**ANNEX XIII**

REFERRED TO IN ARTICLE 2.39 (SPECIFIC PROVISIONS AND ARRANGEMENTS CONCERNING SANITARY AND PHYTOSANITARY MATTERS) OF SECTION 2.3 (SANITARY AND PHYTOSANITARY MEASURES) OF CHAPTER 2 (TRADE IN GOODS)

ANNEX XIII

PROVISIONS AND ARRANGEMENTS CONCERNING SANITARY AND PHYTOSANITARY MATTERS

REFERRED TO IN ARTICLE 2.39 (Specific Provisions and Arrangements concerning Sanitary and Phytosanitary Matters) of section 2.3 (sanitary and phytosanitary measures) of chapter 2 (trade in goods)

INTRODUCTION

When the provisions in this Annex refer to sanitary measures that for Iceland and Norway are governed by the EEA Agreement, the Parties understand that such measures are taken by the EU and that Iceland and Norway, simultaneously with the EU Member States, implement corresponding measures on the basis of the relevant EU acts and in accordance with their obligations under the EEA Agreement.

Part 1

Official Certification

1. Where the importing Party requires official certificates, the model certificates shall be set in line with the principles as laid down in the international standards of the Codex, the IPPC and the OIE.
2. The Parties shall promote the implementation of electronic certification and other technologies to facilitate trade.

Part 2

Import Conditions and Procedures

1. The exporting Party shall ensure that products exported to the other Parties, such as animals and animal products, plants and plant products, or other related objects, meet the SPS requirements of the importing Party.
2. The importing Party may require that imports of particular products are subject to authorisation. Such authorisation shall be granted where a request is made by the relevant competent authority of the exporting Party which objectively demonstrates, to the satisfaction of the importing Party, that the authorisation requirements of the importing Party are fulfilled.
3. The importing Party shall not introduce authorisation requirements which are additional to those which were applicable on 31 December 2020, unless the application of such requirements to further products is justified to mitigate a significant risk to human, animal or plant health.
4. The importing Party shall establish and communicate to the other Parties import conditions for all products. The importing Party shall ensure that its import conditions are applied in a proportionate and non-discriminatory manner.
5. Each Party shall ensure that all SPS control, inspection and approval procedures are initiated and completed without undue delay. Information requirements shall be limited to what is necessary for the approval process to take into account information already available in the importing Party, such as on the legislative framework and audit reports of the exporting Party.
6. Except in duly justified circumstances related to its level of protection, each Party shall provide a transition period between the publication of any changes to its approval procedures and their application to allow the other Parties to become familiar with and adapt to such changes. Each Party shall not unduly prolong the approval process for applications submitted prior to publication of the changes.
7. In relation to the processes set out in paragraphs 2 to 5, the following actions shall be taken:
   1. as soon as the importing Party has positively concluded its assessment, it shall promptly take all necessary legislative and administrative measures to allow trade to take place without undue delay;
   2. the exporting Party shall:
      1. provide all relevant information required by the importing Party; and
      2. give reasonable access to the importing Party for audit and other relevant procedures.
8. The importing Party shall accept consignments without requiring that the importing Party verifies compliance of those consignments before their departure from the exporting Party.
9. A Party may collect fees for the costs incurred to conduct specific SPS border checks, which should not exceed the recovery of the costs.
10. The importing Party shall have the right to carry out import checks on products imported from the exporting Party for the purpose of ensuring compliance with its SPS import requirements.
11. The import checks carried out on products imported from the exporting Party shall be based on the SPS risk associated with such importations. Import checks shall be carried out only to the extent necessary to protect human, animal or plant life or health, without undue delay and with a minimum effect on trade between the Parties.
12. Information on the proportion of products from the exporting Party checked at import shall be made available by the importing Party upon request of the exporting Party.
13. If import checks reveal non-compliance with the relevant import conditions the action taken by the importing Party must be based on an assessment of the risk involved and not be more trade restrictive than required to achieve that Party’s appropriate level of SPS protection.

Part 3

Lists of Approved Establishments

1. Whenever justified, the importing Party may maintain a list of approved establishments meeting its import requirements as a condition to allow imports of animal products from these establishments.
2. Unless justified to mitigate a significant risk to human or animal health, lists of approved establishments shall only be required for the products for which they were required on 31 December 2020.
3. The exporting Party shall inform the importing Party of its list of establishments meeting the importing Party’s conditions which shall be based on guarantees provided by the exporting Party.
4. Upon a request from the exporting Party, the importing Party shall approve establishments of the exporting Party, based on guarantees provided by the exporting Party, without prior inspection of individual establishments.
5. Unless the importing Party requests additional information and subject to guarantees being provided by the exporting Party, the importing Party shall take the necessary legislative or administrative measures, in accordance with its applicable legal procedures, to allow imports from those establishments without undue delay.
6. The list of the approved establishments shall be made publicly available by the importing Party.
7. Where the importing Party decides to reject the request of the exporting Party to accept adding an establishment to the list of approved establishments, it shall inform the exporting Party without delay and shall submit a reply, including information about the non-conformities which led to the rejection of the establishment’s approval.

Part 4

Recognition of Animal Disease Status and Regional Conditions

1. The Parties shall recognise the concept of zoning including disease-free areas, and areas of low disease prevalence and shall apply it to the trade between the Parties, in accordance with the SPS Agreement, including the guidelines to further the practical implementation of Article 6 of the SPS Agreement (WTO/SPS Committee Decision G/SPS/48) and the relevant recommendations, standards and guidelines of the OIE. The SPS Sub-Committee may define further details for these procedures, taking into account any relevant SPS Agreement and OIE standards, guidelines or recommendations.
2. The Parties may also agree to cooperate on the concept of compartmentalisation as referred to in Chapters 4.4 and Chapter 4.5 of the OIE Terrestrial Animal Health Code and Chapters 4.1 and Chapter 4.2 of the OIE Aquatic Animal Health Code.
3. When establishing or maintaining the zones referred to in paragraph 1, the Parties shall consider factors such as geographical location, ecosystems, epidemiological surveillance and the effectiveness of sanitary controls.
4. With regard to animals and animal products, when establishing or maintaining import conditions upon the request of the exporting Party, the importing Party shall recognise the disease-free areas established by the exporting Party as a basis for consideration towards the determination of allowing or maintaining the import, without prejudice to paragraphs 6 and 7.
5. The exporting Party shall identify the areas referred to in paragraph 4 and, if requested, provide a full explanation and supporting data based on the OIE standards, or in other ways established by the SPS Sub-Committee, based on the knowledge acquired through experience of the exporting Party’s relevant authorities.
6. The Parties shall recognise disease-free areas which are in place on 31 December 2020.
7. Paragraph 6 shall also apply to subsequent adaptations to the disease-free areas except in cases of significant changes in the disease situations.
8. The Parties may carry out audits and verifications pursuant to Part 5 (Audits and Verifications) to implement paragraphs 4 to 7.
9. The Parties shall establish close cooperation with the objective of maintaining confidence in the procedures in relation to the establishment of disease-free areas, and areas of low disease prevalence, with the aim to minimise trade disruption.
10. The importing Party shall base its own determination of the animal health status of the exporting Party or parts thereof on the information provided by the exporting Party in accordance with the SPS Agreement and OIE standards, and take into consideration any determination made by the exporting Party.
11. Where the importing Party does not accept the determination made by the exporting Party as referred to in paragraph 10, the importing Party shall objectively justify and explain to the exporting Party the reasons for that rejection and, upon request, hold consultations, in accordance with paragraph 2 of Article 2.44 (Notifications and Consultation) of Section 2.3 (Sanitary and Phytosanitary Measures) of Chapter 2 (Trade in Goods).
12. Each Party shall ensure that the obligations set out in paragraphs 4 to 7, 10 and 11 are carried out without undue delay. The importing Party will expedite the recognition of the disease status when the status has been recovered after an outbreak.
13. Where a Party considers that a specific region has a special status with respect to a specific disease and which fulfils the criteria laid down in the OIE Terrestrial Animal Health Code Chapter 1.2 or the OIE Aquatic Animal Health Code Chapter 1.2, it may request recognition of this status. The importing Party may request additional guarantees in respect of imports of live animals and animal products appropriate to the agreed status.

Part 5

Audits and Verifications

1. The importing Party may carry out audits and verifications of the following:
   1. all or part of the exporting Party’s authorities’ inspection and certification system; and
   2. the results of the controls carried out under the exporting Party’s inspection and certification system.
2. The Parties shall carry out those audits and verifications in accordance with the provisions of the SPS Agreement, taking into account the relevant international standards, guidelines and recommendations of the Codex, the OIE or the IPPC.
3. For the purpose of carrying out such audits and verifications, the importing Party may conduct audits and verifications by means of requests of information from the exporting Party or audit and verification visits to the exporting Party, which may include:
   1. an assessment of all or part of the responsible authorities’ total control programme, including, where appropriate, reviews of regulatory audit and inspection activities;
   2. on-the-spot checks; and
   3. the collection of information and data to assess the causes of recurring or emerging problems in relation to exports of products.
4. The importing Party shall share with the exporting Party the results and conclusions of the audits and verifications carried out pursuant to paragraph 1. The importing Party may make these results publicly available.
5. Prior to the commencement of an audit or verification, the Parties concerned shall discuss the objectives and scope of the audit or verification, the criteria or requirements against which the exporting Party will be assessed, and the itinerary and procedures for conducting the audit or verification which shall be laid down in an audit or verification plan. Unless otherwise agreed by the Parties concerned, the importing Party shall provide the exporting Party with an audit or verification plan at least 30 days prior to the commencement of the audit or verification.
6. The importing Party shall provide the exporting Party the opportunity to comment on the draft audit or verification report. The importing Party shall provide a final report in writing to the exporting Party normally within two months from the date of receipt of those comments.
7. Each Party shall bear its own costs associated with such an audit or verification.

Part 6

Emergency Measures

1. If the importing Party considers that there is a serious risk to human, animal or plant life or health, it may take without prior notification the necessary measures for the protection of human, animal or plant life or health. For consignments that are in transit between the importing Party and the exporting Party, the importing Party shall consider the most suitable and proportionate solution to avoid unnecessary disruptions to trade.
2. The Party taking the measures shall notify the other Parties of an emergency SPS measure as soon as possible after its decision to implement the measure and no later than 24 hours after the decision has been taken. If a Party requests technical consultations to address the emergency SPS measure, the technical consultations must be held within 10 days of the notification of the emergency SPS measure. The Parties concerned shall consider any information provided through the technical consultations. These consultations shall be carried out in order to avoid unnecessary disruptions to trade. The Parties concerned may consider options for the facilitation of the implementation or the replacement of the measures.
3. The importing Party shall consider, in a timely manner, information that was provided by the exporting Party when it makes its decision with respect to consignments that, at the time of adoption of the emergency SPS measure, are being transported between the Parties concerned, in order to avoid unnecessary disruptions to trade.
4. The importing Party shall ensure that any emergency measure taken on the grounds referred to in paragraph 1 is not maintained without scientific evidence or, in cases where scientific evidence is insufficient, is adopted in accordance with paragraph 7 of Article 5 of the SPS Agreement.

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