



Australian Government

Australian Quarantine and Inspection Service

Approved Arrangement

A Guideline to Compliance with the

***Export Control (Dairy, Eggs and Fish) Orders
2005***

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Background

The *Export Control (Dairy, Eggs and Fish) Orders 2005* (the Orders; EC(DEF)O) together with the *Export Control (Prescribed Goods - General) Orders 2005* (the PGGOs) provide the legislative basis for the placing of conditions and restrictions on the export of the dairy, eggs and fish.

Electronic copies of the legislation can be downloaded from www.aqis.gov.au/fish.

The Orders revoke and replace the *Export Control (Processed Food) Orders*.

The Orders:

- Reflect changes to domestic and international legislation, such as the *Australia New Zealand Food Standards Code*, and the World Trade Organisation's regime for international trade, including Codex standards;
- Take into account overseas government authorities' requirements, including recommendations from overseas reviews by the European Commission and United States Food and Drug Administration;
- Reflect current scientific knowledge;
- Remove unnecessary requirements resulting in legislation that is less prescription and more outcome based and refocusses the relationship between the current Orders and the PGGOs; and
- Take into account the Australian Quarantine and Inspection Service (AQIS) experience in implementing the Orders;
- Fulfil the Government's response to the recommendations made by the National Competition Policy (NCP) Review of the *Export Control Act 1982* as far as current developments allow.

The Orders achieve several outcomes:

- A reduction in prescription
- Further harmonisation with domestic standards
- Ability to adapt to changes in importing country requirements

Objectives

The objectives of the Orders are to facilitate trade based on effective food safety and suitability procedures and accurate descriptions of product. Audit provisions are required to substantiate the adequacy of these procedures. On this basis, certification is provided as required by importing countries, thereby facilitating trade.

This document specifically addresses the requirements of registered establishments to meet the requirements of Order 36 of the Orders. Order 36.1 of the Orders states that:

Export Control (Dairy, Eggs and Fish) Orders 2005- Part 3 – Order 36

36.1 The occupier of:

- (a) a registered establishment: and
- (b) an unregistered establishment in relation to which an approval referred to in order 34 has effect;

must have an approved arrangement that complies with the requirements of the Schedule 2 (Management of food safety and suitability).

The purpose of this guideline is to assist registered establishments and authorized officers in the development, implementation and maintenance of Approved Arrangements that address the requirements set out in the Orders.

This guideline provides a framework to ensure that the wholesomeness and integrity of fish and fish products are maintained during their preparation for export.

The Approved Arrangement should adhere to the following principles:

- Be outcome based
- Address the relevant requirements of the Act and the Orders;
- Be auditable against, and be capable of being related back to, the requirements of the Act and the Orders
- Be capable of being understood by all users of the system
- Use a risk based approach to food safety (HACCP); and
- Be subject to formal internal review to maintain it in a current form.

The Approved Arrangement requires occupiers to demonstrate a commitment to food safety principles through the application of HACCP, Good Manufacturing Practice (GMP) and hygienic practices to ensure that food safety outcomes are met.

The guideline serves to provide recommendations and guidance only. Reference to the guideline and documenting appropriate controls as described will assist in the development of an Approved Arrangement that is acceptable to AQIS.

Manufacturers may choose to use other tools in the development of an Approved Arrangement. However, all aspects affecting the safety and suitability of processed food must be detailed in the Arrangement along with any specific importing country requirements and measures necessary for ensuring that there is a sound basis for issuing export documentation.

2.0 Minimum Requirements for an Approved Arrangement

The safety of dairy, eggs, fish and their products has and continues to attract international attention from both consumers and importing government authorities.

This raises the need for food destined for export to be managed under systems that effectively control the hazards that can compromise food safety and which will provide a sound basis for AQIS to issue government to government assurances in export certification.

AQIS has the responsibility for ensuring that the systems implemented in Australia result in the production of dairy, eggs and seafood products that are safe to eat and as free as possible from hazards that are potentially harmful to humans.

It is now internationally accepted that improved food safety outcomes can be achieved through the implementation of a systems approach to the identification, analysis, prevention and control of hazards.

Each Approved Arrangement must meet the minimum requirements set out in subclause 2.1 of Schedule 2, which states:

Export Control (Dairy, Eggs and Fish) Orders 2005- subclause 2.1 of Schedule 2

Minimum requirements for approved arrangements

- 2.1** An arrangement for the preparation of processed food at an establishment that is required for the purposes of order 36 of these Orders must cover each step of the preparation of processed food undertaken at the establishment and must:
- (a) contain a HACCP plan referred to in clause 3 of this Schedule; and
 - (b) document the controls used to ensure that the applicable requirements of these Orders (other than a requirement of Schedule 3) are complied with at the establishment; and
 - (c) identify the applicable importing country requirements and document the controls used to ensure compliance with these requirements; and
 - (d) document any other measures necessary to ensure there is a sound basis for giving any export permit or issuing any government certificate for processed food prepared at the establishment.
- 2.2** Paragraph 2.1 (c) applies only to each importing country requirement for which compliance with these Orders would not be sufficient to result in compliance with the importing country requirement.

3.0 Why is an ‘Approved Arrangement’ required?

Export Control (Dairy, Eggs and Fish) Orders 2005- Part 4 - Order 44

44 Requirement for an approved arrangement

- 44.1** Processed food for export as food must be prepared in an establishment where the occupier has an approved arrangement that covers the preparation undertaken.

The Approved arrangement is a condition of AQIS registration.

4.0 Who needs an ‘Approved Arrangement’?

This includes occupiers of all AQIS Registered land based Establishments and Registered Vessels.

Catcher boats are exempt from this requirement, provided that the occupier of an AQIS Registered Establishment has a system of controls in place to ensure the fitness for human consumption of fish caught by the catcher boat (Order 45).

Note: Fish caught by a catcher boat must be prepared at a Registered Establishment before export.

5.0 What is an ‘Approved Arrangement’?

An Approved Arrangement is a documented system of controls that will be approved by AQIS for the preparation of food at each individual export Registered Establishment.

The Approved Arrangement must show how the relevant conditions and restrictions set out in the Orders will be complied with by each Establishment.

The purpose of the Approved Arrangement is to provide assurance to AQIS through an auditable system that the food is prepared in such a way as to:

- Meet the minimum requirements for Approved Arrangements (subclause 2.1 of Schedule 2); and
- Demonstrate that industry compliance with the controls specified in the Approved Arrangement will ensure that the objectives and applicable requirements of the Orders will be complied with; and
- Ensure the importing country requirements specified in the Approved Arrangement for the food will be complied with; and
- Provide a sound basis for giving export permits and for issuing government certificates.

Industry compliance with Approved Arrangements and AQIS’s system of approving and monitoring them through audit contributes to importing country confidence that Australian food is safe, suitable, accurately described, traceable and meets their requirements to be eligible for importation.

6.0 Components of the Approved Arrangement

An Approved Arrangement must document as a minimum the following requirements. The following checklist has been designed to assist in ensuring you cover each component in the Approved Arrangement before making an application to AQIS for approval of the documented Approved Arrangement.

7.0 Summary checklist

Components of an Approved Arrangement
Management Practices (Orders 36-38 and Schedule 2) <ul style="list-style-type: none">• Occupiers commitment (Sch 2, Clause 1.1)• Management practices, organisational structure, resources and competence (Sch 2, Clause 4.1)• Verification (Sch 2, Clause 6.1)• Corrective and preventative action (Sch 2, Clause 7.1 & 7.2)• Internal audit and management review (Sch 2, Clause 8.1 & 8.2)• Sampling and analysis (Sch 2, Clause 9.1 & 9.2)• When operations other than preparation of processed food for export must not occur at export establishments (Order 38)

Components of an Approved Arrangement

Hygiene Control Programs (Support Programs, Pre-requisite Programs, GMP) (Orders 39.1 (b), 47,48 and Schedule 3 and 4)

- Cleaning and sanitising of premises, equipment and transport vehicles (Sch 3, Clause 12,13) (Sch 4, Clause 2-4)
- Maintenance of establishments and equipment (Sch 4, Clause 3.5)
- Measures to prevent environmental contamination (including water borne and air borne contamination) (Sch 4, Clause 5)
- Exclusion of animals (Sch 4, Clause 6)
- Pest control program (Sch 4, Clause 7)
- Use and storage of hazardous substances (Sch 4, Clause 8,9)
- General controls for storage of food, including protection from contamination, storage, handling and transportation (Sch 4, Clause 10)
- Calibration of measuring equipment (Sch 4, Clause 11)
- Validation of refrigeration chambers (Sch 4, Clause 12)
- Control for ingredients including fitness for purpose, labelling, storage and handling (Sch 4, Clause 13)
- Water usage and testing (Sch 4, Clause 14-18)
- Use of compressed air and other gases (Sch 4, Clause 19)
- Personal hygienic and health requirements (Sch 4, Clause 20-25)
- Catcher boats (Sch 4, Clause 26)

HACCP

Minimum requirements see Schedule 2; clause 2.1

The HACCP plan (Schedule 2; clauses 3.1-3.8) must identify:

- Each of the steps in the preparation of the food (a flow chart may be used); and
- The potential hazards that may reasonably be expected to occur; and
- The means of control of each potential hazard; and
- The critical control points (CCP) for each significant hazard; and
- The critical limit that must be met for each critical control point; and
- The procedures used to monitor the significant hazards to ensure compliance with each critical limit including:
 - The frequency at which monitoring procedures will be performed; and
 - The person/persons (including a class of persons) who will carry out these procedures; and
- The corrective action to be taken if a critical limit is exceeded; and
- Verification procedures and the frequency with which these procedures will be performed; and
- The records to be made and kept to demonstrate compliance with the HACCP plan and its effectiveness.

Components of an Approved Arrangement	
Specific requirements (Order 49 and Schedule 5)	
<ul style="list-style-type: none"> • Harvesting, sourcing, depuration, wet storage and killing (Sch 5, Part 1) • Chilling, freezing, thawing and tempering (Sch 5, Part 2) • Preserving processed food (Sch 5, Part 3) • Packaging (Sch 5, Part 4) • Storage, handling and loading (Sch 5, Part 5) • Transport (Sch 5, Part 6) • Fitness for human consumption (Sch 5, Part 7) 	
Product Standards (Order 50 and Schedule 6)	
<ul style="list-style-type: none"> • Product Standards for Food and Ingredients (Sch 6, Part 1) • Contaminants, natural toxicants, residues and food additives (Sch 6, Clause 1) • Microbiological limits (Sch 6, Clause 2) • Methods of Sampling and examination (Sch 6, Part 2) 	
Trade description	(Order 51 and Schedule 7)
Identification, tracing systems, integrity and transfer	(Order 52 and Schedule 8)
Miscellaneous	
<ul style="list-style-type: none"> • Manufacture etc of official marks and official marking devices (Order 72) and security of official marks and marking devices (Order 76) • Alternative regulatory arrangements (Order 86) 	
Importing country requirements	(Schedule 2 clauses 2.1(c) and 2.2)
Export Permits and Government certificates (Order 53-60 and Schedule 9)	
<ul style="list-style-type: none"> • Maintain permits and government certificates under conditions of security. (Order 55) • Return any revoked export permits, cancelled government certificate. (Order 56) • Notify an authorized officer where there is suspicion that the fitness for human consumption of the food is jeopardised, or its security or integrity is compromised or an importing country requirement has not been met. (Order 57) • Provide accurate and complete information. (Order 58) • Provide all information required by Schedule 9 Clause 2, provide a declaration of compliance, provide a copy of the export permit in 3 working days, be signed by an appropriate person and contain information that is true and correct. (See Schedule 9 and Order 59) • Record keeping (Order 60) 	
Approval process (including variations) Schedule 2 Clause 12-20	
<ul style="list-style-type: none"> • Application (Sch 2, Clause 12) • Desk audit (Sch 2, Clause 13) • On site audit (Sch 2, Clause 13) • Variations to an approved arrangement (Sch 2, Clause 17-20) 	

8.0 AQIS Guidelines:

AQIS has developed a series of “Guidelines to Compliance with the *Export Control (Dairy, Eggs & Fish) Orders 2005*” to assist you with compliance with various aspects of the new legislation. They will discuss what needs to be done and provide examples to assist you.

Guidelines can be accessed from <http://www.aqis.gov.au/fish>

Guidelines to Compliance with the *Export Control (Dairy, Eggs & Fish) Orders 2005*” include:

- Audit Regime for Fish & Fish Products and Egg and Egg Products
- Export Documentation – Audit Regime
- Approved Arrangement
- HACCP
- Validation and Verification
- Product Standards – Verification Testing for Sourcing & Handling of Fish & Fish products
- Traceability
- Trade Description
- Export Documentation

9.0 Comparison of components of the Approved Arrangement with FPA/AQA

To give you an indication of the major changes in the Orders, comparisons of the Approved Arrangement to a traditional Food Processing Accreditation (FPA) and Approved Quality Assurance arrangement (AQA) is included in Attachment 1 and 2 respectively.

For assistance in what information has to be documented in the Arrangement see the checklist above and Attachment 3 which goes into each component separately and gives you examples on how to comply.

10.0 How to apply for an Approved Arrangement

All Approved Arrangements must be evaluated by AQIS to determine if the Arrangement complies with subclause 2.1 of Schedule 2 and that compliance with the controls specified in the Arrangement will ensure that the applicable requirements of the Orders will be complied with, that importing country requirements specified in the arrangement will be complied with and that there is a sound basis for giving an export permit or issuing a government certificate.

When all components of an Arrangement have been documented and implemented the company may then apply for approval of the Arrangement.

Initially a desk audit will be conducted to evaluate the system. When AQIS is satisfied that all the relevant requirements have been appropriately addressed in the Approved Arrangement, a site audit will be conducted.

The purpose of this audit is to ensure that the procedures documented in the Approved Arrangement are being followed and are effective in practice. The initial audit findings, recommendations and any requests for further information will be provided to the

Establishment for rectification. Once all critical and major non-compliances / requests have been rectified / addressed and a reassessment carried out, the Approved Arrangement will be approved by the Secretary (or delegate of the Secretary) and a notice will be provided to formalise the arrangement.

Variations to be recorded

The occupier must make a record of each variation of an Approved Arrangement. This may be in the form of a table setting out the amendment history.

Significant variations that impact directly upon compliance with the Orders must be approved before they are implemented. (Schedule 2, clause 17, 18)

Attachment 1:

Comparison of the Approved Arrangement with a Food Processing Accreditation (FPA)

While the FPA system contains many of the components of an Approved Arrangement – this table indicates which components were not previously required or were not required to be documented under an FPA. Under an Approved Arrangement – all components listed must now be documented and implemented and existing documentation carefully reviewed to ensure compliance with the new Orders

Component of an Approved Arrangement		F P A	Comments
Management Practices	Occupiers commitment	Y	Schedule 7, 9.1(e) EC (DEF) O
	Management practices, organisational structure, resources and staff training	N	See Attachment 3 – Management Practices
	Verification	N	See Attachment 3 & Verification & Verification Guideline
	Corrective and preventative action	Y	Previously documented in HACCP Records must be kept of all Corrective Action taken. See Attachment 3 – Management Practices
	Internal audit and management review	N	See Attachment 3 – Internal Audit
	Sampling and analysis	N	Yes in EU approved estab HACCP Now required by all Reg. Establishments
	When operations other than preparation of processed food for export must not occur at export establishments (Order 38)	N	See Attachment 3 – Management Practices
Hygiene Control Programs (GMP)	Cleaning and sanitising of premises, equipment and transport vehicles	N	High risk Est. and some EU Reg. Est. may already have these documented
	Maintenance of establishments and equipment	N	While all Hygiene Control Programs listed were required to be complied with under an FPA – there is now a requirement that an Establishment documents the controls used to ensure that the applicable requirements of the Orders are complied with. (Sch 2, Div II)
	Measures to prevent environmental contamination (including water borne and air borne contamination)	N	
	Exclusion of animals	N	EC (DEF) O – Schedule 4 – Clause 6
	Pest control program	N	High risk Est. and some EU Reg. Est. may already have these documented
	Use and storage of hazardous substances	N	High risk Est. and some EU Reg. Est. may already have these documented
	General controls for storage of food, including protection from contamination, storage, handling and transportation	N	Not previously required to be documented
	Calibration of measuring equipment	N	Not previously required to be documented
	Validation of refrigeration chambers	N	Required to monitor and record temp daily as GMP
	Control for ingredients including fitness for purpose, labelling, storage & handling	N	Not previously required to be documented
	Water usage and testing	N	Not previously required to be documented
	Use of compressed air and other gases	N	Estab using gases as processing aids covered in HACCP
	Personal hygienic and health requirements	N	Not previously required to be documented
Catcher boats	N	EU establishments currently required to document catcher boat controls	

Component of an Approved Arrangement		F P A	Comments
HACCP	<i>The HACCP plan must identify:</i>		
	Each of the steps in the preparation of the food (a flow chart may be used); and	Y	While previously required to be documented, existing FPA HACCP Plans should be carefully reviewed in conjunction with the new requirements to ensure that they are complete, compliant, and current and are implemented as stated.
	The potential hazards that may reasonably be expected to occur; and	Y	
	The means of control of each potential hazards; and	Y	
	The critical control points (CCP) for each significant hazard; and	Y	
	The critical limit that must be met for each critical control point; and	Y	Documented evidence of validation of Critical Limits is required. See Verification & Validation Guideline for further information
	The procedures used to monitor significant hazards to ensure compliance with each critical limit including the frequency of monitoring and the person/s (including a class of persons) who will carry out these procedures; and	Y	
	The corrective action to be taken if a critical limit is exceeded; and	Y	Records must be kept of all Corrective Action taken. See Attachment 3 – Management Practices
	Verification procedures and the frequency with which these procedures will be performed; and	N	Some high risk and EU estab may have documented – See Verification & Validation Guideline
	The records to be made and kept to demonstrate compliance with the HACCP plan and its effectiveness.	Y	
Specific Requirements (Schedule 5)	Harvesting, sourcing, depuration, wet storage and killing (Part 1)	Y	Documented in HACCP
	Chilling, freezing, thawing and tempering (Part 2)	N	While required to be complied with under an FPA – there is now a requirement that an Establishment documents the controls used to ensure that the applicable requirements of the Orders are complied with. (Sch 2, Div II). See Attachment 3
	Preserving processed food (Part 3)	N	
	Packaging (Part 4)	N	
	Storage, handling and loading (Part 5)	N	
	Transport (Part 6)	N	
Fitness for human consumption (Part 7)	N		
Product Standards (Sch 6)	Contaminants, natural toxicants, residues and food additives		Some Establishments may have been testing under their FPA. Minimum testing to verify HACCP is now required by all Establishments. See Product Standard Guideline for further information
	Microbiological limits		As per the requirements specified for food of that kind in the FSANZ Food Standards Code See Product Standard Guideline for further information on this section
	Methods of Sampling and examination		See Attachment 3 – II – Sch. 2 – Sampling & Analysis
Trade Description (Schedule 7)	See Schedule 7 of the EC (DEF) O 2005 for details	N	See Attachment 3 - Trade Description & Trade Description Guideline for further information

Component of an Approved Arrangement		F P A	Comments
Identification, tracing systems, integrity & transfer (Sch 8)	See Schedule 8 of the EC (DEF) O 2005 for details	N	EU estab should have systems documented. See Traceability Guideline for information regarding Transfer Certificates & Declarations of Compliance
Miscellaneous	Manufacture etc of official marks and official marking devices (Order 72) and security of official marks and marking devices (Order 76)	N	Refer EC (DEF) O – Part 7 – Orders 72 & 76
	Alternative regulatory arrangements (Order 86)	Y	Schedule 7 6.1 EC (DEF) O although not previously documented in FPA
Importing Country Requirements	Where an importing country requirement differs from the requirements of the Orders (Order 87)	Y	EU estab may have requirements in FPA See Attachment 3 - Importing country requirements
Export permits & Government Certificates	Maintain permits and government certificates under conditions of security	Y	For further information on this section see Export Documentation Guideline
	Return any revoked export permits, cancelled government certificate.	Y	
	Notify an authorized officer where there is suspicion that the fitness for human consumption of the food is jeopardised, or its security or integrity is compromised or an importing country requirement has not been met.	N	EC (DEF) O – Order 57
	Provide accurate and complete information.	Y	
	Provide all information required by Schedule 9 clause 2, provide a declaration of compliance, provide a copy of the export permit in 3 working days, be signed by an appropriate person and contain information that is true and correct. (Order 59)	Y	All previously required, except now additional requirements of Schedule 9, 3.1 EC (DEF) O.
	Approval process (including variations)		
	Record keeping		EC (DEF) O – Order 60
Approval process (including variations)	Application	Y	
	Desk audit	Y	
	On site audit	Y	
	Variations to an approved arrangement	Y	ED (DEF) O – Schedule 2 – Clause 17 - 20

Attachment 2:

Comparison of the Approved Arrangement with an Approved Quality Assurance (AQA) arrangement.

While the AQA system contains many of the components of an Approved Arrangement – this table indicates which components were not previously required or were not required to be documented under an AQA. Under an Approved Arrangement – all components listed must now be documented and implemented.

IMPORTANT: While it appears in the following table that the AQA quality manual addresses the majority of components of the new AA system – there may be additional requirements within the components of the new system that must be addressed. Establishments operating on AQA systems should carefully review and amend existing AQA documentation against the new AA requirements to ensure compliance with the new Orders.

Component of an Approved Arrangement		A Q A	Comments
Management Practices	Occupiers commitment	Y	Schedule 8 EC (PF) O. Part 3 AQA handbook See also Attachment 3 – Management Practices
	Management practices, organisational structure, resources and competence	Y	See also Attachment 3 – Management Practices
	Verification	Y	AQA handbook part 3, 5.4 See also Verification & Validation Guideline
	Corrective and preventative action	Y	Existing AQA Elements should be revised against the requirements of the new Orders
	Internal audit and management review	Y	
	Sampling and analysis	Y	
	When operations other than preparation of processed food for export must not occur at export establishments (Order 38)	Y	
Hygiene control programs (Standard Operating Procedures, GMP)	Cleaning and sanitising of premises, equipment and transport vehicles	Y	
	Maintenance of establishments and equipment	Y	
	Measures to prevent environmental contamination (including water borne and air borne contamination)	Y	
	Exclusion of animals	N	EC (DEF) O – Schedule 4 – Clause 6
	Pest control program	Y	
	Use and storage of hazardous substances	Y	
	General controls for storage of food, including protection from contamination, storage, handling and transportation	Y	While previously required to be documented under AQA all existing GMP Programs should be carefully reviewed in conjunction with the new requirements to ensure that they are complete, compliant, and current and are implemented as stated.
	Calibration of measuring equipment	Y	
	Validation of refrigeration chambers	Y	
	Control for ingredients including fitness for purpose, labelling, storage and handling	Y	
Water usage and testing	Y		

Component of an Approved Arrangement		A Q A	Comments
	Use of compressed air and other gases	Y	
	Personal hygienic and health requirements	Y	
	Catcher boats	Y	Should be documented under Part 3 AQA handbook
HACCP	The HACCP plan must identify:		
	Each of the steps in the preparation of the food (a flow chart may be used); and	Y	While previously required to be documented, existing HACCP Plans should be carefully reviewed in conjunction with the new requirements to ensure that they are compliant, current and are implemented as stated.
	The potential hazards that may reasonably be expected to occur; and	Y	
	The means of control of each potential hazards; and	Y	
	The critical control points (CCP) for each significant hazard; and	Y	
	The critical limit that must be met for each critical control point; and	Y	Documented evidence of validation of Critical Limits is required. See Verification & Validation Guideline for further information
	The procedures used to monitor the significant hazards to ensure compliance with each critical limit including the frequency monitoring will be performed and the person/persons (including a class of persons) who will carry out these procedures; and	Y	
	The corrective action to be taken if a critical limit is exceeded; and	Y	Records must be kept of all Corrective Action taken. See Attachment 3 – Management Practices
	Verification procedures and the frequency with which these procedures will be performed; and	N	See Attachment 3 – HACCP and Verification & Validation Guideline for further information
	The records to be made and kept to demonstrate compliance with the HACCP plan and its effectiveness.	Y	
Specific Requirements (Schedule 5)	Harvesting, sourcing, depuration, wet storage and killing (Part 1)	Y	While previously required to be documented under AQA - existing HACCP Plans and GMP Programs should be carefully reviewed in conjunction with the new requirements to ensure that they are complete, compliant, and current and are implemented as stated.
	Chilling, freezing, thawing and tempering (Part 2)	Y	
	Preserving processed food (Part 3)	Y	
	Packaging (Part 4)	Y	
	Storage, handling and loading (Part 5)	Y	
	Transport (Part 6)	Y	
	Fitness for human consumption (Part 7)	Y	
Product Standards (Schedule 6)	Contaminants, natural toxicants, residues and food additives		Some establishments may be testing under their AQA. Minimum testing to verify product source and HACCP is now required by all establishments. See Product Testing Guideline
	Microbiological limits		As per the requirements specified for food of that kind in the FSANZ Food Standards Code

Component of an Approved Arrangement		A Q A	Comments
	Methods of Sampling and examination		See Attachment 3 – II – Sch. 2 – Sampling & Analysis
Trade Description (Schedule 7)	See Schedule 7 of the EC (DEF) O 2005 for details	Y	See Attachment 3 Trade Description and Trade Description Guideline for further information
Identification, tracing systems, integrity and transfer (Schedule 8)	See Schedule 8 of the EC (DEF) O 2005 for details	Y	See Traceability Guideline for information regarding Transfer Certificates & Declarations of Compliance
Miscellaneous	Manufacture etc of official marks and official marking devices (Order 72) and security of official marks and marking devices (Order 76)	N	Refer EC (DEF) O – Part 7 – Orders 72 & 76
	Alternative regulatory arrangements (Order 86)	Y	Part 3, 8.2 AQA handbook details Special Processes – may be revised to include Alternative regulatory arrangements
Importing Country Requirements	Where an importing country requirement differs from the requirements of the Orders (Order 87)	Y	See Attachment 3 XI Importing country requirements
Export Permits and Government Certificates	Maintain permits and government certificates under conditions of security.	Y	For further information on this section see Guideline – Export Documentation
	Return any revoked export permits, cancelled government certificate.	Y	
	Notify an authorized officer where there is suspicion that the fitness for human consumption of the food is jeopardised, or its security or integrity is compromised or an importing country requirement has not been met.	N	EC (DEF) O – Order 57
	Provide accurate and complete information.	Y	
	Provide all information required by Schedule 9 clause 2, provide a declaration of compliance, provide a copy of the export permit in 3 working days, be signed by an appropriate person and contain information that is true and correct. (Order 59)	Y	Except Schedule 9, 3.1 EC (DEF) O
	Approval process (including variations)		
	Record keeping		EC (DEF) O – Order 60
Approval Process (including variations)	Application	Y	
	Desk audit	Y	
	On site audit	Y	
	Variations to an approved arrangement	Y	ED (DEF) O – Schedule 2 – Clause 17 - 20

Attachment 3: Assistance with Documenting the Approved Arrangement

I Minimum Requirements for Approved Arrangements

The *Export Control (Dairy, Eggs and Fish) Orders 2005* details in broad terms the minimum requirements for an approved arrangement, as follows:

Export Control (Dairy, Eggs and Fish) Orders 2005 – subclause 2.1 – 2.2 – Schedule 2

Schedule 2

2.1 An arrangement for the preparation of processed food at an establishment that is required for the purposes of order 36 of these Orders must cover each step of the preparation of processed food undertaken at the establishment and must:

- (a) contain a HACCP plan referred to in clause 3 of this Schedule; and
- (b) document the controls used to ensure that the applicable requirements of these Orders (other than a requirement of Schedule 3) are complied with at the establishment; and
- (c) identify the applicable importing country requirements and document the controls used to ensure compliance with these requirements; and
- (d) document any other measures necessary to ensure there is a sound basis for giving any export permit or issuing any government certificate for processed food prepared at the establishment

2.2 Paragraphs 2.1(c) applies only to each importing country requirement for which compliance with these Orders would not be sufficient to result in compliance with the importing country requirement.

The following information is aimed at providing you with details of what you must do to comply with the minimum requirements.

As some of the concepts in the new legislation may be new to you, AQIS has developed a series of guidelines that should be read in conjunction with this document to give you a better understanding of requirements.

II Schedule 2 - Management Practices

There is a range of responsibilities, which although not being new to occupiers of Establishments, which have been operating on Approved Quality Assurance arrangements, may be new to those previously operating a Food Processing Accreditation. It is important that you understand the legal responsibilities that you have and are aware that there are penalties associated with non-compliance.

Occupier's commitment

The occupier of an establishment used to prepare processed food for export must make a statement in the Approved Arrangement, which commits the occupier to meeting:

1. The objectives of the Orders;
2. Compliance with the requirements of the Orders; and
3. Compliance with applicable importing country requirements. (Sch 2, clause 1.1)

Management practices, organisational structure, resources and competence

Export Control (Dairy, Eggs and Fish) Orders 2005 – subclause 4.1 – Schedule 2

Schedule 2

4.1 The management practices, organisational structure, provision of resources and the provision of personnel and their competence (including knowledge, training skills and experience) must:

- (a) be documented
- (b) be appropriate to ensure each of the following are met:
 - (i) the applicable requirements of the Orders;
 - (ii) the applicable importing country requirements

The Approved Arrangement must document the:

- Management practices - a mission statement/policy statement

Example:

In developing and **signing a Policy Statement**, the occupier is demonstrating his/her intention to:

- Make a statement which describes and endorses how the Approved Arrangement is central to the effective operation of the establishment, and
- Give company commitment to comply with legislative requirements.

In this respect it is the same as the **Occupier Commitment**, but a Policy Statement should also include:

- A statement on the organisation's objectives, including performance improvement and commitment to maintaining product integrity and the preparation of safe and suitable products for export.

The Occupier Commitment can be included in the Policy Statement

- Organisational structure

Example:

The organisation chart should include names and titles of:

- Senior management
- All persons in management and control of operations at the establishment and a brief description of their roles and responsibilities
- Persons with responsibilities listed in the Approved Arrangement and their roles and the communication lines between them.

- The provision of resources.

This should include a description of the Establishment, equipment, materials, etc required for the activities to be carried out at the establishment and how they are to be sourced and maintained.

- The provision of personnel and their competence (including knowledge, training, skills and experience) – this should include information regarding the allocation of appropriately qualified staff and details about their competence, including how competence will be assessed and maintained.

Example:

The AA needs to document:

- The training needs for persons operating under the AA
- Details of what training is provided for new employees (including hygiene, function of the Approved Arrangement, HACCP, significance of export registration, what can and cannot be processed and how etc)
- Refresher training conducted for employees
- Training courses for supervisors and specialist positions eg:
 - Principles of Food safety
 - Fish Handling course
 - Development of HACCP plan – minimum 3 day course
 - Retort operation - Retort Supervisors course
 - Development of thermal processes – Qualified Canning Persons Course
- Instructions and work procedures for employees
- Training in relation to specific importing country requirements documented in the Approved Arrangement
- Details on the frequency of training and how you assess competence of the employee

Persons in Management or Control must be present

Export Control (Dairy, Eggs and Fish) Orders 2005

Schedule 2 Clause 5

5.1 *A person in management or control of the operations must be present whenever operations to prepare processed food for export as food are in progress.*

*Note For the meaning of **person in** management or control see order 8.*

5.2 *If an occupier of an establishment, who must under suborder 37.1 ensure the requirements of this Schedule are complied with, fails to comply with a requirement of subclause 5.1 the occupier is guilty of an offence.*

Level 3 penal provision

Note A level 3 penal provision means a person who is guilty of the relevant offence is punishable by a fine of 30 penalty units, see Regulation 4 of the Export Control (Orders) Regulations 1982.

The *Export Control (Dairy, Eggs and Fish) Orders 2005* now clearly indicates that a person in management or control of the Registered Establishment (i.e a person nominated by the occupier of a Registered Establishment on the Application form for registration – EX26) and who has knowledge of the day to day operations needs to be present in the Establishment when operations are occurring.

The reasons why this is important are as follows:

- If any decisions in relation to the processing needs to be made urgently then the person with appropriate knowledge of the operations is available to assess the situation and make decisions ensuring that the safety of the food being prepared is not compromised.
- In order to provide the Final Declaration of Compliance in relation to preparation of the food (See AQIS Guideline - Traceability), a person in management and control has to declare that all of the Orders, the Approved Arrangement and the conditions of the Arrangement and the importing country requirements have been complied with – this cannot be done if the person making the declaration is not present on the Establishment during preparation of the food for export.

It is essential that all staff are aware of who is in management and control of the Establishment so that if problems arise they know whom to contact. Putting the names, positions and responsibilities of those persons in management and control of the Registered Establishment in the organisational chart and ensuring staff have been trained in the contents of the Approved Arrangement will be sufficient to demonstrate compliance with requirements.

Note: If the occupier fails to comply the occupier is guilty of an offence, which is punishable by a fine.

Verification

The occupier must document how he/she verifies compliance with:

- The requirements of Division III of Part 3 of the Orders; and
- Identified importing country requirements.
- The results of all verification activities must be recorded (Schedule 2, clause 6)

Verify means *apply methods, procedures, tests and other evaluations in addition to monitoring to determine whether a requirement is complied with.*

Export Control (Dairy, Eggs and Fish) Orders 2005 – Order 39

Part 3 Division III

39.1 The occupier of an establishment engaged in the preparation of processed food must ensure that the applicable requirements of the following Schedules are met:

- (a) Schedule 3 – Structural requirements
- (b) Schedule 4 – Operational hygiene
- (c) Schedule 5 – Preparation and transport
- (d) Schedule 6 – Product standards
- (e) Schedule 7 – Trade descriptions
- (f) Schedule 8 – Identification, tracing systems, integrity and transfer

To ensure compliance with this requirement the occupier of the Registered Establishment needs to document in the Approved Arrangement how procedures, tests or other assessments are made to ensure that each of the requirements in the Schedules listed above are complied with.

AQIS has developed guidelines to assist you in documentation of Schedule 6, 7 and 8. These can be found on the following website www.aqis.gov.au/fish.

Examples are given in the guidelines that may be of relevance to your operations. The requirements for compliance with the other schedules will be discussed in Attachment 3 of this document.

For example, the Approved Arrangement may have separate sections, which addresses how the occupier is going to manage the operations under these schedules from a day-to-day perspective. The management is responsible for checking that all of the operations are being conducted in accordance with the documented system so that they are able to make the statement that the product complies with the Orders. Please refer back to the Summary Checklist for items included in each of these schedules.

Corrective and preventative action

The Approved Arrangement must include a record of all action taken (corrective or preventative) where a requirement of any of the above Schedules in Division III, Part 3 of the Orders is not complied with or not likely to be complied with.

The action taken must:

- Address the non-compliance
- Ensure that the failure will not recur; and
- Assess the effectiveness of the action taken (Schedule 2, clause 7).

Internal audit and management review

The Approved Arrangement must document procedures for internally auditing your own Arrangement and conducting management reviews.

To ensure on-going compliance with legislative requirements and the practices carried out under the Approved Arrangement it is necessary for you to audit the Approved Arrangement to identify if everything is running smoothly, to identify any changes in the system, changes to operations, failure of staff to maintain the systems or to identify any activities which are not being complied with which could impact on the preparation of safe and suitable food.

It is part of good management that you know what, if anything, is going wrong so you can be proactive in putting it right.

You need to review your Arrangement to ensure that what you are doing is consistent with what you say you are doing and that the operations are planned and not haphazard and uncontrolled.

Example:

Internal Audit

A method of internal auditing may consist of rolling audits. Rolling audits may be scheduled to look at different parts of the Approved Arrangement over time so that the entire arrangement is audited once or twice per year. The audit should be conducted in a systematic way, with an audit checklist, identification of non-conformances, follow up and close out of non conformances. A record of the audit and associated corrective actions should be kept.

Management review should include an assessment of the entire Approved Arrangement and take into consideration findings from internal reviews conducted by you or your staff and external reviews carried out by AQIS or any other organisation looking at your food safety system.

Example:

Management Review

A management review could be a monthly meeting of key staff where aspects of operations, reviews of internal and external audits are considered and future planning of operations occurs. The meeting should:

- Have a defined agenda
- Be undertaken by nominated responsible personnel eg senior management and QA staff
- Records of the meetings must be kept
- Review internal and external audit outcomes
- Overseas review outcomes (if relevant), customer complaints, detained consignments, monitoring and verification activities to identify breakdowns in systems which need improvement,
- Consider corrective actions that may need to be implemented eg. Maintenance program and consider any incidents that may have occurred since the last meeting.

The outcome of the meeting is to ensure the on-going compliance of the Approved Arrangement to meet legislative requirements.

Internal audit and management review must be

- Conducted at least once every twelve months
- Records of reviews and audits must be maintained.

Exception: Establishments employing less than 3 people are considered to have conducted an internal audit of the Approved Arrangement if a management review is conducted. (Schedule 2, clause 8).

Sampling and analysis (Schedule 2 Clause 9)

Where sampling is required as part of these Orders then the method used for the sampling and analysis must be the one nominated in the *Export Control (Dairy, Eggs and Fish) Orders 2005*.

If the Orders do not specify a particular method of sampling and analysis then you should refer to a method specified in the Food Standards Code, a relevant standard published by Standards Australia or another method which has been scientifically assessed and will give consistently accurate results.

These Orders will require you to sample and analyse product to demonstrate and verify compliance with Product Standards (Schedule 6), in this instance you should contact the laboratory who you wish to carry out the testing and confirm with them the method that they traditionally use to do the test – you will probably find that the laboratory is accredited to carry out the test using a particular Australian Standard methodology.

Details of the minimum testing requirements are provided in an AQIS guideline entitled ‘Product Standards - Verification testing for Sourcing and Handling of Fish and Fish Products – A guideline to Compliance with the *Export Control (Dairy, Eggs and Fish) Orders 2005*’, which will be available on <http://www.aqis.gov.au/fish>

Notifiable diseases

The occupier of the Registered Establishment should familiarise themselves with Schedule 2 Clause 10 which relates to notifying an authorised officer if animals from which food is being prepared is affected by or suspected of being affected by a notifiable disease.

Failure to comply will result in the occupier being guilty of an offence for which Level 5 penalties can be applied.

Requirement to retain documents

The occupier of the Registered Establishment should familiarise themselves with Schedule 2 Clause 11 which relates to the requirement to retain documents for a minimum of three years which comes into their possession or are made in the process of complying with the requirements of the Act, Orders, Approved Arrangement and importing country requirements identified in the Approved arrangement.

Failure to comply will result in the occupier being guilty of an offence for which Level 5 penalties can be applied.

When operations other than preparation of processed food for export must not occur at export establishments (Order 38)

Establishments that prepare processed food for export must not undertake other activities (eg: preparation for domestic consumption or for animal food) unless the approved arrangement has appropriate controls in place. These controls must ensure either:

- Option 1. The fitness for human consumption of the processed food for export is not put at risk; **and**
The identity of the processed food for export is maintained separate from other product; **or**
- Option 2. The ‘other activities’ are conducted in accordance with the requirements of the Act and the Orders i.e the product is prepared in the same way as export product. (However if importing countries require segregation and identification of product, then this must occur eg EU)

Failure to comply will result in the occupier being guilty of an offence for which Level 5 penalties can be applied.

There are certain circumstances which will result in Registered Establishments upgrading their arrangements. The new Primary Production and Processing Standard for the sale of seafood onto the domestic market, which will be regulated by State authorities, comes into force in 2007.

Currently AQIS regulates food for export but Establishments may also wish to prepare food for the domestic market in which case the Approved Arrangement will need to document how the product for domestic is to be handled to ensure compliance with the above, remembering that at all times that export product must be able to be identified from purely domestic product.

Example:

Option 2 – all product “export eligible”

If a Registered vessel freezes prawns on board for export but cooks and freezes prawns for the domestic market, the Approved Arrangement must include controls to:

- Validate the cooking time/temperature to demonstrate that the cook is effective in controlling microbiological hazards
- Verify that each batch is cooked in accordance with the documented procedure
- Ensure that there is no cross contamination between the raw frozen product and any cooked and frozen product
- Ensure cartons are **clearly** designated for export or domestic to ensure cooked product is not accidentally exported.
- Ensure appropriate labelling to meet the FSC for the domestic market or the trade description requirement for export.

Documentation should be maintained so that AQIS can verify these activities.

III Schedule 3 - Structural requirements

Schedule 3 covers the structural requirements that Establishments must meet in order to prepare processed fish and fish products or egg and egg products as food for export.

In general, the assessment of the premises, cleaning and sanitising facilities, amenities and essential services are part of the AQIS registration process of the Establishment, as without ensuring appropriate facilities are available to prepare the food for export, the facilities themselves may present a major hazard to safe production of food.

When you register for export the AQIS inspector will request plans of the Establishment and inspect your premises; this registration inspection is designed to provide you with information as to whether the premises complies with requirements or whether upgrades are required before operations commence. Registration will not occur until the premises meet requirements.

So you do not need to document this in an Approved Arrangement but you will need to advise AQIS of any changes to structural requirements that you wish to make after you are registered, as follows:

Export Control (Dairy, Eggs and Fish) Orders 2005 – subclause 3.1 – 3.2 – Schedule 3

Construction must comply with plans and specifications

3.1 The construction of the premises and equipment must, in the case of registered establishments, comply with the plans and specifications in relation to which the Secretary registers the establishment.

3.2 Alterations or additions for which a proposal is required under Division VII of Part 5 of the Prescribed Goods (General) Orders 1985 must comply with the plans and specifications in relation to which approval for the proposal is given.

Note: For plans and specifications see Part 1 of Schedule 1.

In addition, your Approved Arrangement should detail how you intend to verify compliance with Schedule 3 eg. by periodic internal audit of premises and equipment.

There are some guiding principles that should be considered when constructing premises that are given in Schedule 3 clause 2.1

Export Control (Dairy, Eggs and Fish) Orders 2005 – subclause 2.1 Schedule 3

2.1 The premises and their construction must:

- (a) facilitate the preparation of processed food that is fit for human consumption; and
- (b) be fit for the purpose for which they are used; and
- (c) have sufficient capacity for the maximum quantity of processed food prepared at the premises at any one time; and
- (d) permit the premises to be effectively cleaned and, if necessary, sanitised if there is a risk they may cause contamination of processed food; and
- (e) permit the premises to be effectively accessed, inspected and monitored; and
- (f) not permit the harbourage of pests; and
- (g) to the extent that is practicable:
 - (i) exclude dirt, dust, fumes, smoke and other contaminants; and
 - (ii) not permit the entry of pests; and
 - (iii) minimise the accumulation of contaminating substances.

So whether construction is of the floors, walls, ceiling, equipment, fixtures or fittings, the above principles apply. See Schedule 3 Clauses 5-8 for more information.

IV Schedule 4 – Operational Hygiene

Export Control (Dairy, Eggs and Fish) Orders 2005 – Order 48

Order 48 - Operational Hygiene states:

Processed food for export as food must:

- (a) be prepared at an establishment where there is compliance with the applicable requirements of Schedule 4 (Operational hygiene); and
- (b) be transported to and from establishments engaged in the preparation of the processed food using vehicles and equipment that comply with the applicable requirements of Schedule 4 (Operational hygiene).

A program of operational controls for the hygienic preparation of processed food must be documented and in place at premises used to prepare processed food. (Schedule 4, clause 1.1) These controls are often called Pre-requisite programs, Support programs or Good Manufacturing Practices (GMPs).

Pre-requisite programs are documented systems detailing the operational controls in place for hygienic preparation of food. If general hygiene and sanitation in an Establishment is not controlled then it has the potential to influence the food safety status of the product.

These operational controls should include routine procedures covering:

- Cleaning, sanitising and ongoing maintenance of premises, equipment and transport vehicles (Schedule 4, clauses 2, 3 & 4)
- Measures to prevent environmental contamination (including water borne and air borne contamination) (Schedule 4, clause 5)
- Exclusion of animals from premises (Schedule 4, clause 6)
- Pest control program (Schedule 4, clause 7)
- Use and storage of hazardous substances (Schedule 4, clauses 8 & 9)
- General controls for processed food and ingredients, including protection from contamination, storage, handling and transportation (schedule 4, clause 10)
- Calibration of measuring equipment (Schedule 4, clause 11)
- Validation of refrigeration chambers (schedule 4, clause 12)
- Controls for ingredients including fitness for purpose, labelling, storage and handling (Schedule 4, clause 13)
- Water usage and testing (including reused water, recirculated water, clean sea water, ice and steam) (Schedule 4, clauses 14 – 18)
- Use of compressed air and other gases (Schedule 4, clause 19)
- Personal hygienic and health requirements (Schedule 4, clauses 20 – 25)

Water must be potable

- 14.1 All water used at premises used to prepare processed food (including reused water, recirculated water and ice must be potable unless:
- (a) the water is only used in circumstances where there is no risk of the water coming into contact with or contaminating processed food; and
 - (b) the approved arrangement expressly provides for the use of the non-potable water in the circumstances in which it is used.

Microbial limits

- 15.1 Water required under these Orders to be potable must not contain any Escherichia coli in 100 millilitres.

Use of clean seawater

- 16.1 Notwithstanding subclause 14.1 of this Schedule clean seawater may be used at premises used to prepare fish (other than crocodiles) if the applicable approved arrangement expressly provides for the use of the clean seawater in the circumstances in which it is used.
- 16.2 The clean seawater must not adversely affect the fitness for human consumption of the fish.

Example:

From the legislation you are not limited from where you may source water for processing but it either has to be potable or you have to nominate where you use a particular form of water. If it comes into contact with the processed food it must be documented in your Approved Arrangement and you will have to verify that it will not contaminate processed food for export.

For any type of water used, you will either have to:

- (a) Verify that the water is potable and meets the microbial limits which have been set;
- (b) Verify that it does not come into contact with processed food; or
- (c) Verify that it does not contaminate the processed food

For (a) above you need to test water and for (c) you will need to test the product.

An Approved Arrangement will not be approved by AQIS unless this has been documented.

Water is fundamental to processing, so you need to be able to assure AQIS and yourself that it will not be a critical risk to your processing. What do you stand to lose if the water is contaminated and has the potential to cause a food safety incident?

For this reason **you need to have a regular program of checking your water status.**

AQIS recommends once per month.

There are also other events which should automatically trigger testing of water

- (a) When work has been done on sewage or water piping on your vessel or establishment
- (b) When you commission new refrigerators or ice makers or after breakdowns and repairs
- (c) When there has been flooding or heavy rains which may cause back siphonage of reticulation systems or sewage systems
- (d) When there is obvious colouration of the water, if it contains particles of matter or has an offensive odour or oily film
- (e) If it is taken from harbour locations or marina close in shore, which may also be close to sewage outlet pipes.

Example:

Schedule 4, clause 2 sets out requirements for Standards of cleanliness for premises and equipment used in the premises.

Documenting a procedure that sets out a program of regular surveillance of the Establishment and the equipment would be considered an appropriate means to verify compliance with this clause of Schedule 2.

A procedure should include:

- What is going to be done and why
- When and where the procedure will be carried out, by whom and how often
- What records will be kept to show the procedure has been carried out
- Who will monitor that the procedure has been effective and institute corrective action if not effective.

V HACCP

In relation to the management of food safety and suitability, the Approved Arrangement must document HACCP as part of the minimum requirements.

See AQIS's Guideline titled "HACCP – a Guideline to Compliance with the *Export Control (Dairy, Eggs and Fish) Orders 2005*" for further information in relation to what needs to be documented in your Approved Arrangement.

An Approved Arrangement must contain a HACCP plan (Schedule 2, clause 3).

The HACCP plan must identify:

- **Each of the steps in the preparation of the food (a flow chart may be used); and**
 - ❖ Steps should:
 - Be in the order in which they occur in the preparation of processed foods; and
 - Include operations, delays, storage, transportations and inspections; and
 - Include sufficient detail so as to enable the identification of any potential hazards in the preparation of the processed food; and
 - Be accurate, clear, and concise.
- **The potential hazards that may reasonably be expected to occur; and**
 - ❖ A potential hazard that may reasonably be expected to occur is one for which experience, illness data, scientific reports or other information provides a basis to conclude that there is a reasonable possibility that it will occur in the absence of control.
 - ❖ Potential hazards may be introduced either inside or outside the processing establishment, such hazards may occur before, during and after harvest or processing.

- **The means of control of each potential hazards; and**
 - ❖ Control measures are actions or activities that must effectively prevent or eliminate a food safety hazard or reduce it to an acceptable level
 - ❖ More than one control measure may be required to control a specific hazard and more than one hazard may be controlled by a specified control measure.

- **The critical control points (CCP) for each significant hazard; and**
 - ❖ A critical control point is a step at which control can be applied and is essential to prevent or eliminate the hazard or reduce it to an acceptable level.
 - ❖ There may be more than one CCP at which control is applied to address the same hazard.
 - ❖ Hazards controlled by meeting the operational hygiene requirements of the Orders (those detailed in Schedule 4) need not be identified as part of the HACCP Plan. The HACCP table need only include activities that are essential to controlling the safety of the food in-line, as it is being subjected to processing – all other activities associated with hygienic operations, labelling, documentation control etc must be documented elsewhere in the Approved Arrangement.

- **The critical limit that must be met for each critical control point; and**
 - ❖ A critical limit should include a maximum or minimum value to which a hazard must be controlled at the CCP.
 - ❖ Criteria often used include measurements of temperature, time, moisture level, pH, water activity (Aw) and sensory parameters such as visual appearance and smell.
 - ❖ Critical limits must be validated to demonstrate that they are effective and the validation must be documented.

- **The procedures used to monitor the significant hazards to ensure compliance with each critical limit including:**
 - **The frequency at which monitoring will be performed; and**
 - **The person/persons (including a class of persons) who will carry out these procedures; and**
 - ❖ Monitoring is the scheduled measurement or observation of a CCP relative to its Critical Limit.
 - ❖ The monitoring procedure must be able to identify loss of control at the CCP.
 - ❖ Monitoring at critical control points may be in the form of continuous recording, or documentation to record the checking of any measures at frequent enough intervals to ensure controls are in place.
 - ❖ When detailing who is responsible for a monitoring procedure, positions or titles should be use.

- **The corrective action to be taken if a critical limit is exceeded; and**
 - ❖ Corrective actions must ensure that the CCP has been brought back under control should Critical Limits not be met and include procedures for determining the status for export of any product that may have been affected.

- ❖ Corrective action should address the fact the critical limit is exceeded and ensure that the exceeding of the critical limit does not recur; and include an assessment of the effectiveness of the action taken.
- **Verification procedures and the frequency with which these procedures will be performed; and**
 - ❖ Verification activities are an additional level of control and review used to ensure that the HACCP plan is operating effectively to control potential hazards.
 - ❖ Verification activities are conducted in addition to CCP monitoring but on a less frequent basis. Examples of verification activities include:
 - Internal audit
 - Review of the HACCP system and its records;
 - Review of product deviations, product disposition and customer complaints
 - Confirmation that CCPs are kept under control
 - ❖ Where possible personnel not involved in monitoring the CCP should conduct verification activities.
- **The records to be made and kept to demonstrate compliance with the HACCP plan and its effectiveness.**
 - ❖ Records are generated by the procedures or activities performed (including verification) and any corrective action taken. Record keeping systems should ensure that CCP monitoring records, corrective action records and verification records are complete, accurate and legible. Regular review of records should be conducted as part of Internal audits to ensure that records are being completed as required.

VI Schedule 5 Preparation and Transport (Sector specific requirements)

Export Control (Dairy, Eggs and Fish) Orders 2005 – Order 49

Order 49 - Preparation and Transport states:

Processed food for export as food must:

- (a) be prepared; and
 - (b) be transported to and from establishments engaged in the preparation of the processed food;
- in accordance with the applicable requirements of Schedule 5 (Preparation and transport).

Schedule 5 (preparation and transportation) includes sector specific requirements that must, where applicable, be addressed in the approved arrangement. Many of these requirements may be addressed in HACCP documentation but the approved arrangement must document the controls used to ensure that the applicable requirements of the Orders are complied with at the establishment. Schedule 5 identifies the need for controls for:

1. Harvesting, sourcing, depuration, wet storage and killing (Schedule 5, Part 1)

As a general principle, processed food for export must not be sourced from or washed using water from areas where there are reasonable grounds to believe that potentially harmful pathogens, or harmful substances like pesticides, fungicides, heavy metals, natural toxicants or other contaminants occur or could result in them being present in the food in an unacceptable level.

If you are sourcing product for use in preparing processed food then it must come from:

- Another AQIS Registered Establishment and be transferred with appropriate transfer documentation; or
- From a catcher vessel where the vessel has appropriate hygiene controls and the food is placed under temperature control as soon as harvested. The requirements for catcher vessels should be monitored as part of receival inspections and verified by audit of the vessel and documented as part of the Approved Arrangement.

The Approved Arrangement must include systems of controls to ensure that fish (including crocodile) are obtained from sources that ensure that the processed food to be prepared will be safe/suitable.

Example:

To ensure processed food is safe and suitable, do not:

- Source fish from areas known to be affected with algal blooms as there would be reasonable grounds to believe the fish would likely to be affected by ciguatoxin
- Process fish which are dead at the time of harvest or which have signs of disease
- Source product if you know antibiotics have been used to control disease symptoms or unapproved chemicals have been added to feed
- Source shellfish from areas which are not managed under the ASQAP program unless they are from offshore locations

2. Chilling, freezing, thawing and tempering (Schedule 5, Part 2)

The Approved Arrangement must document how the temperature controls nominated in the Orders for chilled and frozen product are adhered to for all processed food during storage, handling, loading and transport. The monitoring procedure in your HACCP plan will demonstrate this.

Export Control (Dairy, Eggs and Fish) Orders 2005 – subclause 25.1 – 25.4 – Schedule 5

Rate of Chilling

25.1 The chilling of processed food must be performed with sufficient rapidity so as to minimise the growth of pathogens that could adversely affect the fitness for human consumption of the food given the conditions under which the food is to be stored, handled, loaded and transported.

25.2 The applicable approved arrangement must validate that the rate of chilling achieves the outcome specified in 25.1.

See also 27.3 and 27.4 which relates to similar requirements for validation of freezing

Although the Government has verified that the chilling and freezing temperatures (See Schedule 5 Clause 24, 26 and 27) will control pathogen build up, you will need to validate that your equipment has the capacity to reduce the product to the acceptable temperatures rapidly and that the time taken to reduce the product temperatures will not allow pathogen populations to grow to the extent that it compromises the fitness for human consumption before reaching the designated temperatures.

Likewise tempering and thawing must occur under temperature controls that minimise the growth of pathogens that could adversely affect the fitness for human consumption of the food and the Approved Arrangement must document how you are going to validate that the temperature controls which you choose for the tempering and thawing will achieve this.

3. Preserving processed food (Schedule 5, Part 3)

Export Control (Dairy, Eggs and Fish) Orders 2005

Outcome for preservation processes

30.1 Unless otherwise specified in this Part, a process applied to processed food for the purpose of extending its shelf life must ensure the safety of the food by:

- (a) destroying or preventing the growth of pathogens; or
- (b) reducing their growth to a level that ensures the microbiological safety of the food is not adversely affected.

Note For microbiological limits for processed food see Schedule 6.

30.2 The applicable approved arrangement must validate that process controls for extending the shelf life of the food ensures that the objective specified in subclause 30.1 is met.

The Approved Arrangement must validate that process controls for extending the shelf life (eg; canning, pasteurisation) to ensure that the above outcome is achieved.

For canning this may be done by seeking AQIS to approve a Thermal Process Application, which requires the process to achieve certain parameters for the cook, and is verified under commercial operating conditions. Given the contents are commercially sterile if the approved thermal process is applied, the Approved Arrangement must then document evidence that any post processing handling will prevent the introduction of pathogens e.g. ensure appropriate water used for cooling, segregate thermally processed food from cans which have not undergone treatment and ensure shelf life by a program of routine tear downs to determine efficacy of the canning process. (Schedule 5, Part 3).

If vacuum or modified atmosphere packing is utilised in conjunction with a preservation method such as chilling – in order to extend the shelf life of a product - the extension in shelf life needs to be validated as for other traditional preservation techniques like canning, hot smoking etc.

Storage trials are one way to validate the shelf life of a product.

4. Packaging (Part 4)

The Approved Arrangement must provide evidence that all packaging material, tags, and labels are fit for the intended use and will not adversely affect the fitness for human consumption and will protect the food from contamination during storage, handling, loading and transport. (Schedule 5, Part 4)

5. Storage, handling and loading (Part 5)

The Approved Arrangement must include systems of control for the storage, handling and loading of processed food to protect processed food from contamination and to ensure that the fitness for human consumption is maintained. (Schedule 5, Part 5).

Example:

Do not store cartons of frozen packed product directly on the floor of a cold store or where condensation can come in direct contact with the carton or its contents.

Ensure dried packed product is not left open to the elements, where humidity could cause mould or the product can absorb water vapour and encourage pathogen growth.

6. Transport (Part 6)

The Approved Arrangement must include systems of control to ensure that processed food is transported under temperature control as specified by the Orders (Schedule 5, Part 6).

That is, what controls are in place to ensure chilled product or frozen product is transported and maintained at these temperatures. System of controls must be in place for the use of official marks, including ensuring the official marks are maintained during transport (Sch 5, clause 46.1)

7. Fitness for human consumption (Schedule 5, Part 7)

The Approved Arrangement must include procedures for evaluating the fitness for human consumption of:

- All processed food received at the establishment
- Of ingredients received at the establishment and
- Of all processed food prepared for export. (Schedule 5, Part 7)

The Approved Arrangement must also include procedures for the identification, segregation and disposal (where applicable) of:

- All manufacturing grade processed food and
- Processed food not fit for human consumption (including animal food).

Where the Establishment also produces processed food not for export (eg; domestic) procedures must be in place to ensure that processed food not prepared in accordance with the requirements of the Orders is clearly identified, segregated from, cannot contaminate processed food for export or be loaded for export. (Schedule 5, Part 7)

Additionally where processed food is prepared for a particular market (not eligible for export to all markets) the intended market for the food and evidence that the importing country requirements have been met must be readily ascertainable. (Schedule 5, clause 53.1)

VII Schedule 6 – Product Standards for food and ingredients

Under the new Orders occupiers are responsible for verifying that food for export and its ingredients must not contain any of the following:

- Metal or non metal contaminant or natural toxicants or substance in excess of the maximum level specified in the Food Standards Code
- Agricultural or veterinary chemicals in an amount which contravenes the Food Standards Code
- A food additive, processing aid, vitamin, mineral, added nutrient other matter, are or are in contravention of the applicable requirements of the Food Standards Code.

Food for export is also requirement to meet microbiological limits specified for the food in the Food Standards Code.

If an importing country provides for other standards as a condition of importation then the Approved Arrangement must:

- (a) Identify the maximum limit or alternative requirement specified by the importing country, and
- (b) Document the controls used to ensure compliance with that maximum limit or alternative requirement.

AQIS has set some minimum testing requirements for fish for export. Details can be found in the guideline titled “Product Standards - Verification Testing for Sourcing and Handling of Fish and Fish Products – A Guideline to Compliance with the *Export Control (Dairy, Eggs and Fish) Orders 2005*”. This guideline details testing required for each category of fish, samples sizes, frequency of testing and limits not to be exceeded.

The guideline is available at www.aqis.gov.au/fish

The baseline testing is mandatory and will provide the occupier with verification of the HACCP plan but also test results which can underpin certification provided to several importing countries where there are known standards which must be met as a condition of importation.

You will also need to note down what other measures you will take to minimise other contaminants adversely affecting the prepared food or the presence of any additives e.g. metabisulphite in prawn.

VIII Schedule 7 - Trade description

Schedule 7 describes all of the requirements relating to Trade Descriptions.

The Approved Arrangement must describe the procedures put in place to ensure that accurate trade descriptions are applied to processed food for export (Clause 1). Information is also provided relating to trade descriptions for bright cans or unwrapped, processed food bulk loaded into a container (Clause 2) and processed food identified as not for retail sale (Clause 3).

AQIS has developed a guideline titled “Trade Description - A Guideline to Compliance with the *Export Control (Dairy, Eggs and Fish) Orders 2005*” to help you document procedures in your Approved Arrangement. The guideline is available at www.aqis.gov.au/fish

IX Schedule 8 - Identification, tracing systems, integrity and transfer

Establishments preparing processed food must have effective measures (including records and documentation) in place for the identifying, tracing and, if necessary, recalling of processed food. (Schedule 8, clause 1.1)

Where processed food is transferred as part of an inter-company transfer, the information to be provided on despatch need not be complied with provided the Approved Arrangement documents the controls in place to ensure the product can be identified and traced. (Schedule 8, clause 10.1). Schedule 8, clause 7 provides details as to what information must be provided on despatch.

The concept of effective traceability relies on everyone in the through chain taking responsibility for how they handle the food, so that all food received into an Establishment complies with the Orders and is accompanied by appropriate Declarations of Compliance and after further processing the same Establishment is able to provide a Declaration of Compliance stating their handling of the food complies with the Orders when the food is transferred on through the chain – the “one step forward, one step back” approach.

AQIS has developed a guideline titled “Traceability - A Guideline to Compliance with the *Export Control (Dairy, Eggs and Fish) Orders 2005*” to help you document procedures in your Approved Arrangement. The guideline is available at www.aqis.gov.au/fish

X Schedule 9 - Export Documentation

The Approved Arrangement must document the measures that will be taken to ensure compliance with Part 5 of the Orders, namely the requirements to:

- Maintain export permits and government certificates under conditions of security.
- Return any revoked export permits, cancelled government certificate.
- Notify an authorized officer where there is suspicion that the fitness for human consumption of the food is jeopardised, or its security or integrity is compromised or an importing country requirement has not been met.
- Provide accurate and complete information.
- Provide all information required by Schedule 9 clause 2, provide an Exporter declaration of compliance, provide a copy of the export permit in 3 working days, be signed by an appropriate person and contain information that is true and correct. (Order 59)

A Declaration of Compliance must only be made by a person in management and control of operations at the establishment at which the processed food was last prepared and where the Approved Arrangement provides procedures for making Declarations of Compliance and designates the persons who may make such a declaration. (Schedule 9, clause 5.1).

AQIS has developed a guideline to assist you documenting your procedures titled “Export Documentation – A Guideline to Compliance with the *Export Control (Dairy, Eggs and Fish) Orders 2005*”. The guideline is available at www.aqis.gov.au/fish

Approval of Approved Arrangements for issuing permit

A person operating under an Approved Arrangement may issue an export permit if the Approved Arrangement provides for the issuing of export permits under documented systems, which comply with the above requirements. The person issuing the permit must be an approved permit issuer (accredited by AQIS) and be in management and control of the processing establishment which last prepared the food (i.e in EXDOC linked to the inspection establishment).

For the issue of export permits where there is no Approved Arrangement see Schedule 9, clause 14 (for exporters who are not occupiers of an Establishment).

XI Importing country requirements

Importing country requirements are defined as requirements relating to processed food that an importing country authority requires to be complied with before the goods may be imported into that country from Australia.

These could include: requirements that affect the method of processing, composition of food, methods of sampling and analysis, specific microbiological, residue or biotoxin requirements, alternative inspection arrangements, trade descriptions and other information that must appear on labels, design and construction matters for premises and equipment and food safety requirements for food processing.

The minimum requirements for Approved Arrangement requires you to document these importing country requirements where compliance with the Orders would not result in compliance with the importing country requirement i.e. the conditions may be higher or different.

Where an importing country requirement does not require compliance with a requirement specified in the Orders, the occupier can apply to the Secretary for a notice stating that a requirement of the Orders (specified in the application) does not apply to the processed food prepared at the Establishment to be exported to the country identified in the application.

The notice granting an exemption from a requirement of the Orders must be including in the Approved Arrangement along with details of the control measures used for identification and segregation of this product (Order 87) as the food may be made ineligible for domestic sale or export to other markets as a result of not meeting a specific order.

Additionally, where an importing country requires a particular standard to be complied with that differs from a requirement of the Orders and which will require government certification that the standard has been met, the Approved Arrangement must:

- Document the standard
- Detail how the product will comply
- Include any other procedures for ensuring the product is accurately identified throughout the process and segregated from other export product

as compliance with a particular importing country standard may make the product ineligible for export to other markets.

It is the occupiers' responsibility to be aware of the importing country requirements, however AQIS will assist where it is aware of specific requirements.

XIII Miscellaneous

Manufacture etc. of official marks and official marking devices (Order 72) and security of official marks and marking devices (Order 76)

Where an occupier is in possession of an official mark or an official marking device and approval has not been to do so under the *Export Control (Prescribed Goods – General) Order 2005* or by direction from an authorized officer, the Approved Arrangement must include information about the controls in place for the use, possession and security of official marking devices.

In these circumstances the Approved Arrangement must identify the person(s) who may have possession of the official marking device and identify the person(s) who may apply, alter or interfere with official marks and identify the controls in place for such activities (including security of official marks). The occupier of an Establishment must make a record of the receipt, use and return of official marking devices and the receipt, use and defacement of official marks.

Alternative regulatory arrangements (Order 86)

The Orders provides for alternative regulatory compliance. Under these arrangements the occupier of a Registered Establishment can make a written application to the Secretary for a notice stating that an alternative procedure, standard or other requirement specified in the application achieves the purpose of a requirement of Schedule 3 to 8 only of these Orders as specified in the application.

After reviewing the application, if the Secretary is satisfied that the alternative procedure, standard or other requirement would have an equivalent outcome as the Orders provides for, the Secretary may give the occupier a written notice to this effect.

If a notice is granted by the Secretary, the occupier must include in the Approved Arrangement:

- The procedure, standard or other requirement
- Detail how compliance with any alternative regulatory arrangement that has been approved by the Secretary, will be maintained.

Example:

Schedule 5 provides specific temperature requirements for chilling and freezing and allows for alternative temperature requirements provided that the Approved Arrangement validates that the alternative temperature and process will not affect the fitness for human consumption. (Schedule 5, Part 2)