



Australian Government

Australian Quarantine and Inspection Service

Audit Regime For Fish Exports

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

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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.

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*.

Objectives of the Orders

The objectives of the Orders are to facilitate trade based on effective food safety and suitability procedures and accurate descriptions of product.

This guideline specifically addresses the requirements of registered establishments to meet objective 3.2 (b) and (c) and 3.3 (a) of the objectives of the Orders.

Export Control (Fish & Fish Products) Orders – Part 1 – Order 3

3 Objectives of these Orders

3.2 The objectives of these Orders are also to ensure:

- (a) the accuracy of any statement made in relation to the condition and preparation of fish and fish products for export as food; and
- (b) that an accurate assessment can be made as to whether the objectives specified in suborder 3.1 and paragraph 3.2(a) are met; and**
- (c) that an accurate assessment can be made as to whether the requirements of the Act and these Orders are met.**

3.3 These Orders also make provision for other matters generally necessary or convenient to be prescribed for carrying out or giving effect to the Act including:

- (a) audit and other functions of authorized officers; and**
- (b) the approval of approved arrangements, the giving of export permits, the approval of persons to issue export permits, the issue of government certificates, the approval of auditors and the performance of other functions by the Secretary; and
- (c) official marks, specifications for electronic transmissions and other miscellaneous matters.

Audit Regime

For the *Export Control (Fish & Fish Products) Orders 2005*

1.0 Introduction

In preparing this audit regime, the Fish Exports Program is conscious of the existing open, transparent and meaningful relationship that has been established with the export seafood industry, and the history of industry compliance with a HACCP-based food safety system since 1993. The audit regime is designed to reward compliance through a reduced audit frequency.

This audit regime has been prepared as a guide to:

- AQIS staff;
- Authorized officers;
- Approved auditors; and
- Export Registered Establishments

That is consistent with Order 64 of the *Export Control (Fish & Fish Products) Orders 2005*.

The audit regime proposed in this document is intended as a guide. Establishments may request a different audit regime, which must be detailed in the Approved Arrangement (refer to suborder 64.3 of the *Export Control (Fish & Fish Products) Orders 2005*).

Where a different audit regime is proposed, the establishment must provide adequate justification before AQIS will be able to consider the adequacy of the alternative audit regime.

2.0 Definitions used in this document

Critical non-compliance

Order 67 of the *Export Control (Fish & Fish Products) Orders 2005* provides the following definition for critical non-compliance:

A critical non-compliance when used in relation to the audit of an establishment, exporter or approved export permit issuer means a failure (or combination of failures) to comply with the applicable requirements of the Act, these Orders or of the applicable Approved Arrangement that

- (a) results in, or is likely to result in, the preparation or export of fish and fish products for export for food that
 - (i) are not fit for human consumption or their integrity is compromised;
or
 - (ii) do not comply with an importing country requirement; or
- (b) prevents an accurate assessment being made as to whether fish and fish products:
 - (i) are fit for human consumption and their integrity is assured; or
 - (ii) comply with an importing country requirement; or

the Act	a reference to ‘the Act’ means the <i>Export Control Act 1982</i>
the Orders	a reference to ‘the Orders’ means the <i>Export Control (Prescribed Goods-General) Orders 2005</i> and the <i>Export Control (Fish & Fish Products) Orders 2005</i> collectively
the Regulations	a reference to ‘the Regulations’ means the <i>Export Control (Orders) Regulations 1982</i>
unsafe	<p>Order 10 of the <i>Export Control (Fish & Fish Products) Orders 2005</i> provides the following definition for unsafe:</p> <p>Fish and fish products are not safe if it would be likely to cause physical harm to a person who might consume them, assuming they are:</p> <ul style="list-style-type: none"> a) subjected to the preparation (if any) that is relevant to their reasonable intended use; and b) consumed by the person according to their reasonable intended use. <p>However, fish and fish products are not unsafe merely because their inherent nutritional or chemical properties or their inherent nature causes an adverse reaction only in persons with allergies or sensitivities that are not common to the majority of people.</p>
unsuitable	<p>Order 11 of the <i>Export Control (Fish & Fish Products) Orders 2005</i> provides the following definition for unsuitable:</p> <p>Fish and fish products are not suitable if it:</p> <ul style="list-style-type: none"> (a) are damaged, deteriorated, perished or contaminated to an extent that affects its reasonable intended use; or (b) contain any damaged, deteriorated, perished, contaminated substance that affects their reasonable intended use; or (c) is derived from an animal that is diseased or dead: <ul style="list-style-type: none"> (i) for fish – at the time of harvest; and (ii) for crocodile meat – at the time the crocodile from which the meat is derived is presented for slaughter and dressing; <p>and is not declared by or under another Act to be safe for human consumption; or</p> <ul style="list-style-type: none"> (d) contain a biological or chemical agent or other substance that is foreign to the nature of fish and fish products of that kind; or (e) are produced using, or is subjected to a process contrary to the Food Standards Code; or (f) are treated with a substance contrary to a law of the Commonwealth or a law of the State and Territory in which the treatment takes place; or (g) are produced under controls (including hygiene, temperature and other processing controls) that are inadequate to ensure that the food is safe and is not unsuitable (as defined in paragraphs 11.1(a) to 11.1(f))

Table 1: Non-Compliance categories – Registered Establishments (including Vessels)

	<i>Critical Non-compliance</i>	<i>Major Non-compliance</i>	<i>Minor Non-compliance</i>
Definition	<p>A critical non-compliance means a failure or combination of failures to comply with the requirements of the Act, Orders or the approved arrangement:</p> <ul style="list-style-type: none"> • that will result in, or has resulted in, the production of unsafe or unsuitable fish and fish products; or • with regard to the trade description of the food that affects the integrity of the food; 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; or • failure to address a corrective action request for a major non-compliance within the stated time, or in a manner not in accordance and/or not equivalent to the request. 	<p>A major non-compliance means a failure to comply with:</p> <ul style="list-style-type: none"> • 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; or • a requirement to complete documentation to demonstrate compliance under the approved arrangement. 	<p>A minor non-compliance means a failure to comply with:</p> <ul style="list-style-type: none"> • the requirements of the Act, Regulations, Orders, the Approved Arrangement or a condition of the approved arrangement that is not likely to result in the production of unsafe or unsuitable fish and fish products; or • the requirements of the Act, Regulations or Orders with regard to the trade description of the food, but is not false, misleading or deceptive.
Examples	<p>Where the safety or suitability of the fish and fish products is compromised through:</p> <ul style="list-style-type: none"> • variation from the HACCP plan • a serious non-compliance with premises and personal hygiene procedures • evidence of contamination of food, water or equipment • fish and fish products submitted for export that do not comply with product standards, such as microbiological standards • failure to verify the requirements of the Approved Arrangement have been complied with • non-compliance with trade description requirements that results in a trade description that is false, misleading or deceptive, such as the omission of information or incorrect information. • a failure to address a major corrective action within the stated timeframe, or failure to address the corrective action in its entirety 	<p>Where the safety or suitability of the fish and fish products is likely to be compromised through:</p> <ul style="list-style-type: none"> • lack of documentation to demonstrate adequate control of hazards • failure to label chemicals at the establishment • inadequate control of food or ingredients during preparation or processing • variation from the HACCP plan (this may also be a critical non-compliance) • a failure to address a minor corrective action within the stated timeframe, or a failure to address the corrective action in its entirety 	<p>Where the safety or suitability of the fish and fish products is unlikely to be compromised, but poor management commitment is demonstrated by:</p> <ul style="list-style-type: none"> • poorly pest-proofed doors and windows • construction of the premises is not sound • premises are not maintained in good repair • inadequate drainage • inadequate lighting • inadequate pressure or water temperature • failure to adequately supervise staff • inadequate stock rotation • variation from the GMP or pre-requisite programs • a spelling error or typographical error on a trade description
Non - compliance value	64	8	2

3.0 Non-Compliance

It should be noted that some factors which compromise the safety or suitability of the fish and fish products may be attributed to a specific non-compliance category depending on the severity of the non-compliance. The assignment of non-compliance to a particular category requires careful consideration, and where there are extenuating circumstances and appropriate evidence, then the rating of the defect should be assessed accordingly with that knowledge in mind. Table 1: Non-compliance categories – Registered Establishments (including Vessels) has been provided as a guide to non-compliance categories.

When conducting an audit:

- All non-compliances must be recorded by the auditor in the audit report;
- Non-compliances must be based on all available evidence; and
- Non-compliances must be defensible.

4.0 Scope of Audit

The objective of an audit is to assess compliance with legislative requirements.

The *Export Control (Fish & Fish Products) Orders 2005* details requirements for food safety issues as well as export documentation integrity (eg. export permits and government certificates). This audit regime is concerned only with food safety issues, and a separate audit regime has been developed for export documentation.

This means a failure of export documentation, which may not be the responsibility of the AQIS Registered Establishment processing the food or under the control of the processing Establishment, will not necessarily result in a downgrade the rating of your Establishment and therefore increase the audit frequency.

The Approved Arrangement documents how an establishment will comply with the legislative requirements. In terms of food safety, there are two key components to this: Good Manufacturing Practice (GMP) or pre-requisite programs (such as pest control program), and the HACCP Plan.

Whilst this audit regime focuses on both aspects, more emphasis is placed on the HACCP Plan – therefore a failure to adhere to a GMP or pre-requisite program may be regarded as minor non-compliance (depending on its impact), whereas a failure to adhere to the HACCP plan will generally be regarded as a major or critical non-compliance.

When finalising an audit:

- All non-compliances are taken into account, including those not closed out within agreed timeframes;
- All corrective actions are taken into account, and when verified by auditor, recorded in the audit report; and
- A rating is assigned to the establishment.

5.0 Establishment ratings

The rating given to an Establishment following audit represents the Establishment's commitment to complying with the *Export Control (Fish & Fish Products) Orders 2005*.

At the end of the audit, the appropriate numerical value is assigned for each defect and a total given. The total value determines the Establishments' rating.

Table 2: Establishment ratings

<i>Establishment rating</i>	<i>Total value</i>
A	0 – 15
B	16 – 31
C	32 – 47
D	48 – 63
E	64 and greater

An audit rating is assigned at the completion of the audit, with an Establishment receiving one of the following ratings:

- **“A” rating** – the Establishment is able to verify that their Approved Arrangement is effective, and they are proactive in controlling any potential non-compliance activity.
- **“B” rating** – the Establishment is able to verify that their Approved Arrangement is effective, however they may not be proactive in controlling any potential non-compliance activity.
- **“C” rating** – the Establishment is not able to verify that that all aspects of their Approved Arrangement are effective, and they are not proactive in controlling any potential non-compliance activity.
- **“D” rating** – the Establishment is not adequately controlling food safety hazards and/or product integrity. It is likely that this establishment has major system deficiencies that may affect the integrity of the product and/or result in food that is potentially not fit for human consumption. The ability to export is retained, however additional conditions and restrictions may be imposed.
- **“E” rating** – the Establishment presents a risk to public health and safety, and is unable to continue to process food for export until they can demonstrate that adequate controls have been implemented.

When an Establishment is assigned an “E” rating, a follow up audit will be conducted as soon as possible after corrective action has been taken, subject to operational constraints and in consultation with the client. If no critical non-compliances are found during the follow up audit, the establishment will be rated “D”.

When an Establishment is assigned a “D” rating, an audit will be conducted in accordance with Table 3. A minimum of two audits will be conducted before the establishment is assigned a “C” rating.

In addition to an increase in frequency of audits and additional conditions and restrictions on processing to ensure the fitness for human consumption of the food, other sanctions may be applied to Establishments on a “D” or “E” rating, depending on the specific circumstances. These sanctions include, but are not limited to the following:

- Administrative sanctions
- Suspension or revocation of registration
- Withdrawal of AQIS services
- Penal provisions, as provided for in the Act and the Orders

For more information on sanctions, please refer to the *Export Control (Prescribed Goods General) Order 2005* and the *Export Control (Fish & Fish Products) Orders 2005*. Explanation of the role of sanctions in a co-regulatory environment is provided in the publication “Export Assurance – National Competition Policy Review of the *Export Control Act 1982*”¹.

For example, this publication states “Importing countries expect a higher level of sanctions to apply to transgressions where a co-regulatory arrangement is in place. Sanctions and penalties must reflect the degree of risk to be managed under the co-regulatory framework” (page 95).

6.0 Frequency of audit

The frequency of audit is based on the level of risk of the products processed by the Establishment, and their compliance history (that is, rating assigned at the last audit).

Table 3 specifies the standard frequency of audits for land-based Registered Establishments. The audit regime for vessels is slightly different, due to accessibility issues. Vessels that receive a rating of “A”, “B”, “C” or “D” will be audited once per year and required to test/sample products as per Table 1 (“Products Standard Guidelines”) for the respective rating that has been given. Depending on the rating additional corrective actions may be required to foster greater industry compliance. If the vessel owner/operator wishes to have their audit rating raised to a higher level, to decrease the level of testing required, then arrangement will need to be made with an AQIS officer to facilitate this. Vessels that receive an “E” rating will not be permitted to process or export product. In this circumstance, vessel occupiers will be required to meet specific conditions before being permitted to export once again.

Notwithstanding this, there are several reasons for additional visits by an authorized officer or approved auditor:

- Corrective action issued at last audit
 - It may be necessary for an auditor to follow up on the corrective action to ensure that the Establishment has complied within the timeframe specified. Where this timeframe differs from the audit frequency, an additional visit to the Establishment may occur.
- Audit at occupier’s request
 - Under Order 62 of the *Export Control (Fish & Fish Products) Orders 2005*, an occupier may request an additional audit, subject to agreement from AQIS.

¹ See the legislation section of the AQIS website <http://www.aqis.gov.au/legislation>

- Additional audit at AQIS's request
 - Under Section 10 of the *Export Control Act 1982*, an authorized officer may undertake additional audits in order to verify compliance with the Act, Regulations or Orders.

Announced & unannounced audits

Order 63 of the *Export Control (Fish & Fish Products) Orders 2005* provides for unannounced audits. It is general practice for AQIS to conduct a mixture of announced and unannounced audits.

Table 3: Audit frequency – Registered land-based Establishments

<i>Risk Category</i>	<i>Establishment rating</i>			
	A	B	C	D
Low	Annual	6 months	4 months	2 months
Medium	9 months	5 months	3 months	6 weeks
High	6 months	4 months	2 months	1 month

7.0 Risk categories

Table 4 provides the principles for the risk ranking detailed in Table 5. These principles are utilised by domestic regulatory authorities, as well as used internationally. As new information becomes available, the risk rankings will be reviewed and amended as appropriate.

The risk categories (see Table 5) are assigned according to the processes being utilised at the Establishment. Where an Establishment utilises more than one process, the highest risk category is applied for the Establishment. The food safety risks referred to in Table 4 include microbiological, chemical and physical hazards.

Where other factors need to be taken into account (that is, they may adjust the level of risk) but are not included in this table, consultation with Canberra-based AQIS staff will be necessary. These other factors could include (but are not limited to):

- Different processing techniques (e.g. high pressure processing);
- Active packing (e.g. modified atmosphere packaging);
- Biological factors (e.g. fish species linked with accumulation of histamine, ciguatera or tetrodotoxin)

Table 4: Risk ranking (based on Codex approach to risk assessment)

Risk ranking		<i>Likelihood of illness</i>		
		Unlikely	Likely	Very likely
<i>Severity of illness</i>	Moderate	Low	Low	Medium
	Serious	Low	Medium	High
	Severe	Medium	High	High

Table 5: Risk categories (based on International Commission on Microbiological Specifications for Foods approach to risk assessment)

	<i>Low</i>	<i>Medium</i>	<i>High</i>
Principles	<ul style="list-style-type: none"> ▪ unlikely that illness may result, and severity of illness is <i>moderate</i>; or ▪ unlikely that illness may result, and severity of illness is <i>serious</i>; or ▪ likely that illness may result, severity of illness is <i>moderate</i>. 	<ul style="list-style-type: none"> ▪ unlikely that illness may result, and severity of illness is <i>severe</i> ▪ likely that illness may result, and severity of illness is <i>serious</i> ▪ very likely that illness may result, and severity of illness is <i>moderate</i> 	<ul style="list-style-type: none"> ▪ likely that illness may result, and severity of illness is <i>severe</i> ▪ very likely that illness may result, and severity of illness is <i>serious</i> ▪ very likely that illness may result, and severity of illness is <i>severe</i>
Definitions	<p><i>Moderate</i> means when the hazard is likely to cause an illness of short duration with no on-going adverse health effects (sequelae).</p> <p><i>Serious</i> means when the hazard would cause an illness of longer duration, with some chance of on-going chronic and debilitating effects.</p> <p><i>Severe</i> means when the hazard would cause illnesses with serious sequelae or significant mortality rates.</p>		
Discussion	A low risk Establishment might be one where no risk is introduced into the process by this establishment, and the final product is considered low risk.	A medium risk Establishment might process foods to significantly reduce or eliminate a range of hazards; or intend for further processing to address food safety risks and directions for use and storage are applied as per Schedule 7.	A high risk Establishment might prepare or process but may not have reduced or eliminated all food safety risks, and further processing is not intended or unlikely to occur. A high risk establishment might also process foods to significantly reduce or eliminate a range of hazards, but the consequences of this going wrong could result in severe illness.
Examples	<ul style="list-style-type: none"> • Storage Establishments, such as cold stores or fish holding facilities • Packing establishments, such as some live fish packers (other than bivalve molluscs) 	<ul style="list-style-type: none"> • Fish and fish products intended to be cooked prior to consumption, including: <ul style="list-style-type: none"> - raw - frozen or chilled - dried - salted - smoked - battered - breaded - scallop - roe off only 	<ul style="list-style-type: none"> • Ready to Eat fish and fish products, including: <ul style="list-style-type: none"> - raw or cooked - frozen or chilled - fermented or acidified - salted - smoked • canned* • bivalve molluscs (including live and depurated) • vacuum or modified atmosphere packaged fish and fish products

*means thermally processed and enclosed in a hermetically sealed can

8.0 Transition arrangements

This audit regime frequency will apply when a new Approved Arrangement is submitted and is approved by AQIS, at which time your existing FPA or AQA ceases to apply.

Table 6 provides an example of the differences between the two audit regimes.

Table 6: Comparison of the two audit regimes

Audit details	Existing audit regime – <i>Export Control (Fish and fish products) Orders</i>	New audit regime - <i>Export Control (Fish & Fish Products) Orders</i>
Audit 1: 7 minor non-compliances observed	Would be given a “B” rating	Would be given an “A” rating
Audit 2: 5 minor and 1 major non-compliances observed	Would be given an “A” rating	Would be given a “B” rating
Audit 3: 1 serious and 4 major non-compliances observed	Would be given a “B” rating	Assuming serious defect was considered major, would be given a “C” rating