EXPLANATORY STATEMENT

Select Legislative Instrument 2009 No. 348

Issued by the Authority of the Minister for Agriculture, Fisheries and Forestry

Imported Food Control Act 1992

Imported Food Control Amendment Regulations 2009 (No. 2)

Subsection 43(1) of the *Imported Food Control Act 1992* (the Act) provides that the Governor-General may make regulations prescribing matters required or permitted to be prescribed by the Act, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

Section 35A of the Act provides that the Secretary of the Department of Agriculture, Fisheries and Forestry (the Secretary) may, on behalf of the Commonwealth, enter into a compliance agreement with a person in connection with the application of procedures in respect of food that may be imported into Australia in accordance with the agreement, the keeping of records; and the supervision, monitoring and testing of the person's compliance with those procedures. Procedures about food include any dealings with food and also include the inspection and testing (including the incidence of inspection and testing), analysis and treatment of food.

The *Imported Food Control Amendment Regulations 2009 (No. 2)* (the Amendment Regulations) make amendments to the *Imported Food Control Regulations 1993* (the Regulations) relating to the use of compliance agreements under section 35A of the Act and give effect to recommendation 47 of the report by Mr Roger Beale AO entitled *One Biosecurity: A Working Partnership* (2008) (the Beale Report).

The Beale Report is the outcome of an independent review of Australia's quarantine and biosecurity arrangements. The review was commissioned by the Australian Government in early 2008 to identify how Australia's quarantine and biosecurity arrangements could be improved. Recommendation 47 of the Beale Report recommended that the Australian Quarantine and Inspection Service (AQIS) should enter into compliance agreements to recognise formally the food safety management systems of importing businesses.

Formal recognition of the food safety management systems of importing businesses is achieved by establishing compliance agreements under section 35A of the Act as an alternative to inspection and analysis under the Imported Food Inspection Scheme (the scheme). To reduce duplication of regulation, food imported under a compliance agreement will not be routinely inspected and analysed under the scheme. Instead, the food safety management system of an importing business will be assessed against criteria for eligibility and regularly audited by AQIS.

An importer entering into a compliance agreement will be required to first demonstrate that they have procedures in place to manage the compliance of all food imported with the Food Standards Code through a documented and auditable food management system. Eligibility criteria to enter a compliance agreement will include

procedures that provide assurance on the sourcing, manufacture, transport, storage, compliance and traceability of imported food. Approved compliance agreements will be audited by AQIS to ensure the procedures are being followed.

The Amendment Regulations will provide that food imported under a compliance agreement may be classified as 'compliance agreement food', and is not required to be referred for inspection under the scheme.

The rate at which AQIS inspects food under the scheme depends on how food is classified in the Regulations and the *Imported Food Control Order 2001* (the Order). The Amendment Regulations will introduce the new classification 'compliance agreement food'. Food will only be classified as 'compliance agreement food' if it is food to which a compliance agreement applies. Compliance agreement food will not be required to be inspected, or inspected and analysed, under the scheme.

In addition, the Amendment Regulations will prescribe certain services associated with compliance agreements as chargeable services so that AQIS can recover the costs of providing those services.

Subsection 36(1) of the Act provides that a person for whom a chargeable service is provided is liable to pay to the Commonwealth such amount (the payable amount) in respect of the provision of that service as is prescribed. Subsection 36(2) provides that the amount payable in respect of a particular service must not exceed the direct and indirect costs that are properly attributed to the provision of that service in accordance with ordinary commercial principles.

Paragraph 33(1)(a) of the Regulations provides that, for the purpose of section 36 of the Act, a person for whom there is provided a chargeable service referred to in column 2 of an item in Part 2 of Schedule 2 to the Regulations is liable to pay to the Commonwealth the amount, or an amount calculated at the rate, specified in column 3 of that item for the provision of that service.

The Amendment Regulations will also remove the classification 'active surveillance food', which is a classification that imported food can be classified as on advice from Food Standards Australia New Zealand (FSANZ). The Amendment Regulations will also rename the classification 'random surveillance food' to 'surveillance food'.

AQIS has consulted with all relevant stakeholders and the Imported Food Consultative Committee. Industry supports the proposed amendments to the principal Regulations. AQIS has also consulted with the Office of Best Practice Regulation and has completed a Regulatory Impact Statement, which was approved by the OBPR on 7 March 2008 and reviewed again on 17 November 2009.

The Amendment Regulations are a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

The Amendment Regulations commence the day after they are registered on the Federal Register of Legislative Instruments.

Details of the Amendment Regulations are set out below.

Regulation 1 provides that the name of the Regulations is the *Imported Food Control Amendment Regulations 2009 (No. 2)*.

Regulation 2 provides that the Amendment Regulations commence the day after they are registered on the Federal Register of Legislative Instruments.

Regulation 3 provides that Schedule 1 amends the *Imported Food Control Regulations 1993*.

Schedule 1 – Amendments

Item [1] amends subregulation 3(1) by inserting a definition of 'compliance agreement'. This will clarify that the term 'compliance agreement' has the same meaning given by subsection 3(1) of the Act. The term 'compliance agreement' has been defined in the Act to mean a compliance agreement entered into under section 35A of the Act.

Item [2] substitutes paragraphs 8(b) and 8(c). The effect of this amendment will be to omit the classification 'active surveillance food' and to insert the new classification 'compliance agreement food'. The amendment will also rename the classification 'random surveillance food' to 'surveillance food'.

The insertion of the new classification 'compliance agreement food' will permit the Minister to make orders classifying food of a particular kind as compliance agreement food. Food that is imported under a compliance agreement is subject to the scheme. For compliance agreement food to be regulated under the scheme, it is necessary for the Minister to be able to make orders classifying food as compliance agreement food.

The omission of 'active surveillance food' will reflect an amendment made to the Order in 2007. The amendment to the Order removed schedule 2, which listed food classified as active surveillance food. This was in response to advice from FSANZ in 2007 to remove all food from the active surveillance classification. The omission will reflect the fact that there is no longer food classified as active surveillance food.

The renaming of the classification 'random surveillance food' to 'surveillance food' will reflect the making of a single surveillance classification. The 'surveillance food' classification will capture all food that is neither classified as risk food or compliance agreement food or food the subject of a holding order.

Item [3] substitutes regulations 9, 10 and 11.

No substantive change is made to regulation 9. The only change is to italicise the term 'risk food' in the heading to regulation 9.

New regulation 10 will specify what is meant by compliance agreement food. It will provide that food to which a compliance agreement applies may be classified as compliance agreement food. The food is classified only to the extent to which the compliance agreement applies. New regulation 11 will specify what is meant by

surveillance food. It will provide that food must be classified as surveillance food if it is not classified as either risk food or compliance agreement food, or the subject of a holding order. New regulations 10 and 11 will reflect the insertion of the classification 'compliance agreement food' and the renaming of 'random surveillance food' to 'surveillance food' (see item 2).

Item [4] substitutes subregulations 14(2) and 14(3) with a new subregulation 14(2). New subregulation 14(2) will provide that five per cent of consignments of food classified as surveillance food must be referred by the Australian Customs and Border Protection Service for inspection under the scheme. This amendment will reflect the omission of the classification 'active surveillance food' and the renaming of the classification 'random surveillance food' to 'surveillance food' (see item 2).

Item [5] amends the heading to regulation 21 by omitting the words 'active or random'. This amendment will reflect the omission of the classification 'active surveillance food' and the renaming of the classification 'random surveillance food' to 'surveillance food' (see item 2). The word 'Which' will also be substituted with the word 'What' so that the heading is grammatically correct.

Item [6] subsstitutes subregulation 21(1) with a new subregulation 21(1) which will provide that all food classified as surveillance food that is referred for inspection under the scheme must be inspected. This amendment will reflect the omission of the classification 'active surveillance food' and the renaming of the classification 'random surveillance food' to 'surveillance food' (see item 2).

Item [7] amends regulation 22 by inserting a new subregulation 22(3). The effect of new subregulation 22(3) will be that food classified as compliance agreement food will not be subject to inspection by inspection of randomly selected samples of the food. Food can only be classified as compliance agreement food if it is subject to a compliance agreement. The exclusion of compliance agreement food from inspection of randomly selected samples under the scheme makes sure that the importation of food under a compliance agreement is an alternative regulatory arrangement to inspection and analysis under the scheme. It will also enable formal recognition of the food safety management systems of importing businesses.

Item [8] amends regulation 36 by prescribing services for the purposes of the definition of 'chargeable service' in 36(11)(e) of the Act. The effect of this amendment is to insert paragraphs 36(c), (d) and (e), which prescribe services associated with compliance agreements. The amendment also amends paragraph 36(b) so that it is grammatically correct.

New paragraph 36(c) will prescribe the assessment of whether an importer is able to comply with the Act, the Regulations and the conditions in the importer's proposed compliance agreement. New paragraph 36(d) will prescribe the maintenance and administration of a compliance agreement. New paragraph 36(e) will prescribe the assessment of whether an importer is complying with the Act, the Regulations and the conditions in the importer's compliance agreement.

Item [9] omits the words 'active surveillance or random' from paragraph 1(a) in Schedule 1. This amendment will reflect the omission of the classification 'active

surveillance food' and the renaming of the classification 'random surveillance food' to 'surveillance food' (see item 2).

Item [10] substitutes the heading to Table 1 in Schedule 1 with a new heading. The amendment to the heading reflects the omission of the classification 'active surveillance food' and the renaming of the classification 'random surveillance food' to 'surveillance food' (see item 2).

Item [11] amends Part 2 in Schedule 2 by inserting new items 5, 6 and 7. The effect of the amendment is to set a fee for each of the prescribed services associated with compliance agreements (see item 8).

New item 5 will set a fee of $1,300 for the assessment of whether an importer is able to comply with the Act, the Regulations and the conditions in the importer's proposed compliance agreement. The fee will recover the direct and indirect costs of the assessment. The assessment will include, but is not limited to, an examination of the importer's documented food safety and compliance system and visiting the importer's business to examine the importer's food safety and compliance system.

New item 6 will set an annual fee of $2,300 for the maintenance and administration of a compliance agreement. The fee will recover the direct and indirect costs of providing the service. The service will include, but is not limited to, the provision of a help desk liaison service for importers operating under a compliance agreement, planning and scheduling visits to an importer's business premises and maintaining a database of information arising from the maintenance and administration of compliance agreements.

New item 7 will set a fee of $45 per quarter hour for an officer performing an assessment of whether an importer is complying with the Act, the Regulations and the conditions of the importer's compliance agreement. The fee will recover the direct and indirect costs of providing the service. The assessment will include, but is not limited to, an examination of whether the importer's food safety and compliance system is the food safety and compliance system that was documented and an examination of the records related to the food safety and compliance system.

Item [12] amends Part 3 in Schedule 2 by renumbering items 5 and 6 as items 8 and 9. This is a consequential amendment to reflect the insertion of items 5, 6 and 7 in Part 2 of Schedule 2 (see item 11).

Objectives for amending the *Imported Food Control Regulations 1993*

OBPR

Version 4
17 November 2009

Executive summary and statement of reasons

This proposal is based primarily upon recommendations from the 1998 National Competition Policy (NCP) review of the *Imported Food Control Act 1992* (the Act) which closely examined the costs and benefits to the community as a whole of the Act. The committee stated, '*We believe that the recommendations put forward in the Report will lower costs to industry while providing the basis for a more effective and efficient imported food safety system*'.

The Australian government agreed to the 23 recommendations made by the 1998 NCP review of the Act. While many of these recommendations have now been implemented, several remain outstanding. Two of the recommendations are addressed in this proposal.

- Recommendation 14 of the 1998 NCP review recommended that provision be made for the government to enter into compliance agreements based on approved quality assurance-type food management systems which are subjected to auditing functions consistent with other inspection systems' functions conducted by the Australian Quarantine and Inspection Service (AQIS).

- Recommendation 2 of the NCP review recommended that there be only one combined surveillance category for all foods other than risk categorised foods.

The Act was amended in 2004 to allow AQIS to enter into compliance agreements but has been prevented from doing so as the *Imported Food Control Regulations 1993* (the Regulations) do not contain provisions for recognition of importer's quality assurance systems. Therefore the Regulations need to be amended to enable the above two recommendations to be implemented. AQIS has also defined the objectives for amending the Regulations to give effect to the two NCP recommendations listed above.

The Beale Report - One Biosecurity – A working partnership

This proposal to amend the Regulations to allow AQIS to enter compliance agreements with food importers will also address a recommendation made in 2008 in the report by Roger Beale AO: *One Biosecurity: A Working Partnership* (the Beale Report).

- Recommendation 47 of the Beale Report recommended that the Authority should enter into compliance agreements to recognise formally the food safety management systems of importing businesses. These arrangements should provide for a power of audit, inspection, suspension or removal of approvals, and penalties where appropriate for breaches."

This recommendation re-confirms the original recommendation in the NCP review that AQIS should be able to enter into compliance agreements with food importers.

AQIS has chosen to pursue the following action:

Amend the definitions of risk, active surveillance and random surveillance food (regulations 9, 10 and 11, respectively) so that "food subject to a compliance agreement" is excluded.

Amend regulation 22 so that compliance agreement food is not required to be inspected or inspected and analysed under the scheme.

Amend regulation 23 so that compliance agreement food is exempted from holding orders.

Retain the flexibility for an authorised officer to deem compliance agreement food examinable under the Food Inspection Scheme as permitted under Sub-Section 3(1) of the Act.

Remove regulation 10 which relates specifically to active surveillance food and amend regulations 8, 11, 14 and 21 to remove reference to active surveillance foods.

Introduce charges for providing services related to the entering into compliance agreements, ongoing verification and registration of compliance agreements with AQIS.

Statement of reasons

- Legal advice provided to AQIS stated that to give effect to Section 35A of the *Imported Food Control Act 1992* (the Act) and fulfil Recommendation 14 of the 1998 NCP Review, an amendment to the Regulations is required.

- Further legal advice was sought on options available to amend the Regulations to give effect to Section 35A of the Act. Based on this advice, AQIS decided on which option to pursue.

- Amendments to the Regulations is required to fulfil Recommendation 47 of the Beale Report.

- It is expected that the proposal will provide the basis for a more effective and efficient imported food safety system that will benefit the community as a whole.

Introduction

This proposal seeks to deliver the implementation of two recommendations made by the 1998 National Competition Policy (NCP) review of the *Imported Food Control Act 1992* (the Act): recommendations 14 and 2. It will also deliver the implementation of Recommendation 47 of the report by Roger Beale AO: *One Biosecurity: A Working Partnership* (the Beale Report).

The Act was amended during 2004 under the Agriculture, Fisheries and Forestry Legislation Amendment Bill (No.2) 2003 in order to address recommendation 14 of the 1998 NCP review of the Act. Schedule 2, Item 8 makes the following statement regarding the amendment to Section 16(2)(i) of the Act:

"Certain quality assurance arrangements are already permitted under the Act with respect to food produced overseas, and the Act permits the making of regulations to vary the incidence of inspection, or inspection and analysis in such cases. This amendment will extend this authority to apply where a compliance agreement exists. This will enable an importer that has a quality assurance arrangement in place that demonstrates that food imported by that company meets Australian food standards, and that quality assurance arrangement is regulated under a compliance agreement, to have their product inspected at a reduced rate under the Food Inspection Scheme. Such importers will nevertheless be regularly audited to ensure that the requirements set out in their compliance agreement are being met. In this way a compliance agreement can be used as the mechanism to ensure that an importer's quality assurance arrangement delivers demonstrated compliance with the Food Standards Code as well as consistently high food safety outcomes".

This was further discussed under Item 11 where the new section, Section 35A, was to be inserted into the Act. The explanation included the following:

"*The use of compliance agreements will form an alternate mechanism to the current system of inspection of imported food. Currently AQIS officers arrange for the inspection and testing of imported food, including taking samples for analysis and delivering them to approved laboratories. Food is inspected to ensure that it meets Australian food standards and the requirements of public health and safety. Under a compliance agreement, a person will be able to sample, and arrange for testing and analysis of food in accordance with the arrangements specified in that agreement and in accordance with the Food Inspection Scheme"*.

The explanation then went on to further state the following about the compliance agreements intended to be provided for under Section 35A of the Act:

"Alternatively a person may enter into a compliance agreement with respect to quality assurance arrangements that an importer uses to ensure compliance of imported food with Australian food standards. AQIS will audit against compliance with compliance agreements".

Evaluation of the need to amend legislation

Assessing the problem

The Problem for Recommendation 2

In order for recommendation 2 to be implemented, the Regulations must be amended to remove or alter those regulations which refer to Active Surveillance foods.

The Problem for Recommendations 14 of the NCP Review and 47 of the Beale Review
During 2003/04 the Act was amended to provide for compliance agreements through the addition of Section 35A. However legal advice provided to AQIS during March and November 2007 advised that AQIS cannot enter into compliance agreements in the manner that recommendation 14 specified. This is because the current Regulations only permit those inspection activities under the Food Inspection Scheme to be carried out regardless of whether a compliance agreement is in place or not. That is, AQIS cannot recognise importers approved quality assurance – type food management systems and conduct audits to verify compliance as an alternative mechanism under the Food Inspection Scheme.

The following is an extract from legal advice given to AQIS concerning compliance agreements under the Act.

'Under the current Regulations, it is not possible to enter into a compliance agreement and, thereby, become exempt from the requirements to comply with the Food Inspection Scheme established under the Regulations. This is because "random surveillance" food is a default classification applying to all food, including food that is the subject of a compliance agreement under Section 35A of the Act'.

Since the inception of the Imported Food Program, and as recognised by the NCP review, system-based approaches to food safety have emerged as a more effective way of assuring food safety than end-point testing. Indeed, the adoption of systems approaches to food safety is now relatively widespread to meet either government legislated or commercial requirements. For example, food safety management systems are now required in some domestic sectors under the primary production and processing standards developed by FSANZ. Such approaches are also considered international best practice for food safety as detailed by the Codex Alimentarius Commission.

Accordingly, AQIS can enhance the regulatory regime governing food imports by recognising system-based controls which provide a greater level of assurance about the safety and compliance of imported food. This would address the commitment made by the government in response to recommendation 14, where the government stated that, '*in developing these systems AQIS will be required to ensure that they maintain and enhance effectiveness while delivering better efficiency to allow a greater direct focus on imports which are likely to pose the greatest risks*'.

By removing compliance agreement food from requiring inspection under the Food Inspection Scheme, AQIS will then be able to further focus resources on those foods which are not imported under approved quality assurance-type systems.

Background to the problem assessment

The NCP review of the Act was completed in 1998 and all 23 recommendations were agreed by Government in 2000. Progress has been made against a number of the

recommendations, however full implementation of all recommendations is still to be completed.

The 1998 NCP review of the Act made the following two recommendations which have as yet to be implemented:

Recommendation 2: A new combined surveillance category be established in legislation for all foods other than risk categorised foods.

Recommendation 14: Legislation be amended to clearly allow AQIS to enter into compliance agreements with importers based on approved quality assurance-type arrangements;

- AQIS develop a compliance agreement option that includes specifications for importers, and auditing functions consistent with other inspection systems' functions conducted by AQIS;
- the compliance agreement option has the ability to cover the entire production chain and, where appropriate, the transport chain; and
- overseas suppliers be encouraged to enter into approved quality assurance arrangements with AQIS by permitting these arrangements, where appropriate, to be sourced from the importer's own QA systems.

Refer Attachment 2 for further information on the NCP review and the government's response and commitment to implementing the recommendations.

In addition to the NCP Review, a review into Australia's biosecurity and quarantine arrangements, was undertaken during 2008 and made recommendations specifically on food safety risks. The Beale Report was released in September 2008 and re-confirmed that compliance agreements should be entered to recognise food safety management systems of importing businesses.

The Beale report states "*The Panel considers that, providing food safety management systems meet Australian standards, importing food businesses could be regulated by the National Biosecurity Authority through compliance agreements. These arrangements should be analogous to those under the Quarantine Act 1908 and should provide for a power of audit, inspection, suspension or removal of approvals, and penalties where appropriate for breaches of the compliance agreement. There should be consultation with state food safety authorities to ensure mutual recognition and avoid duplication.*"

Recommendation 47: The Authority should enter into compliance agreements to recognise formally the food safety management systems of importing businesses. These arrangements should provide for a power of audit, inspection, suspension or removal of approvals, and penalties where appropriate for breaches."

The government agreed in principle to all recommendations of the Beale Report in December 2008. Refer Attachment 3 for further information on the Beale Report and the government's response to the recommendations.

Objectives of government action

1. The compliance agreement mechanism established under Section 35A of the Act be used by AQIS to allow the importation into Australia of food under a quality assurance based compliance agreement. Such food will not be subject to the current inspection activity under the Food Inspection Scheme but AQIS will subject the compliance agreement to audit activity to verify compliance.

2. Importers that demonstrate they have a documented food management system (quality assurance based system) which meets the essential criteria for a Food Import Compliance Agreement (FICA) will be permitted to enter these compliance agreements under Section 35A of the Act.

3. Compliance agreement food will be exempt from the holding order requirement which reclassifies food subject to a holding order as risk food.

4. Importers importing food under a FICA will not be required to apply for a Food Control Certificate and will be permitted to deal with the food according to the terms and conditions of the compliance agreement. As part of the compliance agreement, the importer will request AQIS to conduct audits to verify that they are acting in compliance with their compliance agreement.

5. Food imported under a FICA may still be deemed examinable by an authorised officer subject to the requirements of Sub-Section 3 (1) of the Act.

6. A fee structure supporting the FICA will be developed to recover the costs for providing services of assessing an importers application to enter into a FICA, registering the importers FICA and auditing the importers documented system to verify the importer's compliance with the FICA at their request.

7. Given the prolonged delay in amending the Regulations following the 2003/04 Act amendments, AQIS seeks to make minimal changes to the Regulations in order to give effect to these recommendations. AQIS will consider a broader review of the Act and Regulations once this first round of amendments have been made in order to deliver the implementation of recommendations 14 of the NCP Review and 47 of the Beale Report.

8. The active surveillance category of food will be removed from the Regulations in accordance with the NCP recommendation 2.

Options that may achieve the objectives

AQIS received legal advice on how the above objectives may be achieved. The advice provided to AQIS was that the objectives could not be achieved through a Ministerial Order under the Regulations. The advice further stated that as they currently stand, the Regulations provide no alternative opportunity to achieve objective 1 above.

However, the legal advice did consider that the rules governing inspection of food could be altered by amending the Regulations. In the view of legal counsel, a rule could be inserted into the Regulations which stated that food which was covered by a compliance agreement need not be inspected. This could be achieved without the need

to amend the Act. Refer to attachment 4 for further details concerning the legal advice and options for amending the Regulations.

Given the legal advice received as detailed above, there were no alternative options other than amending legislation. That is, AQIS could not pursue quasi-regulation or self regulation as the existing legislation captures all food imported into Australia and under the current Regulations, directs AQIS to manage imported food under the Food Inspection Scheme.

Objective 8 can be achieved by removing or amending the regulations that relate to active surveillance foods. The *Imported Food Control Order 2001* was amended during 2007 after consultation with Food Standards Australia New Zealand and removed Schedule 2 which was active surveillance food in preparation for the amendments to the Regulations.

Impact analysis – costs, benefits and risks

Who is affected by the problem?

Importers who currently have documented food management systems in place to meet commercial and domestic requirements are affected by this problem as they receive no acknowledgement for their systems under which foods are imported.

AQIS has limited resources to monitor imports of food under the Act. As the system currently stands, while all risk foods are referred to AQIS by the Australian Customs Service, random surveillance foods are referred to AQIS on a purely random basis. Therefore all importers, regardless of the systems they may or may not have in place to manage the import of food, are put together in the random food selection process.

Who is affected by the proposed solution?

Importers who have documented quality assurance type food management systems in place already to meet commercial and domestic regulatory requirements will benefit from this solution.

As this will be a voluntary alternative to the existing inspection activity under the Food Inspection Scheme, it will also be open to other importers who choose to develop a documented food management system that meets the criteria.

Costs and benefits of the proposal in terms of social, economic and environmental impacts.

Costs on the community as a whole associated with the Regulations amendments to give effect to recommendation 2 would be cost neutral. There are no foods in the active surveillance category and AQIS now seeks to remove reference to this category from the Regulations.

The following analysis of costs and benefits relates to amendments required to achieve recommendations 14 of the NCP Review and 47 of the Beale Report.

Costs to businesses

There will be some costs incurred by businesses seeking to be approved to enter into a compliance agreement with AQIS. These initial costs would be associated with the initial assessment and set up of the compliance agreement. Further costs would then be incurred for the auditing and annual renewal of the compliance agreement with AQIS.

It would be reasonable to expect that while many businesses would have comprehensive food management systems already in place and need no changes, others will not. For those without such systems, changes from their current import processes to a documented and auditable system would be required which will incur costs. These costs would not be expected to be ongoing however and would relate to the initial set up only.

All food management systems are required to keep records for auditing purposes to serve as evidence of compliance. As record keeping is already required under these systems this amendment will not increase the requirement for record keeping where it already exists.

Ongoing compliance costs will also apply to the businesses under these compliance agreements. The AQIS Imported Food Program is a cost recovered program and therefore all service activities, such as audits, will be subject to fees. However, as this is an alternative to the existing inspection activities under the Food Inspection Scheme and fees need to be introduced, whether these costs will be greater than under the existing scheme is as yet unknown.

The proposal will have low compliance costs on businesses for the following reasons.

a. the proposal will be an alternative offered under the inspection scheme and will be entirely voluntary;
b. the proposal seeks to recognise existing food management systems that importers have in place and therefore it is anticipated that the costs incurred to comply with the proposal will be minimal for those importers with these systems already in place; and
c. once an importer is operating under the proposal, they will no longer have the costs associated with the current inspection activity under the Food Inspection Scheme, but will come under the new cost structure for these compliance agreements. Therefore any costs for compliance with the proposal will be offset by the costs they would have had under the existing scheme.

Costs to consumers

There are no costs to consumers anticipated through the implementation of the proposal.

Costs to the community and/or the environment

There are no costs to the community or the environment anticipated through the implementation of this proposal.

Costs to government

As the AQIS Imported Food Program is a cost recovered program, the costs for implementing and ongoing management of this proposal will be recovered through the services provided to industry for the compliance agreements.

Benefits to businesses

Businesses operating under the compliance agreement with AQIS will have greater flexibility in how they manage their imported food. The business will be able to source and distribute imported food with greater assurance of the food's availability for such activity as they will not have to arrange inspections with AQIS prior to release of the food.

Businesses will receive recognition for their quality assurance type food management systems for the import of food. Under the existing inspection scheme importers do not receive any recognition.

Benefits to consumers, community and the environment

As this proposal seeks to offer an alternative under the Food Inspection Scheme, it is not anticipated to provide any net benefit to consumers, community or the environment. Although it is expected that the proposal will provide the basis for a more effective and efficient imported food safety system that will benefit the community as a whole.

Benefits to government

The proposal will allow AQIS to recognise businesses that import food under quality assurance type food management systems. This will then enable AQIS to focus the existing inspection activity upon those businesses that do not have such systems in place by removing those businesses with these systems from the inspection activity under the Food Inspection Scheme.

Consultation

AQIS has consulted with the importing industry through the Imported Food Consultative Committee on the nature of the proposed amendment to the Regulations. At these meetings the importing industry representatives have expressed support for the recognition of quality assurance type food management systems and the need for AQIS to amend the legislation so as to offer an alternative to the existing end product inspection. The Imported Food Consultative Committee have expressed support for the changes to the legislation.

The proposal is based on recommendations from the 1998 National Competition Policy review of the Act which closely examined the costs and benefits to the community as a whole of the Act. The committee stated, '*We believe that the recommendations put forward in the Report will lower costs to industry while providing the basis for a more effective and efficient imported food safety system*'.

The NCP committee consulted widely during their review of the Act in order to provide a report based on input from the community as a whole. This report is available from the AQIS website on the following web page: http://www.daffa.gov.au/aqis/quarantine/legislation/imp-food-control

Page 51 of the NCP review report discusses the views of importers in relation to the recognition of quality assurance based food management systems. Their views were one of calling the government to recognise these systems as an alternative to the existing end product inspection carried out by AQIS currently.

Similarly, during the review of quarantine and biosecurity, the Beale Report panel consulted with a broad range of domestic and international stakeholders, including discussions with state and territory governments, industry and other interested individuals and groups.

AQIS has consulted Food Standards Australia New Zealand (FSANZ) on the proposal and received support. FSANZ have already provided support for the removal of the active surveillance category from the legislation. This was the basis for their advice to the Minister to remove all foods from the active surveillance category as part of the changes made to the *Imported Food Control Act 2001* during 2006.

Conclusion and recommended option for legislation amendments

The legislation must be amended for implementation of recommendations 2 and 14 of the 1998 NCP review and recommendation 47 of the Beale Report. As the Act has already been amended, AQIS will now seek amendments to the Regulations to fully address the recommendations.

Policy proposed by AQIS for quality assurance based Compliance Agreements covering imported food

The proposed approach will enable an importer to enter into a compliance agreement with AQIS that recognises the importer's system for managing the safety and compliance of their food and beverage imports. The AQIS food import compliance agreement (FICA) will contain essential criteria which the importer must meet. The criteria outline the requirements an importer's food safety management system must address to ensure the ongoing food safety and compliance of their food.

The FICA has been developed under the Quarantine compliance agreement model. The model outlines uniform legal and administrative arrangements under which all compliance agreements will operate. This model encompasses the AQIS Model for Co-Regulation as well as the administrative processes that underpin the development and ongoing maintenance of compliance agreements.

The two fundamental elements that make up the Quarantine compliance agreement model are:

(i) Part A, which provide the legal basis upon which co-regulatory initiatives operate to meet the provisions of the relevant legislation. This includes the Standard Terms, the Table of Schedules and Schedule.

(ii) Part B, which cover operational and administrative arrangements to ensure AQIS and the Other Party meet the requirements imposed under Compliance Agreements. This is made up of the Operational Procedures Statements and General Policies. The Operational Procedures Statements will contain the essential criteria and the general policies will contain the audit, compliance, [sanctions], appeals and review policies.

The importer will need to demonstrate to AQIS, via their documented systems, the food they import meets the requirements of the Act and thereby provide an equivalent assurance of food safety and compliance with Australian food standards as the current border controls.

The approval process for a FICA will consist of a desk and site audit of the importer's documented system. Upon signing onto the FICA, the importer will be subject to a follow up audit after approximately 8 weeks and then subject to an annual audit for random foods and 6 monthly audits if the importer imports risk foods. These audits will be conducted at the request of the importer to verify compliance with the FICA.

Once importing under an AQIS FICA, the importer's products will no longer be subject to end-point testing under the Imported Food Inspection Scheme (IFIS). After clearance by the Australian Customs Service and subject to meeting quarantine requirements, the imported food will be released to the importer without AQIS intervention.

Entering into an agreement with AQIS will be voluntary and appropriate audit and sanctions regimes will apply as part of the FICA.

Principles underpinning AQIS food import compliance agreements

The following principles underpin the FICA and the AQIS system under which they will be approved:

- That the agreement and the system under which it is approved, provides, at a minimum, the equivalent level of food safety and compliance with the Australia New Zealand Food Standards Code as the current controls on imported food.
- That an importer's system must meet essential criteria for eligibility to enter an agreement. The essential criteria have been developed by AQIS in consultation with relevant stakeholders.
- That the system for the assessment, approval and audit of an agreement must be nationally consistent and must be consistent with approaches to ensure food safety domestically.
- That the system to recognise an importer's agreement does not impose onerous additional regulatory requirements and where appropriate, an existing food safety management system may be recognised by AQIS.

Update as of November 2009

Progress toward Recommendations 14 of the NCP Review and 47 of the Beale Report

AQIS has developed the essential criteria with which an importer must comply to enter into a compliance agreement with AQIS for importing food. These criteria will be placed within the Operational Procedures Statements documents for the compliance agreement.

These criteria have been developed in consultation with the Imported Food Consultative Committee since 2007 and in reviewing other similar standards, such as ISO 22000. The criteria for entering into a compliance agreement contain similar requirements, where relevant, for food management systems under AQIS export programs. Export programs that oversee the management of food safety for export markets provide a useful model to identify key food safety requirements in a systems-based approach. However, there are significant differences given domestic processing of food is not part of the requirements an importer must meet. The essential criteria that AQIS has determined for a FICA are broadly outlined in Attachment 1 to this document.

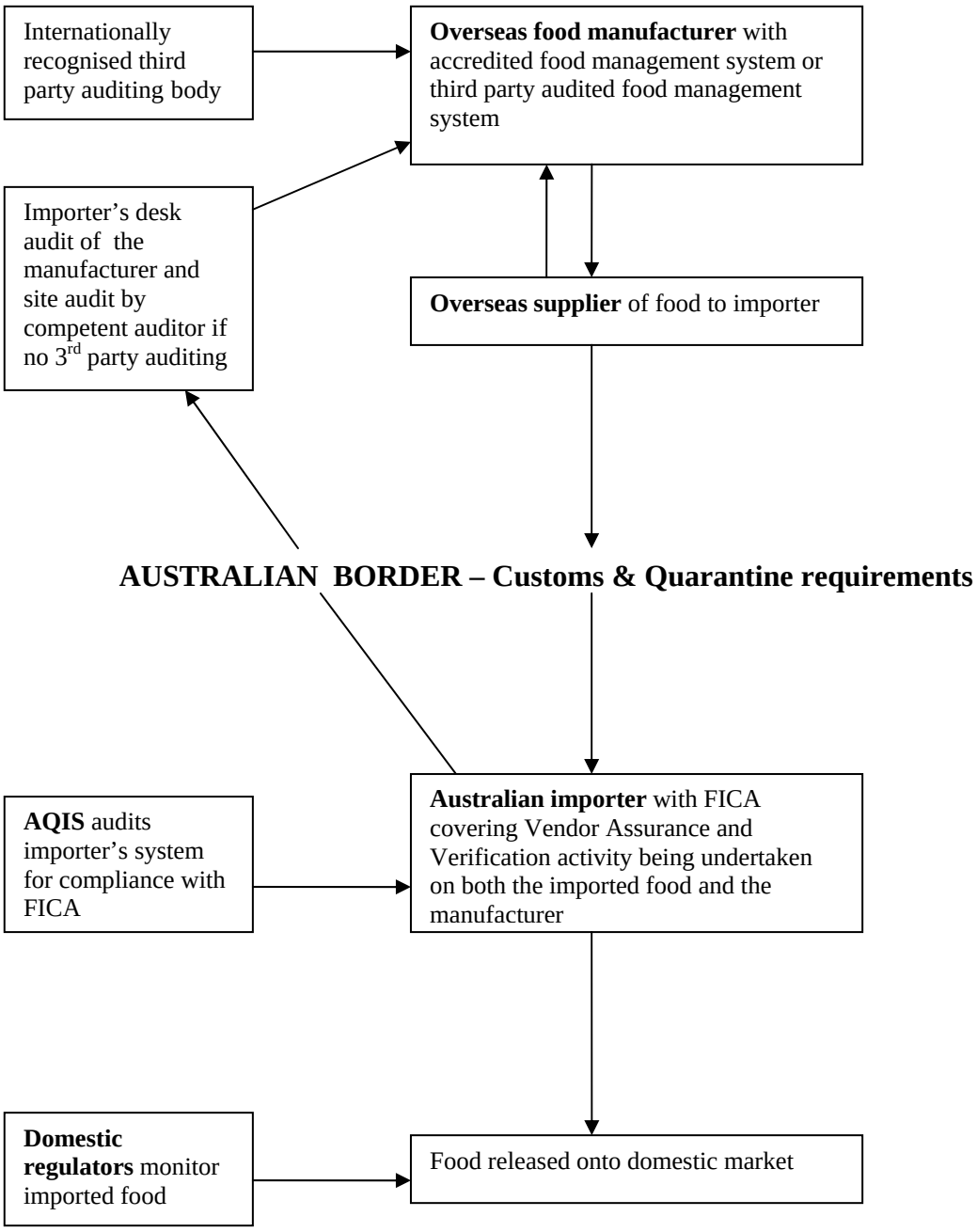
In further developing the criteria and the operational model for the FICA's, AQIS is trialling a contractual arrangement with specific importers. All documentation developed for the FICA was used for the Food Import Deed of Undertaking documentation, which is the basis for the current trial. This documentation has all been reviewed and cleared by the Corporate Legal Unit.

Progress toward Recommendation 2

AQIS has in consultation with Food Standards Australia New Zealand, removed all food from the active surveillance category of food. The amendment to the *Imported Food Control Order 2001* (the Order) made under the *Imported Food Control Amendment Order 2007* (No. 1) gave this effect and the current Order no longer references Schedule 2, which was used to list active surveillance foods.

AQIS will now seek to amend the Regulations to remove reference to active surveillance food.

Diagram of how the Food Import Compliance Agreement will work



Attachment 1

Essential criteria for an importer's food management system under a Compliance Agreement

The following paper describe some of the main features of a documented food management system that is required for an importer to enter into a Compliance Agreement with AQIS for the importation of food.

Key importer obligation under a FICA

1. The fundamental obligation of an importer under a FICA is to develop, maintain and implement a food safety and compliance system that complies with the FICA. The minimum standards that a FSCS will have to conform to are as follows.

   (a) It must prescribe ***adequate and effective measures*** to ensure that food imported by the importer complies with applicable standards (standards adopted by Food Standards Australia New Zealand or included in the Code) and does not pose a risk to human health.

   (b) It must require the ***business objectives of the importer*** to include food safety and compliance objectives.

   (c) It must make ***adequate and effective provision*** for:

      (i) employee and contractor awareness of the importance of food safety generally, and of compliance with the FICA and the Act;

      (ii) clear and easily understood allocation of responsibilities and authority;

      (iii) competence, skills, education and training in food safety of personnel;

      (iv) resources to be applied; and

      (v) reviews of the FSCS, at least once each 12 months.

   (d) The FSCS must be ***fully documented***, and worded and presented in a ***clear, concise and effective*** manner.

2. There are additional, specific requirements for:

   (a) document control;

   (b) premises and equipment;

   (c) BSE;

   (d) verification and notification; and

   (e) dealing with non-compliant food and non-compliances generally.

3. A FICA will not be entered into with an importer unless it has an appropriate FSCS. However, the fact that a FICA has been entered into will not imply that the importer's FSCS is compliant.

Other provisions about FSCSs

4. Other points to note about FSCSs include the following.

   (a) They may incorporate by reference Australian Standards or other documents;

   (b) It is recognised that FSCSs will be dynamic documents. Accordingly, importers can vary them at any time. However, material variations must be notified at least 5 business days before they take effect, unless urgent action is needed.

5. The FSCS is a key document. OPS clause 3.4 specifically ensures that the other detailed requirements of a FICA (for example, as to premises and equipment (OPS clause 4)) will not limit the obligations of the importer in relation to its FSCS.

Food Safety Assessments

6. Importers will have to conduct food risk assessments (**FSAs**) before importing, and must keep them up to date in the light of changing circumstances.

7. Food safety assessments should be directed at identifying risks and the appropriate means of controlling them. They include requirements for hazard analyses.

Manufacturer Assurance Requirements

8. An importer must assess manufacturers and ensure they meet manufacturer assurance requirements. There are different levels of assurance requirements depending on whether the imported food acquired from the manufacturer is surveillance food or risk food.

Non-compliances and non-compliant food

9. Extensive provision is made for dealing with non-compliances and non-compliant food.

   (a) Non-compliances must be identified and remedied, and systems changed so that the non-compliance does not recur.

   (b) An appropriate level of responsibility for food that has left the importer and entered the food chain is imposed on the importer (recognising the limitations in the importer's ability to deal with the non-compliance).

   (c) Detailed provisions about dispositions of non-compliant food are included, involving close supervision by AQIS.

Variations to FICAs

10. Variations to the FICA may be made in certain circumstances.

11. AQIS can vary the provisions of a FICA that deal with breaches of standards and risks to human health posed by imported food (whether or not imported by the importer). Generally speaking, AQIS must notify the importer and give it at least 20 business days to make submissions about the matter. However, AQIS will have the final determination whether the FICA should be varied.

12. Variations of other FICA provisions will broadly follow the same procedure. However, in this case, if the importer made a submission not agreeing with the proposed variation but AQIS nevertheless varies the FICA, the importer may cancel the FICA.

AQIS audits

13. The Standard Terms set out comprehensive requirements for AQIS Audits. An AQIS audit is an examination of the importer's processes, systems, operations and documentation to determine whether they do (or, in the case of a proposed FICA, will) comply with the requirements of the Act and the FICA. AQIS audits will be conducted according to a program developed by AQIS and notified to the importer. They will be conducted on a random as well as on a targeted basis.

14. The importer acknowledges that it derives real and substantial commercial benefit from AQIS audits in terms of risk management.

15. AQIS audit powers are in addition to the monitoring powers that AQIS has under the Act.

16. AQIS audits may be conducted by AQIS officers or by other Commonwealth officers. For example the Commonwealth Auditor General, in terms of program audits, may require to audit importers who have FICAs.

17. The Act does not prescribe any particular corporate structure for an importer. Accordingly, AQIS audits may have to be conducted in relation to Related Bodies Corporate of the actual importer (for example, subsidiaries) and contractors the importer engages in connection with importing food.

Attachment 2

The Government's response to the National Competition Policy Review of the *Imported Food Control Act 1992*

I am indebted to the work of the National Competition Policy Review committee comprising Carolyn Tanner (Chair), Tony Beaver, Andrew Carroll and Elizabeth Flynn for their in depth study of the *Imported Food Control Act 1992* and subsidiary legislation. The review also included a thorough study on how this legislation is administered to regulate the safety of food being imported into Australia, as this is an integral aspect of the effectiveness and efficiency of the legislation. The Review has been completed with the publication of its report and this is the Government's considered response to the 23 recommendations contained in the Review Committee's report.

The Government welcomes the positive suggestions for changes to the legislation and its administration contained in the Review Committee's report. These changes should ensure that Australian importers find importation arrangements are improved, thereby protecting Australian consumers. They will also ensure that the operation of the AQIS Imported Food Program is as effective and efficient as possible by providing a more flexible approach to regulating food imports to maintain consumer confidence and a safe food supply whilst reducing the cost to business.

All the recommendations of the Review Committee are endorsed by the Government. The respective Government agencies will now be required to implement the Review Committee's recommendations as outlined below by making necessary changes to improve their system and recommending appropriate legislative changes.

AQIS and ANZFA have set up working groups with stakeholders to examine the best ways of implementing the required changes, and progress is being monitored by the new Imported Food Consultative Committee.

WARREN TRUSS
Minister for Agriculture, Fisheries and Forestry

EXTRACT:
Recommendation 14: Legislation be amended to clearly allow AQIS to enter into compliance agreements with importers based on approved quality assurance-type arrangements;

- **AQIS develop a compliance agreement option that includes specifications for importers, and auditing functions consistent with other inspection systems' functions conducted by AQIS;**

- **the compliance agreement option has the ability to cover the entire production chain and, where appropriate, the transport chain; and**
- **overseas suppliers be encouraged to enter into approved quality assurance arrangements with AQIS by permitting these arrangements, where appropriate, to be sourced from the importer's own QA systems.**

Agreed. This is one of the most significant recommendations made by the review and is the focus of considerable industry interest. There is a need for a strong commitment from all parties to the development of a partnership (ie co-regulation) approach to imported foods regulation. Importers are already responsible for ensuring that the food they import meets Australia's food safety standards. A partnership approach with AQIS through compliance agreements will help to reinforce and further clarify those responsibilities. Such an approach is consistent with the way AQIS operates many of its other regulatory systems and offers the most effective and efficient way of ensuring program outcomes are achieved. To give effect to this policy AQIS has already commenced development of such a system through a joint AQIS/ANZFA industry working group.

In order to further enhance the effectiveness of imported food controls while maintaining efficiency, AQIS will continue with the development of Quality Assurance and Compliance Agreement arrangements for imported food regulation that are consistent with other inspection systems administered by AQIS. Additionally, AQIS will continue to investigate options to encourage overseas suppliers to enter into approved quality assurance arrangements with AQIS. AQIS will prepare any necessary legislation needed to implement these systems.

In developing these systems AQIS will be required to ensure that they maintain and enhance effectiveness while delivering better efficiency to allow a greater direct focus on imports which are likely to pose the greatest risks.

Extract from 'One Biosecurity – A working partnership'
Beale R, Fairbrother J, Inglis, A, Trebeck, D, 2008.

7.4.3 Food safety risks p160-161

Risk-return principles should also be applied to imported foods. The Panel recommends that the current performance-based approach to border sampling and analysis arrangements be continued. In addition, the National Biosecurity Authority needs to have the capacity to accredit and audit food supply chain safety systems of importers including their product providers. The National Biosecurity Authority should be empowered to require, as a condition of entry to the Australian market, that importers provide certification by the exporting country's competent government authorities that Australian food safety standards are met.

The Panel considers that, providing food safety management systems meet Australian standards, importing food businesses could be regulated by the National Biosecurity Authority through compliance agreements. These arrangements should be analogous to those under the *Quarantine Act 1908* and should provide for a power of audit, inspection, suspension or removal of approvals, and penalties where appropriate for breaches of the compliance agreement. There should be consultation with state food safety authorities to ensure mutual recognition and avoid duplication.

As noted earlier, the Panel is concerned that Australia's imported food legislation does not empower Australia to require competent authority certification of imported foods from the exporting country. This is particularly an issue where safety can only be assured by the application of food safety management systems during production and processing. As with certification processes under the *Quarantine Act 1908*, the Australian authorities should reserve the right to review and accredit, and subsequently audit, these certification arrangements (see Chapter 8).

Further cooperation with New Zealand in harmonising measures for imported food control is desirable. This is particularly relevant given that the *Trans Tasman Mutual Recognition Arrangement* facilitates free trade between Australia and New Zealand.

Recommendations

47 The Authority should enter into compliance agreements to recognise formally the food safety management systems of importing businesses. These arrangements should provide for a power of audit, inspection, suspension or removal of approvals, and penalties where appropriate for breaches.

48 The National Biosecurity Authority should be empowered to require in specific circumstances, as a condition of entry to the Australian market, that importers provide certification by the exporting country's competent government authorities that Australian food safety standards are met.

Attachment 4

Summary of the legal advice provided to AQIS during March and November 2007

The following advice was provided by Blake Dawson in their capacity as the Corporate Legal Unit for the Department of Agriculture, Fisheries and Forestry.

The legal advice provided four options for AQIS as to how the Regulations could be amended, without amending the Act, so that compliance agreement food is no longer subject to the Food Inspection Scheme. These are:

1. amending the definitions of risk, active surveillance and random surveillance food (regulations 9, 10 and 11, respectively) so that "food subject to a compliance agreement" is excluded. Some consequential amendments would also be required;

2. amending regulation 13 which states that all food to which the Act applies may be inspected under the Food Inspection Scheme such that "food subject to a compliance agreement" is not required to be inspected;

3. amending regulation 14 which sets out the rates for inspection of the 3 categories of food so that "food subject to a compliance agreement" is varied to zero, or to a variety of rates which, in the case of compliance agreement food, includes zero. Varying the incidence of inspection of compliance agreement food under the Regulations is permitted by Section 16(2)(i); or

4. creating a new set of regulations altogether employing the general regulation making power in Section 43(1) which deals with compliance agreement food as a separate category not subject to the Food Inspection Scheme in the first place. Such regulations could be made on the grounds that they are "necessary or convenient…for carrying out or giving effect to [the] Act."