



Australian Government

Australian Quarantine and Inspection Service

Product Standards

Verification Testing for Sourcing and Handling of Fish & Fish Products

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

Version 7 – Date of effect 1 November 2011

Amended to include mandatory reporting of unsafe food to AQIS; amended tests for raw crustaceans; and additional guidance regarding EU test methodologies.

This document replaces the AQIS Guideline:
“Product Standards – Verification testing for sourcing & handling of Fish & Fish Products – A Guideline to compliance with the *Export Control (Dairy, Eggs and Fish) Orders 2005*” Version 6

Table of Contents

Definitions	3
Background	5
Objectives	6
Product standards.....	6
1 Introduction	6
1.1 Contaminants, natural toxicants, residues, food additives	8
1.2 Importing country requirements	9
2 Government surveillance	10
3 Principles of the testing requirements	10
4 Testing	12
4.1 Who is required to test product?	12
4.2 When should testing occur?.....	12
4.3 Frequency of testing to verify source	13
4.4 Frequency of testing to verify HACCP plans	14
5 If regulatory levels are not complied with	15
6 Procedure for when test results do not comply	17
7 Taking samples	18
8 What must be documented under the Approved Arrangement.....	19
9 Reference information	19
Table 1. Product risk categories (referenced in Table 2)	21
Table 2. Minimum frequency of testing to verify HACCP	21
Table 3. Testing regime to verify the source of fish and fish products	22
Table 4. Minimum testing regime of fish and fish products to verify HACCP - Microbiological	23
Table 5. Minimum testing regime of fish and fish products to verify HACCP for fish product further processed at your establishment (not including packing) – Other standards	24
Table 6. Biotoxin and contaminates criteria specifically for the EU.....	25
Table 7. Food safety criteria specifically for the EU	26
Table 8. Process hygiene criteria specifically for the EU	27

Definitions

Throughout this document the following terms have the associated meanings.

Term	Definition
Approved Arrangement (AA)	<p>An arrangement approved under:</p> <ul style="list-style-type: none"> • clause 14, Schedule 2 of the <i>Export Control (Fish & Fish Products) Orders 2005</i>, or <p>An AA includes a variation of an arrangement in the circumstances specified in suborder:</p> <ul style="list-style-type: none"> • 84.5 and clause 20 of Schedule 2 of the <i>Export Control (Fish & Fish Products) Orders 2005</i>, or <p>Further information about Approved Arrangements may be found in 'Approved Arrangement - Guideline to compliance with the <i>Export Control (Fish and Fish Products) Orders 2005</i> or 'Approved Arrangement, Guideline to compliance with the <i>Export Control (Eggs and Egg Products) Orders 2005</i>'.</p> <p>This legislation is available from the web page: http://www.daffa.gov.au/aqis/export/fish/guidelines</p>
AQIS	The Australian Quarantine and Inspection Service
ASQAAC	The Australian Shellfish Quality Assurance Advisory Committee. This is a national forum of state and Commonwealth agencies involved in administering the Australian Shellfish Quality Assurance Program. ASQAAC co-ordinates policy and implementation of ASQAP, promoting consistency between all jurisdictions with regard to interpretation of ASQAP requirements.
ASQAP	The Australian Shellfish Quality Assurance Program. This is an agreed, co-operative State-Federal-Industry program to ensure that commercial shellfish produced in accordance with these guidelines are safe, wholesome and properly labelled.
Crustacea	Crustaceans (Crustacea) form a very large group of arthropods, usually treated as a subphylum, which includes such familiar animals as crabs, lobsters, crayfish, shrimp, krill and barnacles
FSANZ	<p>Food Standards Australia New Zealand.</p> <p>FSANZ are a bi-national government agency. Their main responsibility is to develop and administer the Australia New Zealand Food Standards Code (the FSC), which covers requirements for foods such as additives, food safety, labelling and genetically modified foods. Enforcement and interpretation of the FSC is the responsibility of state/territory departments and food agencies within Australia and New Zealand.</p>
Food Standards Code (FSC)	<p>The Australia New Zealand Food Standards Code.</p> <p>The FSC lists Australian food standards which are developed and maintained by FSANZ.</p>
HACCP	<p>Hazard Analysis Critical Control Point.</p> <p>The HACCP system is an internationally recognised system used to manage food safety. It has been endorsed by the Codex Alimentarius Commission as a tool that can be used to systematically identify hazards specific to individual products and processes and describe measures for their control to ensure the safety of food products.</p>
IANZ	International Accreditation New Zealand - the New Zealand equivalent laboratory accreditation body to NATA
Importing country authority	This means the authority or body in the destination country responsible for regulating the import of fish and fish products of that kind into that country.

Lot	A 'lot', when used in relation to processed food, means a quantity of processed food of the same type, processed or packed under essentially the same conditions, during a particular period of time interval not generally exceeding 24 hours, and usually from a particular processing or packing line or other identifiable processing or packing line. For shellfish, a lot also means a single species of shellfish harvested from a particular harvesting area and designated by a single harvest record number.
Molluscs	The Mollusca, common name molluscs or mollusks,[note 1] is a large phylum of invertebrate animals. The phylum Mollusca is typically divided into nine or ten taxonomic classes, of which two are extinct. The gastropods (abalone, snails and slugs) include by far the most classified species, accounting for 80% of the total. Molluscs also include the cephalopods (such as squid, cuttlefish and octopus) and bivalve molluscs (such as oysters, mussels, scallops, clams and others).
NATA	The National Association of Testing Authorities. NATA is the authority that provides independent assurance of technical competence through a proven network of best practice industry experts for customers who require confidence in the delivery of their products and services. NATA provides assessment, accreditation and training services to laboratories and technical facilities throughout Australia and internationally.
NMI	National Measurement Institute – formerly known as the Australian Government Analytical Laboratory (AGAL). Further information is available from the NMI website: www.measurement.gov.au
NRS	The National Residue Survey. The NRS monitors residues of agricultural and veterinary chemicals and environmental contaminants in Australian food commodities. The cost of this monitoring is largely industry-funded through levies on the animal and plant commodities that are tested.
Regulatory level	This is the level set by either the importing country authority (e.g. the EU) or the FSC. Failure to comply with a regulatory level means the food is not eligible for the respective market that the level applies to. If possible, corrective action will be required to bring the food into compliance; or the food directed to an alternate market; or destroyed.
The PGGOs	<i>Export Control (Prescribed Goods – General) Order 2005</i>
The Orders	<i>Export Control (Fish and Fish Products) Orders 2005</i>
The following definitions are for the Tables contained within this document	
cfu	Colony forming unit - A unit of measurement used in microbiology that indicates the number of microorganisms present in a sample.
EU	European Union – the EU is an economic and political union of 27 member states which are located primarily in Europe.
EC	European Commission – the EC is the executive body of the European Union. The body is responsible for proposing legislation, implementing decisions, upholding the EU's treaties and the general day-to-day running of the EU.
g	gram
mg	milligram
kg	kilogram
SPC	Standard Plate Count
MPN	Most Probable Number
MU	Mouse Unit
n	Means the minimum number of sample units which must be examined from a lot of food.

c	Means the maximum allowable number of defective sample units.
m	Means the acceptable microbiological level in a sample unit.
M	Means the level that when exceeded in one or more samples would cause the lot to be rejected.

Background

The *Export Control (Fish & Fish Products) Orders 2005* (the Orders) together with the *Export Control (Prescribed Goods - General) Order 2005* (the PGGOs), provide conditions and restrictions on the export of fish and fish products from Australia as food.

The Orders require fish and fish products for export for human consumption to comply with the food standards prescribed by Schedule 6 of the Orders.

The Orders require fish and fish products for export to comply with the food standards as specified in the Australia New Zealand Food Standards Code (FSC). The exception is where the importing country has an alternate food standard to that which is in the FSC, and the products are in compliance with this alternate standard and are exported to that market.

The FSC is a collection of individual food standards. Standards on related matters are grouped together into Parts, which in turn are collated together into four Chapters. Chapter 1 deals with standards that apply to all foods. Chapter 2 deals with standards affecting particular classes of food. Chapter 3 deals with food hygiene issues specific to Australia. Chapter 4 contains standards dealing with the primary production and processing of food in Australia.

The FSC is called up into relevant state, territory and Commonwealth legislation, making it illegal in Australia to supply food for sale that does not comply with the relevant standards in the FSC. Food legislation also makes it illegal to supply food for sale that is damaged, deteriorated or perished, which is adulterated or which is unfit for human consumption.

This document presumes that the reader has knowledge of the *Export Control (Fish and Fish Products) Orders 2005* and is to be read and interpreted in accordance with export legislation.

Objectives

The objectives of the Orders are to facilitate trade based on effective food safety, suitable procedures and accurate descriptions of products. 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.

An establishment's Approved Arrangement with AQIS requires the implementation of a food management system to produce food that is fit for human consumption and complies with importing country authority requirements. Product testing can be considered a performance indicator of how well the establishment's food management system is performing in meeting these requirements.

This document specifically addresses the requirements of registered establishments to meet objective 3.1 (a) and (c) of the Orders.

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

3. Objectives of these Orders

3.1 The objectives of these Orders are to facilitate trade by ensuring the following:

(a) that fish and fish products for export as food are fit for human consumption or are manufacturing grade processed food and is identified as manufacturing grade for export for further processing; and

(c) that fish and fish products for export as food meet importing country requirements;

Product standards

1 Introduction

This guideline outlines the minimum testing to be carried out by all AQIS registered establishments which source and prepare fish and fish products for export. This testing is required to verify compliance with food safety requirements under the Orders and the minimum testing requirements to satisfy importing country authority requirements for the European Union (EU).

These minimum testing requirements can be integrated into other testing that the establishment already undertakes for commercial arrangements.

Additional testing requirements to verify the effectiveness of the HACCP Plan will be determined by individual establishments when conducting their hazard analysis of each product line prepared for export.

The development of accurate product descriptions and thorough hazard analysis of all product lines will assist in determining where additional product testing may be required to verify that the HACCP Plan is effective in consistently producing compliant fish and fish products.

As each establishment assesses their fish and fish products, additional product testing may be identified to verify that the food management system is producing compliant fish and fish products. For example, where food additives are used (such as sulphur dioxide), you may have additional testing to verify that your product complies with the relevant regulatory levels as detailed in the FSC or as set by importing country authorities.

In addition to the organisms / pathogens specified in the tables to this document, the potential for the presence and growth of other pathogens associated with food poisoning should be considered. Such organisms include *Salmonella spp*, *Staphylococcus aureus*, *Clostridium perfringens*, *Clostridium botulinum*, *Campylobacter spp*, *Listeria monocytogenes*, *Vibrio spp*, *Bacillus cereus* and pathogenic *Escherichia coli*.

Further guidance on this is available from the guidance documents *Hazard Analysis Critical Control Point (HACCP)* and *Validation and Verification* which are available from the AQIS web page www.aqis.gov.au/fish/guidelines.

Any testing that is not covered under Tables 3 to 8 of this document which the establishment determines is appropriate, remains the responsibility of the establishment to manage.

Minimum testing to verify compliance with the Orders

- Table 3 – Minimum testing regime to verify the source of fish and fish products
- Table 4 - Minimum testing regime of fish and fish products to verify HACCP – Microbiological
- Table 5 - Minimum testing regime of fish and fish products to verify HACCP – Other standards

These requirements will address:

- Aspects of Schedule 6 - Product Standards of the Orders; and
- Verification of the Hazard Analysis Critical Control Point (HACCP) plan which forms part of the minimum requirements of an Approved Arrangement (AA) detailed in Schedule 2 of the Orders.

Minimum testing to verify compliance with EU requirements

- Table 6 - Biotoxin and contaminants criteria specifically for the EU.
- Table 7 - Food safety criteria specifically for the EU (in addition to requirements for testing as per Table 4 and 5);
- Table 8 - Process hygiene criteria specifically for the EU (in addition to requirements for testing as per Table 4 and 5);

Please ensure that you have the current version of this document as testing requirements may be subject to change. Current versions of all legislation and AQIS Guidelines are available from the AQIS website <http://www.aqis.gov.au/fish>

1.1 Contaminants, natural toxicants, residues, food additives

While this guideline focuses on the minimum microbiological standards that product must meet – consideration must also be given during hazard analysis to the potential presence of contaminants, natural toxicants (e.g. ciguatoxin), residues and food additives that may have regulated limits. Product testing may be required to verify that documented controls are effective in producing compliant fish and fish products.

For example, where food additives such as sodium metabisulphite are used, testing will be required to verify that procedures in place are effective in ensuring that the regulatory limits for sulphur dioxide as specified in the FSC or those set by importing country governments are not exceeded.

Contaminants, including microbial contamination, natural toxicants, residues and food additives, can occur as a result of:

- (a) where the product is sourced from; and
- (b) how the product is handled and/or prepared.

In order to verify that food is safe and suitable, testing must address:

- a) the sourcing and handling of fish and fish products; and
- b) demonstrate compliance with importing country requirements OR where no specific importing country requirements apply, compliance with the requirements of the FSC.

Fish and fish products prepared for export that may also be supplied to the domestic market must comply with the requirements of the FSC.

**Export Control (Fish & Fish Products) Orders 2005
subclauses 1.1 and 2.1 of Schedule 6**

Contaminants, natural toxicants, residues and food additives

1.1 Fish and products for export as food and their ingredients must not contain any of the following:

- a) a metal or non metal contaminant or a natural toxicant in excess of the maximum level specified for the contaminant or toxicant in the Food Standards Code;
- b) an agricultural or veterinary chemical in an amount that contravenes the requirements of the Food Standards Code;
- c) a food additive, processing aid, vitamin, mineral, added nutrient, other matter or substance in contravention of the applicable requirements of the Food Standards Code.

Note 1: For the meaning of *ingredient* see order 8. See further the meaning of *unsafe* in order 10 and the meaning of *unsuitable* in order 11.

Note 2: For contaminants and natural toxicants see Standard 1.4.1 and Standard 1.4.4 of the Food Standards Code. For histamines see Standard 2.2.3 of the Food Standards Code.

Note 3: For residues see Standard 1.4.2 of the Food Standards Code.

Note 4: For food additives see Standards 1.3.1 to 1.3.4 of the Food Standards Code.

Microbiological Limits

2.1 Fish and fish products for export as food and their ingredients must meet the microbiological limits specified for fish, fish products or ingredients of that kind in the Food Standards Code.

Note: See Standard 1.6.1 of the Food Standards Code.

1.2 Importing country requirements

The relevant seafood requirements of the FSC apply to all fish and fish products exported from Australia unless an importing country authority has specific requirements that differ from those in the FSC. In such cases, the documented food management system must document the importing country government specified limits, the controls which will be put into place to ensure compliance with those limits and details of any testing that will be undertaken to verify that the product for export complies with the specified limits.

NOTE: While this document has specified the minimum testing requirements for the EU, establishments must also document in their food management systems requirements of other export markets. Establishments will need to determine what product testing may be required for these other identified export markets in order to demonstrate that their fish and fish products comply.

Information on other importing country authority food standards may be obtained from the relevant importing country authority, the importer based within that country or from Market Access Advices on the AQIS website at <http://www.daff.gov.au/aqis/export/fish/fish-notices>. Market Access Advices do not list all importing country requirements and should not be used as the only source for this information. If an establishment would like to receive email notification of when these notices are placed onto the AQIS website, please email fish@aqis.gov.au requesting to be added.

2 Government surveillance

FSANZ and other government agencies in Australia and New Zealand monitor the food supply to ensure that it is safe, and to ensure foods comply with standards for microbiological contaminants, pesticide residue limits and chemical contamination. Data is collected from targeted surveillance of various food groups. While these results give a degree of confidence of the safety of the general food supply, the surveillance does not target seafood to the extent necessary for the Australian Quarantine and Inspection Service (AQIS) to provide government-to-government certification. Hence the need for each establishment to establish a testing regime which reflects their operations and handling and which can provide independent assurances to AQIS of the safety of the food they wish to export.

3 Principles of the testing requirements

These testing requirements are in two parts. The first part addresses minimum testing required to verify the sourcing of fish; the second part addresses minimum testing to verify that the HACCP plan is performing satisfactorily (i.e. HACCP verification).

The results of this testing is an indication of the performance of your food management system in producing compliant fish and fish products. A regular program of product testing provides a level of assurance to the Australian Government to be able to issue government-to-government certification.

The following principles have been adopted for this testing regime:

1. Unless specified by an importing country or unless there is a requirement for specific declarations referencing test results on certification, testing can be conducted in-house or at non NATA-accredited laboratories.
If declarations relating to test results are required on certification then all testing must be carried out in a NATA or IANZ accredited laboratory with the relevant scope of accreditation for the testing or a laboratory approved by AQIS to undertake the testing.
2. Those testing methods prescribed in Tables 6, 7 and 8 must be used to analyse samples of product for export to the EU.

3. Alternate test methods are permitted for the purposes of sourcing and HACCP verification in Tables 3, 4 and 5 only where the laboratory has determined equivalence to the test methods prescribed by the FSC (if one is prescribed), but may not be allowable for the purpose of confirming specific declarations on certification.
4. HACCP verification testing frequency is performance based - being linked to the establishment rating (i.e. company compliance with export legislation).
5. Testing may be further minimised for certain environmental or sourcing hazards if technical data can be provided which supports the likelihood that fish taken from particular areas will contain acceptable levels of environmental contaminants.

For example, data may be available from the Fisheries Department, National Residue Survey (NRS) or EU residue monitoring programs and could be used to further reduce the minimum testing tabled in this document, on a case by case basis in consultation with Canberra office.

The testing requirements in this guideline give details of the minimum tests to be carried out, the sample size to be taken, the regulatory levels and any additional regulatory notes and comments.

If the test results do not comply with the relevant regulatory level / food standard in the table, you must institute some corrective action as the test results indicate that there is a problem with where you source your fish or your HACCP plan or that the fish and fish products tested do not comply with the food standards required for export.

Non-compliant test results for HACCP verification is an indication that the food management system is not performing satisfactorily and needs to be reviewed to identify why the fish products are not complying.

It is a requirement of the Orders that a written record be made of the corrective action taken and an assessment of its effectiveness is completed. Where the food is unsafe, such as where a test result indicates the presence of a food pathogen, under Schedule 5, Part 7 of the Orders, fish and fish products not fit for human consumption must be identified, segregated and not be loaded for export. AQIS is to be notified if this should occur.

Order 55 requires mandatory notification to AQIS where product has been found or is suspected of being unsafe and an export permit (RFP) has been issued.

For more information on what is required when regulatory levels / food standards are exceeded please refer to section 5.0 – if regulatory levels are not complied with.

Note: Export establishments may wish to use a higher frequency of testing to the minimum described in this guideline and, to further verify hygiene, include indicator organisms testing such as coliforms.

4 Testing

4.1 Who is required to test product?

Every registered establishment which prepares fish and fish products for export markets is required to comply with the requirements of Tables 3, 4 and 5.

Where the fish and fish products are to be eligible for the EU, additional testing is required. A registered establishment that produces EU eligible fish and fish products will be required to sample and test the nominated products according to Tables 6, 7 and 8.

Contact your state authority for specific information regarding product testing that may be required to verify products intended for domestic supply.

4.2 When should testing occur?

Wherever a food safety hazard may be introduced in the through chain (including sourcing, transport, processing and further preparation of products) then testing should be carried out at the frequency indicated in Table 2 Minimum frequency of testing to verify HACCP.

Example:

If freezing whole raw prawns on board a registered vessel, samples of the product should be taken by the vessel and sent to a laboratory for testing to meet the requirements of this document.

If the frozen raw prawns from the registered vessel are then sent to a registered land based establishment, the prawns should have been sampled and tested already (unless other arrangements have been approved by AQIS). If the prawns are then thawed, or thawed and cooked and then refrozen in the registered land based establishment, then the refrozen product must also be sampled and tested as new hazards may have been introduced and the hazard controls associated with the thawing, cooking and refreezing processes need to be verified by testing.

Number of samples to be tested

For each food category listed in the tables that the establishment prepares for export, the establishment is to consider the risk category for that food category and then refer to Table 2 to determine the minimum testing frequency for one sample of that food category.

For example, if an establishment prepares both raw and cooked prawns for export (i.e. two food categories in the tables) – then one sample of each food category (one for raw and one of cooked crustacea in this example) must be tested to ensure they comply with the stated requirements.

Where an establishment is preparing a number of products based on the same food category (i.e. cooked prawns of various species in 1 kg and 5kg packs and cooked, peeled prawns in 500gm packs) – as only one sample is required of that food category, consideration will need to be given to the sampling of product that best represents verification of the HACCP Plan. That is, consideration of the major species processed, product most handled or most likely to be exposed to temperatures outside of refrigeration during processing.

When should product be sampled for testing?

The FSC (in Standard 1.1.1) requires that foods comply with the prescribed microbiological limits at any stage of their manufacture or sale. When sampling product, consideration should be given to sampling product at times which can verify shelf-life and where “Use-by” labelling is applied to packaging for the purpose of food safety.

4.3 Frequency of testing to verify source

Frequency of testing needs to be sufficient to demonstrate that environmental hazards are being adequately monitored and controlled, including through the implementation of corrective action.

Some fish, due to the area from which they are sourced or the susceptibility of the species, may be potentially hazardous to the health of the consumer (e.g. histamine formation in some fish species) or may not meet importing country requirements for levels of heavy metals (e.g. cadmium levels in prawns intended for export to the EU and China).

In these situations, as no manner of processing will reduce/remove these hazards should they occur – measures must be taken to ensure that the risk of landing these products is reduced or that affected product is not sent to markets whose requirements cannot be met. Testing must be frequent enough to determine that the source of the product is compliant with the intended importing country’s requirements.

However, the source of supply that is being verified may not always be the original source of the product. Products may have already been processed in some way prior to being received by your establishment.

For example: gilled and gutted tuna purchased with the intention of processing into steaks and freezing will have already been gilled, gutted and chilled by the catcher vessel (refer to the Orders for definition of catcher vessel and operations they may perform). If subjected to temperature abuse, or not chilled rapidly, susceptible species can develop high levels of histamine which once formed, cannot be eliminated by freezing or cooking. In this situation you will need to verify at receipt into the registered establishment that the products you are sourcing meet the required product standards. Again, testing must be frequent enough to determine whether the source of the product is safe.

The frequency of testing required to verify the source of the product is indicated in Table 3 – Testing regime to verify the source of fish and fish products. Testing in accordance with Table 3 must be carried out to verify that the source from which the fish and fish products are harvested is not contaminating product which must be in compliance with relevant food standards.

The actual testing frequency for Table 3 may be minimised for certain environmental or sourcing hazards where valid technical data can be provided which supports the likelihood that fish taken from particular areas will contain acceptable levels of environmental contaminants.

Similarly, testing frequency may be further reduced from that documented in Table 3 if valid test results or ‘Supplier Declarations’ can be obtained from the supplier. For example: provision of a supplier declaration which indicates no antibiotics have been used in the growing or feeding of their aquaculture fish or crustacea. In this case, the minimal testing conducted by the processor would be one general antibiotics screen for this supplier per year.

If you process a fish product not detailed in Tables 3 to 5 – you may wish to seek further advice as to tests that you may need to conduct to verify your source and HACCP plan. This advice could be sourced from a service provider with relevant experience in seafood processing, such as a food technologist.

4.4 Frequency of testing to verify HACCP plans

The frequency of testing required to verify that products you have prepared under your HACCP program are compliant with stated food standards and EU requirements is provided in Tables 4, 5, 7 and 8.

These minimum testing requirements to ensure that the HACCP plan as implemented is performing satisfactorily focus primarily on the microbiological food standards that fish and fish products must comply with for Australia and the EU. Poor test results may indicate a breakdown in temperature control, product handling or hygiene procedures that may potentially affect all products. Additional testing may be required to provide verification that other products being produced are safe/compliant. Poor performance of the food management system may be due to the system being poorly managed, monitored or controlled and may require additional procedures to be put in place to address the lack of control.

The risk category of the food category being processed and the current establishment rating, determine the frequency of testing required to verify the HACCP plan. Refer to Tables 1 and 2 for the sampling frequency.

5 If regulatory levels are not complied with

Where regulatory levels outlined in Tables 3 to 8 are exceeded, corrective action to address the non-compliance/s must be undertaken immediately including identifying the potential cause of the non-compliance and to control affected product.

Immediate corrective action must as a minimum include **identification of the affected lot and appropriate segregation** (required under Schedule 5, Part 7 of the Orders) **and immediate notification to AQIS**.

Further testing of other untested lots to identify deficiencies and / or demonstrate compliance with end-product standards will be required where the test result indicates the presence of a food pathogen. Testing of untested lots may also be required in other circumstances where non-compliance with product standards has been found.

This corrective action requirement should be considered when determining the frequency of HACCP verification testing as when a non-compliant test result occurs, initially all product since the last compliant test result is considered as possibly affected.

When specific standards in importing country regulations, such as those in Tables 6, 7 and 8 (e.g. relevant European Commission (EC) Directives) are exceeded, regardless of the Australian requirements in the FSC, product **cannot be exported to *that* country but it may still be eligible for other markets.**

Where importing country requirements are not known and the food is not compliant with the food standard as per the FSC, **the food must not be exported**. You are required to contact AQIS when product testing indicates the fish and fish products do not meet importing country requirements or the FSC.

If the requirements of the FSC have not been complied with, the product may not be eligible for the domestic market - please contact relevant state or territory authorities.

Compliance with these **minimum** testing regimes will be determined at audit. Failure to comply with the **minimum** testing regime may result in a major or critical non-compliance being issued to the establishment which can result in a reduction in the rating of the establishment.

For example, a major non-compliance may be issued for a failure to comply with:

- the requirements of the Act, Regulations, Orders, the Approved Arrangement or a condition of the approved arrangement that is likely to result in the production of unsafe or unsuitable fish and fish products; or
- the requirements of an importing country that is not likely to result in the production of unsafe or unsuitable fish and fish products.

A critical non-compliance may be issued for a failure or combination of failures to comply with the requirements of the Act, Orders or the approved arrangement:

- that will result in, or has resulted in, the production of unsafe or unsuitable fish and fish products; or
- with regard to importing country requirements; or
- that prevents an accurate assessment being made as to whether the fish and fish product is fit for human consumption; or
- that prevents an accurate assessment being made as to whether the fish and fish product has an accurate trade description; or
- that prevents an accurate assessment being made as to whether the importing country requirements (as per the Approved Arrangement) have been met.

NOTE: The above definitions for major and critical non-compliance have been taken from the document 'Audit regime for fish and fish products' available from the AQIS website <http://www.daffa.gov.au/aqis/export/fish/guidelines>

6 Procedure for when test results do not comply

1. Identify the affected product.

(i.e. lot no's, production dates, information used to identify the lot of fish & fish products etc.)



2. Trace back to identify any affected product - that has been sold or exported, is still in the through chain or in storage and investigate the cause/s of the problem (in the case of microbial testing, this would include product processed since the sampling date of the previous satisfactory test).



3. Hold, segregate and appropriately label all affected product available (in circumstances where product is still your possession). **In circumstances where produce has been on-sold, the procedure should be discussed with AQIS to ensure you discharge your obligation to advise the subsequent owner of all relevant information.**



4. If product has been supplied to the domestic market, you may be required to withdraw or recall the product from your customers.

Wholesale suppliers and manufacturers must have a food recall system in place. This requirement is set out in Standard 3.2.2 *Food Safety Practices and General Requirements* of the FSC. There are also requirements to notify the state or territory government authority.



5. Where product has been exported or prepared for export - discuss all of the test results with AQIS to determine the status of the affected product and whether it can be exported or if recall may be necessary



6. Talk to AQIS to discuss how to manage the affected product and the corrective actions that will need to be taken

State / Territory Regulatory Authorities and AQIS Imported Foods may also be involved if the product is returned or has also been supplied to the domestic market



7. Review HACCP Plan, including source of product and institute appropriate corrective actions to prevent the problem from reoccurring. Corrective Action taken must be reviewed for effectiveness.

7 Taking samples

When taking samples, care must be taken to ensure the following:

1. Samples are taken aseptically – that is, are not contaminated by the person taking the samples or by the equipment used. (Laboratories can provide information on where to source aseptic sample bags and containers)
2. Samples should be clearly labelled with:
 - A description of the sample (species etc.) and preservation method i.e. “Frozen Whole Raw Tiger Prawns”
 - The date the sample was taken
 - The registered establishment number of the establishment sending the sample
 - A Lot number that will unite the sample with the Lot of product from which it was taken – or in the case of samples for cadmium or other source related testing – the catch date, area name and the Latitude and Longitude of the product sampled.
3. Accompanying laboratory testing request forms should be clearly labelled with:
 - the sample details as described above
 - details of the tests required as indicated in the tables

Note: It is critical that the laboratory testing the samples is aware of the testing requirements, the testing methods required and the degree of accuracy required in the reported results. For further details of the test methods required refer to the Orders, Part 2 of Schedule 6 – Methods of sampling and examination and those test methods prescribed in Tables 6, 7 and 8 for the EU. It may assist the laboratory if you provide them with a copy of the Tables within this document and highlight the tests that you require conducted for each sample.

Note: Compositing of sub-samples - Where the test is a presence/absence test for a specific food pathogen, the testing laboratory may composite the sub-samples and conduct the one test. It is advisable that you discuss your product testing needs with your laboratory before sending samples for analysis.

8 What must be documented under the Approved Arrangement

The applicable standards required to verify product source and the finished product must be documented especially where there are specific testing requirements for accessing particular markets over and above the requirements of the FSC.

Product standards can be established by referencing the applicable sections of the FSC and any relevant importing country requirements, and should be documented in product descriptions (see AQIS Guideline – HACCP for further information on product descriptions available from the web page - <http://www.daff.gov.au/aqis/export/fish/guidelines>).

Product descriptions or product specifications documented as part of the HACCP Plan should detail any specific requirements of the export destination and applicable requirements of the FSC.

A procedure for product testing should be documented and include details of:

- which products will be sampled and what tests will be applied;
- when sampling and testing will be carried out;
- how product will be sampled (method, transport, laboratory details);
- who will be responsible for testing;
- who will review the sample results and where results will be held/filed (appropriate records to be kept include the Certificate of Analysis, and it is recommended that a copy of the laboratory request form be kept on file as evidence that the correct testing was commissioned and appropriate test methodology was requested) ;
- what action will be taken if product sample results exceed the regulatory limits; and
- how and when the procedure will be reviewed to ensure it is being followed.

9 Reference information

Information	Information Source
<i>Export Control (Fish and Fish Products) Orders 2005</i>	http://www.daff.gov.au/aqis/export/fish
The Food Standards Code -Food Standards Australia and New Zealand	http://www.foodstandards.gov.au
European Community legislation	http://www.europa.eu/index_en.htm
Canadian regulations	http://www.inspection.gc.ca/english/toce.shtml

Japanese regulations	http://www.maff.go.jp/e/index.html
United States of America Food and Drug Administration Legislation	http://www.fda.gov
US Food and Drug Administration HACCP	http://www.cfsan.fda.gov/~lrd/haccp.html
US FDA publication, 'Introduction to Foodborne Pathogenic Microorganisms and Natural Toxins, also known as The Bad Bug Book	http://www.cfsan.fda.gov/~mow/intro.html
United States Department of Agriculture	http://fnic.nal.usda.gov/nal_display/index.php?info_center=4&tax_level=1
US Seafood Network Information Centre seafood HACCP	http://seafood.ucdavis.edu/haccp/ucd.htm
<i>Codex Alimentarius FAO/WHO Food Standards</i>	http://www.codexalimentarius.net/web/index_en.jsp

Table 1. Product risk categories (referenced in Table 2)

This table provides examples of fish and fish products that fall within the risk categories listed. The risk category from this table is then used in Table 2 to determine the frequency that samples are to be taken for testing.

Low risk	Medium risk	High risk
<ul style="list-style-type: none"> • Live fish • Live crustacea 	Fish and fish products intended to be cooked or further processed prior to consumption	Ready to eat fish and fish products

Table 2. Minimum frequency of testing to verify HACCP

Samples must be taken as per the frequency in Table 2 specific to the risk category for each product type that is eligible for export.

Product risk category	Establishment Rating				
	A	B	C	D	E
Low	6 months	4 months	3 months	2 months	No exports allowed
Medium	4 months	3 months	2 months	6 weeks	No exports allowed
High	3 months	2 months	1 month	1 month	No exports allowed

Establishments rated D should be tested as per the nominated frequency. However, depending on the nature of the non-compliances, D rated establishments may be subject to additional control measures to ensure product compliance with applicable product standards e.g. lot testing.

An establishment rated E is prohibited from exporting fish and fish products unless certain conditions which ensure the ability of the establishment to produce safe food are met.

Seasonal operations: If you are operating in an industry sector that harvests or catches during short seasons – it is recommended that testing be conducted once at the beginning and once at the end of each season. If unsure of your seasonal testing requirements please consult your local AQIS Fish Exports Program officer prior to the start of the season to confirm your testing requirements.

Table 3. Testing regime to verify the source of fish and fish products

This table is the minimum testing regime to verify the source of fish and fish products.

Food Category	Testing Required	Sampling Size & Frequency	Regulatory Levels	Regulatory Notes	Additional Comments
Scallops: roe-on and whole (Scallops exported without roe or intestinal material do not need to carry out these tests) NOTE – EU requirements specified in Table 6.	Amnesic Shellfish Poison (ASP) and Diarrhoeic Shellfish Poison (DSP) and Paralytic Shellfish Poison (PSP)	One 100g sample per lot. A biotoxin test should be carried out at least once per year for each area/zone (relevant to the state fishery) that scallops are sourced from and whenever there are indications, such as severe storms and algal blooms that increase the potential for contamination with biotoxins. The test results must identify the area/zone of the fishery.	ASP Maximum level of 20 mg/kg DSP Maximum level of 0.2 mg/kg PSP Maximum level of 0.8 mg/kg If levels exceeded consult AQIS	The acceptable levels for shellfish toxins are as listed by FSANZ standards for bivalve molluscs (FSC Standard 1.4.1). Refer the Orders Schedule 5 clause 3.1 and 3.2 – offshore locations may be exempt from ASQAP.	ASQAP Export Standard includes biotoxin management; no further biotoxin testing is required for products harvested under an export approved ASQAP management plan. Roe on and whole scallops that are derived from offshore fisheries may not be subject to ASQAP Export Standards. The principle risk pre-harvest associated with offshore harvested whole and roe-on scallops is biotoxins.
Aquaculture fish (including crocodile, crustacea and gastropods but excluding bivalve molluscs)	Antibiotics – general screen	One 100g sample per lot. Frequency must be sufficient to verify source. If a Supplier Declaration is supplied - a <u>minimum</u> of one annual test <u>per aquaculture farm</u> is required.	Refer levels in the Australia New Zealand Food Standards Code, Standard 1.4.2 If level exceeded consult AQIS	Compliance with the FSANZ standard 1.4.2 means that there are several maximum residue limits for specific seafood chemical combinations.	Documented evidence of nil use of antibiotics, including in feed, may be used <u>to justify minimum testing of 1 sample per year per supplier</u> for antibiotic testing of product. National test results for antibiotics can be substituted for this test or where the supplier provides laboratory test results.
Finfish – for sourcing only the following families are tested: <i>Scrombridae</i> (tuna & mackerels), <i>Clupeidae</i> (herrings, sardines etc.), <i>Engraulidae</i> (Anchovy), <i>Coryphaenidae</i> (dolphin fish)	Histamine	One (5 x 100g sub-sample) per lot as described in the Food Standards Code A histamine test should be carried out at least once per year per catcher vessel / aquaculture farm and when there is an indication that temperature control has not been maintained.	Maximum level of 200 mg/kg If levels exceeded consult AQIS.	FSANZ standard for all fish (Standard 2.2.3)	This histamine testing is only required where the finfish are exported as whole (whether gilled and gutted or not). Where the finfish are to be further processed by the establishment, this testing is not required . However, the establishment may determine that some level of source testing is desirable in addition to the testing requirements in Table 5.

Table 4. Minimum testing regime of fish and fish products to verify HACCP - Microbiological

This table is the minimum testing regime of fish and fish products to verify HACCP – Microbiological.

NB: Foods listed in this Table must meet the prescribed microbiological limits at any stage of their manufacture or sale.

Food category	Micro-organisms	Sampling plan (1)		Regulatory levels (Food Standards Code, Standard 1.6.1)		Frequency
		n	c	m	M	
Raw crustacea (i.e. uncooked dead animals, either chilled or frozen)	Coagulase positive staphylococci /g	5	2	100	1000	As per Table 2
	SPC /g	5	2	500 000	5 000 000	
Cooked crustacea (cooked, either chilled or frozen)	Coagulase positive staphylococci /g	5	2	100	1000	As per Table 2
	Salmonella /25g	5	0	0		
	SPC /g	5	2	100 000	1 000 000	
Ready to eat processed finfish, other than retorted finfish	Listeria monocytogenes /g	5	1	0	100	As per Table 2
Bivalve molluscs (but not scallops)	Escherichia coli /g	5	1	2.3	7	As per Table 2
Bivalve molluscs (including scallops) that have undergone processing (refer NOTE below), other than depuration– this test is in addition to the above tests for Bivalve molluscs (except for scallops for which E coli is not applied).	Listeria monocytogenes	5	0	0		As per Table 2
		If levels are exceeded talk to AQIS immediately as product may not be eligible for export.				

NOTE: These food standards have been taken from the FSC, Standard 1.6.1. Refer to the User Guide to Standard 1.6.1 of the FSC for clarification of bivalve molluscs that have **undergone further processing** and **ready to eat processed finfish** (available from this webpage <http://www.foodstandards.gov.au/foodstandards/userguides/>).

Further processing of bivalve molluscs includes such treatments as smoking and marinating but does not include physical measures such as half shelling or freezing.

Ready to eat processed finfish includes fish from both salt and freshwater environments that have undergone some processing such as hot or cold smoking, salting, drying, pickling or fermenting. Foods such as sushi and other raw fish foods are not covered by this standard.

Crocodile – compliance with AS 4467:1998 Australian Standard for hygienic production of crocodile meat for human consumption, Appendix A.

Table 5. Minimum testing regime of fish and fish products to verify HACCP for fish product further processed at your establishment (not including packing) – Other standards

This table is the minimum testing regime of fish and fish products to verify HACCP – Other standards.

Food category	Contaminant or Chemical	Sample size	Regulatory Level	Frequency
<p>Finfish – only the following families to be tested: <i>Scrombridae</i> (tuna & mackerels), <i>Clupeidae</i> (herrings, sardines etc.), <i>Engraulidae</i> (Anchovy), <i>Coryphaenidae</i> (dolphin fish)</p> <p>Additional finfish should be considered where there have been previous known incidents with histamine levels.</p> <p>NOTE: This testing is to verify the management of food safety during further handling and processing. This testing is not applied where the finfish being exported are whole (whether gilled and gutted or not) and testing to verify the source of the product is in place.</p>	Histamine	One (5 x 100g sub-sample) per lot as described in the Food Standards Code.	<p>Maximum level of 200 mg/kg</p> <p>Refer Food Standards Code, Standard 2.2.3</p> <p>If levels exceeded talk to AQIS immediately as product may not be eligible for export.</p> <p>Where this level is exceeded, the processor must conduct a full trace back to the source to identify whether the source or the processing at the establishment caused the non-compliance. If no testing of the source has been undertaken, the source has also been implicated and histamine testing of the source may be required.</p>	As per Table 2

NOTE: As previously discussed under item 1 - Introduction, the above testing detailed in Tables 3, 4, 5, 6, 7 and 8 are considered the minimum testing requirements. Each establishment, when developing their HACCP plan, would have identified specific processes that require control which may require additional testing to verify that the final product complies with relevant food standards (e.g. sulphur dioxide in crustacea).

Table 6. Biotoxin and contaminates criteria specifically for the EU

This is the minimum testing regime for the sourcing of fish and fish products to be eligible for the EU and is in addition to requirements for testing as per FSC in Tables 3, 4 and 5.

Food category	Micro-organisms / their toxins, metabolites	Sampling size	Regulatory Levels for EU	Frequency of testing	Stage where the criterion applies	Analytical Reference Method	Sampling - plan
<p>Scallops (including both roe-on and roe-off) harvested in the open ocean (i.e. off-shore areas).</p> <p>Abalone (regardless of whether from aquaculture or wild origin)</p>	Amnesic Shellfish Poison (ASP)	100g	Maximum level of 20mg/kg of Domoic acid	once every 10 shipments	End of the manufacturing process	High-Performance Liquid Chromatography (HPLC), or equivalent.	<p>A biotoxin test must be carried out at least once per year for each area/zone (relevant to the state fishery) and whenever there are indications, such as algal blooms that increase the potential for contamination with biotoxins.</p> <p>Testing methodology – Liquid chromatography mass spectrometry (LCMS). As stated in Section 3 of this document, this test must be covered under the laboratory's NATA/IANZ scope of accreditation.</p>
	Paralytic Shellfish Poison (PSP)	100g	Maximum PSP level 0.8mg/kg	once every 10 shipments	End of the manufacturing process	Mouse bioassay (MBA), Pre-column HPLC (Lawrence method), or equivalent.	
	Okadaic acid, dinophysistoxins & pectenotoxins together	100g	Okadaic acid maximum level 0.16mg equivalents /kg	once every 10 shipments	End of the manufacturing process	Mouse bioassay (MBA), Liquid Chromatography-Mass Spectrometry (LC-MS/MS), or equivalent.	
	Yessotoxins	100g	Maximum level 1mg equivalents /kg	once every 20 shipments	End of the manufacturing process	<p>NOTE: after 31 December 2014 the EU will not accept results generated using mouse bioassay for detection of lipophilic toxins.</p>	
	Azaspiracids	100g	Maximum level 0.16mg equivalents /kg	once every 20 shipments	End of the manufacturing process		
<p>Prawns</p> <p>NOTE: this testing may be minimised on a case by case basis – refer Section 3, point 5, page 12.</p>	Cadmium	100g	Maximum level 0.5mg/kg	<p>One sample every 6 months.</p> <p>For seasonal operations, refer to comment under Table 2.</p>	End of the manufacturing process – as packaged for export.	As the EU may test product from each vessel on arrival you are strongly advised to discuss what test results are required by your agent or buyer before the consignment is consolidated for export.	

Note: the information stated in Tables 6 to 8 is sourced from Commission Regulation No. 853/2004 laying down the specific hygiene rules for food of animal origin; Commission Directive No 22/2001 laying down the sampling methods and the methods of analysis for the official control of the levels of lead, cadmium, mercury and 3-MCPD in foodstuffs; and Commission Regulation No 2073/2005 on microbiological criteria for foodstuff. Also referenced are Commission Regulation No. 2074/2005, 1664/2006 and 15/2011.

Table 7. Food safety criteria specifically for the EU

This table is the food safety criteria specifically for the EU (in addition to requirements for testing as per Table 4 and 5).

Food category	Micro-organisms, their toxins, metabolites	Sampling - plan (1) n	Sampling - plan (1) c	Regulatory Levels for EU		Analytical reference method (2)	Stage where the criterion applies	Frequency of testing
1.2. Ready to eat foods able to support the growth of <i>L. monocytogenes</i> , other than those intended for infants and for special medical purposes – applied to food categories as identified in Table 4.	Listeria monocytogenes	5	0	Absence in 25 g		EN/ISO 11290-2 or AS 5013.24.1-2009	Before the food has left the immediate control of the food business operator who has produced it	As per Table 2
1.16. Cooked crustacea and cooked molluscan shellfish	Salmonella	5	0	Absence in 25 g		EN/ISO 6579 or AS 5013.10.2009	Products placed on the market during their shelf-life	As per Table 2
1.17. All live bivalve molluscs, echinoderms, tunicates and gastropods	Salmonella	5	0	Absence in 25g		EN/ISO 6579 or AS 5013.10.2009	Products placed on the market during their shelf-life	As per Table 2
1.24. All live bivalve molluscs, echinoderms, tunicates and gastropods (4)	E.coli	1	0	230 MPN/100g of flesh and intra-valvular liquid		ISO TS 16649-3 or AS 5013.15.2006	Products placed on the market during their shelf-life	As per Table 2
1.25. Fishery products from fish species associated with a high amount of histamine (3)	Histamine	9	2	m 100 mg/kg	M 200 mg/kg	High Performance Liquid Chromatography Or AS 4884.2008	Products placed on the market during their shelf-life	As per Table 2
1.26. Fishery products which have undergone enzyme maturation treatment in brine, manufactured from fish species associated with a high amount of histamine (3)	Histamine	9	2	m 200 mg/kg	M 400 mg/kg	HPLC or AS 4884.2008	Products placed on the market during their shelf-life	As per Table 2

(1) n = number of units comprising the sample; c = number of sample units giving values over m or between m and M. For example an EU sampling plan that allows (n=9, c=2, m=100, M=200), means that 9 sub samples should be taken, 2 of which can have histamine content greater than 100 mg/kg but below 200 mg/kg, the remainder must be below 100 mg/kg

(2) The most recent edition of the standard shall be used.

(3) Particularly fish species of the families: Scrombridae, Clupeidae, Engraulidae, Coryfenidae, Pomatomidae, Scombrosidae. For points 1.1 - 1.24 m=M.

(4) A pooled sample comprising a minimum of 10 individual animals.

Table 8. Process hygiene criteria specifically for the EU

This table is the process hygiene criteria specifically for the EU (in addition to requirements for testing as per Table 4 and 5).

Food category	Micro-organisms	Sampling plan ⁽¹⁾		Regulatory Levels for EU		Analytical reference method	Stage where the criterion applies	Action in case of unsatisfactory results	Frequency of testing
		n	c	m	M				
2.4.1. Shelled and shucked products of cooked crustacea and cooked molluscan shellfish	E.coli	5	2	1 MPN or cfu/g	10 MPN or cfu/g	ISO TS 16649-3 or AS 5013.15.2006	End of the manufacturing process	Investigation to identify where the breach is occurring, then corrective action.	Frequency as per Table 2
	Coagulase-positive staphylococci	5	2	100 cfu/g	1 000 cfu/g	EN/ISO 6888-1 or 2 or AS 5013.12.	End of the manufacturing process	Investigation to identify where the breach is occurring, then corrective action.	Frequency as per Table 2

(1) n = number of units comprising the sample; c = number of sample units giving values between m and M.

Interpretation of the test results

The limits given refer to each sample unit tested.

The test results demonstrate the microbiological quality of the product tested.

E. coli in shelled and shucked products of cooked crustaceans and molluscan shellfish:

- satisfactory, if all the values observed are < m,
- acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are ≤ m,
- unsatisfactory, if one or more of the values observed are >M or more than c/n values are between m and M.

Coagulase-positive staphylococci in shelled and cooked crustaceans and molluscan shellfish:

- satisfactory, if all the values observed are < m,
- acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are < m,
- unsatisfactory, if one or more of the values observed are >M or more than c/n values are between m and M