



Australian Government

Australian Quarantine and Inspection Service

Approved Arrangement

**A Guideline to Compliance with the
*Export Control (Fish & Fish Products) Orders
2005***

Table of contents:

Background	3
Objective.....	3
Introduction.....	4
Section 1. Minimum Requirements for an Approved Arrangement.....	5
1.0 Why is an ‘Approved Arrangement’ required?.....	5
2.0 Who needs an ‘Approved Arrangement’?.....	5
3.0 What is an ‘Approved Arrangement’?	6
4.0 Documenting an Approved Arrangement	6
5.0 Approved Arrangement Documentation	8
6.0 Comparison of components of the Approved Arrangement with FPA/AQA.....	9
7.0 Components of the Approved Arrangement	9
Suggested structure - Approved Arrangement:.....	9
8.0 AQIS Guidelines:	17
9.0 How to apply for an Approved Arrangement	17
10.0 Variations to Approved Arrangements	17
Section 2: Documenting the Approved Arrangement – Specific Requirements	19
I Minimum Requirements for Approved Arrangements.....	19
II Schedule 2 - Management Practices	19
III Schedule 3 - Structural requirements	26
IV Schedule 4 – Operational Hygiene	27
V HACCP	29
VI Schedule 5 Preparation and Transport (Sector specific requirements).....	32
VII Schedule 6 – Product Standards for food and ingredients.....	36
VIII Schedule 7 - Trade description	36
IX Schedule 8 - Identification, tracing systems, integrity and transfer.....	37
X Schedule 9 - Export Documentation.....	37
XI Importing country requirements.....	38
XIII Miscellaneous	39
Appendix 1:	40
Appendix 2:	43

Background

The *Export Control (Fish & Fish Products) Orders 2005* (the Orders) together with the *Export Control (Prescribed Goods General) Order 2005* (the PGGOs) and the *Export Control Act 1982* (the Act) provide conditions and restrictions on the export of fish and fish products. Electronic copies of the legislation can be downloaded from www.aqis.gov.au/fish

Prior to the 1st of October 2005, fish and fish products for export were regulated under the *Export Control (Dairy, Eggs and Fish) Orders 2005* – these Orders have now been separated into the *Export Control (Fish & Fish Products) Orders 2005*, the *Export Control (Egg & Egg Products) Orders 2005* and the *Export Control (Dairy & Dairy Products) Orders 2005*.

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.

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;
- 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

Objective

This guideline addresses the requirement of registered establishments to meet the requirements of Order 34 of the Orders by documenting, implementing and complying with an auditable system of controls and procedures – an "Approved Arrangement".

Export Control (Fish & Fish Products) Orders 2005- Part 3 – Order 34

34.1 The occupier of:

- (a) a registered establishment: and
- (b) an unregistered establishment in relation to which an approval referred to in order 32 has effect;

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

Introduction

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.

The safety of fish and fish 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 fish and fish 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.

An Approved Arrangement provides a documented system 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:

- Address the relevant requirements of the Act and the Orders;
- Provide details of how compliance with the legislation will be achieved
- 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.

This 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.

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

Section 1. Minimum Requirements for an Approved Arrangement

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

Export Control (Fish & Fish Products) Orders 2005- subclause 2.1 of Schedule 2

Minimum requirements for approved arrangements

- 2.1** An arrangement for the preparation of fish and fish products at an establishment that is required for the purposes of order 34 of these Orders must cover each step of the preparation of fish and fish products 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 fish and fish products 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.

1.0 Why is an ‘Approved Arrangement’ required?

Export Control (Fish & Fish Products) Orders 2005- Part 4 - Order 41

41 Requirement for an approved arrangement

- 41.1** Fish and fish products for export as food must be prepared in an establishment where the occupier has an approved arrangement that covers the preparation undertaken.

2.0 Who needs an ‘Approved Arrangement’?

All AQIS registered land-based establishments and registered vessels involved in the preparation of fish and fish products (including crocodiles) are required to have an Approved Arrangement in place.

AQIS registered establishments sourcing fish from catcher boats (unregistered vessels defined as catcher vessels under the Orders) must ensure that fish are sourced only from catcher boats with a system of controls in place to ensure the fitness for human consumption of the fish caught by the catcher boat (Refer to Order 42 and subclause 6.1 of Schedule 5)

Note: Fish caught by a catcher boat must be prepared at a registered establishment before export.

3.0 What is an ‘Approved Arrangement’?

An Approved Arrangement is a documented system that will be approved by AQIS for the preparation of fish and fish products at each export registered establishment.

The Approved Arrangement must describe the procedures used to ensure the applicable conditions and restrictions set out in the Orders will be complied with.

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

- Meet the minimum requirements for Approved Arrangements (subclause 2.1 of Schedule 2); and
- Ensure the requirements specified (including applicable importing country requirements) 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, and traceable and meets their requirements for importation.

4.0 Documenting an Approved Arrangement

An Approved Arrangement is a documented system – typically in the form of a manual, developed by the establishment to describe the system in operation at the establishment.

It summarises policies and documents the procedures, controls and documentation that will be utilized to ensure that all export product prepared by the establishment meets the requirements of the *Export Control (Fish & Fish Products) Orders*.

The Approved Arrangement should address all of the applicable requirements of the Orders – that is, statements should be made describing the controls that will be put in place by the establishment and the methods that will be used to verify that the controls are effective and being complied with.

For a small operation, the Approved Arrangement may describe all requirements, including all procedures. However, larger companies may find it useful to produce an Approved Arrangement that is a guide or index to the system. The Approved Arrangement will still address all the relevant components of the Approved Arrangement (See [6.0-Components of an Approved Arrangement](#) – in this guide) but will provide only a brief outline of each component – stating how the system is set up to meet the requirements of that component.

The outline at each component will then cross reference to detailed work procedures or Standard Operational Procedures (SOPs) explaining exactly how things are done – these may be held in separate procedural manuals. A further tier of work instructions may also be useful for instructing staff in particular tasks.

Example:

The Approved Arrangement should address the requirement of Schedule 4, Clause 2.1– Standard of Cleanliness by:

Policy

Stating that the establishment has procedures in place to ensure that the premises will be maintained to a standard of cleanliness where there is no accumulation of garbage, recycled matter, food waste, grease, or other visible matter that may contaminate food through the implementation of a Standard Operational Procedure for Cleaning.

Procedure

The associated SOP for Cleaning should describe how cleaning is to be conducted and include how the program will be monitored to ensure that it is being followed.

Procedures should include details of:

Why – the procedure is required

What – the scope of the procedure is (what areas does the procedure cover)

Who – will follow the procedure and who is responsible for ensuring that the procedure is followed?

How – the procedure is to be carried out

When – the procedure is followed

Where – the procedure is followed

Monitoring

Procedures should also include details of how they are monitored to ensure they are effective, who is responsible for monitoring, the frequency of monitoring and where the results of monitoring are recorded.

For example: A visual check of processing areas may be conducted prior to commencing processing and the results of the check documented on a Pre-operational Check Form.

Corrective Action

Procedures should also include details of what action is to be taken if monitoring indicates that the procedure has not been followed, including what action will be taken regarding any product that may have been affected.

Verification

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

The SOP for Cleaning may also include details of how the procedure will be verified – this may include a schedule of swabbing food contact surfaces after cleaning has taken place to ensure that the procedure is effective.

Verification should also include a scheduled review of monitoring records to ensure that the procedure is being carried out, monitoring is being documented and any problems that have been identified during checks have been addressed (Corrective Action).

Note: Cleaning chemicals can be a potential hazard to the preparation of safe food if not approved, used or stored incorrectly. The SOP for Cleaning may also describe the controls required for sourcing appropriate chemicals, storing chemicals and training staff in chemical usage – or these controls may be documented in separate procedures, for example a SOP for Storage of Hazardous Chemicals or a SOP for Staff Training

5.0 Approved Arrangement Documentation

Aside from meeting AQIS requirements the fundamental purpose of documentation is to guide staff. To meet this purpose – the Approved Arrangement should be:

- Useable
- Easily understood; and
- Concise

To achieve this:

- Use tables, diagrams and other forms of easily assimilated instructions wherever possible.
- Group sections together rather than scatter references throughout a manual.
- Cross-reference thoroughly, particularly where monitoring forms and records are concerned.
- Identify monitoring forms and records by a title and form or document number, both of which should be quoted whenever the form is referred to in the manual.
- Clearly label flow charts, diagrams, tables and checklists for easy reference.

To facilitate amendments, all manuals should:

- Be prepared in loose leaf form;
- Have a number and date on each page. The numbering system should ideally identify the total number of pages in each section (e.g. Page 1 of 20). The date will assist in identifying current documents.
- Include a table of contents
- Include a table for recording amendments – including the date that amendments were made, the reason for the amendment and the new date of issue or version number allocated to the revised section.

Major sections or chapters can be tabbed for quick reference. A well-structured manual assists all parties, being easier for company staff and auditors to use.

If your establishment has been operating without a fully documented food safety program, you may find the development of an Approved Arrangement a valuable means of clarifying and defining objectives, standards and procedures. In some cases, such as when hazard analysis tables are constructed, it may be possible to refine, rationalize and improve some practices and procedures.

If your establishment has a food safety, FPA or AQA program in place you will need to review your existing program against the requirements of the *Export Control (Fish & Fish Product) Orders 2005* to ensure that any additional requirements have been addressed.

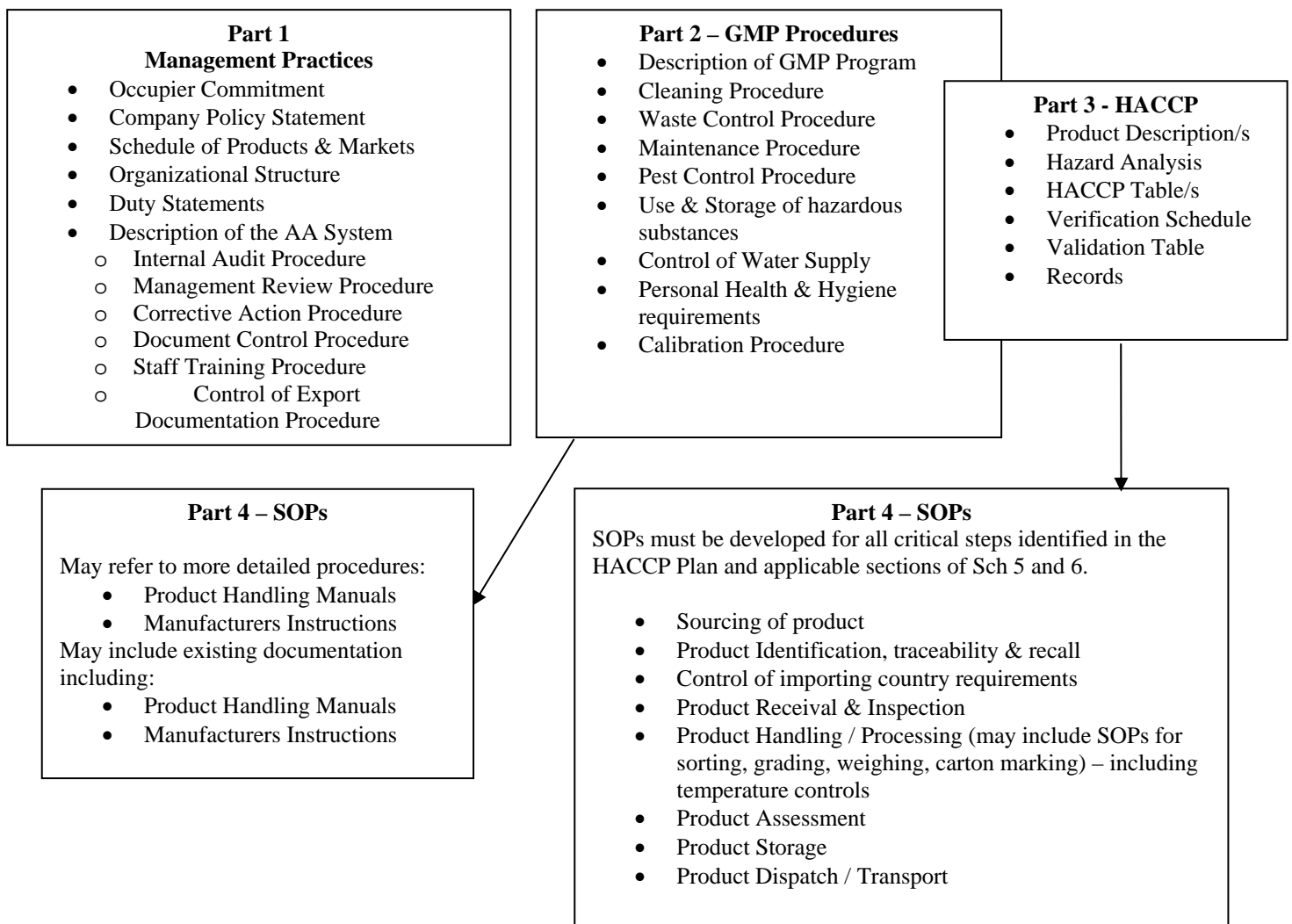
6.0 Comparison of components of the Approved Arrangement with FPA/AQA

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) are included in Appendix 1 and 2 respectively.

7.0 Components of the Approved Arrangement

The checklist provided on the following pages 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.

Suggested structure - Approved Arrangement:



An Approved Arrangement must document as a minimum the following requirements:

Components of an Approved Arrangement	EC(F&FP)O Ref:	What Must be documented	<input checked="" type="checkbox"/>
Management Practices		Orders 34-36 and Schedule 2	
Occupiers commitment	Sch 2, C 1.1	A statement as to the occupiers commitment to the objectives specified in suborders 3.2 & 3.2, compliance to the requirements of the Orders and to applicable importing country requirements	
Management practices, organisational structure, provision of resources and competence	Sch 2, C 4.1	A description of management practices, an organizational chart and a brief description of how the organization will provide the required resources to maintain the establishment and Approved Arrangement, including the provision of appropriately trained personnel. Developing Duty Statements or Job Descriptions for all the positions identified in the organizational chart is a way of documenting some of these requirements.	
Verification	Sch 2, C 5.1	How the occupier is going to verify that the applicable requirements of the Orders are being complied with, for example – by Internal Audit, document review, product testing. This is typically documented in a table or Verification Schedule detailing when and how requirements will be verified and what records will be kept.	
Corrective and preventative action	Sch 2, C 6.1 & 6.2	A procedure describing how the organisation will insure that corrective action is taken (including all of the requirements of Clause 6.1) and documented. This procedure must also address the disposition of any product that may have affected by the non-conformance.	
Internal audit and management review	Sch 2, C 7.1 & 7.2	A procedure for conducting Internal Audits and Management Review Meetings, including what will be done and how this will be documented. If specific sections of the system are to be audited separately – an Internal Audit Schedule should be included detailing what audits are scheduled for when.	
Sampling and analysis	Sch 2, C 8.1 & 8.2	This section relates to specific methods of testing that may be required and may be addressed in a section that describes how products will be tested.	
Requirement to retain documents	Sch 2, C 10.1	A document control procedure that describes how documents will be controlled, including how changes will be recorded, how AQIS approval will be obtained if required and how documents will be retained and for what period of time.	
Variations to an approved arrangement	Sch 2, C 17-20		
When operations other than preparation of fish and fish products for export must not occur at export establishments	Order 36 & Sch 5, C 37.1 – 42.1	If products other than fish and fish products for export as food are prepared in the establishment, for example animal food or food only for the domestic market – these products must be identified and procedures put in place to ensure that they are clearly identified, segregated from and will not contaminate export product. A list of all products processed and their intended use (and intended market) will assist in identifying the controls that will be required. Controls for identification and separation may be documented in a separate procedure.	
Importing country requirements	Sch 2, C 2.1(c) & 2.2	Applicable importing country requirements must be identified and the controls used to ensure compliance with the requirements documented. As above – a list of products processed and their intended market (importing country) will assist in identifying the controls that will be required. Controls for verifying that importing country requirements are accurately identified and are being met may be documented in a separate procedure	

Components of an Approved Arrangement	EC(F&FP)O Ref:	What Must be documented	<input checked="" type="checkbox"/>
Structural Requirements		Schedule 1 & 3	
Structural requirements Plans & Specifications	Order 37 & Sch 1, C 1.1 – 3.1	The method by which the occupier will verify that the establishment continues to meet the requirements of Schedule 3 must be documented – for example: Internal Audit inspection of premises by using a checklist based on the requirements of Schedule 3. Appropriate plans and specifications for the establishment must be current and available.	
Hygiene Control Program		Orders 37, 46 & Sch 4 (Support Programs, Pre-requisite Programs, GMP)	
Cleaning and sanitising of premises, equipment and transport vehicles	Sch 4, C 2-4	Procedures must be developed for all of the applicable components of Schedule 4. Procedures must describe the controls that are in place to ensure the requirement will be met, who is responsible, how the procedure will be carried out, monitored, recorded and verified. Procedures should include details of the corrective action to be taken if a procedure is not followed or a non-conformance occurs.	
Maintenance of premises, equipment and transport vehicles	Sch 4, C 2-4	Note: Separate monitoring records may not be required for all procedures. For example: A pre-operational checklist – to be completed prior to commencing production can be used to document regular checks on several areas of operation, including: <ul style="list-style-type: none"> • Structure and maintenance of equipment • Staff compliance with hygiene procedures • Cleaning • Pest Sightings • Calibration checks of equipment 	
Measures to prevent environmental contamination (including water borne and air borne contamination)	Sch 4, C 5		
Exclusion of animals Pest control program	Sch 4, C 6 Sch 4, C 7		
Use and storage of hazardous substances & substances which could contaminate food	Sch 4, C 8,9		
General controls for storage, handling and transportation of food, including protection from contamination.	Sch 4, C 10		This section includes the requirement that effective measures be put into place to prevent contamination and ensure appropriate temperature control of fish, fish products and their ingredients during handling, storage and transport. Handling practices and controls can be described in Standard Operational Procedures which should document how these activities are carried out in your establishment.
Calibration of measuring equipment	Sch 4, C 11	Procedures for the calibration of measuring equipment must include details of how equipment is calibrated, when checks are conducted and recorded and what corrective action will be taken if equipment is found to be inaccurate – including what will be done with any product that may have been affected	
Validation of refrigeration chambers	Sch 4, C 12	This may be in the form of a statement from the supplier of the refrigeration system stating the chambers capacity or validated through time and temperature trials.	

Components of an Approved Arrangement	EC(F&FP)O Ref:	What Must be documented	<input checked="" type="checkbox"/>
Control for ingredients including fitness for purpose, labelling, storage and handling	Sch 4, C 13	Procedures must be in place to ensure that any ingredients used in processing fish & fish products are suitable, correctly labelled, handled and stored. Procedures should describe how ingredients are sourced; how it is ensured that they are safe (testing against the required standard, letters from the supplier).	
Water supply, usage and testing	Sch 4, C 14-17	Water and ice are common inputs to processing. Procedures must be in place to ensure that fish & fish products are not contaminated by water, ice, steam or other gases (if used). Procedures should describe how these inputs are sourced, how it is determined that the source is safe, when these inputs are used and how the effectiveness of the control procedure is verified (for example – water testing)	
Use of steam, compressed air and other gases	Sch 4, C 18,19		
Personal hygienic and health requirements	Sch 4, C 20-25	Procedures must be in place to ensure that all staff are trained in and aware of their responsibilities with regards to health and hygiene. Procedures should document how staff will be trained, what they will be trained in, how it will be determined that they are competent and how their compliance with requirements for health and hygiene will be monitored.	
HACCP - Minimum requirements	Sch 2; C 2.1	For guidance on this section reference can be made to the Codex document “HACCP system & Guidelines to its application CAC/RCP 1-1969, Rev. 4-2003 – Annex” available at: http://www.codexalimentarius.net/download/standards/23/CXC_001_2003e.pdf and the “AQIS Guidelines to Compliance with the Export Control (Fish & Fish Products) Orders 2005 – HACCP”	
Product Description		A complete product description is a useful way of describing the finished product and its intended use. See the “AQIS Guidelines to Compliance with the Export Control (Fish & Fish Products) Orders 2005 – HACCP”	
The HACCP plan must identify:			
Each of the steps in the preparation of the food	Sch 2 C 3.1	This may be documented in the form of a flow diagram.	
The potential hazards that may reasonably be expected to occur at each step; and	Sch 2 C 3.2	Potential hazards are typically categorised as physical, chemical or biological. For each step in the process, consideration should be given to each category together with a determination of the possible cause of the hazard – to ensure that the most appropriate controls are applied.	
The means of control of each potential hazard; and	Sch 2 C 3.3	Despite subclause 3.3 hazards controlled by meeting the operational hygiene requirements of Sch 4 of the Orders need not be identified as part of the HACCP Plan	
For each significant hazard that is identified the HACCP Plan must identify:			
a) The Critical Control Points (CCP) and	Sch 2 C 3.5	Means a factor, practice, procedure, process or location which can be controlled in order to prevent, control, eliminate or reduce a hazard or minimize the likelihood of its occurrence	
b) The Critical Limits that must be met for each CCP; and	Sch 2 C 3.5	Means the limit to which a hazard must be controlled to prevent, control eliminate or reduced to an acceptable level the occurrence of a hazard.	

Components of an Approved Arrangement	EC(F&FP)O Ref:	What Must be documented	<input checked="" type="checkbox"/>
Validation		Evidence must be provided to demonstrate that the Critical Limits selected are valid – that is, that they will control the hazard – For more information see: “AQIS Guidelines to Compliance with the Export Control (Fish & Fish Products) Orders 2005 – Verification & Validation”	
c) The procedures used to monitor the potential hazards to ensure compliance with each critical limit.	Sch 2 C 3.5	Monitoring procedures must include at a minimum: Who: will do the monitoring What: will be monitored (this must relate to the critical limits) and if required, How this will be done. When & Where: monitoring will occur (frequency of monitoring) Where: monitoring will be recorded	
d) The corrective action to be taken if a critical limit is exceeded; and	Sch 2 C 3.5	Corrective Action must include the action to be taken to ensure that product that may have been affected is controlled and action to ensure that the CCP has been brought under control. Corrective Actions should include who is responsible for taking action and where Corrective Actions are documented.	
Corrective Action	Sch 2 C 3.6	Corrective Action must include the action taken to address the fact that the critical limit is exceeded, action to ensure that the exceeding of the critical limit does not reoccur and an assessment of the effectiveness of the action taken. As a Corrective Action Procedure is required for addressing all non-conformances – the Corrective Action section of the HACCP Plan may refer to this procedure – however HACCP Plans must contain the specific Corrective Actions to be taken at each step of the process should the critical limits relevant to that step be exceeded	
Verification procedures and the frequency with which these procedures will be performed; and	Sch 2 C 3.7	This requirement is typically documented in the form of a Verification Schedule – a table which identifies each component of the HACCP Plan that requires verification, the method of verification to be used, the frequency of verification, who is responsible and what records will be kept. As verification of the entire Approved Arrangement is required – this information may be combined into the one Verification Schedule.	
The records to be made and kept to demonstrate compliance with the HACCP plan and its effectiveness.	Sch 2 C 3.8	Records will include: monitoring records for CCPs and GMPs, provision of records of corrective action, validation information, verification records (see above)	

Components of an Approved Arrangement	EC(F&FP)O Ref:	What Must be documented	<input checked="" type="checkbox"/>
Preparation & Transport – Specific Requirements		Order 47 and Schedule 5	
Harvesting, sourcing, depuration, wet storage and killing	Sch 5, Part 1	<p>Many of the clauses in Schedule 5 will be addressed during the development of the HACCP Plan as they apply specifically to the processing of product and the controls that must be in place to ensure that the product is safe. The requirements of this Schedule can be addressed by documenting procedures for how your product is sourced, received, processed, labelled, stored and transported, how these activities are monitored and how it is verified that procedures are being carried out as documented.</p> <p>For example: A Receiving procedures should include details of where product may be received from, how it is received, how it is inspected on receipt to ensure that it meets the required standards (visually inspected, temperature probed etc.) and where this information is recorded. Procedures should also include details of who is responsible for ensuring the procedure is carried out and who may make decisions if product received is outside of temperature requirements, does not meet the required product specification or is not accompanied by the correct documentation etc.</p>	
Temperature Controls	Part 2		
Preserving fish & fish products	Part 3		
Packaging & Identification	Part 4		
Storage, handling and loading	Part 5		
Transport	Part 6		
Fitness for human consumption	Part 7		
Product Standards			Order 48 and Schedule 6
Product Standards for fish, fish products and Ingredients	Sch 6, Part 1	<p>Product Descriptions or Specifications should be developed for each product line processed (including any ingredients used) and should include information on the applicable standard to which they must comply (including any applicable importing country requirements). This will assist in determining what testing will be required to verify that the product meets the applicable standard.</p> <p>A procedure should be developed that states how and when product will be tested, who is responsible and what action will be taken should results be outside of the required limits.</p> <p>This clause details the laboratory methods that must be used to demonstrate product compliance with the microbiological limits for the Food Standards Code. This may need to be discussed with your chosen laboratory.</p>	
Contaminants, natural toxicants, residues and food additives	Sch 6, C 1		
Microbiological limits	Sch 6, C 2		
Methods of Sampling and examination	Sch 6, Part 2		
Trade description		Order 49 and Schedule 7	
Contents of a Trade Description	Sch 7, C 4.1	Examples of Trade Descriptions to be applied to specific products can be included with Product Descriptions and must be checked against the requirements of this Schedule to ensure that requirements are met.	
Application of Trade Descriptions	Sch 7, Part 3	Procedures must be in place to ensure that Trade Descriptions applied to fish & fish products are accurately and correctly applied and that both product and procedure are monitored to verify that the procedure is being followed and that the labels applied to products contain all of the required information – including information that will enable the product to be traced back to the specific date on which it was processed.	

Components of an Approved Arrangement	EC(F&FP)O Ref:	What Must be documented	<input checked="" type="checkbox"/>
Identification, tracing systems, integrity and transfer		Order 50 and Schedule 8	
Identification, tracing systems, integrity and recall	Sch 8, Part 1	Effective measures for tracing systems, for making records, retaining documents and identifying fish and fish products must be documented to ensure that products can be identified, traced and if necessary recalled.	
Supply and Preparation Sourcing fish & fish products	Sch 8, Part 2	Procedures must be documented to ensure that fish, fish products and ingredients are sourced only from suppliers with traceability procedures in place and records made of the suppliers of all products (including ingredients) received by the establishment and that Production records are kept of all the information required to ensure trace-back.	
Transfer	Sch 8, Part 3	Procedures must be documented that ensure that transfer information given and received is complete and accurate and should include details of who is responsible for documentation and how it is controlled.	
Declarations of Compliance	Sch 9, C 5.1, 5.2, 6.1, 7.1	Procedures must be documented to ensure that Declarations of Compliance given are complete, accurate and made only by persons nominated in the Approved Arrangement as authorised to make such declarations. For further information see AQIS Guideline – Traceability.	
Export Permits and Government certificates		Order 53-58 & Schedule 9	
Maintain permits and government certificates under conditions of security.	Order 53	Orders 52 – 58 (Part 5) detail the requirements that must be met by persons responsible for issuing export permits – and includes the requirement to document the measures that will be taken to comply with Orders 52 – 58 and subclauses 11.5, 11.6, 12.4 and 12.5 of Schedule 9 and the conditions of an approval of an approved export permit issuer referred to in subclause 16.8 of Schedule 9.	
Return any revoked export permits, cancelled government certificate.	Order 54	Regardless of the level of involvement your establishment has in the raising and issuing of export documentation – documented procedures must be in place to ensure that when supplying information relating to export documentation – such as Transfer Certificates and Through – chain Declarations of Compliance when product is unloaded from a vessel – that the information provided is correct and complete and is signed by a person designated in the Approved Arrangement to make such declarations.	
Notify an authorized officer	Order 55	For further information see - “AQIS Guidelines to Compliance with the Export Control (Fish & Fish Products) Orders 2005 – Export Documentation ” and “Traceability”	
Provide accurate and complete information.	Order 56		
Provide all information required by Schedule 9 Clause 2,	See Schedule 9		
Record keeping	Order 58	Procedures must be in place to ensure that all export documentation is retained for a minimum of 3 years.	
Alternative regulatory arrangements	Order 84	If an occupier has made an application to the Secretary to use an alternative procedure or standard other than what is a requirement of the Orders – written notice must be received and controls documented to ensure that the alternative requirements are met.	

8.0 AQIS Guidelines:

AQIS has developed a series of “Guidelines to Compliance with the *Export Control (Fish & Fish Products) Orders 2005*” to provide additional detail on specific requirements of the Approved Arrangement and further assist you with compliance with the new legislation.

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

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

- Audit Regime for Fish & Fish Products Exports
- 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 How to apply for an Approved Arrangement

Approved Arrangements must be evaluated by AQIS to determine if the Approved Arrangement complies with subclause 2.1 of Schedule 2 and that compliance with the controls specified in the Approved Arrangement will ensure that the applicable requirements of the Orders and any importing country requirements specified will be complied with.

When all components of an Arrangement have been documented and implemented the company may then apply for approval of the Approved Arrangement by submitting both the Approved Arrangement and a completed “Application for approval of an Approved Arrangement” form, available from the AQIS website.

Initially a desk audit will be conducted to evaluate the documented 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 occupier of 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.

10.0 Variations to Approved Arrangements

Approved Arrangements should not be considered as static documents that once completed and approved are finalized.

Establishments regularly make changes to their operations for a range of reasons including:

- Introduction of new product lines
- Changes in processing methods

- Changes required to improve efficiency
- Changes in operation to address non-conformances found during external and internal audits

Schedule 2, Clauses 17 & 18 detail the requirements for documenting all variations made to the Approved Arrangement. This may be in the form of a table setting out the amendment history.

Procedures will also need to be in place to ensure that:

- Variations to the Approved Arrangement are controlled – that is, that someone is responsible for making changes.
- Staff have access to current documentation and are made aware of any changes to procedures that may affect operations.
- Superseded documentation (including superseded forms) are withdrawn from use and replaced with amended documents.
- Documentation and records are retained for a period of not less than 3 years

See Schedule 2, Clause 10 for further details on the requirement to retain documents.

Notifying AQIS of variations to the Approved Arrangement

If a proposed variation to the Approved Arrangement has the potential to adversely affect the likelihood of compliance with the requirements of the Orders, importing country requirements or the fitness for human consumption or integrity of the fish and fish products at the establishment, an application for approval of the variation will need to be made to AQIS in writing and a written approval received before the changes are implemented.

Section 2: Documenting the Approved Arrangement – Specific Requirements

I Minimum Requirements for Approved Arrangements

The minimum requirements for an Approved Arrangement are detailed in broad terms in Schedule 2 – Subclause 2.1 – 2.2 of the *Export Control (Fish & Fish Products) Orders 2005*.

To ensure that all the applicable requirements of the Orders are addressed when developing an Approved Arrangement, reference must be made to all Orders and Schedules of the *Export Control (Fish & Fish Products) Orders 2005*.

The following information is aimed at providing you with details of what you must do to comply with the minimum 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 (AQA) arrangements, may be new to those previously operating a Food Processing Accreditation (FPA). 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 - Schedule 2, Clause 1.1

The occupier of an establishment used to prepare fish and fish products for export must make a statement in the Approved Arrangement, which documents the occupier's commitment to:

1. The objectives of the Orders;
2. Compliance with the requirements of the Orders; and
3. Compliance with applicable importing country requirements.

Management practices, organisational structure, resources and competence – Schedule 2, Clause 4.1

Export Control (Fish & Fish Products) Orders 2005 – subclause 4.1 of 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** – this may be addressed with a mission statement/policy statement

Example:

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

- Endorse 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 may be included in the Policy Statement

- **Organisational structure**

Example:

An Organizational Chart may be used to illustrate the organizational structure of an organization and should include:

- All positions with responsibilities documented in the Approved Arrangement (including positions responsible for management, product handling and control of export documentation)
- An illustration of the reporting lines between the positions – who reports to whom.

Duty Statements or Job Descriptions for each position illustrated in the organizational chart may be used to give further details of the qualifications that are required of each position and the responsibilities to the Approved Arrangement that each position holds. Details of persons who will be responsible in the absence of key staff should also be included.

It is essential that all staff are aware of who has operational and managerial 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 associated documentation and ensuring staff have been trained in the contents of the Approved Arrangement will assist in demonstrating compliance with requirements.

- **The provision of resources.**

This should include a brief description of the Establishment, the facilities, equipment, etc required for the activities to be carried out at the establishment effectively and a commitment to how the applicable resources are to be sourced and maintained.

- **The provision of personnel and their competence (including knowledge, training, skills and experience)**

This should include information regarding commitment to the allocation of appropriately qualified staff and details about their competence, including how competence will be assessed and maintained.

Reference should also be made to any Staff Training Programs or Standard Operational Procedures that may be relevant to demonstrating that the organization has controls in place

to ensure that staff training needs have been appropriately identified and that there are procedures in place to ensure that staff are appropriately trained.

Example:

The Approved Arrangement needs to identify and document:

- The responsibilities of each position documented in the organizational structure to the Approved Arrangement
- The training needs for persons operating under the Approved Arrangement – for example:
- Training courses for supervisors and specialist positions eg:
 - Principles of Food safety
 - Fish Handling course
 - Development of HACCP plan
 - Retort operation - Retort Supervisors course
 - Development of thermal processes – Qualified Canning Persons Course
- 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 in work procedures for employees
- Training in relation to specific importing country requirements documented in the Approved Arrangement
- Details on the frequency of training, how it will be delivered and how competence of the employee will be assessed

Verification – Schedule 2, Clause 5.1 & 5.2

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.

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

The results of all verification activities must be recorded

Export Control (Fish & Fish Products) Orders 2005 – Order 37 - Division III Part 3

37.1 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 how, when and which procedures, tests or other assessments are going to be made to ensure that the requirements in the Schedules listed above applicable to the operations of their establishment are complied with.

The Approved Arrangement may have separate sections or Standard Operational Procedures, which address how the occupier is going to control, manage and monitor operations under these Schedules from a day-to-day perspective.

However, the management is also responsible for verifying 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 being produced complies with the Orders. Verification may include activities such as scheduled Internal Audit of procedures and review of monitoring records to ensure that procedures are being followed and monitored as described in the Approved Arrangement.

The AQIS guideline “Verification and Validation” – a guideline to compliance with the *Export Control (Fish & Fish Products) Orders 2005* provides further detail on verification activities and their documentation.

Corrective and preventative action – Schedules 2, Clause 6.1 & 6.2

The Approved Arrangement must include a record of all action taken (corrective or preventative) where a requirement of any of the Schedules in Division III, Part 3 of the Orders are not complied with or not likely to be complied with. A written record must also be made of the assessment of the effectiveness of the action taken.

The action taken must:

- Address the non-conformance
- Ensure that the failure will not recur; and
- Assess the effectiveness of the action taken

A procedure should be documented to ensure that corrective action is taken in accordance with the above steps and should also address the disposition of any product that may have been affected by the non-compliance.

Measures should also be put in place to ensure that any product affected by non-conformance is identified and segregated until its disposition can be determined.

Corrective actions are typically documented on Corrective Action Reports or Non-Conformance Reports – forms that provide sections for detailing the non-conformance, the action taken, details of any product that may have been affected and measures put in place prevent reoccurrence.

Assessment of the effectiveness of the action taken may be undertaken as part of the Management Review process. A series of non-conformances within the same area, or repeat non-conformances may suggest that the corrective action that has been taken was not effective.

Internal audit and management review – Schedule 2, Clause 7.1

The Approved Arrangement must document procedures for internally auditing your own Approved Arrangement and conducting management reviews. Internal audit and management review must be conducted at least once every twelve months

To ensure on-going compliance with legislative requirements and the practices carried out under the Approved Arrangement it is necessary 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.

Properly conducted and recorded internal audits are an essential management tool to verify that the system is in place and effective. They must be properly planned and scheduled and cover every element of the system.

You need to review your Arrangement to ensure that:

- What has been documented in the Approved Arrangement is current; and
- What you are doing is consistent with what you have documented that 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 Approved 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 must be kept.

Internal Audit procedures should include a description of how and when internal audits will be conducted and by whom.

Note: When developing internal audit checklists it is important to ensure that they are developed by closely referencing the requirements that they are intended to meet. For example: When developing an internal audit checklist to assist in determining if the establishment meets the applicable structural requirements – close reference should be made to Schedule 3.

Management Review

Management should review the Approved Arrangement; a regular formal meeting is acceptable. Minutes of such meetings are to be kept and made available to auditors on request.

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 all aspects of operations 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
- Review internal and external audit outcomes
- Review importing country requirements (if applicable), customer complaints, detained consignments
- Review monitoring and verification activities to identify breakdowns in systems which need improvement,
- Review corrective actions taken for effectiveness, consider additional corrective actions that may need to be implemented and consider any incidents that may have occurred since the last meeting.
- Record the discussions and outcomes

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

Sampling and analysis - Schedule 2, Clause 8

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 (Fish & Fish Products) 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 require product to be sampled and analysed to demonstrate and verify compliance with Product Standards (Schedule 6). Test methods are also specified and therefore the occupier is responsible for ensuring that all sampling and analysis is conducted in accordance with specified methods.

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 (Fish & Fish Products) Orders 2005*', which is available at <http://www.aqis.gov.au/fish>

Notifiable diseases – Schedule 2, Clause 9

The occupier of the Registered Establishment should familiarise themselves with Schedule 2, Clause 9 which relates to notifying an authorised officer if fish and fish from which food is being prepared is affected by or suspected of being affected by a notifiable disease.

Requirement to retain documents – Schedule 2, Clause 10

The occupier of the Registered Establishment should familiarise themselves with Schedule 2 Clause 10 which relates to the requirement to retain documents 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 for a minimum of 3 years.

This should be documented as part of a procedure for document control, which may also include requirements for variations and amendments. See [9.0–Variations to Approved Arrangements](#) in this guide.

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 fish and fish products for export must not occur at export establishments (Order 36)

Establishments that prepare fish and fish products 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 fish and fish products for export is not put at risk; **and**
The identity of the fish and fish products 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.

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

The Approved Arrangement should identify all the products prepared by the establishment and their intended use and market. This may be documented in a list form or as a “Schedule of Products”. This will assist in determining the controls required to ensure that the requirements of Order 36 are met.

Currently AQIS regulates food for export but establishments may also wish to prepare food for the domestic market. The Approved Arrangement will need to document how the domestic product 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.

See also subclauses 37.1 – 4.1 of Schedule 5 – for further details of controls that must be in place to ensure that products that are not intended for export as food are clearly identified, segregated and prevented from being a potential source of contamination to export 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:

- A HACCP Plan for cooking prawns in accordance with clause 3 of Schedule 2
- Procedures to ensure that there is no cross contamination between the raw product and any cooked product
- Procedures to ensure cartons are **clearly** designated for export or domestic to ensure that only frozen raw prawn is exported

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 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 initially register for export, the AQIS inspector will request plans and specifications of the establishment and inspect your premises. The plans and specifications must be sufficiently detailed to show whether the establishment is suitable for the preparation of fish and fish products for export as food. Clauses 1 – 3 of Schedule 1 provide details of what must be included in plans and specifications for registered establishments (including registered vessels).

The initial registration inspection is designed to provide you with information as to whether the premises comply with requirements or whether upgrades are required before operations commence. Registration will not occur until the premises meet requirements.

There are some legislative requirements that must be considered when constructing premises that are given in Schedule 3 clause 2.1

Export Control (Fish & Fish Products) 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.

How structural requirements will be met is not required to be documented in the Approved Arrangement, however the following documentation is required:

- Current plans and specifications
- Advice to AQIS and applicable approvals for any structural alterations or additions intended to be made following registration.

Export Control (Fish & Fish Products) Orders 2005 – subclause 3.1 – 3.2 of 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.

What must be documented

The Approved Arrangement must include details of how you intend to verify compliance with Schedule 3 eg. By periodic internal audit of premises and equipment.

IV Schedule 4 – Operational Hygiene

Export Control (Fish & Fish Products) Orders 2005 – Order 46

Order 48 - Operational Hygiene

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 fish and fish products must be documented and in place at premises used to prepare fish and fish products. (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
- Measures to prevent environmental contamination (including water borne and air borne contamination)
- Pest control and the exclusion of live animals from premises
- Use and storage of hazardous substances
- General controls for fish and fish products and ingredients, including protection from contamination during storage, handling and transportation
- Calibration of measuring equipment
- Validation of refrigeration chambers

- Controls for ingredients including fitness for purpose, labelling, storage and handling
- Water usage and testing (including reused water, recirculated water, clean sea water, ice and steam)
- Use of steam compressed air and other gases
- Personal hygienic and health requirements

Water must be potable

Export Control (Fish & Fish Products) Orders 2005 – subclauses 14.1 – 17.2 of Schedule 4

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:

The legislation does not limit 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. Where non-potable water is used the Approved Arrangement needs to document under what circumstances it will be used and must verify that if it comes into contact with the processed food or food contact surfaces it 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?

There are also other events that 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

Occupiers must also consider procedures for ensuring that similar controls are in place when producing or purchasing ice.

Example:

Schedule 4, subclause 3.5 sets out the requirement for maintaining premises and equipment in a good state of repair and working order.

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 include a documented HACCP plan as part of the minimum requirements. (Schedule 2, Clause 3).

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

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 fish and fish products; 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 fish and fish products; 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 (A_w) 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 (Fish & Fish Products) Orders 2005 – Order 47

Order 47 - Preparation and Transport

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, fish and fish products 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.

Example:

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 the appropriate controls in place (Clause 6.1 of Sch 5 and Order 42) including appropriate hygiene and temperature control.

The Approved Arrangement must include systems of controls to ensure that fish (including crocodiles) are obtained from sources that ensure that the fish and fish products to be prepared will be safe/suitable

How the receiving registered establishment verifies compliance with the sourcing provisions must be documented in the Approved Arrangement.

Example:

To ensure fish and fish products are 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 or suspect that 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. Temperature Controls - 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 fish and fish products during storage, handling, loading and transport. The monitoring procedure in your HACCP plan should demonstrate this.

Export Control (Fish & Fish Products) Orders 2005 – subclause 19.1 – 19.2 – Schedule 5

Rate of Chilling

- 19.1 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
- 19.2 The applicable approved arrangement must validate that the rate of chilling achieves the outcome specified in subclause 19.1.

See also subclauses 21.3 and 21.4 which relates to similar requirements for validation of freezing

Even though the *Export Control (Fish & Fish Products) Orders 2005* states the chilling and freezing temperature ranges (See Schedule 5 Clause 18, 20 and 21) within which fish and fish products must be held to control pathogen growth, you will need to validate that:

1. Your equipment has the capacity to reduce the product to the acceptable temperatures and
2. That the time taken to reduce the product temperature to within the designated range will be rapid enough to prevent potential pathogen growth to the extent that it compromises the fitness for human consumption of the food.

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 fish and fish products - Schedule 5, Part 3

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

Outcome for preservation processes

24.1 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.

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 fish and fish products 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 and Identification - Schedule 5, 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 - Schedule 5, Part 5

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

Example:

Procedures may be developed that detail requirements for product storage including instructions such as:

- 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- Schedule 5, Part 6

The Approved Arrangement must include systems of control to ensure that fish and fish products are transported under temperature control as specified by the Orders (Schedule 5, Part 6).

That is, what controls are in place to ensure chilled or frozen product is transported and maintained at the appropriate 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

Evaluation of fitness for human consumption – subclause 36.1

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

- All fish and fish products received at the establishment
- Of ingredients received at the establishment and
- Of all fish and fish products prepared for export.

Procedures for evaluating the fitness for human consumption for fish and fish products and ingredients received by the establishment should also include the controls developed for ensuring the source of the food and ingredients is safe. (Sch 5, subclause 36.1)

Example:

Procedures may be developed that detail requirements for product receipt including instructions for:

- Inspecting all fish and fish products received by the establishment for wholesomeness and compliance with temperature requirements
- Ensuring that all shellfish received are identified by lot and lease number

Fish and fish products not for human consumption, manufacturing grade products, animal food – subclauses 37.1 – 41.1

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

- All manufacturing grade fish and fish products and
- Fish and fish products not fit for human consumption (including animal food).

Where the establishment also produces fish and fish products not for export (eg; domestic) procedures must be in place to ensure that fish and fish products not prepared in accordance with the requirements of the Orders are clearly identified, segregated from and cannot contaminate fish and fish products for export or be loaded for export.

Fish and fish products for export to identified markets – subclause 42.1

Additionally where fish and fish products are 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.

VII Schedule 6 – Product Standards for food and ingredients

Under the new Orders occupiers are responsible for verifying that fish and fish products for export and their ingredients do 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 and fish products for export as food. 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 (Fish & Fish Products) 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 document 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 fish and fish products for export as food (Clause 1). Information is also provided relating to trade descriptions for bright cans or unwrapped fish and fish products bulk loaded into a container (Clause 2) and fish and fish products identified as not for retail sale (Clause 3).

AQIS has developed a guideline titled “Trade Description - A Guideline to Compliance with the *Export Control (Fish & Fish Products) 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 fish and fish products must have effective measures (including records and documentation) in place for the identifying, tracing and, if necessary, recalling of fish and fish products. (Schedule 8, clause 1.1)

Where fish and fish products are 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 (Fish & Fish Products) 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 (Order 52 – 58) of the Orders, namely the requirements to:

- Maintain export permits and government certificates under conditions of security.
- Return any revoked export permits, cancelled government certificates.
- Notify an authorized officer where there is suspicion that the fitness for human consumption of the fish and fish products are jeopardised, 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 57)

Declarations of Compliance must only be made by either the occupier of an establishment or a person designated in the applicable Approved Arrangement as a person who may make such a declaration on behalf of the occupier of the establishment at which the fish and fish products were was last prepared (other than merely stored, handled or loaded). (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 (Fish & Fish Products) Orders 2005*”. The guideline is available at www.aqis.gov.au/fish

Approval etc. of Approved Arrangements for issuing export permits

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 requirements of subclause 15.1 of Schedule 9. The person issuing the permit must be an *approved permit issuer* (accredited by AQIS), and be either the occupier of the processing establishment which last prepared the food or be a person designated by the occupier who has management responsibilities at the establishment and who is also a fit and proper person as described in the PGGOs.

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 fish and fish products 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 fish and fish products prepared at the Establishment to be exported to the country identified in the application.

If granted by the Secretary, details of the written notice must be including in the Approved Arrangement along with details of the control measures used for identification and segregation of this product (Order 85) as the food may be made ineligible for domestic sale or export to other markets as a result of not meeting the requirements of 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 and controls 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 and security of official marks and marking devices - Order 70 -74

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 84

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 written notice is given 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:

Subclause 11.4 of Schedule 5 details requirements for the depuration of shellfish stating that “shellfish must be depurated for at least 36 hours and if any interruption occurs, the process of depuration must be restarted”.

Under the alternative regulatory arrangements – an occupier may wish to seek approval for an alternative procedure that may be approved - provided that it can be demonstrated that the alternative procedure will achieve the same required outcome.

Appendix 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	See Section 2 – Occupiers Commitment
	Management practices, organisational structure, resources and staff training	N	See Section 2 – Management Practices
	Verification	N	See Section 2 & Verification & Verification Guideline
	Corrective and preventative action	Y	Specific Corrective Actions previously documented in HACCP – now the requirement to action and document <u>all</u> non-conformances See Section 2 – Management Practices
	Internal audit and management review	N	See Section 2 – Internal Audit
	Sampling and analysis	Y	Yes in EU approved estab HACCP Now required by all Reg. Establishments
	When operations other than preparation of fish and fish products for export must not occur at export establishments (Order 38)	Y	While non-export product has always been required to be segregated from export product – there have been some changes to the requirement. See Section 2 – 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 (F&FP) O – Schedule 4 – Clause 6
	Pest control program	N	High risk Est. and some EU Reg. Est. may already have been required to have these documented
	Use and storage of hazardous substances	N	High risk Est. and some EU Reg. Est. may already have been required to have these documented
	General controls for storage of food, including protection from contamination, storage, handling and transportation	N	Previously covered by the requirements of the Orders, however now required to be documented
	Calibration of measuring equipment	N	Previously covered by the requirements of the Orders, however now required to be documented
	Validation of refrigeration chambers	N	Previously covered by the requirements of the Orders, however now required to be documented
Control for ingredients including fitness for purpose, labelling, storage & handling	N	Previously covered by the requirements of the Orders, however now required to be documented	

Component of an Approved Arrangement		F P A	Comments
	Water usage and testing	N	Previously covered by the requirements of the Orders, however control measures now required to be documented
	Use of compressed air and other gases	N	Estab using gases as processing aids would have addressed this requirement in their HACCP
	Personal hygienic and health requirements	N	Previously covered by the requirements of the Orders, however control measures now required to be documented
	Catcher vessels	N	EU establishments currently required to document catcher boat controls – now required by all establishments sourcing from catcher vessels.
HACCP	<i>The HACCP plan must identify:</i>		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.
	Each of the steps in the preparation of the food (a flow chart may be used); and	Y	
	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)	Y	Many of these requirements will have previously been documented as part of the HACCP Plan required under an FPA.
	Preserving fish and fish products (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 (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

Component of an Approved Arrangement		F P A	Comments
Trade Description (Schedule 7)	Contents an application of Trade Descriptions	N	Previously covered by the requirements of the Orders, however now required to be documented See Attachment 3 - Trade Description & Trade Description Guideline for further information
Identification, tracing systems, integrity & transfer (Sch 8)	See Schedule 8 of the EC (F&FP) O 2005 for details	N	Previously covered by the requirements of the Orders, however now required to be documented 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	Previously covered by the requirements of the Orders, however now required to be documented
	Alternative regulatory arrangements (Order 86)	Y	Previously covered by the requirements of the Orders, however now required to be documented
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 Section 2 - 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	
	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.	Y	All previously required, except now additional requirements of Schedule 9, EC (F&FP) O including the requirement to provide Declarations of Compliance
	Record keeping	Y	
Approval process (including variations)	Application	Y	Application process is similar to FPA Approval and continues to require application, desk audit of documentation and site audit.
	Desk audit	Y	
	On site audit	Y	
	Variations to an approved arrangement	N	All variations made to an Approved Arrangement are now required to be recorded. Prior approval may be required for some variations. (Sch 2, Clause 17)

Appendix 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 Section 2 – Management Practices
	Management practices, organisational structure, resources and competence	Y	See also Section 2 – 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 fish and fish products 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 (F&FP) 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		

Component of an Approved Arrangement		AQA	Comments
	Control for ingredients including fitness for purpose, labelling, storage and handling	Y	Should be documented under Part 3 AQA handbook
	Water usage and testing	Y	
	Use of compressed air and other gases	Y	
	Personal hygienic and health requirements	Y	
	Catcher boats	Y	
HACCP	<i>The HACCP plan must identify:</i>		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.
	Each of the steps in the preparation of the food (a flow chart may be used); and	Y	
	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	
	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	
	Verification procedures and the frequency with which these procedures will be performed; and	N	
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	The majority of these elements would previously been addressed in the HACCP Plan. 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 fish and fish products (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

Component of an Approved Arrangement		A Q A	Comments
	Microbiological limits		As per the requirements specified for food of that kind in the FSANZ Food Standards Code
Trade Description (Schedule 7)	See Schedule 7 of the EC (F&FP) O 2005 for details of requirements for content and application of Trade Descriptions	Y	See Section 2 - Trade Description and Trade Description Guideline for further information
Identification, tracing systems, integrity and transfer (Schedule 8)	See Schedule 8 of the EC (F&FP) 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 and security of official marks and marking devices	N	Refer EC (F&FP) O – Part 7 – Orders 70 - 74
	Alternative regulatory arrangements (Order 84)	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 85)	Y	See Section 2 - 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 (F&FP) O – Order 55
	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.	Y	All previously required, except now additional requirements of Schedule 9, EC (F&FP) O including the requirement to provide Declarations of Compliance
	Record keeping		EC (F&FP) O – Order 58
Approval Process (including variations)	Application	Y	Application process is similar to FPA Approval and continues to require application, desk audit of documentation and site audit.
	Desk audit	Y	
	On site audit	Y	
	Variations to an approved arrangement	Y	All variations made to an Approved Arrangement are now required to be recorded. Prior approval may be required for some variations. (Sch 2, Clause 17)