable to prioritize it by using expert judgement before the next step. According to the results obtained, it may or may not be necessary to conduct a risk assessment on all pests on the list.



– A new pest risk is identified by scientific research
– A pest is introduced into a new area other than the PRA area
– A pest is reported to be more damaging in a new area other than the PRA area itself, than in its area of origin
– Audits reveal that a particular pest is repeatedly intercepted
– A request is made to import, as such, an organism, for example by researchers, educators, biological practitioners, businesses (pet store owners), the food industry (snails for consumption) or hobbyists (aquatic plants for aquaria)
– A policy decision is taken to revise phytosanitary regulations or requirements concerning specific pests
– A proposal is made by another country or by an international organization (RPPO, FAO)
– A new treatment system, process, or new information impacts on an earlier decision.

The specific pest identified is then subjected to Stage 2 in the PRA process.

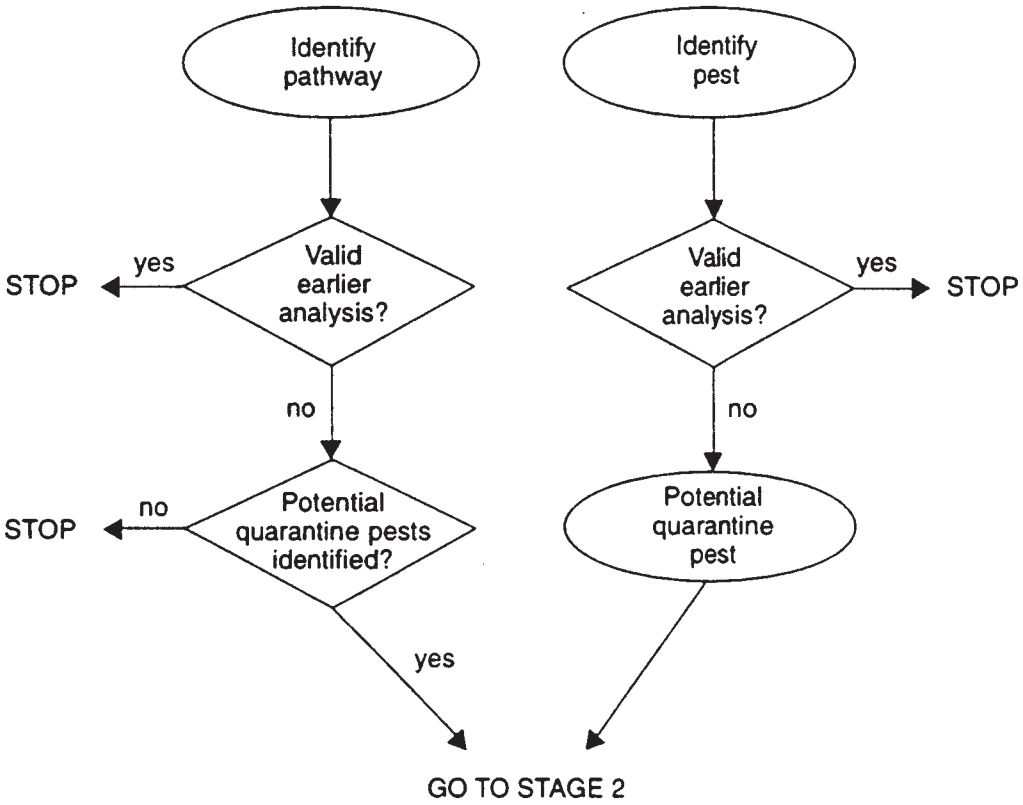
1.3 Review of Earlier PRAs

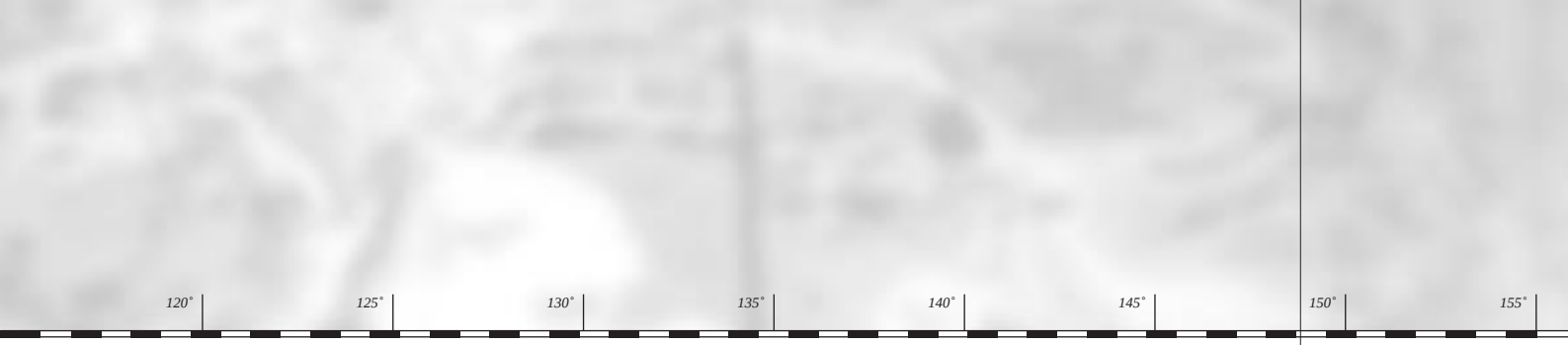
Prior to proceeding with a new PRA, a check should be made as to whether the pathway or pest has already been subjected to the PRA process, either nationally or internationally. If a PRA exists, its validity should be checked as circumstances may have changed. The possibility of using a PRA from a similar pathway or pest, that may partly or entirely replace the need for this PRA, should also be investigated.

1.4 Conclusion for Stage 1

At the end of Stage 1, pests have been identified as potential quarantine pests, individually or in association with a pathway.

Figure 1. Pest risk analysis Stage 1: Initiation





2. Stage 2: Pest Risk Assessment

Stage 1 has identified a pest, or list of pests (in the case of initiation by a pathway), to be subjected to risk assessment. Stage 2 considers these pests individually (see Figure 2). It examines, for each, whether the criteria for quarantine pest status are satisfied:

> "a pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled".

In this context, "area" should be understood to mean:

> "an officially defined country, part of a country, or all or part of several countries",

and "endangered area" should be understood to mean:

> "an area where ecological factors favour the establishment of a pest whose presence in the area will result in economically important loss".

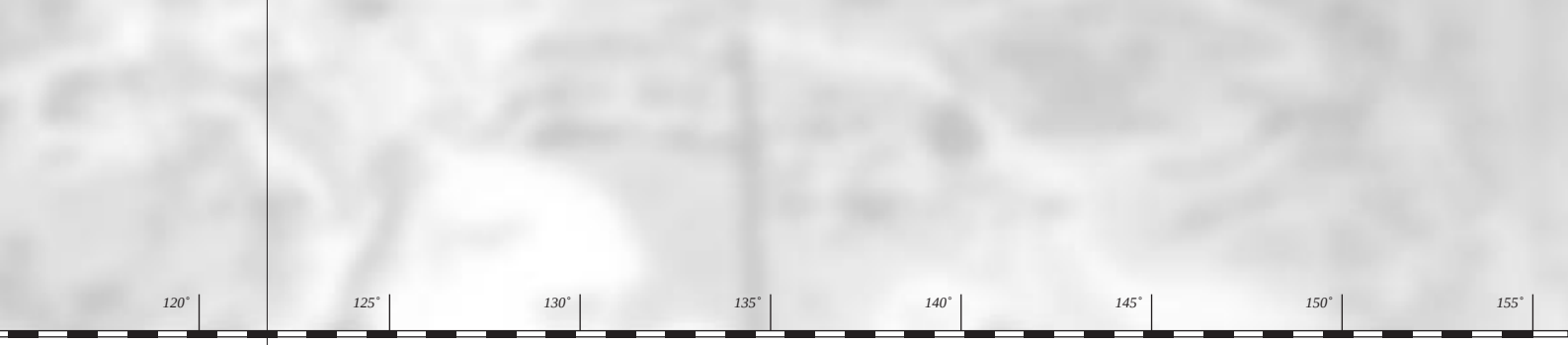
In doing so, the PRA considers all aspects of each pest and in particular actual information about its geographical distribution, biology and economic importance. Expert judgement is then used to assess the establishment, spread and economic importance potential in the PRA area. Finally, the potential for introduction into the PRA area is characterized.

In characterizing the risk, the amount of information available will vary with each pest and the sophistication of the assessment will vary with available tools. For example, one country may have elaborate pest databases and geographical information systems, another may depend on books, printed soil maps, and climate maps. In some cases, virtually no information may be available, or research may be needed to obtain it. Assessments will be limited by the amount of information available on the biology of a particular pest. Countries where the pest is present may provide available information for the country conducting the PRA, on request.

2.1 Geographical and Regulatory Criteria

For each pest subjected to the PRA process, the geographical and regulatory criteria in the quarantine pest definition should be considered:

- If the pest is present in the PRA area and has reached the limits of its ecological range (i.e. is widely distributed), then the pest does not satisfy the definition of a quarantine pest and the PRA for the pest stops at this point
- If the pest is present in the PRA area and has not reached the limits of its ecological range (i.e. not widely distributed), and the pest is subject to official control in the PRA area, then the pest satisfies this aspect of the definition of a quarantine pest
- If the pest is not widely distributed but is under consideration of future official control in the PRA area, then the PRA will determine whether the pest should be placed under official control. If the conclusion is reached that the pest should be subject to official control, then the pest satisfies this aspect of the definition of the definition of a quarantine pest.



– If the pest is not widely distributed but is not subject to official control or consideration of future official control in the PRA area, then the pest does not satisfy the definition of a quarantine pest and the PRA for the pest stops at this point
– If the pest is absent from the PRA area, then it satisfies this aspect of the definition of a quarantine pest.

2.2 Economic Importance Criteria

For potential economic importance to be expressed, a pest must become established and spread. Thus the risk of a pest, having entered, becoming established and spreading in the PRA area must be characterized. The factors to be considered are set out below[2].

2.2.1 Establishment potential

In order to estimate the establishment potential of a pest, reliable biological information (life cycle, host range, epidemiology, survival etc.) should be obtained from the areas where the pest currently occurs.

The situation in the PRA area can then be carefully compared with that in the areas where it currently occurs and expert judgement used to assess the establishment potential. Case histories concerning comparable pests can usefully be considered. Examples of the factors to consider are:

– availability, quantity and distribution of hosts in the PRA area
– environmental suitability in the PRA area
– potential for adaptation of the pest
– reproductive strategy of the pest
– method of pest survival.

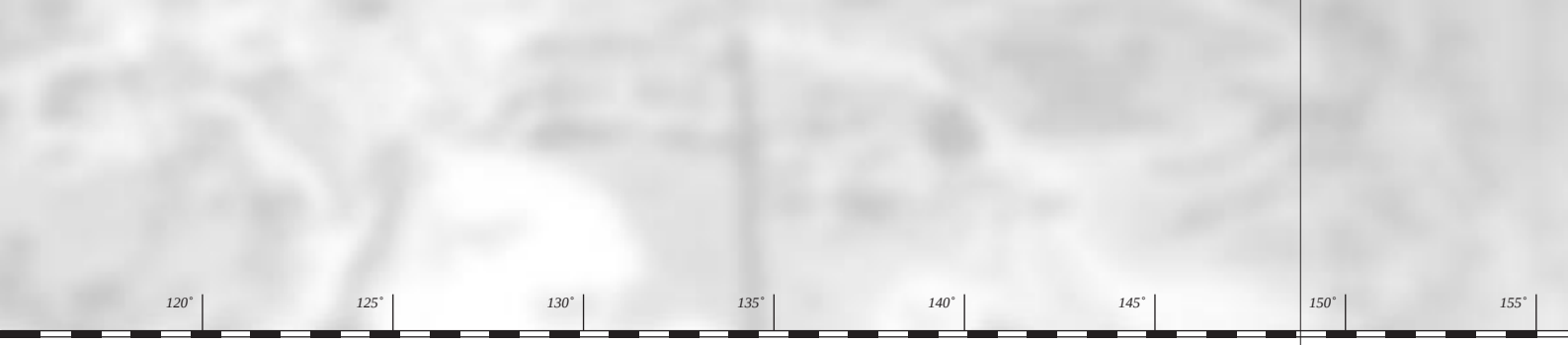
If a pest has no potential for establishment in the PRA area, then it does not satisfy the definition of a quarantine pest and the PRA for the pest stops at this point.

2.2.2 Spread potential after establishment

In order to estimate spread potential of the pest, reliable, biological information should be obtained from areas where the pest currently occurs.

The situation in the PRA area can then be carefully compared with that in the areas where the pest currently occurs and expert judgement used to assess the spread potential. Case histories concerning comparable pests can usefully be considered. Examples of the factors to consider are:

[2] Fuller checklists of information which can usefully be considered in assessing the potential for establishment, spread and economic importance, are available from national and international sources.



– suitability of the natural and/or managed environment for natural spread of the pest
– movement with commodities or conveyances
– intended use of the commodity
– potential vectors of the pest in the PRA area
– potential natural enemies of the pest in the PRA area.

The information on spread potential is used to estimate how rapidly a pest's potential economic importance may be expressed within the PRA area. This also has significance if the pest is liable to enter and establish in an area of low potential economic importance and then spread to an area of high potential economic importance. In addition it may be important in the risk management stage (see Figure 3) when considering the ease with which an introduced pest could be contained or eradicated.

2.2.3 Potential economic importance

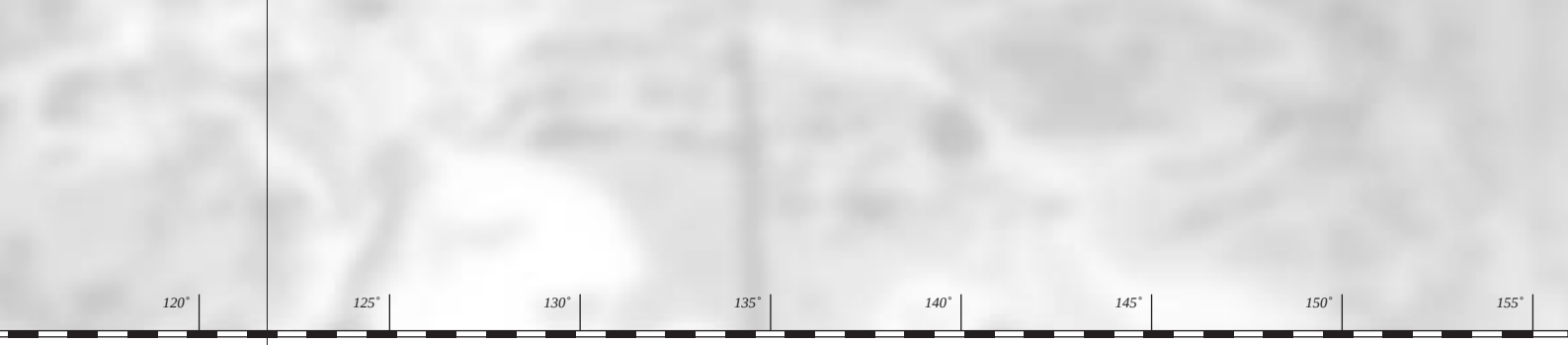
The next step in the PRA process is to determine whether the pest is of potential economic importance in the PRA area.

In order to estimate the potential economic importance of the pest, information should be obtained from areas where the pest currently occurs. For each of these areas, note whether the pest causes major, minor or no damage. Note whether the pest causes damage frequently or infrequently. Relate this, if possible, to biotic and abiotic effects, particularly climate.

The situation in the PRA area can then be carefully compared with that in the areas where the pest currently occurs. Case histories concerning comparable pests can usefully be considered. Expert judgement is then used to assess the potential for economic importance. Examples of the factors to consider are:

– type of damage
– crop losses
– loss of export markets
– increases in control costs
– effects on ongoing integrated pest management (IPM) programmes
– environmental damage
– capacity to act as a vector for other pests
– perceived social costs such as unemployment.

If a pest has no potential economic importance in the PRA area, then it does not satisfy the definition of a quarantine pest and the PRA for the pest stops at this point.



2.3 Introduction Potential

The final stage of assessment concerns the introduction potential which depends on the pathways from the exporting country to the destination, and the frequency and quantity of pests associated with them. Documented pathways for the pest to enter new areas should be noted. Potential pathways which may not currently exist should be assessed if known.

The following is a partial checklist that may be used to estimate the introduction potential divided into those factors which may affect the likelihood of entry and those factors which may affect the likelihood of establishment.

Entry:

- opportunity for contamination of commodities or conveyances by the pest
- survival of the pest under the environmental conditions of transport
- ease or difficulty of detecting the pest at entry inspection
- frequency and quantity of pest movement into the PRA area by natural means
- frequency and number of persons entering from another country at any given port of entry.

Establishment:

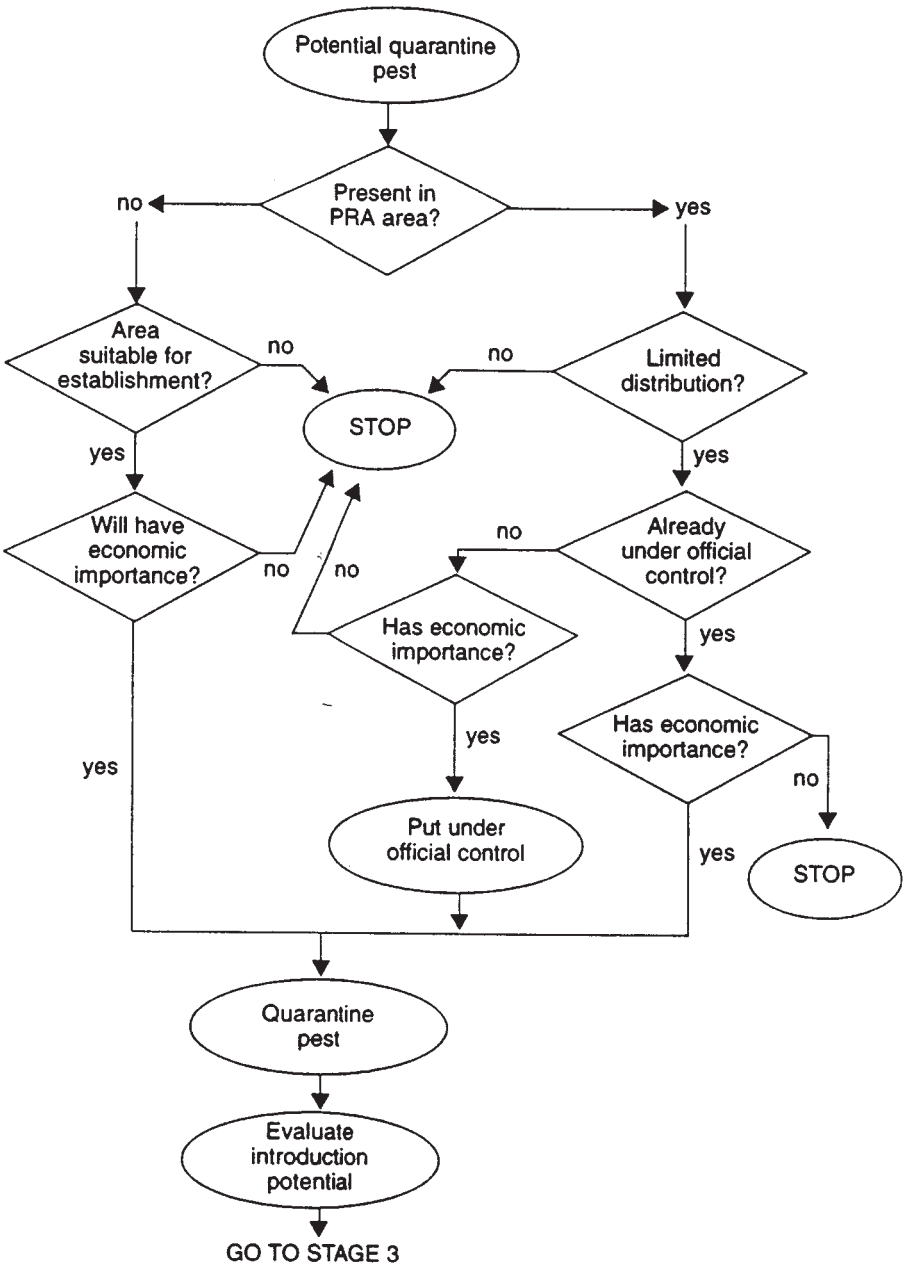
- number and frequency of consignments of the commodity
- number of individuals of a given pest associated with the means of conveyance
- intended use of the commodity
- environmental conditions and availability of hosts at the destination and during transport in the PRA area.

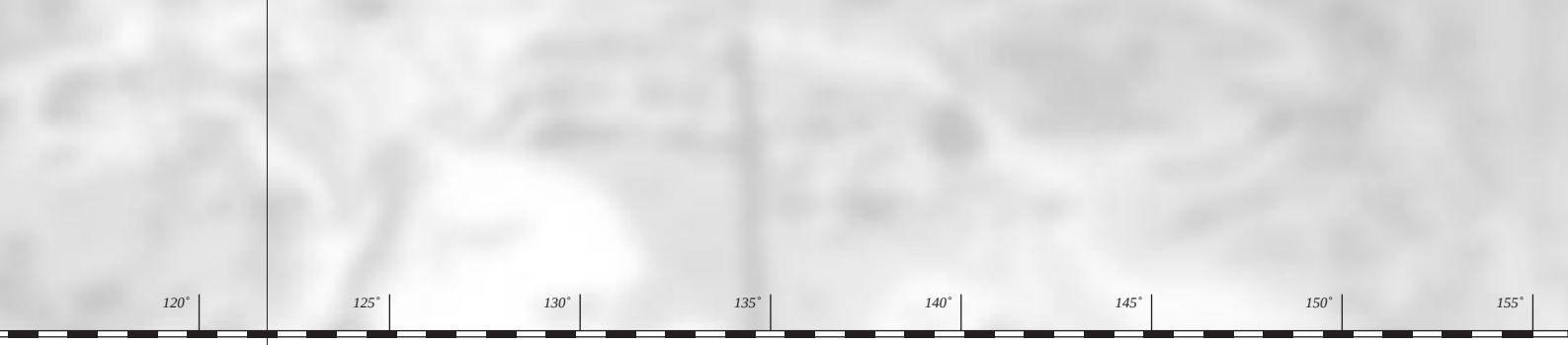
2.4 Conclusion for Stage 2

If the pest satisfies the definition of a quarantine pest, expert judgement should be used to review the information collected during Stage 2 to decide whether the pest has sufficient economic importance and introduction potential, i.e. sufficient risk, for phytosanitary measures to be justified. If so, proceed to Stage 3; if not, the PRA for the pest stops at this point.[3]

[3] Decision-making schemes, or expert systems, may be useful at this stage to assist expert judgement.

Figure 2. Pest Risk Analysis Stage 2: Assessment





3. Stage 3: Pest Risk Management

Pest risk management (see Figure 3) to protect the endangered areas should be proportional to the risk identified in the pest risk assessment. In most respects it can be based on the information gathered in the pest risk assessment. Phytosanitary measures should be applied to the minimum area necessary for the effective protection of the endangered area.

3.1 Risk Management Options

A list of options for reducing risks to an acceptable level should be assembled. These options will primarily concern pathways and in particular the conditions for permitting entry of commodities. Examples of the options to consider are:

- inclusion in list of prohibited pests
- phytosanitary inspection and certification prior to export
- definition of requirements to be satisfied before export (e.g. treatment, origin from pest free area, growing season inspection, certification scheme)
- inspection at entry
- treatment at point of entry, inspection station or, if appropriate, at place of destination
- detention in post-entry quarantine
- post-entry measures (restrictions on use of commodity, control measures)
- prohibition of entry of specific commodities from specific origins.

They may also, however, concern ways of reducing the risk of damage, for example, introduction of a biological control agent, or ease of eradication or containment.

3.2 Efficacy and Impact of the Options

The efficacy and impact of the various options in reducing risk to an acceptable level should be evaluated, in terms of the following factors:

- biological effectiveness
- cost/benefit of implementation
- impact on existing regulations
- commercial impact
- social impact
- phytosanitary policy considerations
- time to implement a new regulation
- efficacy of option against other quarantine pests
- environmental impact.

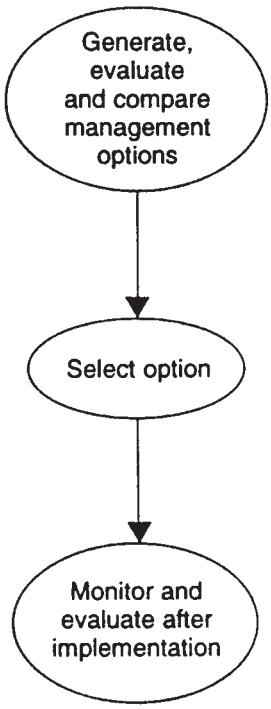
The positive and negative aspects of the options should be specified. While it is recognized that countries according to the sovereignty principle may exercise their sovereign right to utilize phytosanitary measures, countries should also take particular note of the "Minimal impact" principle:

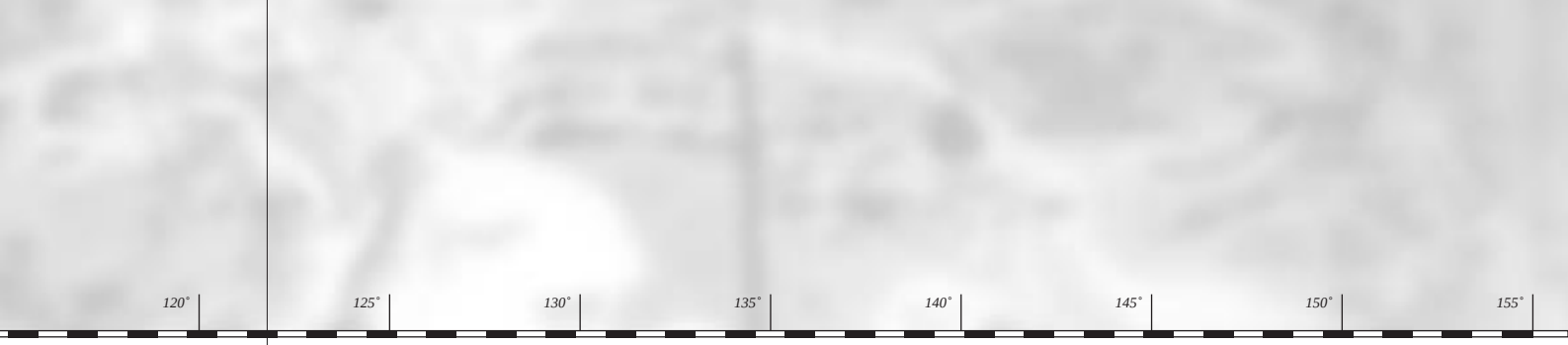
Phytosanitary measures shall be consistent with the pest risk involved, and shall represent the least restrictive measures available which result in the minimum impediment to the international movement of people, commodities and conveyances.

Article VI.2(f) of the International Plant Protection Convention makes a similar but less comprehensive provision. Phytosanitary measures recommended should be based on all of the above factors.

In order to determine which options are appropriate, it may be advisable to communicate with interested and affected groups within and outside the PRA area.

Figure 3. Pest Risk Analysis Stage 3: Management from Stage 2





3.3 Conclusion for Stage 3

At the end of Stage 3, the appropriate phytosanitary measures concerning the pest or pathway have been decided. Completion of Stage 3 is essential; it is in particular not justified to complete only Stages 1 and 2 and then take phytosanitary measures without proper assessment of risk management options. After implementation of the phytosanitary measures, their effectiveness should be monitored and the risk management options should be reviewed, if necessary.

4. Documenting the PRA Process

A PRA should be sufficiently documented so that when a review or a dispute arises, the PRA will clearly state the sources of information and the rationales used in reaching a management decision regarding phytosanitary measures taken or to be taken.

Other Documents Published by the IPPC Secretariat Under the Framework of International Standards for Phytosanitary Measures (ISPMs)

All documents listed below are published in Arabic, Chinese, English, French and Spanish.

Part 1. Import Regulations

Code of conduct for the import and release of exotic biological control agents, 1996. ISPM Pub. No. 3, FAO, Rome.

Pest risk analysis: supplementary standard for pest categorization, economic impact assessment, probability of introduction, and pest risk management (in preparation)

Part 2. Export Certification

Framework for an export certification system (in preparation)

Inspection methodology (in preparation)

Part 3. Compliance Procedures

(in preparation)

Part 4. Pest Surveillance

Guidelines for survey and monitoring systems (in preparation)

Requirements for the establishment of pest free areas, 1996. ISPM Pub. No. 4, FAO, Rome.

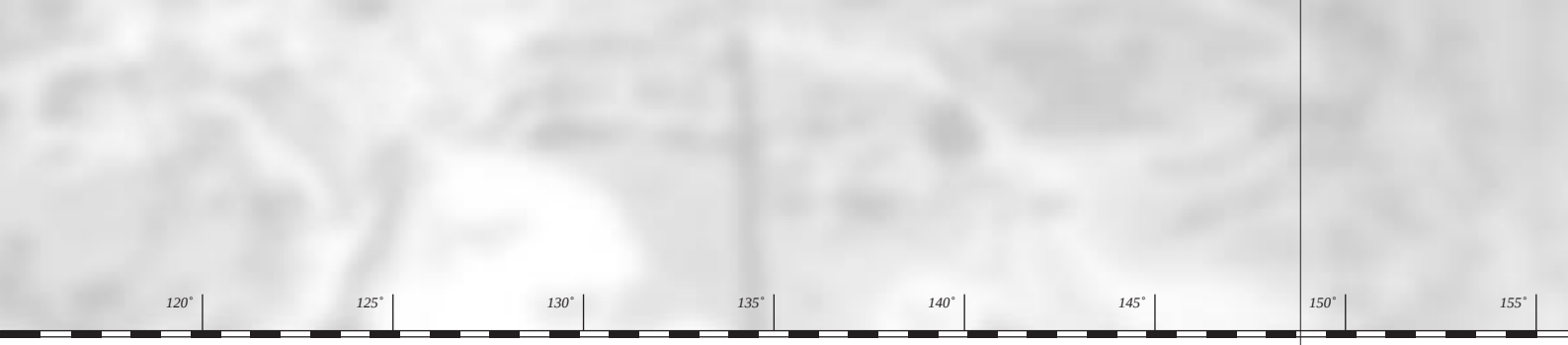
Requirements for the establishment of pest free production sites (in preparation)

Part 5. Exotic Pest Response

Guidelines for pest eradication programmes (in preparation)

Part 6. Pest Management

(in preparation)



Part 7. Post-Entry Quarantine

(in preparation)

Reference Standards

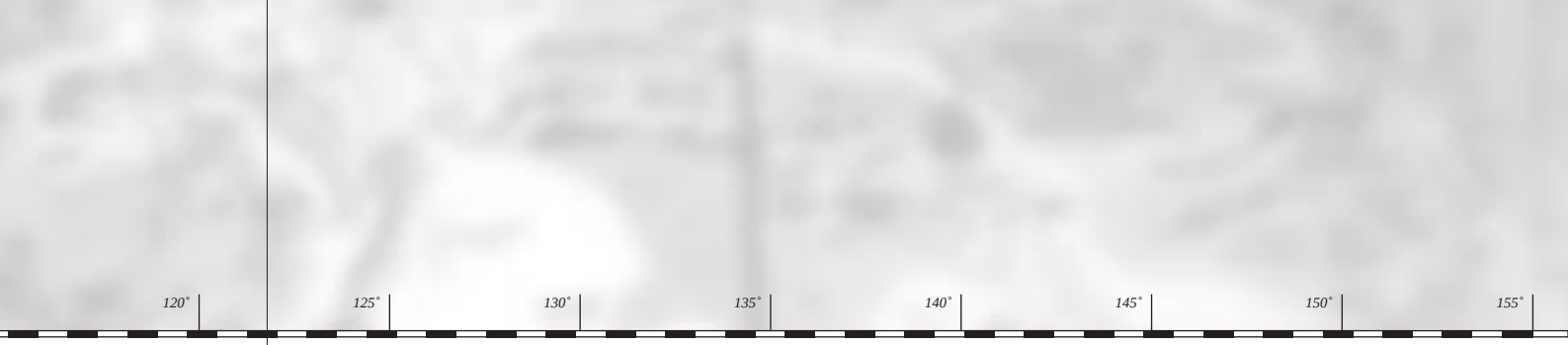
Glossary of phytosanitary terms, 1996. ISPM Pub. No. 5, FAO, Rome

International Plant Protection Convention, 1992. FAO, Rome

Principles of plant quarantine as related to international trade, 1995. ISPM Pub. No. 1, FAO, Rome

For further information, contact:

Secretariat
International Plant Protection Convention
Food and Agriculture Organization of the United Nations
Viale delle Terme di Caracalla
00100 Rome, Italy



Annex 3

SUMMARY OF PROCEDURES FOR APPLICATIONS FOR ACCESS TO AUSTRALIA FOR PLANTS AND PLANT PRODUCTS

Keeping unwanted pests and diseases out of the country while facilitating the international flow of goods and people wherever possible is the primary role of quarantine in Australia.

Quarantine is essential to the maintenance of Australia's highly favourable human, animal and plant health status and is an important element in the regulatory framework that governs trade within and between nations. Effective and efficient quarantine enhances our way of life by safeguarding the natural resource base on which we are critically dependent as a nation in social, economic and cultural terms.

The establishment of a major disease such as foot-and-mouth, which would have a devastating effect on our cattle, sheep and pig industries, could cause billions of dollars of damage to our economy through lost production, trade and employment. It would directly or indirectly affect all Australians. Similarly introduced weeds and feral animals can become major threats to agricultural production.

While no quarantine service can totally eliminate the risk that pests and diseases will enter the country, quarantine represents a vital first line of defence against these threats. Quarantine in Australia is administered by the Australian Quarantine and Inspection Service (AQIS), an operating group within the Commonwealth Department of Primary Industries and Energy.

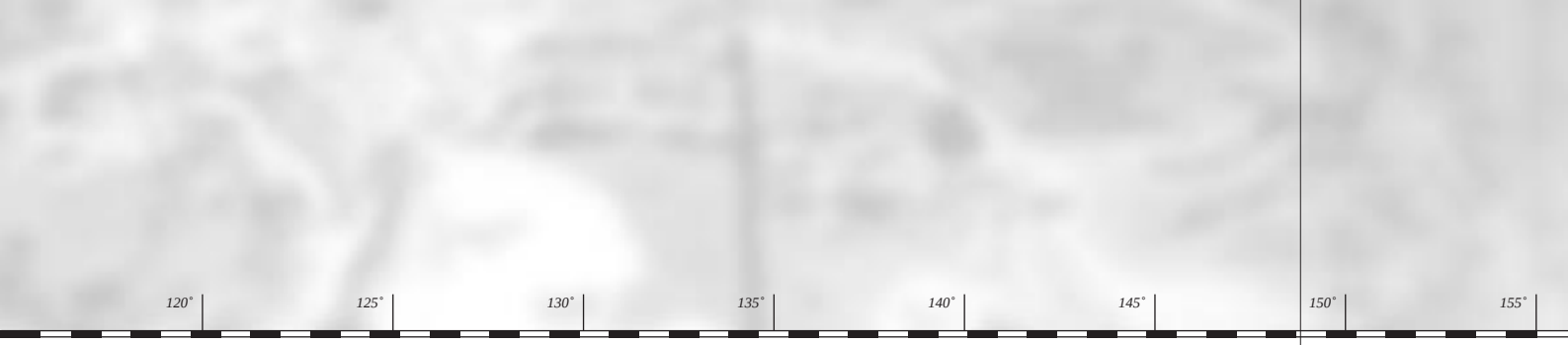
The Australian Government recently released its response to the major review of Australian quarantine, *Australian Quarantine — A shared responsibility*, carried out by Professor Malcolm E Nairn. One of the most contentious areas of quarantine policy in recent times has been the process for carrying out import risk analyses. The Nairn Committee made a number of recommendations to address this issue and these recommendations have been endorsed by the Australian Government.

AQIS receives many applications to import agricultural commodities each year. These range from items that can be imported from a country with similar pest and disease status to ours (that is an import risk analysis has already been conducted), to items where considerable scientific analysis is required. The first category of applications referred to is usually approved within days of receipt, while the latter may take years to resolve. Notwithstanding this difference, the principles behind the import risk analysis process must be the same so that the final decision is the correct one.

To accommodate the different types of import risk analysis that have to be undertaken, the Government has decided on an Import Risk Analysis (IRA) procedure which, while consistent, has different steps for 'routine analyses' and 'non-routine analyses'.

Prior to the commencement of an import risk analysis the applicant is required to provide the scientific data from the national quarantine service of the prospective exporting country on the distribution records of pests associated with specific plants or plant products in production areas. Where these records are not available, special surveys and monitoring may be necessary.

Risk analysis is the foundation stone on which all quarantine policy and action must be built. The Australian Government has identified six fundamental principles that should apply to import risk analysis. It should be:



- conducted in a consultative framework;
- a scientific process and therefore politically independent;
- a transparent and open process;
- consistent with both Government policy and Australiaís international obligations;
- harmonised through taking account of international standards and guidelines; and
- subject to appeal on the process.

Data Requirements

1. Information on the Crop (Botanist)

1.1 scientific name, author
1.2 common name
1.3 variety/cultivator name (susceptibility/resistance to pests and diseases)
1.4 export destinations

2. Production Area (Botanist)

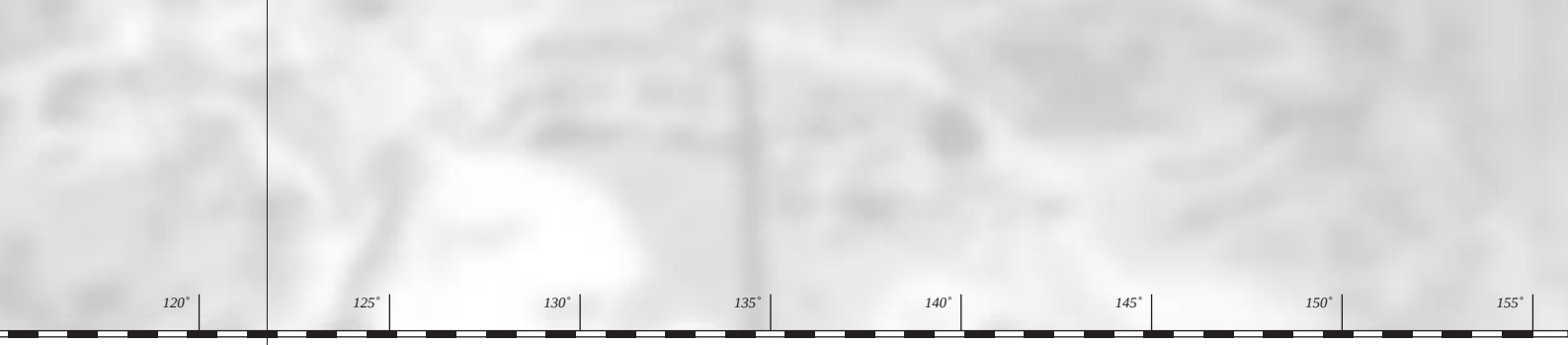
2.1 states, regions, provinces, districts etc.
2.2 area maps (general and enlarged)
2.3 amount proposed for export

3. Cultivation Methods (Botanist)

3.1 pest management and general surveillance programs (eg survey data/sampling methods, fruit fly)
3.2 sourcing product from pest free zones
3.3 harvesting methods, dates
3.4 internal legislative restrictions (pest free areas)

4. Pest List (Pathologists, entomologists, nematologists etc)

4.1 scientific names and authors
4.2 classification
4.3 synonyms commonly used
4.4 common names (most accepted ones)
4.5 hosts (variety if relevant)
4.6 plant part attacked
4.7 symptoms/damage
4.8 distribution
4.9 prevalence (common, occasional or rare)



4.10 control measures

- 4.10.1 cultural (host erradication, crop rotation, sanitation, use of traps)
- 4.10.2 biological (use of insects/pathogens, suppressive soils, antagonism, cross protection)
- 4.10.3 physical
- 4.10.4 chemical active ingredient (foliage sprays/dusts, method, time, frequency of application)
- 4.10.5 biology (life cycle-brief, epidemiology, vectors, transmission)

4.11 technical references to biology of pests

4.12 data sheets (may be on request after the preliminary PRA)

5. Packhouse

5.1 packing methods

5.2 inspection procedures (inspection rates)

5.3 post harvest disinfestation treatment

5.4 storage conditions and security

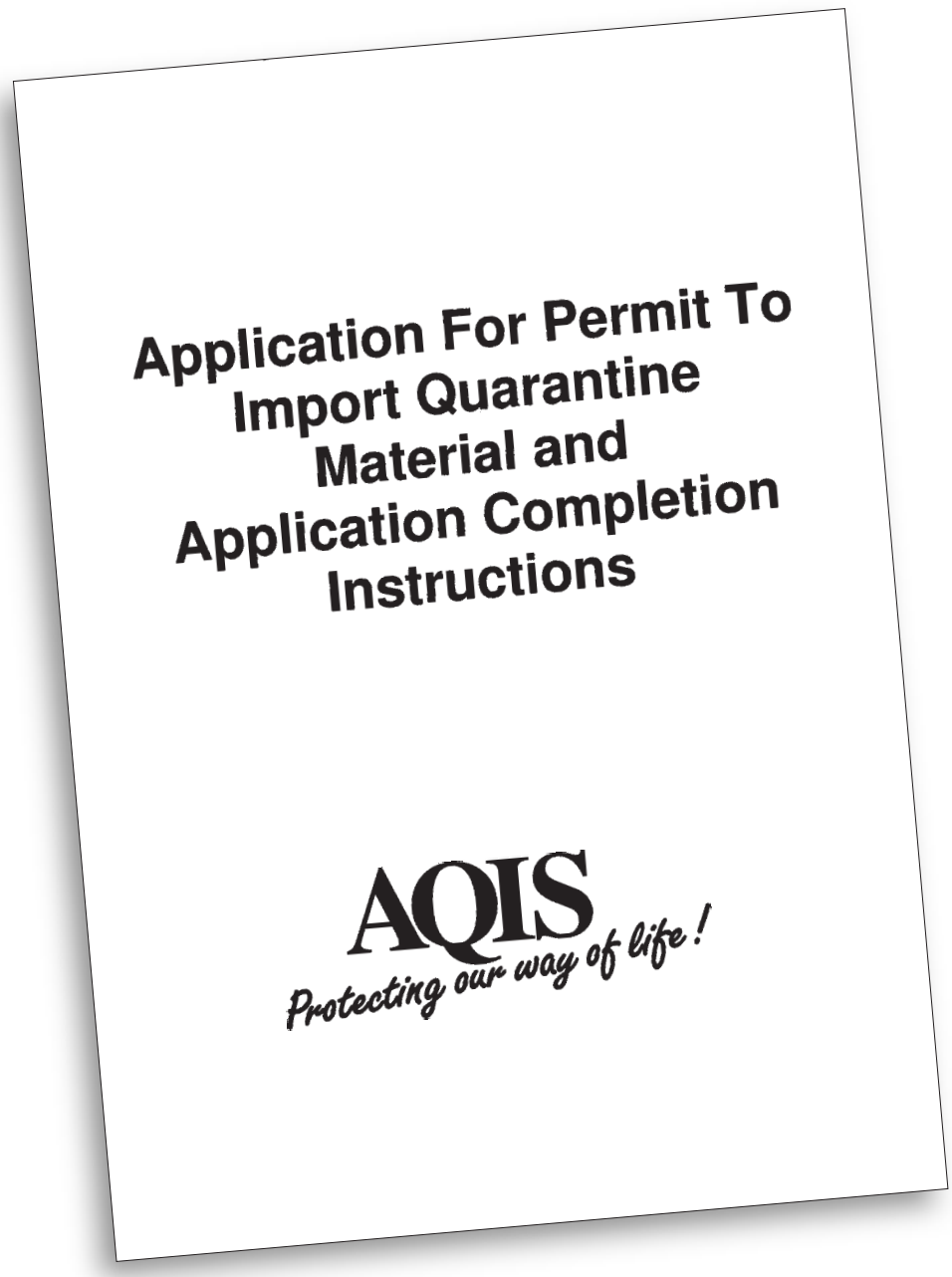
6. Export Program (Policy/Operations)

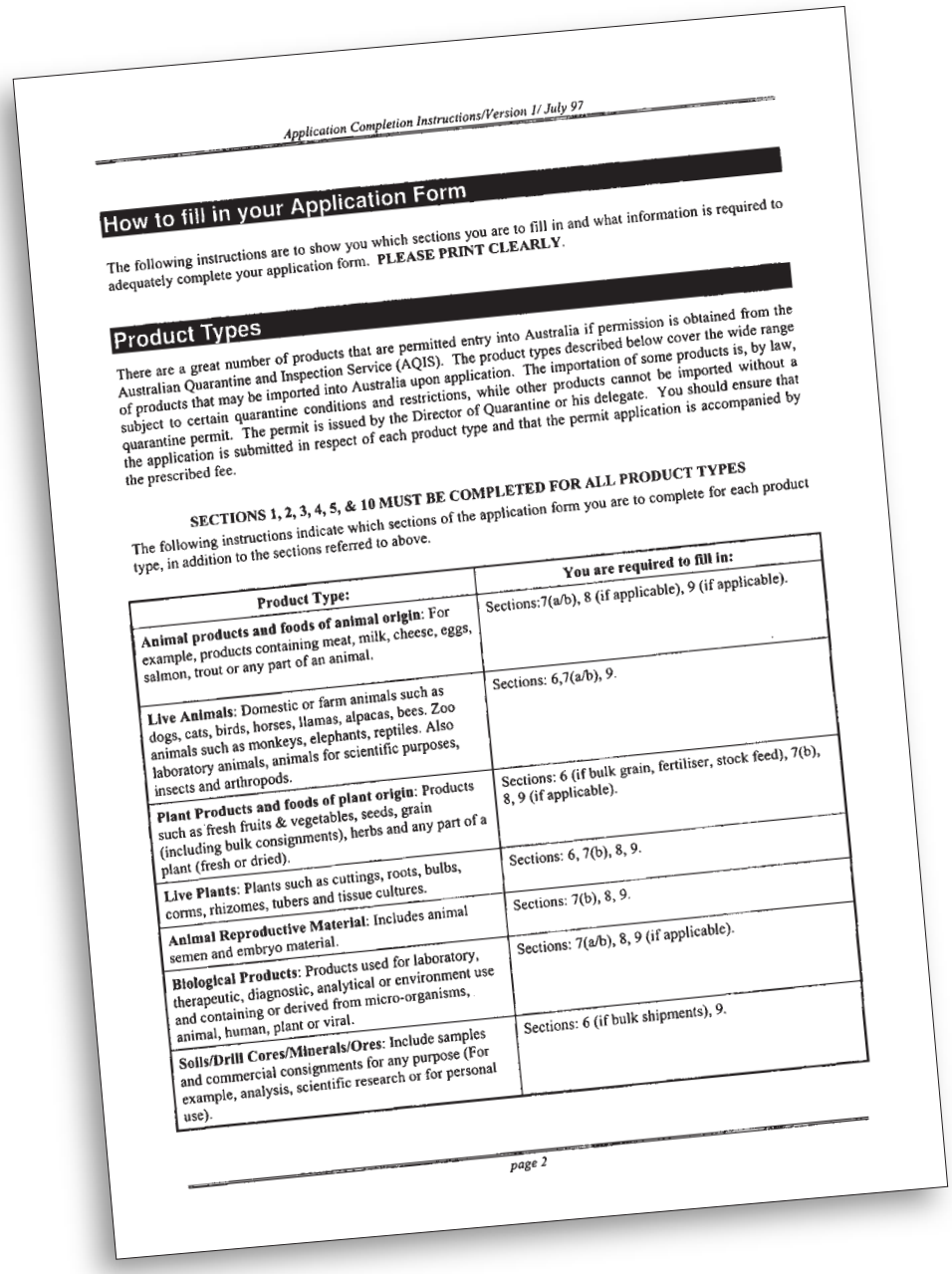
6.1 export destinations

6.2 current phytosanitary certification procedures (standard/specific, additional declarations etc)

7. Copies of Relevant References

Note: All data (if possible) provided to be less than 10 years old and validated/endorsed by the national plant protection organisation of the exporting country.


Application For Permit To Import Quarantine Material and Application Completion Instructions
AQIS
Protecting our way of life!



Application Completion Instructions/Version 1/ July 97

How to fill in your Application Form

The following instructions are to show you which sections you are to fill in and what information is required to adequately complete your application form. **PLEASE PRINT CLEARLY**.

Product Types

There are a great number of products that are permitted entry into Australia if permission is obtained from the Australian Quarantine and Inspection Service (AQIS). The product types described below cover the wide range of products that may be imported into Australia upon application. The importation of some products is, by law, subject to certain quarantine conditions and restrictions, while other products cannot be imported without a quarantine permit. The permit is issued by the Director of Quarantine or his delegate. You should ensure that the application is submitted in respect of each product type and that the permit application is accompanied by the prescribed fee.

SECTIONS 1, 2, 3, 4, 5, & 10 MUST BE COMPLETED FOR ALL PRODUCT TYPES

The following instructions indicate which sections of the application form you are to complete for each product type, in addition to the sections referred to above.

Product Type:	You are required to fill in:
Animal products and foods of animal origin: For example, products containing meat, milk, cheese, eggs, salmon, trout or any part of an animal.	Sections:7(a/b), 8 (if applicable), 9 (if applicable).
Live Animals: Domestic or farm animals such as dogs, cats, birds, horses, llamas, alpacas, bees. Zoo animals such as monkeys, elephants, reptiles. Also laboratory animals, animals for scientific purposes, insects and arthropods.	Sections: 6,7(a/b), 9.
Plant Products and foods of plant origin: Products such as fresh fruits & vegetables, seeds, grain (including bulk consignments), herbs and any part of a plant (fresh or dried).	Sections: 6 (if bulk grain, fertiliser, stock feed), 7(b), 8, 9 (if applicable).
Live Plants: Plants such as cuttings, roots, bulbs, corms, rhizomes, tubers and tissue cultures.	Sections: 6, 7(b), 8, 9.
Animal Reproductive Material: Includes animal semen and embryo material.	Sections: 7(b), 8, 9.
Biological Products: Products used for laboratory, therapeutic, diagnostic, analytical or environment use and containing or derived from micro-organisms, animal, human, plant or viral.	Sections: 7(a/b), 8, 9 (if applicable).
Soils/Drill Cores/Minerals/Ores: Include samples and commercial consignments for any purpose (For example, analysis, scientific research or for personal use).	Sections: 6 (if bulk shipments), 9.

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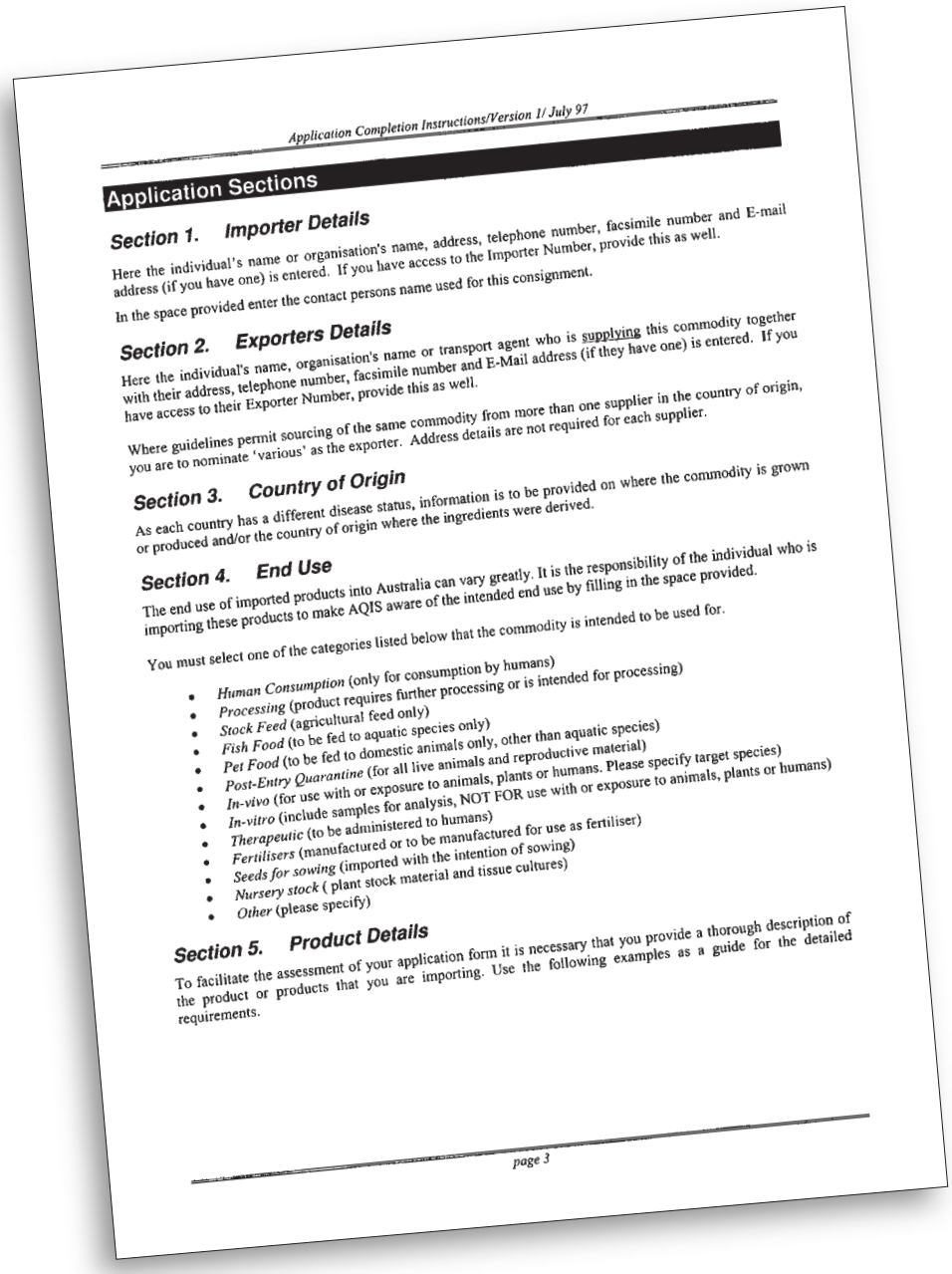


Application Sections

Section 1. Importer Details

Here the individual's name or organisation's name, address, telephone number, facsimile number and E-mail address (if you have one) is entered. If you have access to the Importer Number, provide this as well.

In the space provided enter the contact persons name used for this consignment.

Section 2. Exporters Details

Here the individual's name, organisation's name or transport agent who is supplying this commodity together with their address, telephone number, facsimile number and E-Mail address (if they have one) is entered. If you have access to their Exporter Number, provide this as well.

Where guidelines permit sourcing of the same commodity from more than one supplier in the country of origin, you are to nominate 'various' as the exporter. Address details are not required for each supplier.

Section 3. Country of Origin

As each country has a different disease status, information is to be provided on where the commodity is grown or produced and/or the country of origin where the ingredients were derived.

Section 4. End Use

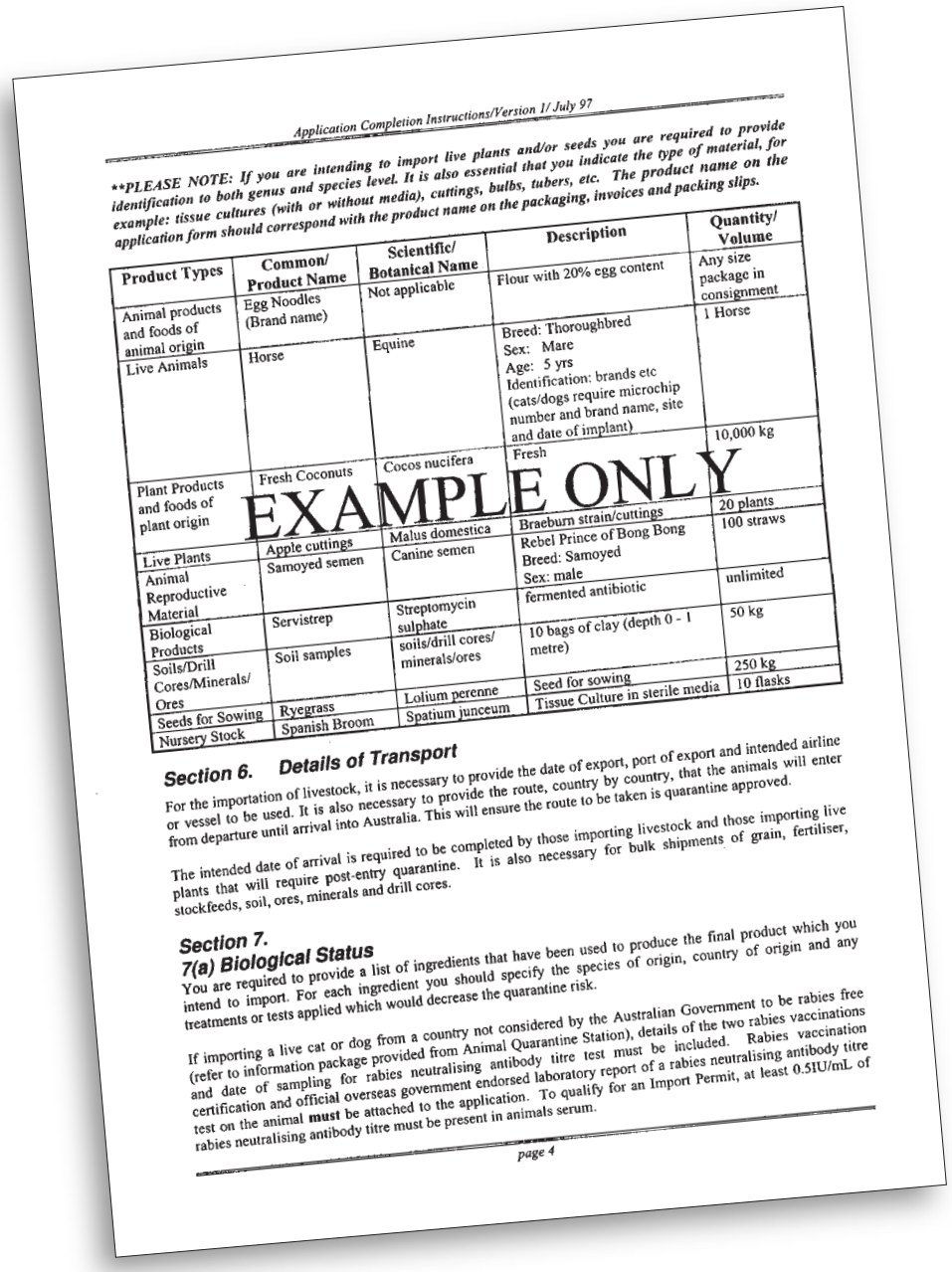
The end use of imported products into Australia can vary greatly. It is the responsibility of the individual who is importing these products to make AQIS aware of the intended end use by filling in the space provided.

You must select one of the categories listed below that the commodity is intended to be used for.

- *Human Consumption* (only for consumption by humans)
- *Processing* (product requires further processing or is intended for processing)
- *Stock Feed* (agricultural feed only)
- *Fish Food* (to be fed to aquatic species only)
- *Pet Food* (to be fed to domestic animals only, other than aquatic species)
- *Post-Entry Quarantine* (for all live animals and reproductive material)
- *In-vivo* (for use with or exposure to animals, plants or humans. Please specify target species)
- *In-vitro* (include samples for analysis, NOT FOR use with or exposure to animals, plants or humans)
- *Therapeutic* (to be administered to humans)
- *Fertilisers* (manufactured or to be manufactured for use as fertiliser)
- *Seeds for sowing* (imported with the intention of sowing)
- *Nursery stock* (plant stock material and tissue cultures)
- *Other* (please specify)

Section 5. Product Details

To facilitate the assessment of your application form it is necessary that you provide a thorough description of the product or products that you are importing. Use the following examples as a guide for the detailed requirements.



Application Completion Instructions/Version 1/ July 97

PLEASE NOTE: If you are intending to import live plants and/or seeds you are required to provide identification to both genus and species level. It is also essential that you indicate the type of material, for example: tissue cultures (with or without media), cuttings, bulbs, tubers, etc. The product name on the application form should correspond with the product name on the packaging, invoices and packing slips.

Product Types	Common/ Product Name	Scientific/ Botanical Name	Description	Quantity/ Volume
Animal products and foods of animal origin	Egg Noodles (Brand name)	Not applicable	Flour with 20% egg content	Any size package in consignment
Live Animals	Horse	Equine	Breed: Thoroughbred Sex: Mare Age: 5 yrs Identification: brands etc (cats/dogs require microchip number and brand name, site and date of implant)	1 Horse
Plant Products and foods of plant origin	Fresh Coconuts	Cocos nucifera	Fresh	10,000 kg
Live Plants	Apple cuttings	Malus domestica	Braeburn strain/cuttings	20 plants
Animal Reproductive Material	Samoyed semen	Canine semen	Rebel Prince of Bong Bong Breed: Samoyed Sex: male	100 straws
Biological Products	Servistrep	Streptomycin sulphate	fermented antibiotic	unlimited
Soils/Drill Cores/Minerals/ Ores	Soil samples	soils/drill cores/ minerals/ores	10 bags of clay (depth 0 - 1 metre)	50 kg
Seeds for Sowing	Ryegrass	Lolium perenne	Seed for sowing	250 kg
Nursery Stock	Spanish Broom	Spatium junceum	Tissue Culture in sterile media	10 flasks

EXAMPLE ONLY

Section 6. Details of Transport

For the importation of livestock, it is necessary to provide the date of export, port of export and intended airline or vessel to be used. It is also necessary to provide the route, country by country, that the animals will enter from departure until arrival into Australia. This will ensure the route to be taken is quarantine approved.

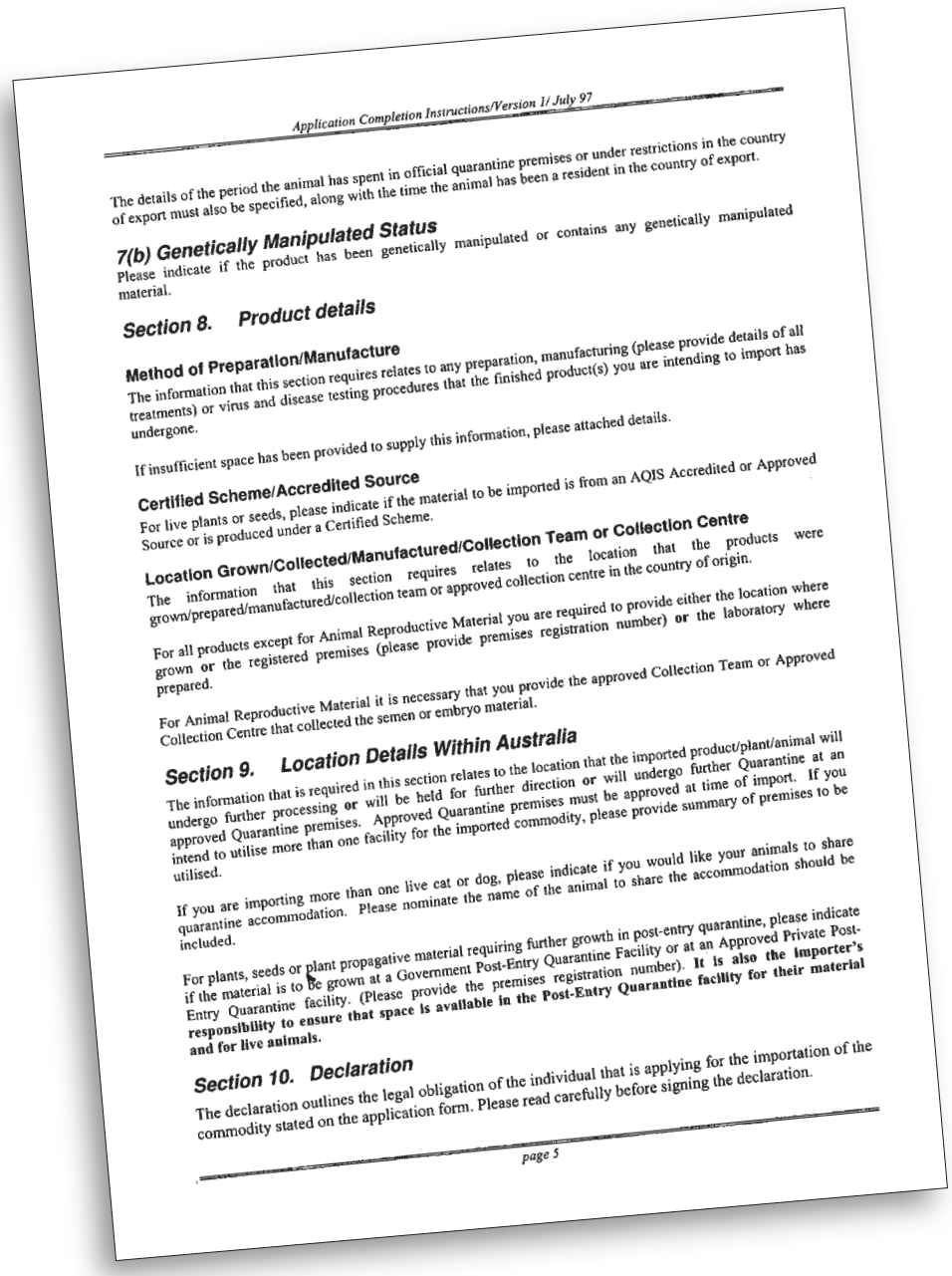
The intended date of arrival is required to be completed by those importing livestock and those importing live plants that will require post-entry quarantine. It is also necessary for bulk shipments of grain, fertiliser, stockfeeds, soil, ores, minerals and drill cores.

Section 7.
7(a) Biological Status

You are required to provide a list of ingredients that have been used to produce the final product which you intend to import. For each ingredient you should specify the species of origin, country of origin and any treatments or tests applied which would decrease the quarantine risk.

If importing a live cat or dog from a country not considered by the Australian Government to be rabies free (refer to information package provided from Animal Quarantine Station), details of the two rabies vaccinations and date of sampling for rabies neutralising antibody titre test must be included. Rabies vaccination certification and official overseas government endorsed laboratory report of a rabies neutralising antibody titre test on the animal **must** be attached to the application. To qualify for an Import Permit, at least 0.5IU/mL of rabies neutralising antibody titre must be present in animals serum.

page 4



The details of the period the animal has spent in official quarantine premises or under restrictions in the country of export must also be specified, along with the time the animal has been a resident in the country of export.

7(b) Genetically Manipulated Status

Please indicate if the product has been genetically manipulated or contains any genetically manipulated material.

Section 8. Product details

Method of Preparation/Manufacture

The information that this section requires relates to any preparation, manufacturing (please provide details of all treatments) or virus and disease testing procedures that the finished product(s) you are intending to import has undergone.

If insufficient space has been provided to supply this information, please attached details.

Certified Scheme/Accredited Source

For live plants or seeds, please indicate if the material to be imported is from an AQIS Accredited or Approved Source or is produced under a Certified Scheme.

Location Grown/Collected/Manufactured/Collection Team or Collection Centre

The information that this section requires relates to the location that the products were grown/prepared/manufactured/collection team or approved collection centre in the country of origin.

For all products except for Animal Reproductive Material you are required to provide either the location where grown **or** the registered premises (please provide premises registration number) **or** the laboratory where prepared.

For Animal Reproductive Material it is necessary that you provide the approved Collection Team or Approved Collection Centre that collected the semen or embryo material.

Section 9. Location Details Within Australia

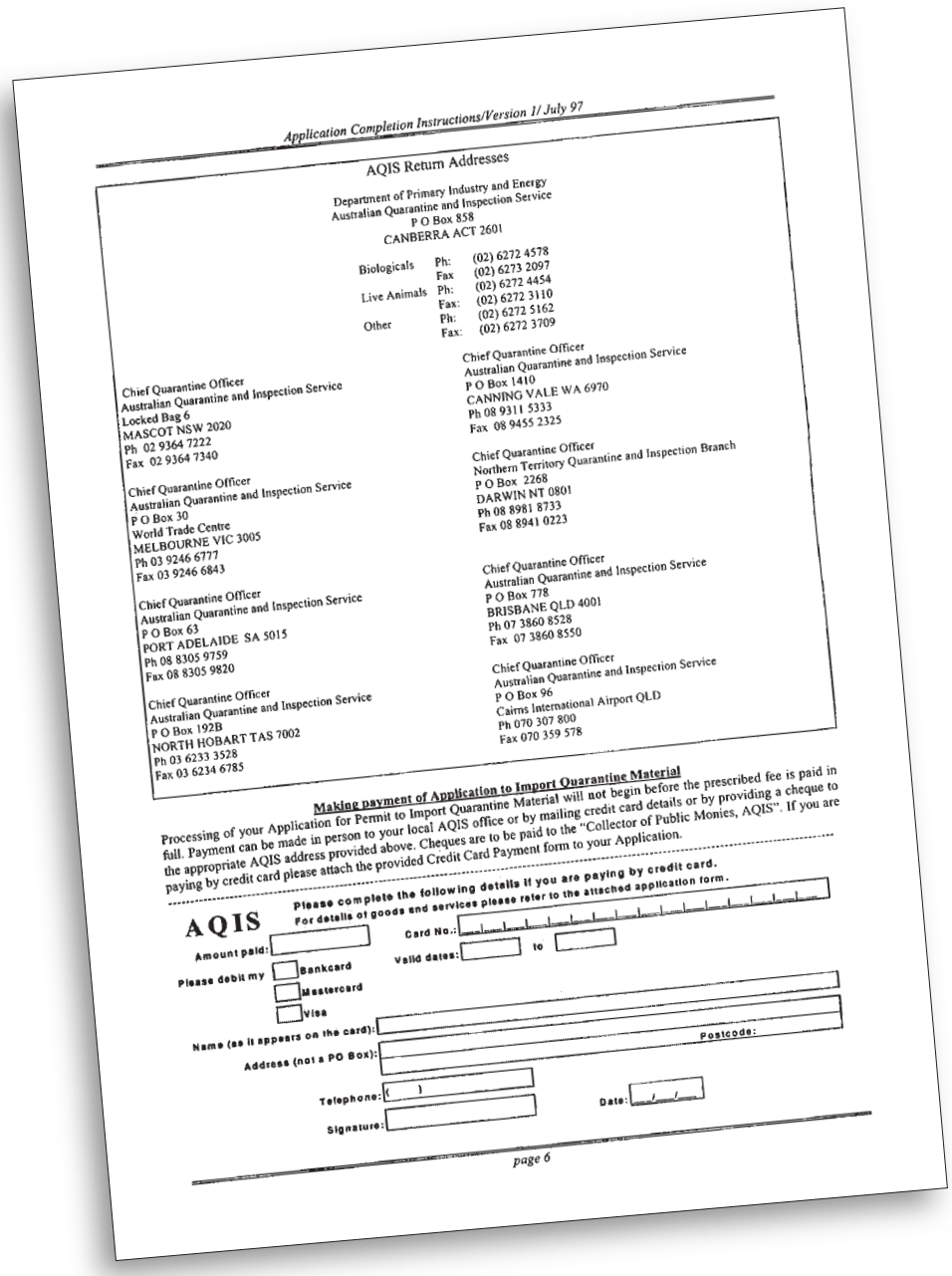
The information that is required in this section relates to the location that the imported product/plant/animal will undergo further processing **or** will be held for further direction **or** will undergo further Quarantine at an approved Quarantine premises. Approved Quarantine premises must be approved at time of import. If you intend to utilise more than one facility for the imported commodity, please provide summary of premises to be utilised.

If you are importing more than one live cat or dog, please indicate if you would like your animals to share quarantine accommodation. Please nominate the name of the animal to share the accommodation should be included.

For plants, seeds or plant propagative material requiring further growth in post-entry quarantine, please indicate if the material is to be grown at a Government Post-Entry Quarantine Facility or at an Approved Private Post-Entry Quarantine facility. (Please provide the premises registration number). **It is also the importer's responsibility to ensure that space is available in the Post-Entry Quarantine facility for their material and for live animals.**

Section 10. Declaration

The declaration outlines the legal obligation of the individual that is applying for the importation of the commodity stated on the application form. Please read carefully before signing the declaration.



Application Completion Instructions/Version 1/ July 97

AQIS Return Addresses

Department of Primary Industry and Energy
Australian Quarantine and Inspection Service
P O Box 858
CANBERRA ACT 2601

Biologicals	Ph:	(02) 6272 4578
	Fax	(02) 6273 2097
Live Animals	Ph:	(02) 6272 4454
	Fax:	(02) 6272 3110
Other	Ph:	(02) 6272 5162
	Fax:	(02) 6272 3709

Chief Quarantine Officer
Australian Quarantine and Inspection Service
Locked Bag 6
MASCOT NSW 2020
Ph 02 9364 7222
Fax 02 9364 7340

Chief Quarantine Officer
Australian Quarantine and Inspection Service
P O Box 30
World Trade Centre
MELBOURNE VIC 3005
Ph 03 9246 6777
Fax 03 9246 6843

Chief Quarantine Officer
Australian Quarantine and Inspection Service
P O Box 63
PORT ADELAIDE SA 5015
Ph 08 8305 9759
Fax 08 8305 9820

Chief Quarantine Officer
Australian Quarantine and Inspection Service
P O Box 192B
NORTH HOBART TAS 7002
Ph 03 6233 3528
Fax 03 6234 6785

Chief Quarantine Officer
Australian Quarantine and Inspection Service
P O Box 1410
CANNING VALE WA 6970
Ph 08 9311 5333
Fax 08 9455 2325

Chief Quarantine Officer
Northern Territory Quarantine and Inspection Branch
P O Box 2268
DARWIN NT 0801
Ph 08 8981 8733
Fax 08 8941 0223

Chief Quarantine Officer
Australian Quarantine and Inspection Service
P O Box 778
BRISBANE QLD 4001
Ph 07 3860 8528
Fax 07 3860 8550

Chief Quarantine Officer
Australian Quarantine and Inspection Service
P O Box 96
Cairns International Airport QLD
Ph 070 307 800
Fax 070 359 578

Making payment of Application to Import Quarantine Material

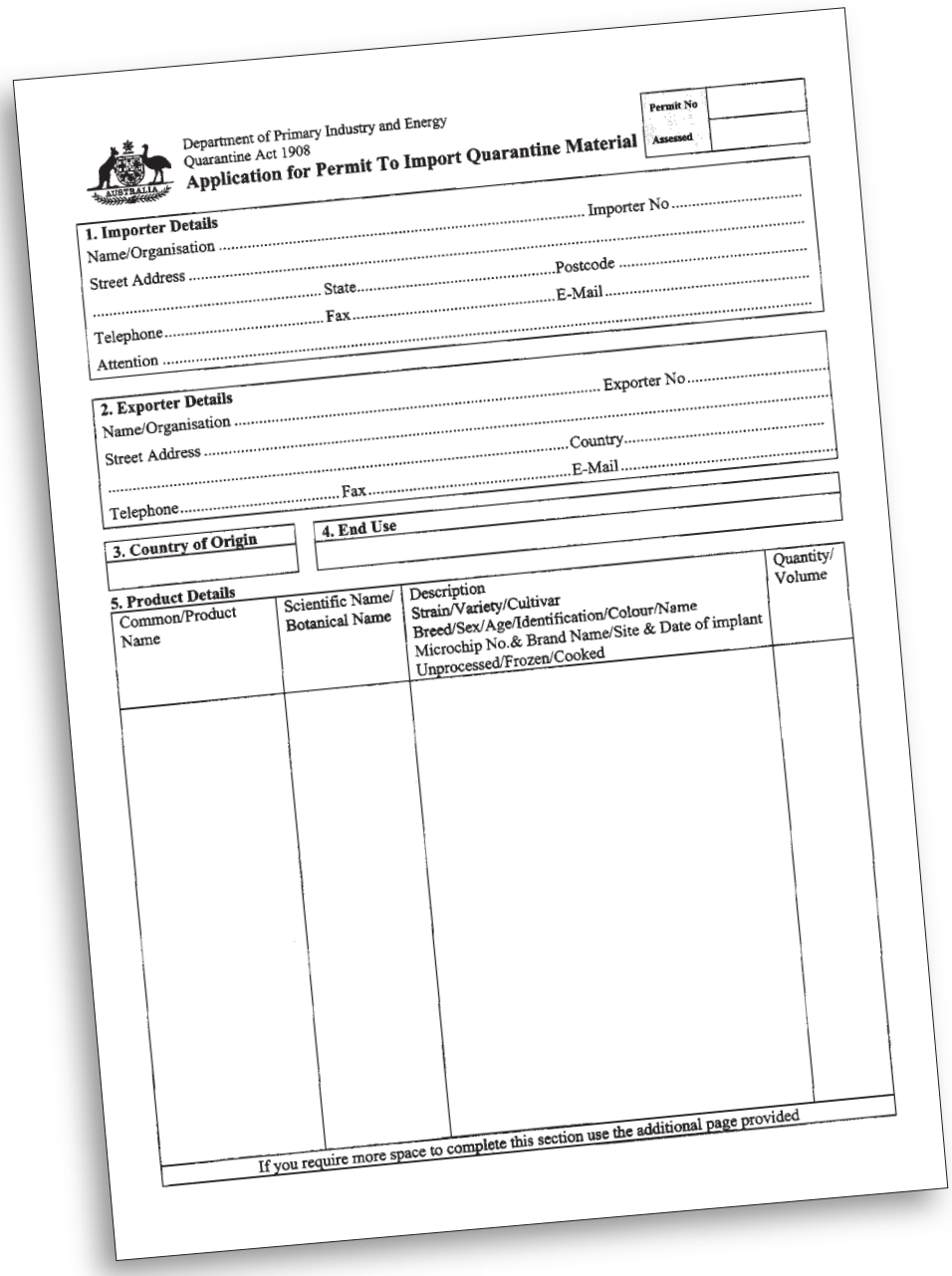
Processing of your Application for Permit to Import Quarantine Material will not begin before the prescribed fee is paid in full. Payment can be made in person to your local AQIS office or by mailing credit card details or by providing a cheque to the appropriate AQIS address provided above. Cheques are to be paid to the "Collector of Public Monies, AQIS". If you are paying by credit card please attach the provided Credit Card Payment form to your Application.

AQIS

Please complete the following details if you are paying by credit card.
For details of goods and services please refer to the attached application form.

Amount paid:
Please debit my ☐ Bankcard ☐ Mastercard ☐ Visa
Card No.:
Valid dates: to
Name (as it appears on the card):
Address (not a PO Box):
Postcode:
Telephone: ( )
Date: / /
Signature:

page 6



Department of Primary Industry and Energy
Quarantine Act 1908

Application for Permit To Import Quarantine Material

Permit No
Assessed

1. Importer Details

Name/Organisation ..... Importer No .....
Street Address .....
..... State ..... Postcode .....
Telephone ..... Fax ..... E-Mail .....
Attention .....

2. Exporter Details

Name/Organisation ..... Exporter No .....
Street Address .....
..... Country .....
Telephone ..... Fax ..... E-Mail .....

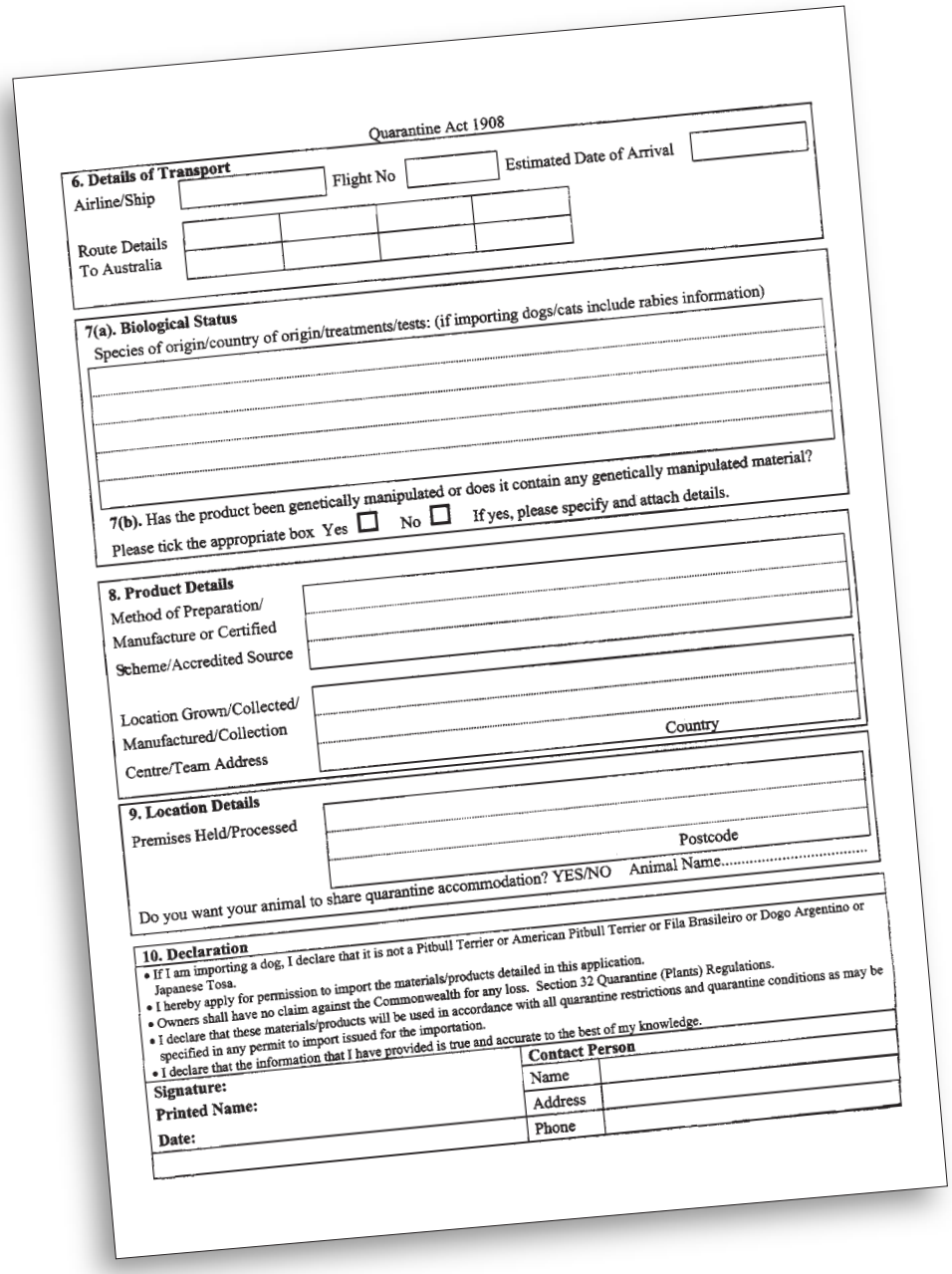
3. Country of Origin

4. End Use

5. Product Details

Common/Product Name	Scientific Name/ Botanical Name	Description Strain/Variety/Cultivar Breed/Sex/Age/Identification/Colour/Name Microchip No.& Brand Name/Site & Date of implant Unprocessed/Frozen/Cooked	Quantity/ Volume

If you require more space to complete this section use the additional page provided



Quarantine Act 1908

6. Details of Transport

Airline/Ship _____ Flight No _____ Estimated Date of Arrival _____

Route Details To Australia

7(a). Biological Status

Species of origin/country of origin/treatments/tests: (if importing dogs/cats include rabies information)

7(b). Has the product been genetically manipulated or does it contain any genetically manipulated material?

Please tick the appropriate box Yes ☐ No ☐ If yes, please specify and attach details.

8. Product Details

Method of Preparation/ Manufacture or Certified Scheme/Accredited Source

Location Grown/Collected/ Manufactured/Collection Centre/Team Address

Country

9. Location Details

Premises Held/Processed

Postcode

Do you want your animal to share quarantine accommodation? YES/NO Animal Name.....

10. Declaration

- If I am importing a dog, I declare that it is not a Pitbull Terrier or American Pitbull Terrier or Fila Brasileiro or Dogo Argentino or Japanese Tosa.
- I hereby apply for permission to import the materials/products detailed in this application.
- Owners shall have no claim against the Commonwealth for any loss. Section 32 Quarantine (Plants) Regulations.
- I declare that these materials/products will be used in accordance with all quarantine restrictions and quarantine conditions as may be specified in any permit to import issued for the importation.
- I declare that the information that I have provided is true and accurate to the best of my knowledge.

Signature:

Printed Name:

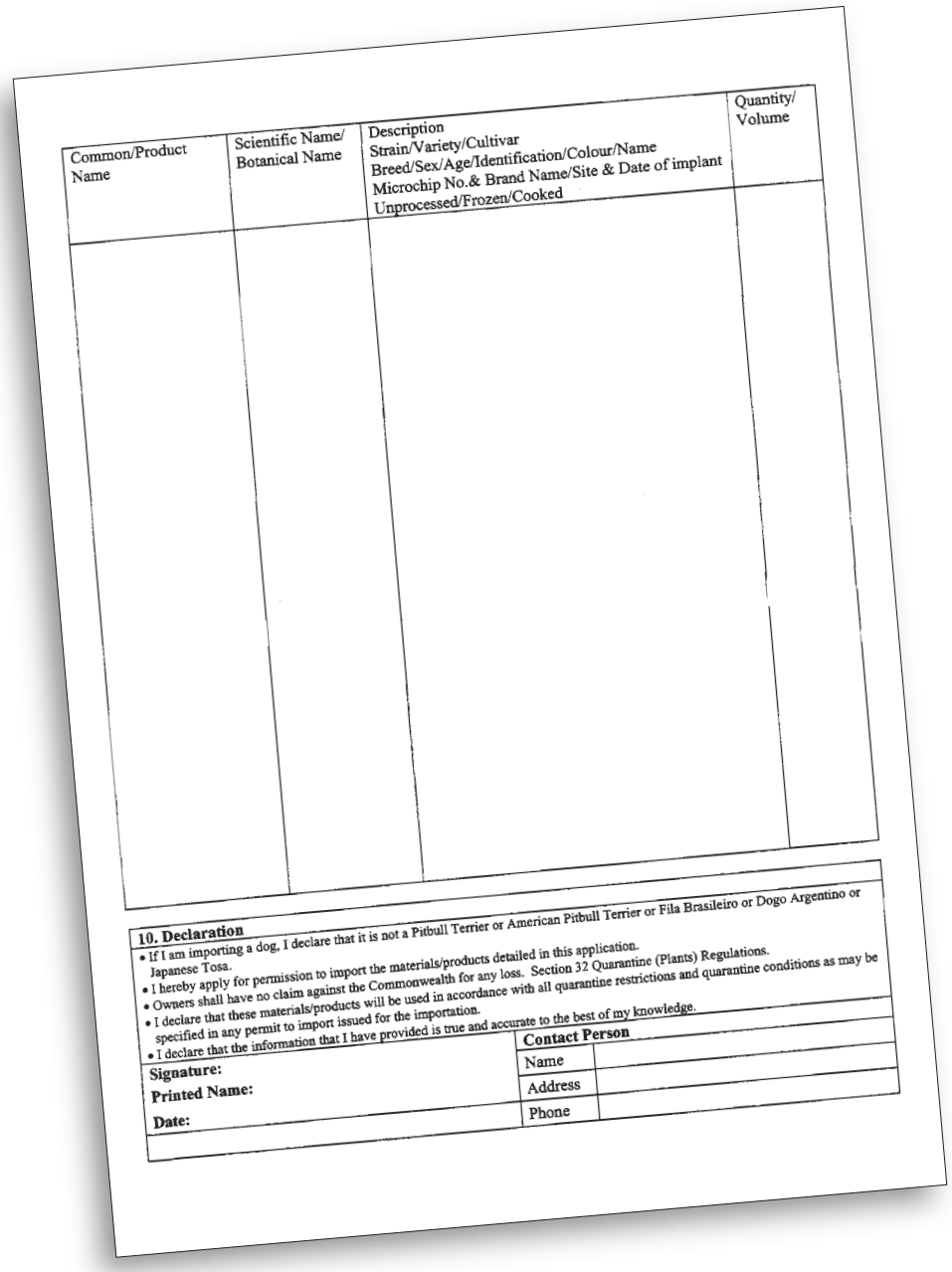
Date:

Contact Person

Name

Address

Phone



Common/Product Name	Scientific Name/ Botanical Name	Description Strain/Variety/Cultivar Breed/Sex/Age/Identification/Colour/Name Microchip No.& Brand Name/Site & Date of implant Unprocessed/Frozen/Cooked	Quantity/ Volume

10. Declaration

- If I am importing a dog, I declare that it is not a Pitbull Terrier or American Pitbull Terrier or Fila Brasileiro or Dogo Argentino or Japanese Tosa.
- I hereby apply for permission to import the materials/products detailed in this application.
- Owners shall have no claim against the Commonwealth for any loss. Section 32 Quarantine (Plants) Regulations.
- I declare that these materials/products will be used in accordance with all quarantine restrictions and quarantine conditions as may be specified in any permit to import issued for the importation.
- I declare that the information that I have provided is true and accurate to the best of my knowledge.

Signature:	**Contact Person**	
Printed Name:	Name	
Date:	Address	
	Phone	