Content

Title：	Regulations Governing Implementation of Hygiene and Safety Management System Certification of Fishery Products for Export Ch
Date：	2020.05.26
Legislative：	1.Adopted and promulgated by Ministerial Order on June 19, 2002. Adoption by Ministerial Order on November 11, 2002 and enter into force from January 1, 2003. 2.Amended and promulgated by Ministerial Order on April 14, 2011. 3.Article 17 amended, Articles 18 deleted, and promulgated by Ministerial Order on October 29, 2014. 4.Amended and promulgated by Ministerial Order on May 26, 2020.
Content：	Article 1 These Regulations are established in accordance with paragraph 2 of Article 14 of the Commodity Inspection Act. Article 2 The fishery products mentioned in these Regulations refer to the products made from the aquatic animals (except for mammals, reptiles and frogs), and the processed or composite products resulting from the edible parts of such animals as the main ingredients. The certification audit authority(ies) mentioned in these Regulations refers to the Bureau of Standards, Metrology and Inspection of Economic Affairs (hereinafter referred to as BSMI) and its branches, or other commissioned government agencies (bodies), juristic persons or organizations, to implement the matters including document review, on-site certification audits, surveillance audits, acceptance for the application of alteration of registration or suspension of production and business. Article 3 The hygiene and safety management system certification of fishery products for export (hereinafter referred to as certification) refers that BSMI conducts impartial and independence conformity assessments to the management system established by the operator for his establishment, and certifies such system comply with certification audit criteria for applied certification categories including the EU system certification (herein refer as EU certification), Hazard Analysis and Critical Control Points system certification (herein refer as HACCP certification) and warehouse system certification. The certification audit criteria referred to in the preceding paragraph shall be prescribed by BSMI referred with the related applicable principles of international organizations and adopted provisions of the import country or regions. Article 4 The operator(s) mentioned in these Regulations refers to the business, juridical persons or organizations that own the processing plants or cold chain warehouse for export fishery products. The operator shall manage factory registration according to the Factory Management Act before applying the certification, and establish food safety management and control team (hereinafter referred as the HACCP team), which composed of at least 3 staffs, and the responsible person or his authorized representative shall be the necessary member. Article 5 The operator shall submit a certification application for owned processing plant with filled application form and the following documents to BSMI: 1. The copy of the company registration, business registration or other document of legal registration. Where the application form is correctly filled with unified business administration number which can be verified on the government public websites, the copy can be exempted. 2. The copy of factory registration. 3. The copies of the training certificates related to the courses over thirty hours of hygiene and

safety management system for each HACCP team members; additionally copies of the training documents related to the courses of EU's legislations on fishery products chain for at least one member for applying the EU certification.
4. The processing flow chart.
5. The hygiene and safety management system plan, including written standard operation procedures based on Good Hygiene Practices (GHP) and Hazard Analysis Critical Control Points (HACCP).
6. The factory layout, including personnel flow, material flow, water flow and air flow.
7. Other documents specified by BSMI.
To apply for EU certification could apply for HACCP certification at the same time.
The operator shall submit a certification application for owned warehouse with filled application form and the documents referred to in subparagraph 1, GHP in subparagraph 5, subparagraph 6 and
7 of paragraph 1.

Article 6
BSMI shall notify the operator who submitted nonconforming or uncompleted documents to take corrections during one month; where the operator does not submit corrected ones before a given date, BSMI cannot accept the application; where otherwise BSMI shall notify the operator in written
to accept the application formally once the submitted documents complying with the requirements.
After accepting the certification application, BSMI should forward all documents to a certification audit authority for review. Once found any noncompliance in documents after reviewing, the certification audit authority shall notify the operator to correct the findings during one month.
Where the operator has not completed the corrections or failed to correct before indicated date, BSMI shall notify the operator in written to reject the application.
The certification audit authority shall notify the operator in written to take arrangements for an on-site certification audit after ensuring all documents complying to the requirements as required reviewing in the preceding paragraph.

Article 7
The operator shall cooperate with the on-site certification audit within three months from the next day receiving the notice in paragraph 3 of the preceding article, and the operator could apply single extension of no longer than three months with a reasonable explanation to the certification audit authority. BSMI shall reject the certification application after receiving a notice from the certification audit authority in which described the operator failed to cooperate with the audit before given period.

Article 8
Where the operator's establishment assessed and deemed comply with the certification audit criteria,
BSMI shall grant certification with an approval number based on certification category, product category and the information stated in the application and issue a certificate valid for three years.
The certification audit authority shall notify the operator, whose establishment assessed and deemed noncompliant to the certification audit criteria, to take corrective actions within a given period; when necessary, the certification audit authority should verify the effectiveness of corrections on-site after given period. For that establishment, incapable of making corrective actions or failing to complete the corrections according to the requirements, the certification audit authority shall notify BSMI, and BSMI shall send a notice of failure to grant the certification. That operator could re-submit a certification application after two months from the next day receiving the written notice.

Article 9
The certification audit authority shall conduct surveillance audits for the registered establishments at least once a calendar year; the date of the first surveillance audit shall not exceed twelve months after the date of the initial certification decision. Where necessary, BSMI should conduct unannounced audits based on risk.
The certification audit authority shall notify the operator, whose establishment assessed and deemed noncompliant to the certification audit criteria upon surveillance audit, to take corrective actions within a given period; when necessary, the certification audit authority should verify the effectiveness of corrections on-site after given period.

Article 10
The registered establishment shall take all arrangements for audits conducted by the certification

audit authority.

Article 11
The registered establishment shall not mislead the third parties to recognize as product certification upon product labeling, advertisement and publicity.

Article 12
Whenever BSMI amends or changes the certification audit criteria, the registered establishment shall complete the corrections within the transition period designated by BSMI. The certification audit authorities shall validate that all the registered establishments have completed the corrections within one month after the transition period.

Article 13
BSMI shall review the conformity assessments of surveillance audits for the last three years before the expiration of certificate, then notify the operator for a renewal certificate after all programs deemed to comply with the requirements.
The establishment registered with HACCP certification, hereafter to apply for EU certification and be granted EU certification, could apply for HACCP certificate with the same validity period as EU certificate, and combine the subsequent surveillance audits.

Article 14
The registered establishment, whose registered basic information or items described in certificate were altered, shall apply for alteration of registration with the original certificate and relevant documents to the certification audit authority within one month from the date of any changes. The operator, whose establishment relocating the site, shall re-apply in accordance with the requirements in Article 5.
The certification audit authority shall conduct document review for the application in the preceding paragraph, and shall notify the operator whose application do not comply with the requirements to take corrections within a given period; when necessary, the certification audit authority should conduct an on-site verification audit. After verified the alteration to comply with the requirements, the certification audit authority shall approve the alteration application for that do not affect the content of certificate, otherwise shall report to BSMI to re-issue a new certificate.
The operator should apply for re-issuance of certificate to BSMI when the original one was gone or damaged.

Article 15
The operator shall report his suspension of production or business over month to the certification audit authority within one month from the day of suspension. For mandatory one, it shall be reported within five day from the next day receiving the mandatory punishment order.
The autonomous suspension mentioned in preceding paragraph should be limited to no more than six months. The operator could apply single extension of no longer than six months with a reasonable explanation to the certification audit authority before the expiration of first suspension.
The operator, whose registered establishment is autonomous to suspend production or business for more than six months, or is mandatory to suspend production or business, shall apply to the certification audit authority for a surveillance audit before resuming production or business.

Article 16
BSMI shall revoke the operator's certificate(s) which was granted due in a fraudulent manner.

Article 17
To the registered establishment under any of the following circumstances, the granted certification shall be ceased by BSMI:
1. Where it was deemed noncompliant to the certification audit criteria in compliance with the audits described in the Article 9(1) and did be incapable of make corrections.
2. Where it did not complete the corrections as required in Article 9(2), or still was deemed noncompliant to the certification audit criteria upon on-site re-verification.
3. Where it did not take arrangements to facilitate the audits as required in Article 10.
4. Where it violated the requirements described in the Article 11 and did not make corrections within a given period.
5. Where it did not complete the corrections within the transition period as required in Article 12.
6. Where it did not apply the alteration as required in Article 14(1), and has not taken actions within 15 days after receiving notice.
7. Where it did not report or apply single extension as required in Article 15, and has not taken

actions within 10 days after receiving notice or did not resume production or business.
8. Where it reported or applied single extension as required in Article 15, but has not resumed production or business in time.
9. Where it did not apply for a surveillance audit as required in Article 15(3), and resumed production or business before the certification audit authority deemed comply with the certification audit criteria.
10. Where it did not pay the fees in accordance with related regulations, and did not deal with the overdue fees in time after receiving notice.
11. Where its company registration, business registration, factory registration or other equivalent registration has been revoked, cancelled or repealed by the competent authority(ies).
12. Where it applied for rescinding the registration itself.
13. Where the certification audit criteria or product categories were rescinded.
14. Where it was dissolved or gone out for business.

Article 18
The operator, whose registered establishment was subjected to the revocation or cease disposition by BSMI, shall surrender the certificate(s) within 15 days after the next day from receiving the notice of disposition, and could apply for returning the certificate(s) with labeled the cancelled mark by BSMI.
The operator, whose registered establishment was subjected to the cease disposition by BSMI as required in subparagraph 1-9 of preceding article, can re-submit a new certification application after four months from the next date receiving the notice of cease disposition. For whose registered establishment was subjected to the revocation by BSMI as required in Article 16, the operator cannot re-submit a new certification application shorter than three years from the next date receiving the notice of revocation disposition.

Article 19
The operator, whose registered establishment granted certification in accordance with those Regulations regarding hygiene and safety management system certification of food and feed for export, could continue to use the certificate(s) before the expiration of the certificate(s); and the certification audit authority could conduct the surveillance audit as required in the procedures governing implementation of hygiene and safety management system certification of food and feed for export.

Article 20
These Regulations shall come into force from the date of promulgation.

Data Source：Ministry of Economic Affairs R.O.C.(Taiwan) Laws and Regulations Retrieving System