



APPLICATION GUIDE FOR APPROVAL TO EXPORT FISHERY PRODUCTS TO THE EUROPEAN UNION

BACKGROUND

Processing establishments intending to export to the European Union (EU) shall comply with all the EU requirements on fishery products. Such establishments shall obtain raw materials and ice for use in the EU supply chain from sources approved by the Competent Authorities.

APPROVAL OF SOURCES OF RAW MATERIALS AND ICE FOR USE IN THE EU SUPPLY CHAIN

APPLICATION PROCESS

Application Form

The application shall be made through online system namely Food Export Official Control System (FExOC) at <http://fexoc.moh.gov.my/fexoc/index.php> for the approval of sources of raw materials and ice.

Note: Source of ice obtained from independent ice producers shall be licensed from Ministry of Health, Malaysia in accordance to Regulation 394A, Food Regulations 1985.

Application for the approval of aquaculture farm and fishing vessel shall be made through <http://mutiara.dof.gov.my> and for approval of landing sites, the application shall be made through <http://www.lkim.gov.my> according to the following application forms:

Aquaculture farm:

- *Aquaculture Farm Registration Form (Fish for Human Consumption) – ARF01 Form*
- *Application Letter for Fish Quality Certificate*

Fishing vessel:

- *Application Form for the Approval of Fishing Vessel in the European Union (EU) Supply Chain (Fish for Human Consumption) – FVA01 Form*

Landing site:

- *Application Form for the Approval of Fish Landing Site in the European Union (EU) Supply Chain – LKIM/EU/01 Form*

Inspection Procedure

1. Upon receipt of the application submitted by the applicant, the relevant Competent Authority (CA) shall verify the completeness of the application form. Once satisfied, the designated CA officers shall carry out inspection of the sources of raw material and ice to check on its compliance to the EU requirements.

2. Corrective actions shall be taken on all non-conformances by the source of raw material and ice.
3. Follow-up inspection shall be carried out, where necessary by designated CA officers to verify that the corrective actions have been taken.
4. The compliance audit process will be carried out by using the online system FExOC and applicant shall communicate with the auditors i.e. giving feedback on all the non conformances issued by auditors during the compliance audit through the online system.
5. The auditor will then submit the final report and all the relevant supporting documents to FSQD HQ through FExOC.

Approval Process

1. The CA shall grant approval to the source of raw material and ice if it is found to be in compliance with the EU requirements.
2. The successful applicant shall be officially notified by the relevant CA on the approval status.

APPROVAL OF EXPORT ESTABLISHMENT

REQUIREMENTS FOR APPROVAL

1. Fishery products to be exported shall be certified under the Ministry of Health (MOH) Hazard Analysis and Critical Control Point (HACCP) Certification Scheme. Guideline for HACCP Certification is available at the website <http://fsq.moh.gov.my>.
2. The applicant shall obtain the raw materials and ice for use in the EU supply chain from sources approved by appropriate Competent Authorities (CAs) i.e. Ministry of Health (MOH), Department of Fisheries (DOF) and Fisheries Development Authority of Malaysia (LKIM).
3. Aquaculture farms and fishing vessels are approved by DOF; landing sites are approved by LKIM; transport vehicles, independent refrigerated stores, source of semi-processed raw materials, source of imported raw materials and ice are approved by MOH.

APPLICATION PROCESS

Application Form

The application shall be made through online system namely Food Export Official Control System (FExOC) at <http://fexoc.moh.gov.my/fexoc/index.php> for the approval of export establishment.

Inspection Procedure

1. Upon receipt of the application submitted by the applicant via FExOC, a designated MOH officer shall verify the completeness of the application form. Once satisfied, the designated MOH officers shall carry out inspection of the establishment to check its compliance to the EU requirements.
2. Corrective actions shall be taken on all non-conformances by the establishment.
3. Follow-up inspection shall be carried out, where necessary, by designated MOH officers to verify that the corrective actions have been taken.
4. The compliance audit process will be carried out by using the online system FExOC and applicant shall communicate with the auditors i.e. giving feedback on all the non conformances issued by auditors during the compliance audit through the online system.
5. The auditor will then submit the final report and all the relevant supporting documents to FSQD HQ through FExOC.

Approval Process

1. The MOH shall grant approval to the establishment if it is found to be in compliance with the EU requirements.
2. The MOH shall notify *Directorate General for Health and Food Safety* (DG SANTE) on the addition of the new approved export establishment. The export establishment shall be informed by MOH when the notification is made.
3. Once the Export Establishment is included in the updated European Commission (EC) Third Country Establishment List as published on the EC website https://sanco.ec.europa.eu/traces/output/listsPerCountry_en.htm, the MOH shall officially notify the export establishment of its EU Approval Number.
4. The establishment shall only export fishery products to the EU from the date the updated EC Third Country Establishment List comes into force.

ADDITIONAL INFORMATION

1. The Protocols and Standard Operating Procedures related to export of fishery products to the EU are available at the websites <http://fsq.moh.gov.my>, <http://mutiara.dof.gov.my> and <http://www.lkim.gov.my>.
2. The current legislations on export of fishery products to the EU are as follows and are available at the website <http://eur-lex.europa.eu/en/index.htm>.

(It is to be noted that the EC legislations are subject to change from time to time)

- i. **Regulation (EC) No 178/2002:** laying down the general principles and requirements of food

law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

- ii. **Regulation (EC) No 852/2004**: on hygiene of foodstuffs.
- iii. **Regulation (EC) No 853/2004**: laying down specific hygiene rules for food of animal origin.
- iv. **Regulation (EC) No 854/2004**: laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption.
- v. **Regulation (EC) No 882/2004**: on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.
- vi. **Commission Regulation (EC) No 2073/2005**: on microbiological criteria for foodstuffs.
- vii. **Commission Regulation (EC) No 2074/2005**: laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004.
- viii. **Commission Regulation (EC) No 2076/2005**: laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004.
- ix. **Commission Regulation (EC) No 776/2006**: amending Annex VII to Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards Community reference laboratories.
- x. **Commission Regulation (EC) No 1662/2006**: amending Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin.
- xi. **Commission Regulation (EC) No 1881/2006**: setting maximum levels for certain contaminants in foodstuffs.
- xii. **Commission Regulation (EC) No 1883/2006**: laying down methods of sampling and analysis for the official control of levels of dioxins and dioxin-like PCBs in certain foodstuffs.
- xiii. **Commission Regulation (EC) No 333/2007**: laying down the methods of sampling and analysis for the official control of the level of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs.
- xiv. **Council Directive 94/35/EC**: on sweeteners for use in foodstuffs.
- xv. **Council Directive 95/2/EC**: on food additives other than colours and sweeteners.
- xvi. **Council Directive 96/23/EC**: on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/644/EEC.
- xvii. **Council Directive 98/83/EC**: on the quality of water intended for human consumption.

- xviii. **Council Directive 2006/52/EC**: amending Directive 95/2/EC on food additives other than colours and sweeteners and Directive 94/35/EC on sweeteners for use in foodstuffs.
- xix. **Council Regulation (EC) No 2406/96**: laying down common marketing standards for certain fishery products.
- xx. **Directive 2000/13/EC**: on the approximation of the laws of the Member States relating to the labeling, presentation and advertising of foodstuffs.
- xxi. **Commission Decision 2002/657/EC**: implementing Council Directive 96/23/E concerning the performance of analytical methods and the interpretation results.

For more information, please contact:

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- Fisheries Biosecurity Division
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Ministry of Agricultural and Agro-Based Industry
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