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Updated Customs Union SPS Measure Notified to WTO

Report Categories:
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Sanitary/Phytosanitary/Food Safety
Trade Policy Monitoring
Livestock and Products
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Report Highlights:
On May 13, 2013, Russia notified the World Trade Organization (WTO) of revised draft amendments to the CU regulation on joint inspections of production facilities (G/SPS/N/RUS/14/Add.2). This draft has been supplemented with the guidelines for inspectors regarding the equivalence of veterinary and sanitary measures and with the guidelines for inspections of third countries' establishments. The 60-day public comment period ends on
July 12, 2013. Interested U.S. parties are encouraged to share their comments and concerns with USDA's enquiry point (us.spsenquirypoint@fas.usda.gov).

General Information:
The Russia-Kazakhstan-Belarus Customs Union (CU) published the following draft document amending its regulation on joint inspections of production facilities on its website:

- Amendments to the Regulation on Common System of Joint Inspections of Facilities and Sampling of Goods (Products), Subject to Veterinary Control (Surveillance).

This draft has been supplemented with the guidelines for inspectors regarding the equivalence of veterinary and sanitary measures (for the original version of these guidelines please see GAIN report *RS1274 - Customs Union Publishes Inspection Guidelines for Public Comment*, notified to the WTO as G/SPS/N/RUS/6) and with the guidelines for inspections of third countries' establishments, which were published for the first time.

An unofficial English translation of the above draft document with its new appendices can be found below.

On May 13, 2013, Russia notified the World Trade Organization (WTO) of this draft document in its WTO notification: G/SPS/N/RUS/14/Add.2. The 60-day public comment period ends on July 12, 2013. Interested U.S. parties are encouraged to share their comments and concerns with USDA's enquiry point (us.spsenquirypoint@fas.usda.gov).

For earlier versions of this draft document please see GAIN reports *RS1307 Customs Union Publishes SPS Measures for Public Comment* (notified to the WTO as G/SPS/N/RUS/14) and *RS1320 Customs Union Publishes SPS Measures for Public Comment* (notified to the WTO as G/SPS/N/RUS/14/Add.1).

BEGIN UNOFFICIAL TRANSLATION:

APPENDIX
to Decision of the Council
of the Eurasian Economic Commission
of "____" _____ 2012, No. _____

AMENDMENTS
TO THE REGULATION ON
COMMON SYSTEM OF JOINT INSPECTIONS
OF FACILITIES AND SAMPLING OF GOODS (PRODUCTS),
SUBJECT TO VETERINARY CONTROL (SUPERVISION)

1. Throughout the text of the Regulation to substitute the acronym "CUC" for the word "Commission."

2. Paragraph 4: to add item q) as follows:

"Register of establishments of third countries – a register of organizations and individuals producing, processing and (or) storing controlled goods imported into the territory of the Customs Union."

3. Paragraph 4: to add item r) as follows:

"Experts/auditors - the employees of supranational and governmental bodies and institutions who

possess knowledge and expertise required for applying properly the Customs Union requirements and assist the competent authorities (CA) of a third party in conducting inspections of facilities and sampling goods (products)."

4. Paragraph 7: after the words "on the basis of" to add the word "results."

5. Paragraph 8: to add the following language: "In order to protect confidential information and to avoid conflict of interests in relation to the controlled establishments being inspected, the preliminary and final reports published by the authorized bodies of the Parties should not contain numbers (identifiers) or names of the organizations and individuals involved in the production (manufacture), processing, transportation and/or storage of controlled goods subject to inspection."

6. Paragraph 12: after the words "the scope of the audit" to add the following statement: "including groups of the controlled goods and types of activity of the controlled facilities."

7. Paragraph 13: to reword the first sentence as follows:

"During audits of the foreign systems of supervision, inspectors may take into account (give consideration to) the results of similar activities carried out by other WTO member-states and should take into account the history of trade with such states and information that the authorized body of the Party currently has on the following issues:"

8. Item 14 shall read as follows:

"During assessment of the foreign official system of supervision inspectors should use the assessment criteria as defined by the relevant articles of the Terrestrial Animal Health Code and Aquatic Animal Health Code, as well as the documents of the Codex Alimentarius Commission, other international standards and guidance recognized by the WTO, as well as Annex No. 2 to the present Regulation."

9. Paragraph 21: to replace the word "inspection" with the word "audit."

10. Paragraph 28: after the words "within 2 months" to add the following language: "after publishing the preliminary audit report on the official website of the authorized body of the Party."

11. Paragraph 31: after the words "within 2 months" to add the following language: "after publishing the preliminary audit report on the official website of the authorized body of the Party."

12. Paragraph 32: after the words "within 2 months" to add the following language: "upon receipt of a formal letter from the competent authority of a third party with comments on the preliminary report."

13. Paragraph 34:

to substitute the words "the CU Commission" with the words "the Eurasian Economic Commission;"

after publishing the final audit report on the official website of the authorized body of the Party.

14. Paragraph 35 shall be reworded as follows:

"After the adoption of such decision, the CA of a third country shall develop a preliminary list of establishments, which will have the right to export controlled goods to the CU, for their inclusion in the Register of establishments of third countries."

15. Paragraph 36 shall be reworded as follows:

"The CA of a third country developing a preliminary list of establishments for their inclusion in the Register of establishments of third countries shall send a letter with the said list of establishments to the authorized body of the Party."

16. Paragraph 37: substitute the words "5 working days" with the words "30 working days."

17. Paragraph 38: to add the following wording:

"The Commission shall, without undue delays, inform the authorized bodies of the Parties about

these changes."

18. Paragraph 39: the first sentence shall be reworded as follows:

"In consideration of requests of the authorized bodies of the Parties, the Commission may make a decision to re-audit the official supervision system of a third country, but not more often than once a year except for the case indicated in paragraph 41."

19. Paragraph 40: to substitute the words "as result of" with the words "based on."

20. Paragraph 42: after the words "has been started but not completed" to add "or if the audit of a foreign system of supervision was not carried out."

21. Paragraph 43 shall be revised as follows:

"The CA of a third country shall send request to the authorized body of the Party to accept its guarantees on compliance of the controlled goods produced by a particular establishment (establishments) attaching all the necessary information, according to paragraph 43^1, including a list of establishments with the names of manufactured products. Guarantees of the CA of a third country shall be accepted for each group of goods pursuant to HS codes.

When such request is received, the authorized body of the Party shall review the attached and other available data within a reasonable period of time but for no more than three months.

If necessary, the authorized body of the Party while reviewing such request may require additionally the necessary information from the CA of a third country. In this case, the duration of request review is extended taking into account the time when the relevant information was received."

22. To add the following paragraphs:

«43^1. The assessment of the request for accepting guarantees is made by the authorized body of the Party on the basis of the following criteria:

a) Level of development of the CA of a third country;
b) Level of justification of guarantees provided by the CA of a third country;
c) Risk of import into and further spread on the territory of a third country of agents causing contagious animal diseases, including those common to humans and animals;
d) Epizootic situation in a third country;
e) The results of monitoring tests of the controlled goods, imported into the CU customs territory from this third country (if available);
f) The data of monitoring of the controlled goods, carried out by the CA of a third country;
g) Compliance with the CA requirements as provided in paragraph 10 with regard to the controlled goods imported into the CU territory from a third country;
h) The results of inspections of establishments on the territory of a third country by the authorized bodies of the Parties (if available);
i) The experience of trade with a third country (if available);
j) The list of establishments by product type (if available).

43^2. In case of positive assessment of the request for accepting guarantees, the authorized body of the Party shall develop a conclusion to be sent to other authorized bodies of the Parties for agreement. The period of agreement shall be no more than 10 working days starting from the date when an electronic notification on the availability of formal conclusion on the agreement by the other Parties is received at the official e-mail address. Non-response from the CA of the Parties, once this period expires, means concurrence with the proposals on adopted decision. In case of non-concurrence of the authorized body of the Party(ies), a letter shall be sent specifying the reasons of agreement rejection within the said time period.

When the Parties agree on a positive conclusion, the authorized body of the Party shall send a written notification to the CA of a third country on the acceptance of guarantees with the indication of

product type(s). If a list of establishments of third countries is available, the authorized body of the Party shall include them in the Register of establishments of third countries no later than within one month from the date of agreement on positive conclusion concerning the acceptance of guarantees.

In case of negative assessment of the request for accepting guarantees, the authorized body of the Party shall develop a conclusion to be sent to the CA of a third country specifying the reasons of the rejection."

23. Article 44 shall be revised as follows:

In case of accepting guarantees from the CA of a third country, the CA of this country shall prepare a list of establishments and send the list to the authorized body of the Party.

The authorized body of the Party shall review the provided list of establishments within one moth and make decision on including them in the Register of establishments of third countries. The authorized body of the Party shall send a notification on inclusion/non-inclusion of establishments in the Register specifying the reasons (in case of non-inclusion) to the CA of a third country.

The CA of a third country, whose guarantees had been accepted according to the established procedure, in future may send to the authorized body of the Party an additional list of facilities for reviewing their inclusion in the Registry of establishments of third countries. Based on the review results, the authorized body of the Party shall send a notification on inclusion/non-inclusion of establishments in the Register specifying the reasons (in case of non-inclusion) to the CA of a third country.

Later on, the authorized body of the Party may inspect once a year a representative percentage of the establishments included in the Registry of establishments of third countries against guarantees.

In case of repeated negative results of on-site inspections in some of such inspected establishments the authorized body of the Party may make a decision to suspend temporarily exports from these establishments, if the appropriate actions had not been taken in a timely manner.

In case of obtaining negative results during inspections in more than 50 percent of inspected establishments, which reflects serious failures in the official system of control, the authorized body of the Party may make decision to refuse to accept guarantees from the CA of a third country and require a mandatory joint inspection of establishments of the third country."

24. Paragraph 46: to substitute the words "the Register of establishments located on the territory of third countries" with the words "the Register of establishments of third countries."

25. Paragraph 55: after the words "who are employees of" to add the words "the Commission"; to delete the words "to assist the inspectors."

26. In paragraph 56:

a) to substitute the words "two months" with the words "two weeks";

b) to substitute the words "a shorter period" with the words "another period";

c) in item (d) to substitute the word "enterprises" with the words "controlled facilities"

d) to delete item (e);

e) to revise item "f" as follows:

"the list and quantity of organizations, involved in the production (manufacture) and/or control of the relevant controlled goods produced by the establishments included in the schedule of visits during the inspection."

f) to add the following paragraph: "Information sent to the competent authority of a third country may be corrected before the commencement of inspection by the authorized body of the Party, which initiated the joint inspection."

27. To delete paragraph 57.

28. The first paragraph of item 59 shall read as follows:

"During the joint inspection the inspector, being guided by Annex No. 3 to the present

Regulation, shall:"

29. Paragraph 62: to substitute the words "Upon request of the CA of the third country" with the words "Upon agreement with the CA of a third country."

30. Paragraph 64 shall be revised as follows:

"A preliminary report on joint inspection shall be prepared and published and a letter with the attached report shall be sent by:

- the authorized body of the Party that conducted the inspection, within two months upon completion of the joint inspection in a third country, in case when the inspection had been conducted by the authorized body of one Party;
- the authorized body of the Party that initiated the inspection in case when the inspection had been conducted by the authorized bodies of two or more Parties, according to the following procedure. The authorized body of the Party, which initiated the inspection, prior to publication of a preliminary report, but no later than within two months from the date of inspection completion in a third country, should develop proposals on preliminary report publication and send them to the authorized bodies of the Parties, which had conducted the inspection. The authorized bodies of the other Parties shall, no later than two weeks from the receipt of proposals on preliminary report publication[1], send the report to the authorized body of the Party, which had initiated the inspection. Non-response upon expiration of the established period means agreement with the proposals on preliminary report publication. The authorized body of the Party, which initiated the inspection, with consideration given to the feedback from the authorized bodies of the other Parties that had conducted the inspection shall, within three months upon completion of the joint inspection in a third country, publish a preliminary report on the joint inspection and send this report to the CA of the third country."

To add the following footnote: "[1]Starting from the date of electronic notification on receipt of the proposals for preliminary report publication by the other Parties at the official e-mail address."

Article 65 shall be revised to read:

The CA of a third country may, within two months from the date of publication of a preliminary report on the official website of the authorized body of the Party, send comments, additional data (including information on the corrective actions taken), clarifications on the information and conclusions of the preliminary report to:

- the authorized body of the Party, which conducted the inspection, in case when the inspection was performed by the authorized body of one Party;
- the authorized body of the Party, which initiated the inspection, in case when the inspection was performed by the authorized bodies of two or more Parties."

31. Article 66 shall be revised as follows:

Final report shall be prepared (taking into account comments received on a preliminary report from the CA of a third country) and published by:

- the authorized body of the Party, which conducted the inspection, within two months from the date of official receipt of the letter of the CA of a third country with comments on a preliminary report in case when the inspection was performed by the authorized body of one Party;
- the authorized body of the Party, which initiated the inspection, in case when the inspection was performed by the authorized bodies of two or more Parties according to the following procedure. The authorized body of the Party, which initiated the inspection, shall, prior to the publication of the final report, but no later than two months from the date of official receipt of the letter with comments on a preliminary report from the CA of a third country, prepare and send proposals on the publication of final report to the authorized bodies of the Parties, which conducted the inspection. The authorized bodies of the other Parties shall, no later than two weeks after receipt of the proposals on final report

publication[2], send their feedback to the authorized body of the Party, which initiated the inspection. Non-response upon expiration of the established period means agreement with the proposals on final report publication. The authorized body of the Party, which initiated the inspection, with consideration given to the feedback from the authorized bodies of the other Parties involved in the inspection should, within three months from the date of receipt of a letter with comments on a preliminary report from the CA of a third party, publish the final report on the joint inspection and send the report to the CA of the third country."

To add the following footnote: "[2]Starting from the date of electronic notification on receipt of the proposals for final report publication by the other Parties at the official e-mail address."

32. Paragraph 70, item (d): after the words "findings of incompliance" to add the words: "with the CU requirements."

33. To add the following language to Paragraph 76:

"If the CA of a third country refuses to permit an on-site inspection of one or more of the selected establishments, this may constitute a reason for the authorized body of the Party that initiated the joint inspection to suspend export of products from these establishments to the CU unless the authorized body of the Party recognizes the causes of such refusal provided by the CA of the third party as valid."

34. Paragraph 77 shall be revised as follows:

"Preliminary and final reports on the re-inspection shall be prepared and published according to the procedure described in p.p. 64, 65 and 66."

35. Paragraph 78 shall be revised as follows:

"In case when during a re-inspection and/or preparation of a preliminary report, an incompliance with the Customs Union requirements is found, which results in a serious threat to human or animal life and health posed by the controlled goods shipped from a third country to the territory of the CU member-states, the authorized body of the Party that initiated the inspection shall make decision on the immediate application of one or more of the below measures depending on the severity of the situation:

- temporary suspension of shipments of controlled goods from the controlled facilities being inspected from a part of the third country or from its entire territory, or, if necessary, from the third country used for transit;
- introduction of special conditions for controlled goods of the controlled facilities being inspected, from the entire third country or its part;
- any other adequate preliminary actions.

Information on the reasons for taking actions shall be communicated to the authorized bodies of the Parties and the CA of a third country within 5 working days upon completion of the joint inspection in the third country and published on the official website of the authorized body of the Party, which had taken the measures."

36. To delete paragraph 79.

37. To add the following wording to paragraph 90:

"If the CA of a third country refuses to permit an on-site inspection of one or more of the selected establishments, this may constitute a reason for the authorized body of the Party, which initiated the joint inspection, to suspend export of products from these establishments to the CU unless the authorized body of the Party recognizes the causes of such refusal provided by the CA of the third party as valid."

38. Paragraph 91 shall be revised as follows:

"Preliminary and final reports on the re-inspection shall be prepared and published according to the procedure described in paragraphs 64, 65, and 66."

39. Paragraph 92 shall be revised as follows:

"In case when during a re-inspection and/or preparation of a preliminary report, an incompliance

with the Customs Union requirements is found, which results in a serious threat to human or animal life and health posed by the controlled goods shipped from a third country to the territory of the CU member-states, the authorized body of the Party that initiated the inspection shall make decision on the immediate application of one or more of the below measures depending on the severity of the situation:

- temporary suspension of shipments of controlled goods from the controlled facilities being inspected from a part of the third country or from its entire territory, or, if necessary, from the third country used for transit;

- introduction of special conditions for controlled goods of the controlled facilities being inspected, from the entire third country or its part;

- any other adequate preliminary actions.

Information on the reasons for taking actions shall be communicated to the authorized bodies of the Parties and the CA of a third country within 5 working days upon completion of the joint inspection in the third country and published on the official website of the authorized body of the Party, which had taken the measures."

40. Paragraph 93 shall be deleted.

41. Paragraph 96: the first sentence shall be revised as follows:

"The final report may contain conclusions regarding the inspected establishments and establishments included in the Register of establishments of third countries against guarantees."

42. Paragraph 119, item (1): the words "the Common veterinary requirements" shall be substituted with the words "the CU requirements."

43. Paragraph 129 shall be revised as follows:

"In cases specified in items 125(a) (except the case mentioned in para. 2 of this Article) and 125(d), sampling, transportation of collected samples to a laboratory and their laboratory examination shall be performed free of charge for the owner of the controlled product.

Should violations of the veterinary and sanitary requirements be found during documentary or physical control, the owner of the controlled goods shall cover expenses related to sampling of the controlled goods, transportation of collected samples to a laboratory and their laboratory testing.

In case specified in item 125(c), the owner of the controlled goods shall cover expenses related to sampling of the controlled goods, transportation of collected samples to a laboratory and their laboratory testing.

In case specified in para. 2 of this Article, laboratory testing of the samples must cover all safety indicators to determine whether a particular shipment of the controlled goods should be used further or destroyed."

44. To add paragraph 134^1 as follows:

"In case specified in item 125(c), after a single detection of a violation, samples should be taken from ten shipments of the produced goods and within no more than three months. Samples should be taken only from the goods of the same type where the violation was found. The performed laboratory tests should cover all safety indicators of the relevant group of parameters*."

45. In paragraph 135:

a) to delete the phrase "directly or via the laboratory or via publishing on the internet site";

b) to replace figure "5" with figure "10."

46. Paragraph 137: to add items (d), (e), and (f) as follows:

d) conducting control of shipments of supervised goods from the manufacturing facilities where temporary restrictions on import have been posed, but which had been shipped prior to the date of introduction of the temporary restrictions;

e) conducting control of shipments of supervised goods from the manufacturing establishments

where temporary restrictions on import have been lifted;

f) conducting control of shipments of supervised goods from the manufacturing establishments, which are included in the Register of establishments of third countries against guarantees on the CA of a third country as described in Article 7 of this Regulation.

47. Paragraph 141 shall be revised as follows:

"In cases specified in item 137(a) (except the case mentioned in para. 2 of this Article), sampling, transportation of collected samples to a laboratory and their laboratory testing shall be performed free of charge for the owner of the controlled product.

Should violations of the veterinary and sanitary requirements be found during documentary or physical control of the imported controlled goods at the state border checkpoints or at the stations of complete customs clearance, the owner of the controlled goods shall cover expenses related to sampling of the controlled goods, transportation of collected samples to a laboratory and their laboratory testing.

In cases specified in items 137(c), 137(d), 137(e), and 137(f), the owner of the controlled goods shall cover expenses related to sampling of the controlled goods, transportation of collected samples to a laboratory and their laboratory testing.

In case specified in para. 2 of this Article, the performed laboratory testing of the samples must cover all safety indicators to determine whether a particular shipment of controlled goods should be used further or destroyed."

48. To add paragraph 141^1 as follows:

"In case specified in item 137(d), samples should be taken from all shipments of all the goods imported and shipped prior the date of posing temporary restrictions on a particular manufacturing facility. The performed laboratory testing should cover all safety indicators of the relevant group of parameters."

49. To add paragraph 141^2 as follows:

"In cases specified in items 137(e) and 137(f), samples should be taken from the first ten shipments of the imported goods from a particular manufacturing facility*."

50. Paragraph 145 shall be revised as follows:

"In case specified in item 137(c), after a single detection of a violation, samples should be taken from ten shipments of the imported goods and within no more than three months. Samples should be taken only from the goods of the same type where the violation was found. The performed laboratory tests should cover all safety indicators of the relevant group of parameters*."

51. Paragraph 146: the first sentence shall be revised as follows:

"The authorized body of the Party shall inform the CA of the third country where the controlled goods were produced and the CA of the third country from where the controlled goods were exported to the CU, the owner of goods, the producer, the inspector of the administrative territory and the authorized bodies of the other Parties about the violations detected during the monitoring and/or enhanced laboratory control of the controlled goods as soon as possible but in any case no later than within 10 working days after receiving the laboratory testing results from the laboratory."

52. In paragraph 148 the words "upon request of the CA of a third country" shall be substituted with the words "upon agreement with the CA of a third country."

53. Paragraph 155: to replace figure "5" with figure "10."

54. In paragraph 159:

a) item (a): to substitute the word "or" with the words "and/or";

b) item (b): to delete the words: "or in case of its absence, given by the authorized body of the Party";

c) item (c) shall be revised as follows: "type of activity"

d) to add item (e) as follows:

“address of the establishment,”

e) to add item (f) as follows:

“region (district, province, county, state, etc.).”

55. Paragraph 160: after the words “have no” to add the word “right.”

56. Paragraph 161:

a) in item (a) the word “unrestricted” shall be substituted with the word “allowed”;

б) item (b) shall be reworded as follows:

“Temporary restrictions” - means that exports of controlled goods from the establishment is currently temporarily suspended. In case when temporary restrictions are posed by the authorized body of one of the Parties, the temporary restrictions shall apply to shipments of the controlled goods throughout the territory of the CU”;

57. Paragraph 162, item (c): the words “in the result of” shall be substituted with the words “based on the results of”.

58. Paragraph 165, item (c): the words “by the establishment” shall be substituted for the words “by this establishment.”

59. To add Paragraph 179 as follows:

“In accordance with the regulatory measures established by the Common veterinary requirements for the controlled goods imported into the customs territory of the Customs Union that are not required to be included in the Register of establishments of third countries, the following scheme shall be applied:

1) If an audit of a foreign official system of supervision was not carried out or is not completed or if, as a result of such audit, the foreign official system of supervision is not recognized as being capable to provide a level of protection at least equivalent to that provided by the CU requirements, the controlled goods shall be imported from establishments included in the Register of establishments of third countries.

2) such establishments shall be included in the Register of establishments of third countries on the basis of joint inspections or guarantees provided by the CA of the third country.

3) with regard to such goods, the establishments shall be included in the Register of establishments of third countries before the audit is completed and before the country’s official system is recognized as being at least equivalent to the level of protection meeting the CU requirements.”

“Note:

*

- in case of detection of incompliance of the controlled goods based on the results of monitoring tests for one or more microbiological indicators, a series of tests shall be conducted under the conditions of enhanced laboratory control covering the overall group of microbiological indicators,
- in case of detection of incompliance of the controlled goods based on the results of monitoring tests for one or more chemico-toxicological indicators, a series of tests shall be conducted under the conditions of enhanced laboratory control covering the overall group of chemico-toxicological indicators,
- in case of detection of incompliance of the controlled goods based on the results of monitoring tests for one or more radiological indicators, a series of tests shall be conducted under the conditions of enhanced laboratory control covering the overall group of radiological indicators,
- in case of detection of incompliance of the controlled goods based on the results of monitoring tests for one or more biochemical indicators, a series of tests shall be conducted under the conditions of enhanced

laboratory control covering the overall group of biochemical indicators.

Draft

Annex No. 2
To the Regulation on common system of joint inspections
of facilities and sampling of goods (products),
subject to veterinary control (supervision)

Guidelines for Inspectors for Confirming Equivalence of Applied Veterinary Measures during Inspections of Objects that are Subject to Veterinary Control in Third Countries and Audit of Official Control Systems of Third Countries

I. Preamble

These guidelines are designed taking into account:

1. The fact that some importing and exporting countries have different systems for inspection of objects controlled by veterinary supervision. These differences are due to differences in the prevalence of certain risks selected by the country risk management activities, and the differences in the historical development of systems of veterinary supervision.

2. In such circumstances, in order to facilitate trade and thus to protect animal and human health, the exporting and importing country can organize a joint analysis of the efficiency of veterinary and sanitary measures of the exporting country in achieving the appropriate level of veterinary and sanitary protection in the importing country consistent with the principle of equivalence under the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization (WTO SPS Agreement).[2]

3. Application of the principle of equivalence is mutually beneficial for both the importing country and the exporting country. Protecting animal and human health, it facilitates trade and reduces the costs of regulation to governments, industry, producers and consumers, enabling the exporting country to use the most effective means in the circumstances in order to achieve an adequate level of protection of the importing country.[3]

4. Importing countries must avoid application of unnecessary measures if they are already carried out by the exporting country. Importing countries should be able to reduce the frequency and volume of confirming measures following the decision on the equivalence of measures applied in the exporting country.

5. Normative legal acts of the Customs Union:

- Agreement on the Customs Union on veterinary and sanitary measures of 11 December 2009;
- Decision of the Customs Union Commission of June 18, 2010 No. 317 "On the application of veterinary and sanitary measures in the Customs Union" (as amended by the decision of the Commission

[2] In accordance with the definition of "equivalence" in Section 3, the equivalent measures (i.e. measures that are different from those used by the importing country, but, nevertheless, ensuring appropriate level of protection of the importing country) must be different from measures that coincide with those in the importing country.

[3] Benefits to the exporting country on the application of the principle of equivalence can be rejected if the request for equivalence is used as an excuse for breaking the existing trade. Such action of the importing country would be contrary to the principles of international trade.

of the Customs Union No. 342 of August 17, 2010, No. 455 of November 18, 2010, No. 623 of April 7, 2011, No. 724 of June 22, 2011);

- Decision of the Customs Union Commission No. 625 of April 7, 2011 "On ensuring the harmonization of legislation of the Customs Union on the application of sanitary, veterinary and phytosanitary measures with international standards";

- Decision of the Customs Union Commission No. 721 of June 22, 2011 "On the application of international standards, recommendations and guidelines";

- Decision of the Customs Union Commission No. 801 of September 23, 2011 "On the Regulation on the common procedure of the examination of legal acts of the Customs Union on the application of sanitary, veterinary and phytosanitary measures";

- Decision of the Customs Union Commission No. 834 of October 18, 2011 "On the Regulation of a single system of joint inspections of sites and sampling of goods (products) subject to veterinary control (supervision)."

- Decision of the Customs Union Commission No. 835 of October 18, 2011 "On the equivalence of sanitary, veterinary and phytosanitary measures, and risk assessment."

6. When inspecting the controlled objects the inspector shall consider the Codex Alimentarius guidelines, such as the CAC / RCP 1-1969 (recommended international general principles of food hygiene), CAC / RCP 58 - 2005 (code of hygienic practice for meat), CAC / RCP 57-2004 (Code Hygienic Practice for Milk and milk products), CAC / RCP 52-2003 (Code of practice for fish and fishery products) and other relevant international standards, guidelines and related documents.

II. Sphere of application

7. Definitions present in the document correspond to the Codex Alimentarius and the WTO SPS Agreement.

Hazard: Biological, chemical or physical agents in the controlled products that have the potential to cause adverse effects on health.[4]

Risk: The probability of adverse effects on health and the severity of the impact, which follows logically from the dangerous controlled goods.

Risk assessment: assessment of the likelihood of entry, establishment, or spread of a pest or disease within the territory of the importing country with respect to sanitary or phytosanitary measures which might be applied, and the associated potential biological and economic consequences; or assessment of the possible adverse effects on human or animal health, arising from the presence of additives, contaminants, toxins or disease-causing organisms in controlled goods.

Scientifically-based process consisting of the following steps: 1) hazard identification, 2) hazard characterization and 3) exposure assessment, and 4) risk characterization.[4]

The appropriate level of veterinary and sanitary protection (hereinafter – the ALOP): The level of protection that is deemed appropriate for the protection of human life and health in the country establishing veterinary and sanitary measures. (In other words, this concept can be defined as an "acceptable level of risk").

Equivalence of veterinary and sanitary measures:[5] Equivalence - a condition in which the veterinary and sanitary measures applied in the exporting country, although different from those used in

[4] Commission "Codex Alimentarius": Procedures Manual (Version 12), pages 43-44.

the importing country, achieve the level of veterinary and sanitary protection, corresponding to the level of the importing country, as demonstrated by the exporting country.

III. General principles for determination of equivalence

8. Determination of equivalence of veterinary and sanitary measures relating to inspection of the controlled objects is based on the application of the following principles:

a) The importing country has the right to determine the level of veterinary and sanitary protection, which it considers necessary for the protection of animal and human health.[6] ALOP may be expressed in qualitative and quantitative terms.

b) Veterinary and sanitary measure[7] used in the importing country, shall actually achieve the ALOP of the importing country and should be applied in accordance with the provisions of the WTO SPS Agreement.

c) The importing country must describe how its veterinary and sanitary measure achieves the ALOP.

d) The importing country must recognize that the veterinary and sanitary measures other than its own, can achieve the ALOP of the importing country.

e) Veterinary and sanitary measure, proposed by the exporting country as equivalent must achieve the ALOP of the importing country.

f) At the request of the exporting country the importing country within a reasonable time should rapidly begin consultations to determine the equivalence of certain veterinary and sanitary measures[9].

g) The exporting country should objectively demonstrate that its veterinary and sanitary measure can achieve the ALOP of the importing country.

h) A comparison of veterinary and sanitary measures of the countries should be done in an objective and scientifically justified way.

i) If during the demonstration of equivalence a risk assessment is used, countries should make every effort to achieve consistency in the methods used, using, where appropriate, the internationally accepted methodology and taking into account the relevant texts of the "Codex Alimentarius" Commission (hereinafter - the Codex).

j) The importing country must take into account the knowledge and experience gained by the inspection of controlled objects in the exporting country in order to carry out the determination in a more effective way and faster.

k) The exporting country should provide access to the inspection and certification systems, which are the subject of the equivalence determination, for their review and evaluation at the request of

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[5] Equivalence is defined in CAC / GL 26-1997 as "the ability of different systems of inspection and certification meet the same objectives."

[6] Agreement on SPS measures defines the rights and obligations of WTO Members in respect of determining the appropriate level of sanitary protection.

[7] A reference to "measure" in this section in the singular can also mean a reference to "measures" or "a package of measures", depending on the circumstances.

[9] Guidelines for the development, implementation, evaluation, and accreditation of the systems of inspection and certification of imports and exports of food, CAC / GL 26 - 1997.

the importing country bodies supervising the control goods.

l) All equivalence assessments should take into account the means, by which equivalence is maintained.

m) Countries should ensure transparency both in the demonstration, and the evaluation of equivalence, providing consultations to all interested parties, in cases where this is feasible. Exporting and importing countries should consider the procedure for evaluating the equivalence in coordination with each other.

n) In order to help the exporting country to demonstrate the equivalency of its inspection and certification systems, the importing country should without hindrance provide sufficient information about its system of control.

o) The importing country should consider favorably the request of a developing country exporting country to provide appropriate technical assistance that will contribute to a better determination of equivalence.

IV. Conditions for determination of equivalence

9. The determination of equivalence may be required for any veterinary and sanitary measure or series of measures relating to controlled goods. Appropriate veterinary and sanitary measures, which form a system of veterinary control in the exporting country, which are not the object of equivalence determination, must meet the requirements of the importing country.

10. The scope of determination of equivalence should depend on previous experience, knowledge, and confidence that the importing country takes into account the measures of veterinary control of the exporting country.

11. When the importing country has accumulated experience, knowledge, and confidence in the veterinary control measures, in respect of which equivalence is evaluated, and the countries agree that the import requirements are fully met (for example, when there is an experience of trade), determination of equivalence of veterinary and sanitary measures can be carried out without further consideration of other relevant measures constituting the system of veterinary control.

12. If the importing country has no accumulated experience, knowledge, or confidence in the veterinary control measures, whose equivalence is being assessed, and the countries have not established that the import requirements are fully met (for example, if the proposal on trade in controlled goods is made for the first time), determination of equivalence of veterinary and sanitary measures would require further consideration of the relevant measures, which form the basis of the system of veterinary control.

13. In order to determine the equivalence, the veterinary and sanitary measures associated with the system of inspection can be roughly classified as follows:

a) Infrastructure: including the legal framework (e.g., food legislation and implementing laws) and administrative systems (e.g., organization of national or regional authorities, the law enforcement system, etc.);

b) a draft program, implementation and monitoring: including documents on systems, monitoring, implementation, criteria for decision-making and action, laboratory facilities, transport infrastructure and regulations on certification and audits, and / or

c) specific requirements, including requirements applicable to individual facilities (e.g. premises, structures), equipment (e.g. models of mechanisms that come into contact with food products), processes (e.g. HACCP plans), procedures (e.g. pre-and post-mortem inspections), tests (e.g. laboratory tests for microbiological and chemical hazards), and the methods of sampling and inspection.

14. This categorization is likely to facilitate an agreement between the countries based on a

comparison of veterinary and sanitary measures that are the subject of determination of equivalence (see Section V). In the future, breaking measures into certain categories can help countries to simplify determination of equivalence relating to other veterinary and sanitary measures that make up the control system of controlled goods.

V. Objective basis of comparison

15. Since veterinary and sanitary measures applied by importing country are designed to achieve its ALOP, the exporting country can demonstrate achievement of the ALOP of the importing country by demonstrating that the measures, which it proposes as equivalent, have the same effect in achieving the ALOP of the importing country, as the appropriate veterinary and sanitary measures applied by importing country with the help of an objective basis of comparison.

16. The importing country on request of the exporting country shall specify as precisely as possible, the objective basis for comparison of the veterinary and sanitary measures, proposed by the exporting country with its own measures[11]. The dialogue between the exporting country and the importing country will promote understanding and agreement on the objective basis for comparison. Additional information provided by the importing country, may include:

a) the reason / purpose of veterinary and sanitary measures, including identification of specific risks, which are addressed by the measure;

b) the interrelationship of the veterinary and sanitary measures and the ALOP, i.e. how the veterinary and sanitary measure achieves the ALOP;

c) if necessary, the expression of the level of hazard control in controlled goods, achieved by the veterinary and sanitary measure;

d) scientific basis for the veterinary and sanitary measure under consideration, including risk assessment, if necessary;

e) any additional information that may assist the exporting country in presenting an objective demonstration of equivalence.

VI. Procedure for determination of equivalence

17. The importing country should make public the details of its veterinary and sanitary measures to the exporting country on request. The exporting country should review all applicable veterinary and sanitary measures of the importing country with respect to the controlled goods in question and identify those that meet the requirements and those, which require determination of equivalence. Importing and exporting countries should use agreed processes for the exchange of relevant information to assist in determining equivalence. This information must be limited to that, which is necessary for this purpose.

18. Determination of equivalence is ensure both by the exporting country and the importing country, following the successive stages, such as those described below and illustrated in Figure 1. The

[11] The objective basis for comparison of veterinary and sanitary measures that are classified as "Infrastructure" is likely to have a qualitative nature, for example, ability of legislation to control food and to achieve the main objectives of food security. Objective basis for comparison of veterinary and sanitary measures that are classified as "Specific requirements" is likely to have a quantitative nature, for example, comparison of the level of control of hazards, achieved by this measure. The objective basis for comparison of veterinary and sanitary measures that are classified as "the program" is likely to contain a mixture of qualitative and quantitative elements, for example, correct application of principles and the corresponding critical limits in the food control system HACCP.

Parties must work together on these steps in order to reach agreement:

a) The exporting country indicates the veterinary and sanitary measure of the importing country, which she would like to replace with another measure, and asks about the reason / ground for application of that measure.

b) The importing country provides the reason / ground for the application of that measure and other relevant information in accordance with paragraph 15.

c) In accordance with paragraph 15 the importing country should indicate as accurately as possible an objective basis for a comparative analysis of veterinary and sanitary measures proposed by the exporting country and its own. At the initiative of the exporting country, the importing and exporting countries should enter into a dialogue on the objective basis for the specified comparison in order to reach agreement.

d) The exporting country prepares a package of documents, using a risk assessment or other relevant methodology (based on feasibility), to demonstrate that with the application of other veterinary and sanitary measure an appropriate level of veterinary and sanitary protection (ALOP) of the importing country is achieved, and provides it to the importing country.

e) The importing country analyzes the documents and, if this is enough, uses the specified documents to determine whether the appropriate level of protection (ALOP) of the importing country is achieved by the measure of the exporting country.

f) If the importing country has any concerns about the package of documents submitted, it should in no time notify the exporting country thereof and should elaborate on the reasons for its concerns. If possible, the importing country should submit proposals for the way, in which these concerns can be addressed.

g) The exporting country should respond to these concerns by providing additional information, changes in its proposals, or taking other action as appropriate.

h) The importing country notifies the exporting country of its view over the relevant time period. In case of a decision that the measure is not equivalent, the importing country provides a scientific justification for its decision on the fact that the mentioned sanitary measure is not equivalent, i.e. that when it is used an appropriate level of sanitary protection (ALOP) of the importing country is not achieved.

i) Efforts should be made to resolve differences of opinion concerning the evaluation of the submitted documents, both preliminary, and final.

VII. Assessment of equivalence

19. Assessment of equivalence by the importing country should be based on the transparent analytical process that is objective and consistent, and includes consultations with all interested parties, to the extent practicable and appropriate.

20. In assessing the equivalence of veterinary and sanitary measures the following should be taken into account:

a) the experience, expertise and reliability of the systems of inspection and certification of food products in the exporting country (see Section IV);

b) supporting data provided by the exporting country;

c) analysis of the strength of the relationship between this veterinary and sanitary measure of the exporting country and the achievement of an appropriate level of veterinary and sanitary protection of the importing country, as reflected in an objective basis for comparison (see Section V);

d) parameters must be specified in quantitative terms, to the extent possible;

e) the adequacy of the quality characteristics in cases where the level of hazards control in controlled goods is not quantifiable;

f) Analysis of variability and other sources of uncertainty in the data;

g) analysis of the expected impact on animal and human health as a result of this veterinary and sanitary measure of the exporting country;

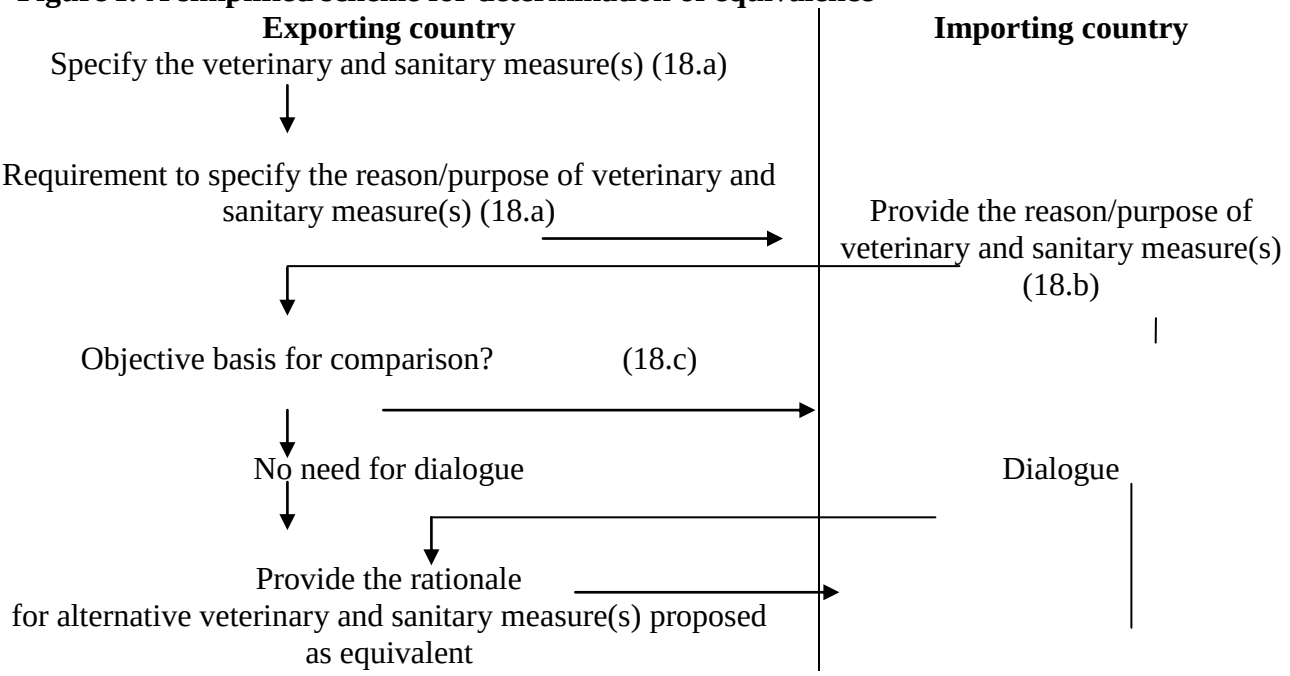
h) Codex texts on the issues of safety of the controlled goods.

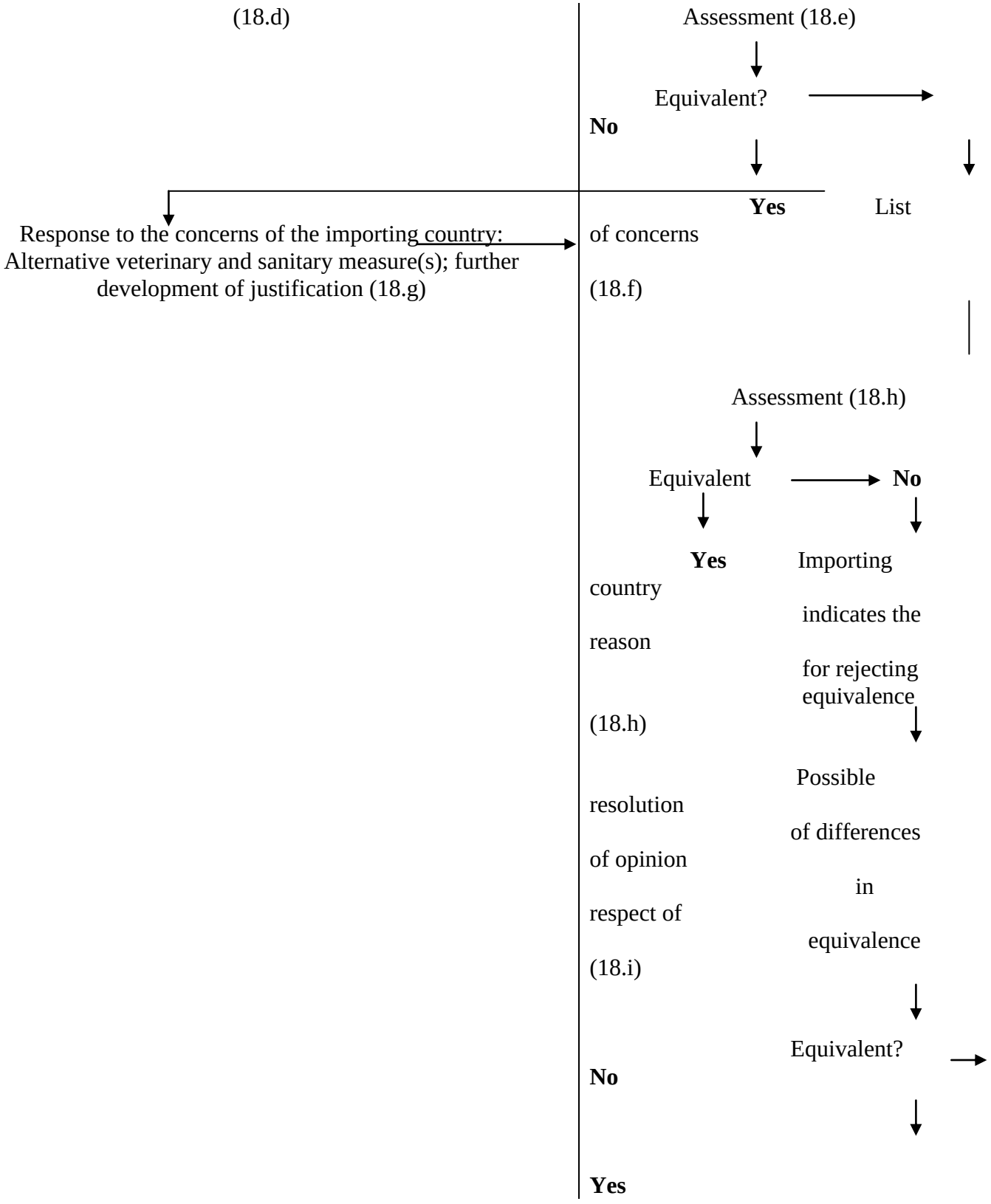
After conducting any assessment of equivalence, the exporting and importing countries should immediately inform each other of important changes in their support programs and infrastructure that may have an impact on the determination of equivalence.

21. Procedures Manual for carrying out assessments of the exporting country's systems by the importing country can be found in the Annex.

22. During audits and joint inspections the norms and requirements of the national legislation that are in conflict with the norms and requirements of the Customs Union shall not be applicable.

Figure I: A simplified scheme for determination of equivalence




(18.d)
Assessment (18.e)
Equivalent?
No
Yes
List of concerns
(18.f)
Response to the concerns of the importing country: Alternative veterinary and sanitary measure(s); further development of justification (18.g)
Assessment (18.h)
Equivalent
No
Yes
Importing country indicates the reason for rejecting equivalence
(18.h)
Possible resolution of differences of opinion in respect of equivalence
(18.i)
Equivalent?
No
Yes

Annex A

Procedure manual for conducting an assessment of an exporting country's systems by an importing country.

Principles to the actions by inspectors and experts of the competent authorities of the importing and exporting country in the process of assessment

A. Assessments should focus on the result, they should be transparent, constructive, and should be conducted in an agreed, ethical, and professional manner, as necessary, with respect to confidential information.
B. The importing and exporting countries should apply an agreed process for reviewing all the issues that may arise during the process assessment.
C. The importing and exporting countries should agree on the appropriate method of assessment before its start, based on the agreed scope and purpose.

Principles of the process of assessment

D. The process of assessment should be planned, it should be systematic, transparent, consistent, fully documented, and communicated.
E. The plan, including the rationale, objectives, scope, requirements and evaluation methods for assessing the system of state inspection and certification should be clearly defined by the importing country, communicated to the competent body(ies) of the exporting country and agreed with him within a reasonable time prior to the start of assessment.

Principle of accounting for assessment

F. Agreed corrective actions, timeframes and subsequent verification procedures should be clearly established and documented.
G. The final report on assessment should be clear and transparent, it can be published, if necessary, subject to confidentiality.

Principle A

Assessments should focus on the result, they should be transparent, constructive, and should be conducted in an agreed, ethical, and professional manner, as necessary, with respect to confidential information.

1. Inspectors and experts from the competent authority of the importing country should be able to demonstrate that the results of the assessment, conclusions and recommendations are focused on whether there is a likelihood that the desired results will be achieved by the system and that they are supported by objective data or the data that have been approved as accurate and reliable.

2. During the assessment, all arising issues should be solved by the inspectors and experts of the competent authorities in an agreed, ethical and professional manner.

3. Inspectors and experts from the competent authorities of the importing country should observe impartiality. Inspectors and experts should have the appropriate qualifications, experience, and must be

trained both in the relevant field of expertise, and in the field of audit methods.

4. During the assessment the inspectors and experts of the importing country should ensure that confidential information is protected.

Principle B

The importing and exporting countries should apply an agreed process for reviewing all the issues that may arise during the process assessment

5. Prior to the start of assessment, the key elements of the process of addressing issues that may arise during the assessment should be agreed upon. The competent authorities of the importing and exporting countries should seek to resolve all issues arising in the assessment together in an open and transparent manner. If any questions remain unresolved, they should be included in a report on the assessment with appropriate explanations.

Principle C

The importing and exporting countries should agree on the appropriate method of assessment before its start, based on the agreed scope and purpose.

6. The most efficient and effective method should be chosen, that which can evaluate the effectiveness of the public system for inspection and certification of the exporting country, including the possibility for the competent body(ies) of the exporting country to organize and implement control, and provide the necessary guarantees to the importing country.

7. When choosing a method of assessment, it is important to consider the reason for the assessment. For example, assessments may be part of a risk analysis conducted before trade is launched, they can assess a system of state inspection and certification or control of a single element (e.g., chemical residues) or special exporting establishments.

8. When choosing a method of assessment, the experience, knowledge and reliability[1] of the importing country regarding the system of state inspection and certification of the exporting country should be taken into account.

Audit Methods

9. The method of the audit, which is often called a "system audit," should focus on the assessment whether the system of state inspection and certification, or its components, of the exporting country serves its purpose.

10. In contrast to the study of all the procedures, system audits are based on the study of an example

[1] Paragraph 9-14 of Appendix to the *Guidelines for assessing the equivalence of sanitary measures associated with the system of inspection and certification of food products* (CAC / GL 53-2003) provide additional guidance as to what is the experience, expertise and reliability, as well as expanding the information out in paragraph 10.12 of this manual.

system procedures, documents or records and, if required, a number of sites within the scope of the system being audited.

11. The system approach focuses on the system(s) of control and according to it, all items identified as compliant/incompliant should be considered in the context of the whole system.

12. A system audit may include the study of the elements (legal framework, means of control, procedures, facilities, equipment, laboratories, vehicles, communications equipment, personnel and training to achieve the objectives of the inspection and certification prorgram), or, if necessary, other elements.

Method of inspection

13. In some cases, a method of inspection may be used to confirm the efficiency of control inspections conducted by a competent body(ies) in the exporting country.

14. Inspections may include the study of the following:

(a) How the company meets the requirements, including consideration of specific activities and product specifications, supervision and review of the company's activities and the relevant records of activities;
(b) The number of employees in the company, if it is specified in the request;
(c) What inspectors are allowed to do, if it is particularly pointed out in the requirements.

Principle D

The process of assessment should be planned, it should be systematic, transparent, consistent, fully documented, and communicated.

15. Documents confirming the findings, conclusions and recommendations should be executed so that the efficiency of the assessment and presentation of its results were uniform, transparent, and reliable.

16. The competent authorities of the importing and exporting countries should be consulting each other in preparation for and during the assessment on all points of the process, from development of a plan for the assessment to the final report and decisions on all issues that arise during the assessment. To ensure regular and transparent communication, the competent authorities of the importing and exporting countries should designate contact persons or points of contact for the assessment.

Principle E

The plan, including the rationale, objectives, scope, requirements and evaluation methods for assessing the system of state inspection and certification should be clearly defined by the importing country, communicated to the competent body(ies) of the exporting country and agreed with him within a reasonable time prior to the start of assessment.

17. In determining the rationale, objectives, scope, frequency, and methods of assessment the competent

authority of the importing country should take into account the established level of experience, knowledge, and reliability, along with a history of previous assessments for the period since the last assessment, and any other relevant factors.

18. The procedure of systematic evaluation for the assessment should be based on the pre-defined and structured program in accordance with the purpose of assessment.

Notice

19. The following information should be exchanged at the time of initial request and before the start of assessment of an existing system of state inspection and certification:

a) Rationale for or the need for assessment may occur for several reasons, including the legal obligations of the importing country or the need to understand the respective roles of the competent authorities of the importing country and the exporting country or the need to ensure the ability of the exporting country's system or facilities for food production/processing to ensure compliance with the requirements.
b) The purpose of assessment may, for example, be as follows: confirmation of the fact that the exporting country's measures reach the ALOP of the importing country. If necessary, an audit of a risk assessment component of the food safety control system of the exporting country to support risk management practices may be conducted.
c) It is necessary to define the scope of assessment, that is: whether the assessment covers the entire system, or only some of its components, measures, technical requirements, or products.
d) It is necessary to define the intended method of assessment, including requirements, which will be covered by the assessment of the state system of inspection and certification of the exporting country.

20. In all cases, the competent authority of the importing country shall inform the competent authority of the exporting country of the proposed assessment so that the competent authority could organize the necessary activities, such as logistics and information gathering. If the rationale for the assessment is an important public health problem, the notice shall reflect the urgency associated with the risk to human health.

Preparation for assessment

21. It is necessary to prepare a plan for carrying out the assessment, including methods of assessment, timing, and exchange of necessary information, and submit it to the competent authority of the exporting country within a reasonable period of time. The plan should include the following:

a) Objectives and scope of assessment, including whether it is a separate assessment or if it is related to another assessment (for example, control of the previous assessment) or a series of assessments;
b) Areas / elements for review / analysis, which may include the records and evaluation of checklists;
c) The expected period for carrying out the assessment and drawing the report;
d) The criteria for assessment of the public system for inspection and certification of the exporting

country;

e) Contact person for the members of the assessment team, who can negotiate the details of the assessment plan, and - if necessary - the members of the assessment team, including foreign auditors / inspectors, chief auditor / inspector, technical experts and interpreters;
f) The language that will be used during the assessment, including translation, availability of the competent and impartial interpretation and resources.
g) Specification of the type, and if possible / necessary the places of visits (e.g., offices, laboratories, or other facilities), and the timing and responsibility for the notification about the places if necessary (although this can be done at the opening meeting prior to the assessment);
h) Date of assessment, dates of the opening and final meetings and the expected date for communicating the comments on the assessment;
i) route and other logistics necessary for the assessment visit,
j) Methods of protection of confidential information.

22. Since it is necessary to ensure compliance with the assessment plan, it should be flexible so that it would be possible to make changes based on the information collected prior to or at the time of the assessment. Proposed significant changes to the assessment plan should be made only under mitigating circumstances, and they should be reported as soon as possible to the appropriate authority.

23. It is necessary to agree beforehand on the language to be used during the assessment, including translation, availability of the competent and impartial interpretation and resources.

24. To the extent possible, documentary information required for the planning, conducting and completion of the assessment is to be sought and provided prior to assessment using means of electronic communication as possible.

a) A request for the preparation of an assessment should specify the scioe of assessment and its purpose.
b) If this is a verification assessment, then the exporting country will only need to provide information that has changed since the previous assessment, or has not been requested in the previous assessment;
c) If the purpose of a request for information is not clear to the exporting country, and there are several problems associated with the requested information, the exporting country may require that the importing country provide explanations of the purpose and use of such information.
d) If a visit to a facility is proposed as a method for assessment, prior to the visit, it is necessary to analyze the documents that describe the system, including legislative support.

25. In some cases, the assessment can be suspended or terminated prior to a facility visit, depending on the nature of the information provided by the competent authority of the exporting country, and in this case the competent authority of the importing country should clearly inform the competent authority of the exporting country of the cause. The competent authority of the exporting country should have the opportunity to receive explanations on the information provided, if deemed necessary.

Starting / Opening Assessment Meeting

26. If the assessment includes a visit, it is necessary to hold a starting or introductory meeting.

a) The meeting shall be held at a place designated by the competent authority of the exporting country.
b) The meeting should address all aspects of the assessment plan, including final adjustments; the purpose of the meeting - to review the system of state inspection and certification in the country and to confirm the parameters and logistics of the assessment.
c) It is necessary to agree on ways to ensure continuous interaction and communication between the parties during the assessment.

Closing / Summary Meeting

27. If the assessment includes a visit, it is necessary to hold a closing or summary meeting.

a) The meeting shall be held at a place designated by the competent authority of the exporting country.
b) The evaluation team should summarize and present the main findings and preliminary conclusions. It is necessary to specify any inconsistencies and bring objective evidence to support the conclusions. Correction of inconsistencies should be the responsibility of the competent authority of the exporting country and verified by the competent authority of the importing country, including the verification assessment if necessary.
c) At the meeting the competent authority of the exporting country shall be given the opportunity to ask questions and get clarification on the results and the comments made at the meeting.

Principle F

Agreed corrective actions, timeframes, and verification procedures should be clearly established and documented.

Principle G

The final report on assessment should be clear and transparent, and it can be published subject to confidentiality of information, where applicable.

28. The side, which was assessed, should be given the opportunity to review a draft report during an agreed period of time, to submit comments and to correct factual errors prior to compiling the final version of the report. The final report shall include or be accompanied by comments of the competent authority of the exporting country.

29. The assessment report should present a balanced picture of results, and include conclusions and recommendations that accurately reflect the results. The report should:

a) contain the purpose, scope, and results;
b) contain the criteria and the process of assessment;
c) include assessment results with supporting evidence for each conclusion along with the importance, which was discussed at the final meeting;
d) be accessible by prior agreement with the competent authority of the exporting country,

including comments from the competent authority of the exporting country in order to improve the accuracy of the report;

e) consider the time frame for finalizing the report and for response measures, as agreed between the competent authorities of the importing country and the exporting country;
f) include a description of how corrective actions will be communicated and agreed upon, including the way for carrying out a verification assessment;
g) if necessary, include a checklist of elements to be assessed, to support the findings;
h) include the list of results of the assessment;
i) include the key issues and problems that arose during the assessment if there is no agreement on the findings and corrective actions;
j) include uncertainties and / or any obstacles that have arisen and may have affected the reliability of the conclusion of the assessment,
k) contain description of the areas not covered in the assessment report, although falling within the scope, and the reasons for the deviation from the agreed scope.

30. It is necessary to clearly indicate the timing and the protocol of the verification assessment. Confirmation of corrective actions may include:

a) guarantees provided by the competent authority of the exporting country;
b) documents submitted by the competent authority of the exporting country, or
c) the declared corrective actions in the subsequent assessment.

31. In compiling and subsequent distribution of the assessment report, confidential information should be considered.

32. After drawing up the final report the competent authorities of the importing and exporting country should discuss and possibly agree on whether the report will be published and how it should be done in view of the confidentiality of information, if any.

Annex No. 3
To the Regulation on common system of joint inspections
of facilities and sampling of goods (products),
subject to veterinary control (supervision)

1. GUIDELINES FOR FACILITIES AND VESSELS FOR HARVESTING AND PROCESSING OF FISH, AQUATIC MAMMALS, AQUATIC INVERTEBRATES, AND OTHER AQUATIC ANIMALS (APPENDIX A).

2. GUIDELINES FOR INSPECTING DAIRY INDUSTRY ESTABLISHMENTS (APPENDIX B).

3. GUIDELINES FOR INSPECTING ANIMAL SLAUGHTERHOUSES AND MEAT INDUSTRY ESTABLISHMENTS (APPENDIX C).

Appendix A

GUIDELINES FOR FACILITIES AND VESSELS FOR HARVESTING AND PROCESSING OF FISH, AQUATIC MAMMALS, AQUATIC INVERTEBRATES, AND OTHER AQUATIC ANIMALS

1. DESIGN AND CONSTRUCTION OF FISHING AND HARVESTING VESSELS FOR PROCESSING OF FISH, AQUATIC MAMMALS, AQUATIC INVERTEBRATES AND OTHER AQUATIC ANIMALS (HERINAFTER – AQUATIC ANIMALS).

When designing and constructing vessels that are used for harvesting (catch) and processing aquatic animals the following should be taken into consideration:

1) Easy cleaning and disinfection

Vessels should be designed and constructed to minimize sharp inside corners and projections in order to avoid dirt traps;

A good supply of clean water or potable water at adequate pressure;

Construction should facilitate ample drainage, and in addition:

Exclude counter and cross flows of raw material and edible fish product;

Exclude counter and cross flows of edible fish products with processing waste.

Internal surface of tanks and capacities should be waterproof, made of plain material or be plainly painted, can be easily subjected to cleaning and desinfection. Coatings should not contaminate fish products with the substances, harmful for human health.

2) To minimize contamination

All surfaces in handling areas should be non-toxic, smooth and waterproof, easily accessible for removal fish slime, blood, scales and guts and to reduce the risk of physical and microbial contamination.

Where appropriate, adequate facilities should be provided for the handling and washing of aquatic animals and also should have an adequate supply of cold potable water or clean water for that purpose.

Adequate facilities should be provided for washing and disinfecting equipment, where appropriate.

The intake for clean water should be located to avoid contamination.

All plumbing and waste lines should be capable of working under parameters indicative of peak demand.

Non-potable water lines should be clearly identified and separated from potable water to avoid contamination.

Objectionable substances, which could include bilge water, smoke, fuel oil, grease, drainage and other solid or semi-solid wastes, should not contaminate aquatic animals and their production.

Containers for offal and waste material should be clearly identified, suitably constructed with a fitted lid and made of waterproof material.

Separate and adequate areas (facilities) should be provided for storage :

poisonous or harmful substances;

dry storage of materials, packaging, etc.;

offal and waste materials

Adequate hand washing and toilet facilities, isolated from aquatic animals handling areas, should be available where appropriate.

Prevent the entry of birds, insects or other pests, animals and vermin.

To minimize damage to aquatic animals during processing

In handling areas, surfaces should have a minimum of sharp corners and projections;

In boxing and shelving storage areas, the design should preclude excessive pressure being exerted on aquatic animals.

Chutes and conveyors should be designed to minimize physical damage of aqautic animals caused by long drops or crushing, etc.;

The fishing gear and its usage should minimize damage and deterioration to aquatic animals.

3)To minimize damage during harvesting of aquacultured and aquatic inadvetebates (aquacultured objects)

When harvesting aquaculture objects using seines and nets or other means and when transported live to facilities:

Seines, nets and traps should be carefully selected to ensure minimum damage during harvesting;

Harvesting areas and all equipment for harvesting, catching, sorting, grading, conveying and transporting of live products should be designed for their rapid and efficient handling without causing mechanical damage.

Surfaces, equipment and materials, that are in contact with fish, aquatic invertebrates and their products, should be constructed of suitable corrosion-resistant material, plain material that are easily cleaned and desinfected. Coatings of surfaces should be solid and constructed of materials, intended for contact with edible production.

Where fish is transported live, care should be taken to avoid overcrowding and to minimize bruising;

Where fish are stored or transported live, care should be taken to maintain factors that affect fish health (e.g. CO2, O2, temperature and nitrogenous wastes and maintaining optimal temperature, etc).

2. FISH FACILITY DESIGN AND CONSTRUCTION

The territory of fish processing facility should have transport, pedestrian and processing areas with solid waterproof surface, storm sewage system that prevents atmospheric participations, fence and meet sanitary requirements in reference to landscape and planting trees, natural lighting and air ventilating, level of standing ground waters.

Location of fish processing facility should not be subjected to unfavorable effects from other nearby facilities.

The facility should have sufficient processing grounds that allow carry out production in appropriate hygienic conditions.

Organization and facility planning should done in a way to prevent product contamination and isolate “dirty” and “clean” parts of the building.

The following should be taken into consideration when constructing a fish processing facility:

exclude counter and cross flows of raw material and edible fish product;

exclude counter and cross flows of edible fish products with production wastes;

minimize process delays which could result in further reduction in essential quality of aquatic animals and their production.

aquatic invertebrates are highly perishable foods and should be handled carefully and chilled without undue delay.

Therefore, the facility should be designed to facilitate rapid processing and subsequent cold storage.

The design and construction of a facility should take into consideration the following:

1) Easy cleaning and disinfection

The surfaces of walls, partitions and floors should be made of impervious, non-toxic materials;

All surfaces with which aquatic animals and their products might come into contact should be of corrosion-resistant, impervious material that is light-coloured, smooth and easily cleanable;

Walls and partitions should have a smooth surface up to a height appropriate to the operation;

Floors should be constructed to allow adequate drainage;

Ceilings and overhead fixtures should be constructed and finished to minimize the buildup of dirt and condensation, and the shedding of particles;

Windows should be constructed to minimize the buildup of dirt and, where necessary, be fitted with removable and cleanable insect-proof screens. Where necessary, windows should be fixed;

Doors should have smooth, non-absorbent surfaces;

Joints between floors and walls should be constructed for ease of cleaning.

2) To minimize contamination

Facility layout should be designed to minimize cross-contamination products with raw material and that may be accomplished by physical or time separation of their flows.;

All surfaces in handling areas should be non-toxic, smooth, impervious and in sound condition in order to minimize the buildup of fish slime, blood, scales and guts and to reduce the risk of physical contamination;

Working surfaces that come into direct contact with aquatic animals and their products should be in sound condition, durable and easy to maintain. They should be made of smooth, non-absorbent and non-toxic materials, and inert to aquatic animals and their products, detergents and disinfectants under normal operating conditions;

Adequate facilities should be provided for the handling and washing of products and should have an adequate supply of cold potable water for that purpose;

Suitable and adequate facilities should be provided for storage and/or production of ice;

Ceiling lights should be covered or otherwise suitably protected to prevent contamination by glass or other outside materials;

Ventilation should be sufficient to remove excess steam, smoke and objectionable odours, and cross-contamination through aerosols should be avoided.

Adequate facilities should be provided for appropriate storage of washing and disinfecting tools for premises and equipment;

Non-potable water lines should be clearly identified and separated from potable water to avoid contamination;

All plumbing and waste lines should be capable of supporting indicators of peak demands;

Accumulation of solid, semi-solid or liquid wastes should be minimized to prevent contamination;

Where appropriate, containers for offal and waste material should be clearly identified, suitably constructed with a fitted lid and made of impervious material;

Separate and adequate facilities (areas) should be provided in order to prevent contamination by:

poisonous or harmful substances;

dry storage of materials, packaging, etc.;

offal and waste materials with the purpose to prevent contamination with them, there should be:

Adequate hand washing and toilet facilities, isolated from handling area, should be available;

Prevent the entry of birds, insects or other pests and animals;

Water supply lines should be fitted with back-flow devices, where appropriate.

All personnel and processing facilities should be equipped as medical decontamination stations

and at entries should be equipped with hand washing facilities and for footwear cleaning and disinfection**.**

3) To provide adequate lighting

Adequate lighting should be provided to all work surfaces.

3. DESIGN AND CONSTRUCTION OF EQUIPMENT AND UTENSILS

Condition of the equipment and utensils should be performed in a way to minimize their contamination.

The design and construction equipment and utensils should take into consideration the following:

1) Sanitary cleaning and disinfection

Equipment should be durable and movable and/or capable of being disassembled to allow for maintenance, sanitary cleaning and disinfection.

Construction and assembley of equipment, containers and utensils coming into contact with aquatic animals and their products should be designed to provide for adequate drainage and constructed to ensure that they can be adequately cleaned, disinfected and maintained to avoid contamination.

Equipment and utensils should be designed and constructed to minimize sharp inside corners and projections and tiny crevices and gaps in order to avoid physical damage of product during processing and to minimize possibilities for dirt traps.

A suitable and adequate supply of cleaning utensils and cleaning agents, approved by the official agency having jurisdiction, should be provided.

2) To minimize contamination

All surfaces of equipment in handling areas should be non-toxic, smooth,
impervious and in sound condition to minimize the buildup of fish slime, blood, scales and guts and to reduce the risk of physical contamination;

Accumulation of solid, semi-solid or liquid wastes should be minimized to prevent contamination of fish;

Adequate drainage should be provided in storage containers and equipment;

Drainage should not be permitted to contaminate products.

3) To minimize damage

Surfaces should have a minimum of sharp corners and projections;

Chutes and conveyors should be designed to prevent physical damage caused by long drops or crushing;

Storage equipment should be fit for the purpose and not lead to crushing of the product.

4. HYGIENE MAINTENANCE PROGRAM

The hygiene maintenance program should consider potential effects of harvesting and handling of products, on-board vessel handling or in-plant production activities on the safety and suitability of aquatic animals and their products.

In particular, it should include implementing control in all points where contamination may exist and taking specific measures to ensure the production of a safe and wholesome product. The type of control and supervision needed will depend on the size of the operation and the nature of its activities. Measures for maintaining hygiene control should be implemented to:

prevent the buildup or timely removal of waste and debris;

protect aquatic animals and their products from contamination and dirt;

dispose of any rejected material in a hygienic manner;
monitor personal hygiene of staff and check whether they comply with hygiene norms;
monitor the pest control programme;
monitor cleaning and disinfecting programs;
monitor the quality and safety of water and ice supplies.

The hygiene maintenance program should take into consideration the following:

1) A permanent cleaning and disinfection schedule

A permanent cleaning and disinfection schedule should be drawn up to ensure that all parts of the vessel, processing facility and equipment therein are cleaned appropriately and regularly. The schedule should be reassessed whenever construction changes occur on the vessel, or processing facility and/or equipment. Part of this schedule should include a "clean as you go" policy.

A typical cleaning and disinfecting process may involve as many as seven separate steps:

2) Precleaning

Preparation of area and equipment for cleaning, involves steps such as removal of all aquatic animals and their products from area, protection of sensitive components and packaging materials from water, removal by hand or squeegee of fish scraps, wastes, etc.

3) Pre-rinse - A rinsing with water to remove remaining large pieces of loose material.

4) Cleaning - The removal of soil, food residues, dirt, grease or other objectionable matters.

5) Rinse - a rinsing with potable water or clean water, as appropriate, to remove all soil and detergent residues.

6) Disinfection - application of chemicals, approved by the official agency having jurisdiction, and/or heat to destroy most micro-organisms on surface.

7) Post-rinse - as appropriate, a final rinse with potable water or clean water to remove all disinfectant residues.

8) Storage - cleaned and disinfected equipment, container and utensils should be stored in a fashion that would prevent their contamination.

9) Check of the efficiency of the cleaning - the efficiency of the cleaning should be controlled as necessary. Handlers or cleaning personnel, as appropriate, should be well trained in the use of special cleaning tools and chemicals, and in methods of dismantling equipment for cleaning and they should be knowledgeable in terms of the significance of contamination and the hazards involved with poor quality implementation of cleaning and disinfection.

10) Designation of personnel for cleaning

In each processing plant or vessel, a trained individual should be designated to be responsible for the sanitation of the processing facility or vessel and the equipment therein.

11) Maintenance of premises, equipment and utensils

Buildings, materials, utensils and all equipment in the vessel or establishment – including drainage systems – should be maintained in a good state and order;

Equipment, utensils and other physical facilities of the plant or vessel should be kept clean and in good repair.

Procedures for the maintenance, repair, adjustment and calibration, as appropriate, of apparatus should be established, as needed. For each item of equipment, these procedures should specify the methods used, the persons in charge of their application, and their frequency.

12) Pest control systems

Good hygienic practices should be employed to avoid creating an environment conducive to

pests;

Pest control programs could include preventing access, eliminating harbourage and infestations, and establishing monitoring detection and eradication systems;

Physical, chemical and biological agents should be properly applied by appropriately qualified personnel and complied with established rules.

13) Supply of water, ice and steam

Water

There must be an adequate supply of hot and cold potable water and/or clean water where it necessary;

This potable water must be used whenever necessary to ensure that foodstuffs are not contaminated.

Ice

Ice should be produced using potable water or clean water.

Ice should be protected from contamination.

Steam

For operations that require steam, an adequate supply at sufficient pressure should be maintained.

Steam used in direct contact with fish and invertebrates or food contact surfaces should not constitute a threat to the safety or suitability of the food.

14) Waste management

Offal and other waste materials should be removed from the premises of a processing facility or vessel on a regular basis;

Facilities for the containment of offal and waste material should be properly maintained;

Vessel waste discharge should not contaminate vessel water intake systems or incoming product.

5. PERSONAL HYGIENE AND HEALTH

Personal hygiene and facilities should be such to ensure that an appropriate degree of personal hygiene can be maintained in order to avoid contamination.

Facilities and equipment

Facilities and equipment should include:

Adequate means of hygienically washing and drying hands;

Adequate toilet and changing facilities for personnel should be suitably located and designated.

Personnel hygiene

A person who is known to be suffering from, or who is a carrier of, any communicable disease or has an infected wound or open lesion should not be engaged in preparation, handling or transportation.

Where necessary, adequate and appropriate protective clothing, head coverings and footwear should be worn.

All persons working at a facility should maintain a high degree of personal cleanliness and should take all necessary precautions to prevent contamination.

Hand washing should be carried out by all personnel working in a processing area:

at the start of aquatic animals handling activities and upon re-entering a processing area;

immediately after using the toilet.

The following should not be permitted in handling and processing areas:

– smoking;

– spitting;

– chewing or eating;
– sneezing or coughing over unprotected food;
– the adornment of personal effects, such as jewellery, watches or pins, or other items that, if dislodged, might pose a threat to the safety and suitability of the products.

6. TRAINING

Aquatic animals hygiene training is of fundamental importance. All personnel should be aware of their role and responsibility in protecting aquatic animals from contamination and deterioration.

Handlers should have the necessary knowledge and skill to enable them to handle aquatic animals in accordance with hygienic rules.

Those who handle strong cleaning chemicals or other potentially hazardous chemicals should be instructed in safe handling techniques.

Each aquatic animals facility and vessels processing aquatic animals and their products should ensure that individuals have received adequate and appropriate training in the design and proper application of an HACCP system and process control. Training of personnel in the use of HACCP is fundamental to the successful implementation and delivery of the program in aquatic animals processing establishments (vessels).

The practical application of such systems will be enhanced when the individual responsible for HACCP has successfully completed a course.

Managers should also arrange for adequate and periodic training of relevant employees in the facility so that they understand properly the principles involved in HACCP.

7. GENERAL CONSIDERATIONS FOR THE HANDLING OF FRESH AQUATIC ANIMALS

If it is known that the shipment of aquatic animals or its part:

contain parasites,
infected by undesirable micro-organisms,
contaminated with pesticides and veterinary drugs,
contain premises of toxins
contain decomposed substances,
contaminated with substances that are known to be harmful for human consumption.

Unless this contamination can not be removed or reduced to an acceptable level by normal sorting and/or processing, the shipment of aquatic animals should not be further processed.

If aquatic animals determined as unfit for human consumption they should be removed and stored separately from the catch and either processed or disposed of in a proper manner.

All aquatic animals deemed fit for human consumption should be handled properly with particular attention paid to time of processing and its temperature control.

8. TIME AND TEMPERATURE CONTROL

Temperature is the single most important factor affecting the rate of aquatic animals and their products deterioration and intensity of multiplication of micro-organisms. Temperature control is the most effective method for ensuring food safety of food products from aquatic animals. Therefore, it is

essential that aquatic animals and their products to be chilled as quickly as possible and should be stored permanently at a temperature as close as possible to 0°C.

8.1 Minimum processing time – is a guarantee to mitigate probability of deterioration

To minimize probability of deterioration, it is important that chilling should commence as soon as possible, and fresh aquatic animals should permanently be kept chilled. They should be processed and distributed as quickly as possible and be kept chilled during all the time.

8.2 Permanent temperature control – is a means for preventing deterioration.

In the objective to ensure temperature control:

- Chilled or refrigerated water systems, where appropriate, should ensure that fish and other aquatic invertebrates are kept chilled at a temperature as close as possible to 0°C.
- Fish and other aquatic invertebrates should be stored in shallow containers and surrounded by finely divided melting ice

Live fish and aquatic invertebrates are to be transported at lower temperatures according to their biological species.

- Chilled or refrigerated water systems equipment and/or cold storage systems should be designed and maintained in a manner to provide adequate cooling even during peak loads;
- Fish should not be stored in refrigerated water systems to a density that impairs its working efficiency;

monitoring and controlling the time and temperature and homogeneity of chilling should be performed regularly.

9. Spare Handling practices – is the way to Minimize deterioration

Poor handling practices can lead to significant mechanical damage of fresh aquatic animals. Presence of such damage can accelerate the rate of deterioration and decomposition, leading to unnecessary post-harvest losses.

To minimize handling damage by using the following practices:

- while aquatic animals are kept on the deck the impact of unfavorale factors should be minimized in order to prevent unnecessary dehydrating;
- aquatic animals should be handled and conveyed with care particularly during transfer and sorting in order to avoid physical damage such as puncture and mutilation, etc.;
- Where fish and aquatic invetebrates are stored or transported live, care should be taken to maintain optimal indicators of the parameters that can influence their condition (e.g. concentration of CO2, O2, temperature and presense and quantity value of nitrogenous wastes and etc.).
- Fish and aquatic invetebrates should not be trampled or stood upon;
- Where boxes (containers) are used for storage of fish and aquatic animals, they should not be too deep, or overfilled, or stacked in a way that the upper boxes overpress the contents lower boxes;
- Finely divided ice should be used where possible as its small pieces can help minimize damage to fish and aquatic animals and increase cooling capacity
- In refrigerated water storage areas, that are cooled by water, the density of the fish should be controlled to prevent damage.

10. PROCESSING OF FRESH FISH

10.1 Potential hazards: microbiological pathogens, viable parasites, biotoxins, chemicals (including veterinary drug residues) and physical contamination.

Potential hazards: decomposition, parasites, physical contamination

Technical guidance for raw fish material, its technical specifications could include the following:

- organoleptic characteristics, such as appearance, odour, texture and etc.;
- chemical indicators of decomposition and/or contamination, for example, trimethylamine, total volatile basic nitrogen (TVBN), histamine (for fish species that contain histamine) , heavy metals, pesticides, nitrates and etc.;
- microbiological indicators of raw materia, foreign materials;
- physical characteristics, such as size of fish;
- Homogeneity of species in the lot.

Training in species identification and communication in product specification should be provided to fish handlers and appropriate personnel to ensure a safe source of incoming fish and obtain information on product specification, where written protocols should be drawn up.

Warranting special consideration are the reception and sorting methods of fish species that pose a risk of biotoxins such as ciguatoxin in large carnivorous tropical and subtropical reef fish or histamine in histamine species as well as methods of identifying parasites;

Skills should be acquired by fish handlers and appropriate personnel in visual evaluation techniques of the lot to ensure raw fish meet safety requirements;

Fish requiring gutting on arrival at the processing facility(vessel) should be gutted efficiently, without undue delay and with care to avoid contamination.;

Fish should be rejected for processing, if it is known to contain harmful, decomposed or extraneous substances that will not be reduced or eliminated to an acceptable level by normal procedures of sorting or preparation;

10.2 Organoleptic evaluation of fish

The best method of assessing the freshness or spoilage of fish is by organoleptic evaluation.

It is recommended that appropriate evaluation criteria be used to evaluate the acceptability of fish or the need for it utilization.

As an example, fresh whitefish species are considered unacceptable when showing the following characteristics:

Skin/slime	dull, gritty colours with yellow–brown dotting slime
Eyes	concave, opaque, sunken, discoloured
Gills	grey–brown or bleached, slime opaque yellow, thick or clotting
Odour	flesh odour amines, ammonia, milky lactic, sulphide, fecal, putrid, rancid.

10.3 Chilled storage

Potential hazards: microbiological pathogens, biotoxins, histamine (for histamine fish species).

Potential defects: decomposition, physical damage.

Technical guidance:

Fish should be moved to the chilled storage facility or cooling containers for fish storage without undue delay;

- The facility (vessel) should be capable of maintaining the temperature of the fish between 0°C

and +4°C;

- The chill room, cold storages, refrigerators should be equipped with a calibrated indicating thermometer.
- Stock rotation plans should ensure proper utilization of raw material, products and materials for processing;
- The fish should be stored in shallow layers and surrounded by sufficient finely divided ice or with a mixture of ice and water before processing;
- Fish should be stored such that damage from overstacking or overfilling of boxes will be prevented;

Where appropriate, replenish ice supply on the fish or alter temperature of the room.

10.4. Defrostation Control

Potential hazards: microbiological pathogens, toxins and histamine

Potential defects: decomposition

Technical guidance:

- the defrostation method should be clearly defined and should address the time and temperature of defrostation, temperature measuring instrument used and placement of device for measurement in a suitable way. The defrostation schedule (time and temperature parameters) should be carefully monitored. Selection of the thawing method should take into account:
- thickness and uniformity of size of the products to be thawed.
- thawing time and temperature and fish temperature critical limits
- should be selected so as to control the development of micro-organisms and histamine (where high-risk species are concerned) and prevent of persistent objectionable odors or flavors indicative of decomposition;
- Where water is used as the thawing medium, it should be of potable quality;
- Where recycling of water is used, care should be taken to avoid the buildup of micro-organisms;
- Where water is used, circulation should be sufficient to produce even thawing;
- During thawing, according to the method used, products should not be exposed to excessively high temperatures;

Particular attention should be paid to controlling condensation and drip from the fish. Effective drainage should be ensured;

After thawing, fish should be immediately processed or refrigerated and kept at the adequate temperature (temperature of melting ice);

The thawing schedule should be reviewed as appropriate and amended where necessary.

10.5 Washing and gutting

Potential hazards: microbiological pathogens, biotoxins and histamine (for histamine fish species)

Potential defects: presence of viscera, bruising, off-flavors, cutting faults.

Technical guidance:

- Gutting is considered complete when the intestinal tract and internal organs have been completely removed.
- An adequate supply of clean water or potable water should be available for washing of:
- Sorting of whole fish should be done bebore gutting to remove foreign debris and reduce bacterial load;
- gutted fish, to remove blood and viscera from the belly cavity;

- surface of fish, to remove any loose scales, if necessary;
- gutting equipment and utensils to be used in a proper way to minimize buildup of slime, blood and offal;
- separate and proper equipped rooms to ensure storage for fish, roe, milts and livers, in case these are stored for further utilization.

10.6. Filleting, skinning, trimming and candling

Potential hazards: viable parasites, microbiological pathogens, biotoxins, histamine, presence of bones.

Potential defects: parasites, presence of bones, objectionable matter (e.g. skin, scales), decomposition.

Technical guidance*:*

To minimize time delays, the design of the filleting line and candling line, where applicable, should be continuous and sequential to permit uniform flow without stoppages or slowdowns and continued removal of waste;

An adequate supply of clean water or potable water should be available for washing of products, including:

fish prior to filleting or cutting, especially fish that have been scaled;

fillets after filleting, skinning or trimming to remove any signs of blood, scales or viscera;

regular washing of equipment and filleting tools to reduce build up of slime and blood;

for fillets to be marketed and designated as boneless or for further processing, fish handlers should employ appropriate inspection techniques and use the necessary tools to remove bones;

The candling of skinless fillets by skilled personnel, in a suitable location that optimizes the illuminating effect, is an effective technique in removing parasites in fresh fish;

The candling table should be frequently cleaned during operation in order to minimize the microbial activity of contact surfaces and the drying of fish residue caused by heat generated from the lamp.

11. PROCESSING OF MINCED FISH

Mincing fish using mechanical separation process of fish meat from bones.

Potential hazards: microbiological pathogens, biotoxins, histamine and physical contamination (metal, bones, rubber from separator belt, etc.)

Potential defects: incorrect separation (i.e. objectionable matter), decomposition, presence of defect bones, parasites.

Technical guidance:

The separator should be fed continuously but not excessively;

Candling is recommended for fish suspected of high infestation with parasites;

Split fish or fillets should be fed to the separator so that the cut surface contacts the perforated surface;

Fish should be fed to the separator in pieces size that it is able to handle;

In order to avoid time-consuming adjustments of the machinery and variations in quality of the finished product, raw materials of different species and types should be segregated and processing in separate batches should be carefully planned;

The perforation sizes of the separator surface as well as the pressure on the raw material should be adjusted to the characteristics desired in the final product;

The separated residual material should be carefully removed on a continuous or near-continuous

basis to the next processing stage;

Frozen product should be moved to the cold storage facility as quickly as possible;

The core temperature of the frozen fish should be monitored regularly for completeness of the freezing process;

Frequent checks should be made to ensure correct operation of freezing;

if necessary, monitoring is carried over to ensure that injectors are not blocked;

For killing parasites harmful to human health, the freezing temperature and monitoring of duration of freezing should be combined with good inventory control to ensure sufficient cold treatment.

12. FISH PROCESSING PRODUCED IN VACUUM PACKAGING OR PACKAGIN WITH MODIFIED GAS ENVIRONMENT

12.1 Weighing

Weights should be periodically subjected to calibration using standard weights to ensure accuracy.

12.2 Vacuum or modified gas packaging

Packaging process with modified gas invironment should be stricly controled, the control should be performed in regards:

- Volume of gas to product mass unit;
- Types and gas ratio in applied gas mixture;
- Types of tape used for packaging;
- Type and integrity of seal;
- Temprature of production during storage;
- Making proper vacuum and proper packaging;
- Control over the fact that the product was not in contact with area of joints;

Packaging material should be checked before use to ensure that it is not damaged or contaminated;

Skilled personnel should perform periodical checkups to ensure packaging integrity of ready product and effectiveness of pressure-sealing and proper work of packaging equipment;

after pressure-sealing products packaged with gas modified or vacuumed environment should be transferred with care and without delays to cold storages;

proper vacuum and lack of damage on packaging seal should be ensured.

13. PROCESSING OF FROZEN FISH

13.1 Freezing process

The fish product should be subjected to a freezing process as quickly as possible because unnecessary delays before freezing will cause temperature of the fish products to rise, increasing the rate of quality deterioration and reducing shelf-life owing to the action of micro-organisms and undesirable chemical reactions;

An optimal time and temperature regime for freezing should be established and should be taken into consideration the necessary parameters of freezing in freezing equipment and capacity, the nature of the fish product including thermal conductivity, thickness, shape and temperature and the volume of production. This regime should ensure that the range of temperature of maximum crystallization is passed through as quickly as possible in order to minimize deterioration level of product structure by ice crystals;

The thickness, shape and temperature of fish product entering the freezing process should be as uniform as possible;

Processing facility production should be geared to the capacity of freezers.;

Frozen product should be moved to the cold storage facility as quickly as possible.

The core temperature of the frozen fish should be monitored regularly for completeness of the freezing process;

Frequent checks should be made to ensure correct operation of freezing;

Accurate records of all freezing operations should be kept;

For killing parasites harmful to human health, the freezing temperature and monitoring of duration of freezing should be combined with technical characteristics of the equipment to ensure right cold treatment.

13.2 Glazing

Glazing is considered complete when the entire surface of the frozen fish product is covered with a suitable protective coating of ice and should be free of exposed areas where dehydration sublimation (freezer burn) can occur;

If additives are used in the water for glazing, care should be taken to ensure its proper proportion and application with product specifications;

Where the labelling of a product is concerned, information on the amount or proportion of glaze applied to a product or a production cycle should be kept and used in the determination of the net weight, which is exclusive of the glaze;

Where appropriate, monitoring should ensure that spray nozzles do not become blocked.

Where dips are used for glazing, it is important to replace the glazing solution periodically to minimize the bacterial load and buildup of fish protein, which can hamper freezing process.

13.3 Wrapping and packaging

Potential hazards: microbiological pathogens

Potential defects: subsequent dehydration, decomposition

Technical guidance:

Packaging material should be clean, sound, durable, sufficient for its intended use and have necessary characteristics for use in direct contact with food products;

The packaging operation should be conducted to minimize the risk of contamination and decomposition;

Products should meet appropriate standards for labelling and weights.

13.4 Storing in frozen condition

Potential hazards: microbiological pathogens, toxines, viable parasites

Potential defects: Dehydration, rancid odor, loss of nutrition values

Technical guidance:The facility (vessel) should be equipped to maintain the temperature of the fish at or colder than –18°C, and with minimal temperature fluctuations;

- The store should be equipped with a calibrated indicating thermometer with thermo register;
- A systematic stock rotation plan should be developed and maintained;

Product should be glazed and/or wrapped in tape materials to protect it from dehydration;

Fish should be rejected for processing if known to contain defects that cannot be reduced or eliminated to an acceptable level by re-working.

For killing parasites harmful to human health, the freezing temperature and monitoring of duration of freezing should be combined with good inventory control to ensure sufficient cold treatment.

14. TRANSPORTATION

14.1. Vehicles should be designed and constructed:

- walls, floors and ceilings, where appropriate, are made of a suitable corrosion-resistant material with smooth, non-absorbent surfaces.

- Floors should be adequately drained (where necessary);

- where appropriate with chilling equipment to maintain chilled fish or aquatic animals during transportation to a temperature as close as possible to 0°C, or for frozen fish, aquatic animals and their products, to maintain a temperature of –18°C or colder (except for brine frozen fish intended for canning which may be transported at –-- 9°C or colder);

14.2. Transport means should ensure:

- that live fish and aquatic animals are transported at temperatures tolerable for biological species;
- to provide the fish or aquatic animals with protection against contamination, exposure to extreme temperatures and the drying effects of the sun or wind;
- to permit the free flow of chilled air around the load when fitted with mechanical refrigeration means.

Requirements to transportation (transfer) apply to all sections. It is a step of the flow diagram that needs specific skills. Transportation should be considered with the same care as the other processing steps. This section provides examples of potential hazards and defects and describes technological guidelines that can be used to develop control measures and corrective actions.

It is particularly important throughout the transportation of fresh, frozen or refrigerated fish, aquatic animals and their products that care is taken to minimize any rise in temperature of the product and that the chill or frozen temperature, as appropriate, is maintained under controlled conditions. Moreover, appropriate measures should be applied to minimize damage to products and also their packaging.

14.3 For fresh, refrigerated and frozen products

Potential hazards: biochemical development (histamine), microbial growth and contamination

Potential defects: decomposition, physical damage, chemical contamination (fuel).

Technical guidance:

Check temperature of product before loading;

Avoid unnecessary exposure to elevated temperatures during loading and unloading of aquatic animals and their products;

Load in order to ensure a good air flow between product and wall, floor and roof panels; load stabilizer devices are recommended;

It is necessary to monitor air temperatures inside the cargo hold during transportation;

the use of a recording thermometer is recommended;

During transportation frozen products should be maintained at –18°C or below (maximum fluctuation +/-3°C);

Fresh (chelled) aquatic animals and their products should be kept at a temperature as close as possible to 0°C.

Fresh whole fish should be kept in shallow layers and surrounded by finely divided melting ice; adequate drainage should be provided in order to ensure that water from melted ice does not stay in contact with the products or melted water from one container does not cross-contaminate products in other containers.;

Transportation of fresh fish in containers with dry freezer bags and not ice should be considered where appropriate. Chilled seawater or refrigerated seawater (ice) should be used under approved conditions;

Temperature during transportation of chilled products should be maintained at the temperature specified by technological process, but generally should

not exceed 4°C;

Provide aquatic animals and their products with adequate protection against contamination from dust, exposure to higher temperatures and the drying effects of the sun or wind.

Before loading, the cleanliness, suitability and sanitation of the cargo hold of the vehicles should be verified.

Loading and transportation should be should be conducted in such a way as to avoid damage and contamination of the products and to ensure the packaging integrity.

Appendix B

GUIDELINES FOR INSPECTING DAIRY INDUSTRY ESTABLISHMENTS

1. TRACEABILITY

The traceability of dairy products intended for human consumption shall be established at all stages of production and distribution of these products.

Moreover, establishments producing dairy products or participating in its distribution shall ensure that they are able to identify any supplier of raw materials or origin of any component which is part of the products, as well as all recipients of the products from the establishment.

Establishments participating in the product distribution shall have in place systems and procedures which allow for this information to be made available to the competent authorities on demand.

Food which is placed or is ready to be placed on the market shall be adequately marked or identified to facilitate its traceability through relevant documentation or contain information in accordance with the relevant requirements for specific foods.

2. GENERAL HYGIENE RULES FOR FACILITIES

All milk collection and processing operations shall be carried out in such a way as to minimize any risk of products contamination.

The following requirements are essential to good sanitary preparation of the process.

1) Floor surfaces

Floor surfaces are to be maintained in a sound condition and be easy to clean and disinfect. This will require the use of impervious, non-absorbent, washable and non-toxic materials for flooring. Where appropriate, floors are to allow adequate surface drainage. Floor surfaces should be washed at the end of each day (or shift);

2) Wall surfaces

Wall surfaces are to be maintained in a sound condition and be easy to clean and disinfect. This will require the use of impervious, non-absorbent, washable and non-toxic materials and require a smooth surface up to a height appropriate for the specific operation.

3) Other Surfaces

Surfaces (including surfaces of equipment) in areas where foods are handled (processed) and in particular those in direct contact with food products are to be maintained in a sound condition and be easy to clean and disinfect. This will require the use of smooth, washable corrosion-resistant and non-toxic materials. All surfaces must be washed at the end of each day (or shift).

4) Drains

To carry away waste liquids, the facility should have drains of the proper size that are correctly located, trapped and vented. Floor surfaces in all facilities should be sloped toward the drains.

5) Ceilings

Ceilings (or, where there are no ceilings, the interior surface of the roof) and overhead fixtures are to be constructed so as to prevent the accumulation of dirt and to reduce condensation, the growth of undesirable mould (the mould which is not allowed for by the process) and the shedding of particles;

6) Windows

Windows and other openings are to be constructed to prevent the accumulation of dirt. Those which can be opened to the outside environment should be fitted with insect-proof screens which can be easily removed for cleaning. Where open windows would result in contamination, windows are to remain closed and fixed during production;

7) Doors

Doors are to be easy to clean and disinfect. This will require the use of smooth and non-absorbent materials. Wooden doors and doorways should be covered with metal with tightly soldered seams.

8) Water supply

Regardless of the water source used (wells, streams, municipal system, etc.), the water should meet the requirements for potable water. Abundant cold and hot water must be distributed to all parts of the operation.

3. GENERAL REQUIREMENTS FOR MILK AND DAIRY PRODUCT STORAGE AREAS

Milk and dairy product storage areas are to be kept clean and maintained in good condition.

The premises for product storage shall:

permit adequate maintenance, cleaning and disinfection, avoid or minimize air-borne contamination, and provide adequate working space to allow for sanitary and hygienic operations;

be such as to protect against the accumulation of dirt, contact of raw materials and products with toxic materials, the shedding of particles from the ceiling and the formation of condensation or undesirable mould on surfaces;

permit good food hygiene practices, including protection of premises against contamination, rodents and pests;

where necessary, provide suitable temperature-controlled handling and storage conditions for maintaining foodstuffs; at the same time, temperature control systems should ensure that temperatures are constantly monitored and, where necessary, recorded.

allow personnel to change and, where necessary, take a decontamination shower prior to entering the production facilities.

3.1 Lavatories

An adequate number of flush lavatories are to be available and connected to an effective drainage system. Lavatories are not to open directly into rooms in which dairy products are handled (processed).

Lavatories are to have adequate natural or mechanical ventilation.

3.2 Handwash sinks

An adequate number of handwash sinks is to be available, suitably located and designated for cleaning hands. Handwash sinks are to be provided with hot and cold water, materials for cleaning hands

and for hygienic drying. Handwash sinks must be in toilet rooms, locker rooms, and production facilities. They should be other than hand operated.

Where necessary, the facilities for washing products are to be separate from the hand-washing facility.

3.3 Ventilation

The facilities should have suitable and sufficient means of natural or mechanical ventilation preventing airflow from a contaminated (raw materials) area to a clean area (area of production and storage of products). Ventilation systems are to be so constructed as to enable filters and other parts requiring cleaning or replacement to be readily accessible.

3.4 Lightning

Lighting must be intense enough to allow both the establishment and inspection personnel to evaluate sanitary conditions and product contamination.

3.5 Drainage

Drainage facilities are to be adequate for the purpose intended. They are to be so designed and constructed as to minimize the risk of products contamination.

Where drainage channels are fully or partially open, they are to be so designed as to ensure that waste does not flow from a contaminated area into a clean area, in particular the clean area where foods are handled (processed), which presents a high risk to the final consumer.

3.6 Locker rooms

Locker rooms should be separate from facilities where product is prepared, stored, or handled (processed).

Locker rooms should be separated from lavatories.

Separate locker rooms should be provided for each sex if both sexes are employed by the establishment.

Locker rooms should have abundant and well-distributed light.

Separate locker rooms for those working in “dirty” and “clean” areas are desirable.

Receptacles for soiled clothing should be provided adjacent to employees’ locker rooms.

4. EQUIPMENT REQUIREMENTS

All articles, fittings and equipment, which comes into direct contact with food shall:

be effectively cleaned and, where necessary, disinfected. Cleaning and disinfection of equipment shall take place at a frequency sufficient to avoid any risk of products contamination;

be so constructed, be of such materials and be kept in good repair and condition as to minimize any risk of contamination;

with the exception of non-returnable containers and packaging, be so constructed, be of such materials and be kept in such good repair and condition as to enable them to be kept clean and, where necessary, to be disinfected;

be installed in such a manner as to allow adequate cleaning of the equipment and the surrounding area.

Where necessary, equipment is to be fitted with any appropriate control devices. Where chemical substances have to be used to prevent corrosion of equipment and containers, they are to be used in

accordance with good practices ensuring safety.

5. WATER SUPPLY

Establishments shall have constant water supply, including supply of potable water, which should be so organized as to ensure that foodstuffs are not contaminated.

Where non-potable water (hereinafter – industrial water) is used, for example in the fire control system, steam production, refrigeration and other similar purposes, it shall circulate in a separate water supply system. Industrial water shall not connect with, or allow reflux into, potable water systems.

Water used in processing of raw materials or products, or as an ingredient in production shall not present a risk of contamination. It shall meet the standard for potable water, unless the competent authority deems that its quality cannot affect the sanitary condition of the foodstuffs.

Ice which comes into contact with food products or which may contaminate them is to be made from potable water or, when used to chill fishery products, from clean water. Ice shall be made, handled and stored under conditions that prevent it from contamination.

Steam used directly in contact with food products is not to contain any substances that present a hazard to human health or can contaminate food products.

Where heat treatment is applied to raw materials or products in hermetically sealed containers it is to be ensured that water used to cool the containers after heat treatment is not a source of contamination for food products.

6. PERSONAL HYGIENE

Personal hygiene practices should prevent general contamination and cross-contamination of food products with pathogens that may cause food-borne diseases in humans.

Every employee handling food products shall maintain an appropriate degree of personal hygiene and shall wear clean and, where necessary, protective clothing. Any person so affected should immediately report illness or symptoms of an illness to the management.

Conditions which should be reported to management so that any need for medical examination and/or possible suspension from handling (processing) of food products can be considered, include:

jaundice;
diarrhea (scour);
vomiting;
fever (temperature);
sore throat,
chill (shiver);
visibly infected skin lesions (boils, cuts, etc.);
unnatural discharges from the ear, eye or nose.

Personnel directly engaged in milk handling should maintain an appropriate degree of personal hygiene and, where appropriate, wear suitable protective clothing, head covering, and footwear. Cuts and wounds, where personnel are permitted to continue working, should be covered by suitable waterproof dressings.

Personnel must wash their hands when personal hygiene may affect food products safety, for example:

at the start of food handling (processing) activities;

immediately after using the toilet;

after handling raw food products or any contaminated material; this could result in contamination of other food products so such personnel should avoid handling ready-to-eat food.

During work hours, personnel engaged in food handling activities should refrain from:

smoking;

spitting;

chewing or eating;

sneezing or coughing over unprotected food.

Personal effects such as jewelry, watches, pins or other similar items should not be worn or brought into areas for handling food products.

7. TRAINING

Management of food producing establishments are to ensure that food handlers are supervised and instructed and/or trained in food safety and hygiene matters commensurate with their work activity.

Training programs should:

provide personnel with the training, knowledge, skills and ability to carry out specified tasks related to dairy production hygiene, verification of statistical process control, HACCP;

provide practical training to the extent required;

where necessary, arrange for testing of personnel;

ensure that personnel involved in supervisory roles have appropriate skills;

be certified and built on professional qualification requirements;

provide for continuing education of competent persons.

8. HACCP

HACCP systems in dairy production are a proactive means of process control to ensure food safety.

Validation of a HACCP plan for dairy production should ensure that the plan is effective in meeting performance objectives or criteria taking into account the degree of variability in presence of threats and hazards that is normally associated with different lots of animals, from which raw materials were presented for processing.

Verification frequency under a HACCP plan may vary according to the operational aspects of process control and the results of verification itself.

The competent authority may choose to approve HACCP plans and stipulate verification frequencies.

Microbiological testing for verification of HACCP systems (e.g. for verification of critical limits and statistical process control) is the most important feature of HACCP plans efficiency for many products.

9. SANITATION STANDART OPERATING PROCEDURES

Pre-operational and operational sanitation standard operating procedures (SSOPs) should minimize direct and indirect contamination of milk.

A properly implemented SSOP system should ensure that facilities and equipment are clean and

sanitized prior to start of operations, and appropriate hygiene is maintained during operations.

SSOP guidelines may be provided by the competent authority, which may include minimum mandatory requirements for general sanitation.

Characteristics of sanitation standard operating procedures (SSOPs) are:

development of a written SSOP program by the establishment that describes the procedures involved and the frequency of application;

designation by order of establishment personnel responsible for implementing and monitoring SSOPs;

documentation of monitoring and any corrective and/or preventative actions taken, which is made available to the competent authority for purposes of verification;

corrective actions that include appropriate disposition of products;

periodic evaluation of the effectiveness of the system by the management of the establishment.

Microbiological verification of SSOPs can utilize a range of direct or indirect methods. Establishment operators should use statistical process control or other methods to monitor sanitation trends.

For sanitary control of facilities where ready-to-eat products are handled, microbiological verification of SSOPs for food contact and non-food contact surfaces is likely to be of higher intensity than in other cases and for types of products.

10. RODENT AND INSECT CONTROL SYSTEMS

Rodents and insects pose a major threat to the safety and suitability of food products. Pest infestations can occur where there are breeding sites and a supply of food.

Good hygiene practices should be employed to avoid creating an environment conducive to rodents and insects.

Good preventive measures, inspection of incoming materials and thorough control can minimize the likelihood of infestation and thereby limit the need for rodenticides and insecticides.

Buildings should be kept in good repair and condition to prevent access of rodents and insects and to eliminate potential breeding sites.

Holes, drains and other places where rodents and insects are likely to gain access should be mechanically sealed. Appropriate screens on open windows, doors and ventilators will reduce the threat of pest entry.

Animals should, wherever possible, be excluded from the territories of dairy processing establishments.

The availability of food and water encourages rodents and insects harborage and infestation on the territory.

Potential food sources should be stored in pest-proof containers and/or stacked above the ground and away from walls.

The establishment and surrounding territories should be regularly examined for evidence of infestation with rodents and insects.

When detected, pest infestations should be dealt with immediately and without adversely affecting food safety or suitability.

Treatment with chemical, physical or biological agents should be carried out appropriately.

Sanitation control systems should be monitored for effectiveness, periodically verified by means such as audit pre-operational inspections or, where appropriate, microbiological sampling of environment and food contact surfaces and regularly reviewed and adapted to reflect changed

circumstances.

11. PRINCIPLES OF PRIMARY PROCESSING OF MILK

Milk supplied to the consumer should not contain any contaminants jeopardizing human health.

Because of the important influence of primary production activities on the safety of dairy products, potential microbiological contamination from all sources should be minimized to the greatest extent possible.

Appropriate animal husbandry practices should be respected and care should be taken to ensure that proper health of the milking animals is maintained.

Substandard animal management practices, inadequate or low-quality animal feeding, deficient veterinary practices and inadequate general hygiene of milking personnel and their equipment as well as inappropriate milking methods may cause contamination of food products with chemical residues and other contaminants during primary dairy production activities.

Contamination of milk from animal and environmental sources during primary production should be minimized.

Note: A contaminant is any biological or chemical agent, foreign matter, or other substances not intentionally added to food which may compromise food safety or suitability.

The microbial load of milk should be as low as achievable, using good milk production practices, taking into account the technological requirements for subsequent processing.

To provide for a greater margin of safety, measures should be implemented at the primary production level to reduce the initial load of pathogenic microorganisms and micro-organisms affecting food safety and suitability to the allowable initial level.

It is expedient to prepare the milk in a way that permits the application of microbiological control measures of lesser stringency than other applicable technologies to assure product safety and suitability.

12. MANAGEMENT OF PRODUCTION AT ESTABLISHMENTS

12.1 Acceptance of milk

When arriving at the dairy plant (provided that further processing does not allow otherwise) the milk should be cooled and maintained at cool temperature as necessary to minimize any increase of the microbial load of the milk.

The principle of "first arrived, first processed" should apply.

12.2 Intermediate products

Intermediate products of processing that are stored prior to further handling (processing) should be kept under such conditions that limit/prevent microbial growth or be further handled (processed) within the shortest possible time.

The ultimate safety and suitability of milk and dairy products, as well as the intensity of the control measures that need to be applied during processing, depends not only on the initial microbial load in raw materials upon receipt at the dairy establishment but also on effeciency of measures preventing the growth of micro-organisms in the raw materials.

Application of proper storage temperatures and appropriate management of raw materials are the key factors in minimizing microbial growth.

The ability of a product to meet intended food safety objectives and/or related objectives and criteria is dependent upon the proper application of the control measures, including time and

temperature controls.

Establishments should maintain adequate rotation of stocks of raw materials and products, based on the principle of "first in, first out."

12.3 Distribution and location of finished products

It is essential that milk and dairy products be kept at appropriate temperatures in order to maintain their safety and suitability for human consumption from the time they are packaged until consumed or prepared for consumption.

Storage temperature should ensure the product's safety and suitability throughout the shelf life intended by the producer. Storage temperature may vary depending upon whether the product is perishable or non-perishable.

For perishable products, the distribution system should be designed to maintain adequate low-temperature storage to ensure both safety and suitability for consumption.

For non-perishable products designed to be shelf-stable at ambient temperature, extremes of temperature should be avoided, primarily to assure maintaining suitability.

Reasonably anticipated temperature abuse should be taken into account in designing the normal patterns of distribution and handling.

13. MANAGEMENT OF CONTROL MEASURES DURING AND AFTER HANDLING (PROCESSING)

It is important that control measures are applied during both primary production and processing to minimize or prevent the microbiological, chemical or physical contamination of milk. In addition, special attention should be given during the processing of different dairy products so that inadvertent cross-contamination does not occur, including with respect to ingredients that may contain allergenic substances.

Note: A distinction can be drawn between the types of control measures used in respect of microbiological hazards and those used for chemical and physical hazards.

The control measures used for chemical and physical hazards in food are generally preventive in nature, i.e., they focus on avoiding the contamination of food products with chemical or physical hazards. However there are some exceptions, e.g., the use of filters, screens and metal detectors to remove certain physical hazards.

Microbiological food hazards are controlled by appropriate selection of control measures applied during primary production in combination with control measures applied during and after processing.

The result of applying any microbiocidal control measure depends significantly on the microbial load and the concentration of microbiological hazards in the material subjected to it.

It is therefore important that preventive measures are applied in primary production to reduce the initial load of pathogenic micro-organisms as well as during processing to avoid contamination during the production process.

The initial microbial load significantly impacts the performance needed for the microbiological control measures applied during and after processing as well as the performance required for recognition of a product as suitable for consumption as food. The safety and suitability of the end product depends not only on the initial microbiological load and the efficiency of the process, but also on any postprocess growth of surviving organisms and contamination at the subsequent stages of the products' production and distribution.

Individual control measures should be selected and applied in such combination as to achieve a

sufficient performance as to result in end products with acceptable levels of hazards.

Acceptable levels of contaminants in the end product should be identified and be based upon:

food safety objectives, suitability criteria for end product and similar regulatory requirements;

acceptable levels derived from the purchaser constituting the subsequent link of the food chain;

and/or

the maximum levels found acceptable by the manufacturer, taking into account acceptable levels agreed with the customer,

and/or

regulatory measures established by public health authorities.

Specific microbiological control measures can be grouped according to primary function as follows:

Microbiocidal control measures that reduce the microbial load, for instance by killing, inactivation or physical removal. These measures may be applied both during processing as processing steps (e.g. microfiltration, incubation, pasteurization) and after the processing as intrinsic factors (e.g. ageing).

Microbiostatic control measures that prevent, limit or retard the growth of micro-organisms by chemical or physical means. These are used to stabilize the product against activity of pathogens and spoilage organisms and may apply after milk production, during processing (e.g. in between processing steps) and after processing.

Microbiostatic control measures still imply some probability of microbial growth, even if reducing it. Such measures that are efficient after processing may be applied towards the product (e.g. temperature/time control) as extrinsic factors or be built into the product as intrinsic factors (e.g. preservatives, pH).

Microbiostatic control measures that prevent direct contamination of product are aimed at prevention of microbial contamination by physical means or reduction of such contamination. They are impelemnted, for instance, by closed production circuits, special processes, or by appropriate packaging to protect the product.

The use of a single processing step may have significant effects on the level of microbial contamination (e.g. reduction of pH or water content), while other microbiological control measures only reduce the number of micro-organisms contaminating the product (or the area where it is produced) at the point in the manufacturing process, where it is applied.

Combination of microbiological control measures.

As a rule, more than one microbiological control measure is usually needed to control microbial content, to retard or prevent spoilage and to help prevent food borne diseases.

Suitable combinations of control measures can be devised in order that specific organisms of concern can be reduced in number and/or no longer grow/survive in the product. Such suitable combinations are sometimes referred to by the dairy industry as “hurdle technology”.

The combination of control measures has two main objectives:

During processing: Providing assurance that the levels of pathogens (and/or spoilage organisms) of concern, where present, are kept at or reduced to acceptable levels.

After processing (packaging, distribution and storage): Providing assurance that the acceptable levels of the pathogens (and/or spoilage organisms) of concern that have been achieved during processing are kept under control throughout shelf life.

It may be necessary to ensure that growth of micro-organisms is kept to a minimum prior to processing, in between different processing steps, and after processing.

The microbiostatic control measures used should be adapted to the need related to the particular

product in a particular situation.

The resulting outcome in terms ensureing the safety and suitability of the end product does not depend only on the initial microbial load and the effectiveness of the control processes, but also on successful application of methods for subsequent prevention of any post-process growth of surviving organisms and on efficient prevention of new contamination.

Therefore, all microbiological control measure combinations should be supported by appropriate preventive measures prior to and after the process, if their joint application is deemed necessary.

Depending on the source and possible routes of microbial contamination, the hazard(s) may be kept under control by preventive measures implemented at primary production level and/or in processing environments.

When evaluating microbial contamination control measures, it is particularly important to know which of the hazards are affected by the preventive measure and to what extent the measure reduces the probability of the hazard contaminating the milk during milking or dairy products during their processing and/or distribution.

Those microbiological hazards that are not managed adequately by preventive and microbiostatic control measures need to be managed and controlled by adequate microbiocidal control measures with sufficient combined performance.

Microbial contamination control measures having effect only at the point of application must be applied in appropriate combinations with other microbiological measures.

The combination of control measures is most efficient when it is *multi-targeted*, that is, when various individual measures are selected so that different factors effecting microbial survival are targeted, e.g., pH, Aw, availability of nutrients, etc.

In many cases, a multi-targeted combination of measures is much more efficient than any single measure applied with high intensity.

The use of a number of control measures inhibiting or reducing the number of micro-organisms may be *synergistic*, when their combined effect is greater than the sum of their individual effects.

14. MICROBIOLOGICAL AND OTHER SUITABILITY INDICATORS OF RAW MATERIALS

Upon receipt of milk for processing it should be subject to organileptic control.

Other criteria (e.g., temperature, acidity, level of microbial and chemical contamination) should be used to detect raw materials unacceptable for production.

Any non-compliance of the received milk with the above mentioned criteria (in particular for pathogens,) should result in immediate corrective actions at the farm level and in the processing establishment. The examples of the latter would include:

rejection of the particular milk shipment for the production of raw milk products; corrective actions on the milking procedure (cleaning and sanitation procedures of the milking equipment, cleaning or sanitation procedures of the udder, etc.,);

improvement of the quality of feed at the farm from which the milk was received;

improvement of the hygienic quality of the water for watering of animals;

change in livestock management practices;

individual checks of animals to find the animal(s) that may be the carrier; isolation of that animal from the herd as necessary.

Corrective actions should be identified and implemented, and additional specialized assistance to the dairy farm may need to be provided.

In some cases, where more comprehensive control measures are put into place to ensure the safety and suitability of milk, as may be the case for raw milk intended to be used in the production of raw milk products, it may be necessary to classify farms into two categories: those acceptable for use in raw milk products and those that are not, as well as to establish additional provisions for milk used in the manufacture of raw milk products that were not heat-treated.

Depending on the hazard analysis performed by the manufacturer and the combination of control measures applied during and after processing of milk products, specific microbiological criteria regarding pathogens (for example: *Salmonella* spp., *Listeria monocytogenes*) may need to be established.

15. MICROBIOSTATIC CONTROL MEASURES

Note: The control measures described in this appendix are presented as descriptive examples only and require validation prior to use with respect to their effectiveness and safe use.

Microbial growth is dependent upon many conditions in the organism's environment such as: ingredients, nutrients, water activity, pH, presence of preservatives, competitive micro-organisms, gas atmosphere, redoxpotential, storage temperature and time. Control of these conditions can therefore be used to limit, retard, or prevent microbial growth.

Such microbiological control measures as well as microbiological control measures protecting the product against direct microbial contamination from the surroundings have microbiostatic functions.

Many microbiostatic control measures act by interfering with the homeostasis mechanisms that microorganisms have for multiplication or preservation in order to survive environmental stresses.

Maintaining homeostasis of internal environment requires significant energy and plastic resources of the microorganism. So when a microbiological control measure disturbs the homeostasis there will be less energy left for the micro-organism to multiply and it will remain in the lag phase. Some microbial cells may even die out before the homeostasis is re-established.

Examples of typical microbiostatic control measures include the following:

Carbon dioxide (CO2):	The addition and/or formation of carbonic acid as part of processing to obtain a multiple microbiostatic effect, including the creation of anaerobic conditions by replacing oxygen therewith, reducing pH, inhibiting certain intracellular enzymes (decarboxylation), and inhibiting the transport of watersoluble nutrients across the membrane (by dehydrating the cellular membrane). The efficiency depends mainly on the point of application. In ripened cheese, the emission of carbon dioxide from the cheese to the outside environment is often utilized to provide anaerobic conditions in the headspace of cheese packaging.
Coatings	The introduction of a physical barrier against microbial contamination, with or without antimicrobial substances implemented into it (immobilized) to obtain a slow migration of these from the surface.
Freezing:	The lowering of temperature below the freezing point of the product combined with a reduction of the water activity. Freezing has microbiostatic as well as microbiocidal effects.
Lactoferrins:	Retardation through the utilization of naturally present glycoproteins (highest concentration in colostrum) to prolong the lag phases of bacteria for 12–14 hours, by binding iron in the presence of bicarbonates.
Lactoperoxidase	The activation of the lactoperoxidase/thiocyanate/hydrogen peroxide system

system:	(indigenous system in milk) to inactivate several vital metabolic bacterial enzymes, consequently blocking their metabolism and ability to multiply.
Modified atmosphere:	The establishing of a gaseous environment (either low in oxygen and/or high in carbon dioxide or nitrogen) to limit growth of aerobic micro-organisms by impairing the efficiency of biochemical mechanisms for exchange of bacterial cells. Modified atmosphere packaging (MAP) means that a modification of the gas atmosphere in the packaging is created. It is important to take into account that establishing anaerobic environment to limit growth of aerobic micro-organisms may proliferate certain anaerobic pathogenic microorganisms.
Packaging:	Packaging provides a physical barrier that protects products against access of micro-organisms from the surroundings.
pH reduction	The creation of extra-cellular acid conditions that enables hydrogen ions to be imported into the cytoplasma of micro-organisms, thus disturbing the mechanism for maintaining constant intracellular pH responsible for maintaining functionality of key cell components vital for continuing growth and viability. Low pH values are obtained by fermentation or addition of acids (inorganic or organic). The pH value which is low enough for preventing growth depends on the pathogen, but lies typically between pH 4.0–5.0. Micro-organisms become more sensitive to other microbiological control measures at lower pH. Synergy occurs with salt, water activity, organic acids, the LP-system, and antimicrobial substances
Use of preservatives:	The addition of certain additives to enhance keeping quality and stability through direct or indirect antimicrobial and/or fungicidal activity. Most preservatives are rather specificē and have effect only on certain micro-organisms.
Redox potential control:	The redox potential (Eh) is a quantitative measure of the oxidizing or reducing potential of food systems that determines whether aerobic or anaerobic micro-organisms are able to grow. Eh is influenced by removal of oxygen and/or addition of reducing substances (e.g. ascorbic acid, sucrose, etc.).
Refrigeration:	The lowering of product temperature to limit microbial activity.
Time:	The practice of applying very short collection/storage periods, limiting the shelf life of products, or immediate processing of raw milk to ensure that all micro-organisms present are in the lag phase, and therefore not active and more susceptible to other microbiological control measures.
Water activity control:	The control of the water activity (aw) in the product (the accessibility of water for microorganisms, not the water content in the food), expressed as the ratio of water vapour pressure of the food to that of pure water. The aw value for preventing growth depends on the pathogen, but lies typically between 0.90 and 0.96. Water activity can be controlled by: • concentration, evaporation and drying, which also increase the buffering capacity of milk (synergy); • salting (addition of sodium chloride), which also reduces the cell resistance against carbon dioxide and in the solubility of oxygen (synergy); and • sweetening (addition of sugars), which at aw below 0.90–0.95 also results in an antimicrobial effect, depending on the type of sugar

	(synergy).

Microbiocidal or practical elimination control measures act by reducing the microbial load, for instance through killing, inactivation or removal.

Many microbiological control measures have multiple functions. Some of them, such as pH reduction, refrigeration, freezing, preservatives and indigenous antimicrobial systems also have microbiocidal effects, the degree often depending upon the intensity at which they are applied.

Pasteurization and other heat treatments of milk that have at least an equivalent efficiency are applied at such intensities (sufficient time/temperature combinations) that they practically eliminate specific pathogens. They have therefore been traditionally used as key microbiocidal control measures in the manufacture of milk products. Non-thermal microbiocidal control measures with similar efficiencies are not yet applied at such intensities that will render the milk product safe at the point of application.

Examples of typical microbiocidal control measures include the following:

Centrifugation:	The removal of microbial cells of high density from milk using high centrifugal forces. Most efficient against microbial cells of high density, notably bacterial spores and somatic cells
Commercial sterilization:	The application of heat at high temperatures for a time sufficient to render milk or milk products commercially sterile, thus resulting in products that are safe and microbiological stable at room temperature.
Competitive microflora:	The reduction of the number of undesirable micro-organisms by lowering the pH, consumption of nutrients, and production of bacterial antimicrobial substances (such as nisin, other bacteriocins and hydrogen peroxide). Usually, this microbiological control measure is applied by choice of starter cultures. The efficiency is determined by many factors, including the speed and level of pH-reduction and variations in the pH level.
Cooking" of cheese curd:	The application of heat to cheese curd, mainly for technical purposes. The heat treatment has a lower intensity than thermization but stresses micro-organisms to become more susceptible to other microbiological control measures.
Electromagnetic energy treatment:	Electromagnetic energy results from high voltage electrical fields, which alternate their frequency millions of times per second (< 108 MHz). Examples are microwave energy (thermal effect), radio-frequency energy (non-thermal effects) or high electric field pulses (10–50 kV/cm, non-thermal effects). The treatment destroys cells by establishing pores in the cell walls due to the build up of electrical charges at the cell membrane.
High-pressure treatment:	Application of high hydrostatic pressures to irreversibly damage the membranes of vegetative cells.
Microfiltration:	Removal of bacteria, clumps and somatic cells by recirculation over a microfilter. Normally, a pore size of ~0.6–1.4 □m is sufficient to separate most bacteria. Synergy in combination with heat treatment.
Pasteurization:	The application of heat to milk and liquid milk products aimed at reducing the number of any pathogenic micro-organisms to a level at which they do not

	constitute a significant health hazard.
Pulsed highintensity light:	The application of (on e.g. packaging material, equipment and water) high intensity broadband light pulses of wavelengths in the ultraviolet, visible and infrared spectrum (~20 000 times sunlight) to destroy micro-organisms. Due to the inability to penetrate intransparent substances, the technology is only effective against surfaces, for instance, in the removal of biofilm and can therefore prevent cross contamination
Ripening (ageing):	The holding for such time, at such temperature, and under such conditions as will result in the necessary biochemical and physical changes characterizing the cheese in question. When applied as a microbiocidal control measure, the multifactoral, complex system developing in cheese (pH, antagonistic flora, decreased water activity, metabolism of bacteriocins and organic acids) is utilized to influence the microenvironment in and on the food and consequently the composition of the microflora present.
Thermization:	The application to milk of a heat treatment of a lower intensity than pasteurization that aims at reducing the number of micro-organisms. A general reduction of log 3–4 can be expected. Micro-organisms surviving will be heat-stressed and become more vulnerable to subsequent microbiological control measures.
Ultrasonication:	The application of high intensity ultrasound (18-500 MHz) that cause cycles of compression and expansion as well as cavitation in microbial cells. Implosion of microscopic bubbles generates spots with very high pressures and temperatures able to destroy cells. More effective when applied in combination with other microbiological control measures. When applied at higher temperatures, the treatment is often referred to as "thermosonication".
Warm sealed packaging:	The application of heat (80 to 95 °C) to a solid end product in connection with the packaging process, for instance to maintain the product at a viscosity suitable for packaging. Such process can be done in a continuous flow system or in batch processes. The product is sealed at the packaging temperature and chilled for storage/distribution purposes afterwards. When combined with low pH in the product, e.g. below 4.6, the warm sealed product may be commercially sterile as any surviving micro-organisms may not be able to grow. A supplementary microbiostatic control measures is to ensure adequate cooling rates of packaged products to minimizē potential for *B. cereus* growth.

16. PASTEURIZATION OF MILK AND FLUID MILK PRODUCTS

According to validations carried out on whole milk, the minimum pasteurization conditions are those having bactericidal effects equivalent to heating the milk to 72 °C for 15 seconds (continuous flow pasteurization) or 63 °C for 30 minutes (batch pasteurization). Similar conditions can be obtained by joining the line connecting these points on a log time versus temperature graph.

Processing times necessary rapidly decrease with minimal increase in temperature. Extrapolation to temperatures outside the range of 63 to 72 °C, in particular, processing at temperatures above 72 °C

must be treated with the utmost caution as the ability for them to be scientifically [validated] is beyond current experimental techniques.

For example, it would be extremely difficult (if not impossible) to determine pasteurization efficiency at 80 °C given the extrapolated processing time would be around 0.22 seconds to achieve at least a 5 log reduction.

To ensure that each particle is sufficiently heated, the milk flow in heat exchangers should be turbulent, i.e. the Reynolds number should be sufficiently high.

When changes in the composition, processing and use of the product are proposed, the necessary changes to the scheduled heat treatment should be established and a qualified person should evaluate the efficiency of the heat treatment.

For instance, the fat content of cream makes it necessary to apply minimum conditions greater than for milk, minimum 75 °C for 15 seconds.

Formulated liquid milk products with high sugar content or high viscosity also require pasteurization conditions in excess of the minimum conditions defined for milk.

Verification of process

The products subjected to pasteurization should show a negative alkaline phosphatase reaction immediately after the heat treatment as determined by an acceptable method. Other methods could also be used to demonstrate that the appropriate heat treatment has been applied.

Alkaline phosphatase can be reactivated in many milk products (cream, cheese, etc.). Also, micro-organisms used in the manufacture may produce microbial phosphatase and other substances that may interfere with tests for residual phosphatase. Therefore, this particular verification method must be performed immediately after the heat treatment in order to produce valid results.

Appendix C

GUIDELINES FOR INSPECTING ANIMAL SLAUGHTERHOUSES AND MEAT INDUSTRY ESTABLISHMENTS

1. TRACEBILITY

The traceability of meat and meat products intended to be incorporated into a food shall be established at all stages of production, processing and distribution.

Slaughterhouses and meat industry establishments shall be able to identify any person from whom they have purchased an animal, raw materials or any substance intended to be incorporated into a food. To this end they shall have in place systems and procedures, which allow for this information to be made available to the competent authorities on demand.

Slaughterhouses and meat industry establishments shall have in place systems and procedures to identify other entities, to which their meat and meat products have been supplied. This information shall

be made available to the competent authorities on demand.

Meat and meat products which are placed on the market or are likely to be placed on the market shall be adequately labeled or identified to facilitate their traceability, through relevant documentation or information in accordance with the relevant requirements of more specific provisions.

2. GENERAL RULES OF HYIGIENE FOR PRODUCTION FACILITIES OF SLAUGHTERHOUSES AND MEAT INDUSTRY ESTABLISHMENTS

It is essential that all meat-processing operations, cutting or further processing of meat, be carried out in a clean area and, as much as possible, that the meat products be protected from contamination from all sources.

When meat-processing operations are carried out within a facility specifically built and maintained for meat processing, sources of contamination shall be controlled. The following requirements are considered essential to good sanitary preparation.

2.1. FLOOR SURFACE

Floor surfaces in slaughterhouses and meat industry establishments are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of impervious, non-absorbent, washable and non-toxic materials. Where appropriate, floors are to allow adequate surface drainage.

Wooden floors are not allowed in areas where cutting takes place and meat juices and moisture collect.

2.2. DRAINS

To carry away waste liquids, there should be sufficient drains of the proper size that are correctly located, trapped and vented. All floors should be sloped toward the drains.

2.3. WALL SURFACES

Wall surfaces in slaughterhouses and meat industry establishments are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of impervious, non-absorbent, washable and non-toxic materials and require a smooth surface up to a height appropriate for the operations.

2.4. CELLINGS

Ceilings in slaughterhouses and meat industry establishments (or, where there are no ceilings, the interior surface of the roof) and overhead fixtures are to be constructed and finished so as to prevent the accumulation of dirt and to reduce condensation, the growth of undesirable mould and the shedding of particles.

2.5. WINDOWS

Windows and other openings in slaughterhouses and meat industry establishments are to be constructed to prevent the accumulation of dirt. Those which can be opened to the outside environment are, where necessary, to be fitted with insect-proof screens which can be easily removed for cleaning. Where open windows would result in contamination, windows are to remain closed and fixed during production;

2.6. DOORS

Doors in slaughterhouses and meat industry establishments are to be easy to clean and, where necessary, to disinfect. This will require the use of smooth and non-absorbent surfaces. Wooden doors and doorways should be covered with metal with tightly soldered seams.

2.7. SURFACES

Surfaces (including surfaces of equipment) in areas where meat and meat products are handled and in particular those in contact with meat and meat products are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of smooth, washable corrosion-resistant and non-toxic materials. All surfaces must be thoroughly washed down at the end of each day.

2.8. WATER SUPPLY

Whether from individually owned and controlled sources such as wells or streams or from a municipal system, the water supply must be potable and abundant cold and hot water must be distributed to all parts of the operation in slaughterhouses and meat industry establishments.

3. PREMISES OF SLAUGHTERHOUSES AND MEAT INDUSTRY ESTABLISHMENTS

Premises of slaughterhouses and meat industry establishments are to be kept clean and maintained in good repair and condition.

The layout, design, construction, sitting and size of food premises are to:

permit adequate maintenance, cleaning and/or disinfection, avoid or minimize air-borne contamination, and provide adequate working space to allow for the hygienic performance of all operations;

be such as to protect against the accumulation of dirt, contact with toxic materials, the shedding of particles into food and the formation of condensation or undesirable mould on surfaces;

permit good meat and meat products hygiene practices, including protection against contamination and, in particular, pest control;

where necessary, provide suitable temperature-controlled handling and storage conditions of sufficient capacity for maintaining meat and meat products at appropriate temperatures and designed to allow those temperatures to be monitored and, where necessary, recorded.

3.1. LAVATORIES

An adequate number of flush lavatories are to be available and connected to an effective drainage system. Lavatories are not to open directly into rooms in which meat and meat products are handled.

Lavatories are to have adequate natural or mechanical ventilation.

3.2. HANDWASH SINKS

An adequate number of washbasins is to be available, suitably located and designated for cleaning hands. Washbasins for cleaning hands are to be provided with hot and cold running water, materials for cleaning hands and for hygienic drying. Handwash sinks must be in toilet rooms, locker rooms, and production facilities. They should be other than hand operated.

Where necessary, the facilities for washing meat and meat products are to be separate from the hand-washing facility.

3.3. VENTILATION

Ventilation systems in slaughterhouses and meat industry establishments shall be designed, constructed and maintained so that the welfare of the animals is constantly ensured, taking into account the expected range of weather conditions.

There is to be suitable and sufficient means of natural or mechanical ventilation. Mechanical airflow from a contaminated area to a clean area is to be avoided. Ventilation systems are to be so constructed as to enable filters and other parts requiring cleaning or replacement to be readily accessible.

Sanitary conveniences are to have adequate natural or mechanical ventilation.

3.4. LIGHTING

Light fixtures in rooms of slaughterhouses and meat industry establishments where meat and meat products are handled should ensure maximum safety, to preclude contamination of meat and meat products with broken glass and prevent the collection of dirt and debris on lamp surfaces.

Lighting must be intense enough to allow both the establishment and inspection personnel to see sanitary conditions and contamination of meat and meat products.

Premises where meat is handled are to have adequate natural and/or artificial lighting.

3.5. DRAINAGE

Drainage facilities in slaughterhouses and meat industry establishments are to be adequate for the purpose intended. They are to be designed and constructed to avoid the risk of contamination.

Drainage channels shall be fully or partially open and shall be so designed as to ensure that waste is removed from contaminated areas, in particular areas where meat and meat products are handled, which could present a high risk to the final consumer.

3.6. LOCKER ROOMS

Locker rooms for personnel of slaughterhouses and meat industry establishments should be separate from rooms or compartments where product is prepared, stored, or handled.

Locker rooms should be separated from the toilet area.

Separate locker rooms should be provided for each sex if both sexes are employed by the establishment.

Locker rooms should have abundant, well-distributed light of good quality.

Separate locker rooms for raw product and other product department employees will help prevent cross contamination of product.

Receptacles for soiled clothing should be provided adjacent to employees' locker rooms.

4. EQUIPMENT REQUIREMENTS

All articles, fittings and equipment in slaughterhouses and meat industry establishments which come into contact with meat and meat products are to:

be effectively cleaned and, where necessary, disinfected at a frequency sufficient to avoid any risk of contamination;

be so constructed, be of such materials and be kept in such good order, repair and condition as to minimize any risk of contamination;

be so constructed, be of such materials and be kept in such good order, repair and condition as to enable them to be kept clean and, where necessary, to be disinfected, with the exception of non-returnable containers and packaging;

be installed in such a manner as to allow adequate cleaning of the equipment and the surrounding area.

Basic equipment needed for the animal slaughtering operation:

stunning gun, electrical head tongs or simple stunning equipment for direct blow;

knives:

sticking - 15 cm sharpened on both sides;

skinning - 15 cm curved;

a sharpening steel;

oil or water sharpening stone;

scabbard and belt for holding knives;

meat saw - hand or electric and cleaver;

block and tackle or chain hoist strong enough to hold the weight of the animal to be slaughtered;

pritch, chocks or skinning rack (dressing cradle);

a strong beam, tripod or track 2.4 to 3.4 m from floor;

spreader - gambrel or metal pipe;

several buckets;

working platforms;

scalding barrel or tank;

pot, barrel or system for boiling water;

bell scrapers;

solid scraping table or platform;

thermometer registering up to 70°C;

hog or hay hook;

torch or flame for singeing.

The last seven items indicate additional equipment required when hogs are scalded and scraped rather than skinned.

Useful additional equipment:

knocking pen;

bleeding hooks (for vertical bleeding);

blood-catching trough;

wash trough (tripe).

Sanitation of hands and tools:
hand wash-basin;
implement sterilizers.

Where necessary, equipment is to be fitted with any appropriate control device. Where chemical additives have to be used to prevent corrosion of equipment and containers, they are to be used in accordance with good hygiene practice.

5. WATER SUPPLY

Slaughterhouses and meat industry establishments shall have an adequate supply of potable water, which is to be used whenever necessary to prevent contamination of meat and meat products. Where non-potable water is used, for example for fire control, steam production, refrigeration and other similar purposes, it is to circulate in a separate duly identified system. Non-potable water is not to connect with, or allow reflux into, potable water systems.

Recycled water used in processing or as an ingredient is not to present a risk of contamination. It is to be of the same standard as potable water, unless the competent authority is satisfied that the quality of the water cannot affect the wholesomeness of the meat and meat products in their finished form.

Ice which comes into contact with meat products or which may contaminate meat products is to be made from potable water or, when used to chill undressed meat, clean water. It is to be made, handled and stored under conditions that protect it from contamination.

Steam used directly in contact with meat and meat products is not to contain any substance that presents a hazard to health or is likely to contaminate the food.

Where heat treatment is applied to meat products in hermetically sealed containers it is to be ensured that water used to cool the containers after heat treatment is not a source of contamination for the meat products.

6. PERSONAL HYGIENE

Handling and inspection of meat, presents many opportunities for cross-contamination. Personal hygiene practices of personnel of slaughterhouses and meat industry establishments should prevent undue general contamination, and prevent cross-contamination with human pathogens that may cause food-borne disease.

Persons moving from rooms or areas containing raw meat to rooms or areas used for meat preparations and manufactured meat (especially when these products are cooked) should thoroughly wash, change and/or sanitize their protective clothing as appropriate, and otherwise limit the possibility of cross-contamination to the lowest level practicable.

Every person working in the area of meat and meat products handling is to maintain a high degree of personal cleanliness and is to wear the appropriate protective clothing, headwear and footwear. Cuts and wounds, where personnel are permitted to continue working, should be covered by suitable waterproof dressings.

Any person so affected should immediately report illness or symptoms of illness to the management of the slaughterhouse or meat industry establishment.

Conditions which should be reported to management so that any need for medical examination and/or possible suspension of the sick person from food handling can be considered include:

jaundice;
diarrhea;

vomiting;
fever;
sore throat with fever;
visibly infected skin lesions (boils, cuts, etc.);
discharges from the ear, eye or nose.

Personnel should always wash their hands when personal cleanliness may affect safety of meat and meat products, for example:

at the start of meat and meat products handling activities;
immediately after using the toilet;
after handling raw food or any contaminated material, where this could result in contamination of other food items; they should avoid handling ready-to-eat food.

People engaged in meat and meat products handling activities should refrain from behavior which could result in contamination of food, for example:

smoking;
spitting;
chewing or eating;
sneezing or coughing over unprotected food.

Personal effects such as jewelry, watches, pins or other items should not be worn or brought into areas for handling meat and meat products.

7. PERSONNEL TRAINING

Management of slaughterhouses and meat industry establishments shall ensure that meat and meat products handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity;

Training programs should:

provide personnel with the training, knowledge, skills and ability to carry out specified meat hygiene tasks, e.g., post-mortem inspection, verification of statistical process control, HACCP;
provide practical training to the extent required;
where necessary, arrange for formal testing of personnel;
ensure that personnel involved in supervisory roles have appropriate skills;
recognize and build on professional qualifications of personnel;
provide for the continuing education of personnel.

8. HACCP

HACCP systems for production of meat and meat products are a proactive means of process control for the purposes of safety of meat and meat products.

Validation of a HACCP plan for meat and meat products should ensure that it is effective in meeting performance objectives and performance criteria, taking into account the degree of variability in presence of hazards that is normally associated with different lots of animals presented for processing.

Verification frequency may vary according to the operational aspects of process control, the historical performance of the establishment in application of the HACCP plan, and the results of verification itself. The competent authority may choose to approve HACCP plans and stipulate verification frequencies. Microbiological testing for verification of HACCP systems, e.g. for verification of critical limits and statistical process control, is an important feature of HACCP for many

products.

Guidelines should be differentiated according to processing category, e.g.:

Raw ground or comminuted e.g. pork sausage;

Meat with secondary inhibitors / non-shelf stable e.g. cured corned beef;

Heat treated / not fully cooked, non-shelf stable e.g. partially-cooked patties;

Fully cooked / non-shelf stable e.g. cooked ham;

Non-heat treated / shelf stable e.g. dry salami;

Heat treated / shelf stable e.g. beef jerky;

Thermally processed / commercially sterile e.g. canned meat.

When developing HACCP plans for heat-treated meat preparations and manufactured meat, management of slaughterhouses and meat industry establishments should fully document as appropriate to the process, all thermal process parameters, post-heat treatment handling, and additional preservation treatments appropriate to the intended process outcome e.g. a pasteurized product. Process parameters for cooling of heat-treated meat products may incorporate as appropriate to the product, rapid cooling, slow cooling, or interrupted cooling. Previously heated meat products should not be packaged above a minimum temperature, e.g. 4°C, unless it can be demonstrated that cooling after packaging does not compromise product safety.

HACCP plans for meat preparations and manufactured meat that are cooked should include monitoring and documentation of parameters that ensure appropriate internal temperatures are reached.

9. SANITATION STANDART OPERATING PROCEDURES

Pre-operational and operational sanitation standard operating procedures (SSOPs) should minimize direct and indirect contamination of meat to the greatest extent possible and practicable. A properly implemented SSOP system should ensure that facilities and equipment are clean and sanitized prior to star of operations, and appropriate hygiene is maintained during operations. SSOP guidelines may be provided by the competent authority, which may include minimum regulatory requirements for general sanitation.

Characteristics of sanitation standard operating procedures (SSOPs) are:

Development of a written SSOP program by slaughterhouses and meat industry establishments that describes the procedures involved and the frequency of application;

Identification of slaughterhouses' and meat industry establishments' personnel responsible for implementing and monitoring SSOPs;

Documentation of monitoring and any corrective and/or preventative actions taken, which is made available to the competent authority for purposes of verification;

Corrective actions that include appropriate disposition of product;

Periodic evaluation of the effectiveness of the system by the management of slaughterhouses and meat industry establishments.

Microbiological verification of SSOPs shall utilize a range of direct or indirect methods. Management of slaughterhouses and meat industry establishments should use statistical process control or other methods to monitor sanitation trends.

In the case of ready-to-eat products, microbiological verification of SSOPs for food contact and non-food contact surfaces is likely to be of higher intensity than for other types of product.

10. PESTS CONTROL SYSTEM

Pests pose a major threat to the safety and suitability of food. Pest infestations can occur where there are breeding sites and a supply of food. Good hygiene practices should be employed to avoid creating an environment conducive to pests.

Buildings of slaughterhouses and meat industry establishments should be kept in good repair and condition to prevent pest access and to eliminate potential breeding sites. Holes, drains and other places where pests are likely to gain access should be kept sealed. Wire mesh screens, for example on open windows, doors and ventilators, will reduce the problem of pest entry. Animals should, wherever possible, be excluded from the grounds of slaughterhouses and meat industry establishments.

The availability of food and water encourages pest harborage and related infestation. Potential food sources should be stored in pest-proof containers and/or stacked above the ground and away from walls. Areas both inside and outside food premises should be kept clean. Where appropriate, refuse should be stored in covered, pest-proof containers.

Slaughterhouses and meat industry establishments and surrounding areas should be regularly examined for evidence of infestation. Pest infestations should be dealt with immediately and without adversely affecting the safety or suitability of meat and meat products.

11. FOOD CHAIN INFORMATION

Management of slaughterhouses and meat industry establishments must, as appropriate, request, receive, check and act upon food chain information as set out in this Section in respect of all animals, other than wild game, sent or intended to be sent to the slaughterhouses and meat industry establishments.

Management of slaughterhouses and meat industry establishments do not have to accept animals unless they have requested, and been provided with, the relevant food chain information contained in the records kept at the farm of origin.

Management of slaughterhouses and meat industry establishments must be provided with the information no less than 24 hours before the arrival of animals at the slaughterhouses and meat industry establishments.

The relevant food chain information is to cover, in particular:

the status of the holding of provenance or the regional animal health status;

the animals' health status;

veterinary medicinal products or other treatments administered to the animals within a relevant period and with a withdrawal period greater than zero, together with their dates of administration and withdrawal periods;

the occurrence of diseases that may affect the safety of meat;

the results, if they are relevant to the protection of public health, of any analysis carried out on samples taken from the animals or other samples taken to diagnose diseases that may affect the safety of meat, including samples taken in the framework of the monitoring and control of zoonoses and residues;

relevant reports about previous ante- and post-mortem inspections of animals from the same holding of provenance including, in particular, reports from the official veterinarian;

production data, when this might indicate the presence of disease;

the name and address of the private veterinarian normally attending the holding of provenance.

If the operator is already aware of this information (for example, through a standing arrangement or a quality assurance scheme)it is not necessary for the slaughterhouse operator to be provided with following information:

the status of the holding of provenance or the regional animal health status;

the animals' health status;

relevant reports about previous ante- and post-mortem inspections of animals from the same holding of provenance including, in particular, reports from the official veterinarian;

the name and address of the private veterinarian normally attending the holding of provenance.

The information need not be provided as a verbatim extract from the records of the farm of the animals' origin. It may be provided through electronic data exchange or in the form of a standardized declaration signed by the producer.

The manager deciding to accept animals onto the slaughterhouse or meat industry establishment after evaluating the relevant food chain information must make it available to the official veterinarian without delay no less than 24 hours before the arrival of the animal or lot. The manager of the slaughterhouse or meat industry establishment must notify the official veterinarian of any information that gives rise to health concerns before ante-mortem inspection of the animal concerned.

If any animal arrives at the slaughterhouse without food chain information, the operator must immediately notify the official veterinarian. Slaughter of the animal may not take place until the official veterinarian so permits.

If the competent authority so permits, food chain information may accompany the relevant animals to the slaughterhouse, or it should be delivered 24 hours before the arrival. Management of the slaughterhouse or meat industry establishment should have access to any food chain information, knowledge of which may result in serious disruption of the slaughterhouse activity, in sufficient time before the animals arrive at the slaughterhouse, in order to plan the slaughterhouse activity accordingly. Management of the slaughterhouse or meat industry establishment must evaluate the relevant information and submit the documents to the official veterinarian. The slaughter or dressing of the animals may not take place until the official veterinarian so permits.

Management of the slaughterhouse or meat industry establishment must check veterinary passports accompanying domestic cloven-hoofed animals to ensure that the animal is intended for slaughter for human consumption. If the animal is accepted for slaughter, the management must give the passport to the official veterinarian.

12. TRANSPORT OF LIVE ANIMALS TO SLAUGHTERHOUSES AND MEAT INDUSTRY ESTABLISHMENTS

Persons and entities transporting live animals to slaughterhouses or meat industry establishments must ensure compliance with the following requirements.

During collection and transport, animals must be handled carefully without causing unnecessary distress.

Animals showing symptoms of disease or originating in herds known to be contaminated with agents of public health importance may only be transported to slaughterhouses or meat industry establishments when the competent authority so permits.

13. REQUIREMENTS FOR SLAUGHTERHOUSES AND MEAT INDUSTRY ESTABLISHMENTS

Management of slaughterhouses and meat industry establishments must ensure that the construction, layout and equipment of slaughterhouses in which domestic ungulates are slaughtered meet the following requirements.

Slaughterhouses and meat industry establishments must have hygienic lairage facilities or,

climate permitting, waiting pens that are easy to clean and disinfect. These facilities must be equipped for watering the animals and, if necessary, feeding them. The drainage of the wastewater must not compromise the safety of meat and meat products.

Slaughterhouses and meat industry establishments must also have separate lockable facilities or, climate permitting, pens for sick or suspect animals with separate draining and sited in such a way as to avoid contamination of other animals, unless the competent authority considers that such facilities are unnecessary.

The size of the lairage facilities must ensure that the welfare of the animals is respected. Their layout must facilitate ante- mortem inspections, including the identification of the animals or groups of animals.

To avoid contaminating meat, slaughterhouses and meat industry establishments must:

have a sufficient number of rooms, appropriate to the operations being carried out;

have a separate room for the emptying and cleaning of stomachs and intestines, unless the competent authority authorizes the separation in time of these operations within a specific slaughterhouse on a case-by-case basis;

ensure separation in space or time of the following operations:

stunning and bleeding;

in the case of porcine animals, scalding, depilation, scraping and singeing;

evisceration and further dressing;

handling clean guts and tripe;

preparation and cleaning of other offal, particularly the handling of skinned heads if it does not take place at the slaughter line;

packaging offal;

dispatching meat;

have installations that prevent contact between the meat and the floors, walls and fixtures;

have slaughter lines (where operated) that are designed to allow constant progress of the slaughter process and to avoid cross- contamination between the different parts of the slaughter line. Where more than one slaughter line is operated in the same premises, there must be adequate separation of the lines to prevent cross-contamination.

Slaughterhouses and meat industry establishments must have facilities for disinfecting tools with hot water supplied at not less than 82°C, or an alternative system having an equivalent effect.

The equipment for washing hands used by the staff engaged in handling exposed meat must have taps designed to prevent the spread of contamination.

Slaughterhouses and meat industry establishments must have lockable facilities for the refrigerated storage of detained meat and separate lockable facilities for the storage of meat declared unfit for human consumption.

Slaughterhouses and meat industry establishments must have a separate place with appropriate facilities for the cleaning, washing and disinfection of means of transport for livestock. However, slaughterhouses need not have these places and facilities if the competent authority so permits and official authorized places and facilities exist nearby.

Slaughterhouses and meat industry establishments must have lockable facilities reserved for the slaughter of sick and suspect animals. This is not essential if this slaughter takes place in other establishments authorized by the competent authority for this purpose, or at the end of the normal slaughter period.

If manure or digestive tract content is stored in slaughterhouses or meat industry establishments, there must be a special area or place for that purpose.

Slaughterhouses and meat industry establishments must have an adequately equipped lockable facility or, where needed, room for the exclusive use of the veterinary service.

14. ANIMAL SLAUGHTER HYGIENE

Management of slaughterhouses and meat industry establishments, in which domestic ungulates are slaughtered must ensure compliance with the following requirements.

After arrival in the slaughterhouse, the slaughter of the animals must not be unduly delayed. However, where required for welfare reasons, animals must be given a resting period before slaughter.

Meat from animals other must not be used for human consumption if they die otherwise than by being slaughtered in slaughterhouses or meat industry establishments.

Only live animals intended for slaughter may be brought into slaughterhouses or meat industry establishments.

Meat from animals that undergo slaughter following an accident in slaughterhouses or meat industry establishments may be used for human consumption if, on inspection, no serious lesions other than those due to the accident are found.

The animals or, where appropriate, each batch of animals sent for slaughter must be identified so that their origin can be traced.

Animals must be clean.

Management of slaughterhouses and meat industry establishments must follow the instructions of the veterinarian appointed by the competent authority.

Animals brought into the slaughter hall must be slaughtered without undue delay.

Stunning, bleeding, skinning, evisceration and other dressing must be carried out without undue delay and in a manner that avoids contaminating the meat. In particular:

the trachea and oesophagus must remain intact during bleeding, except in the case of slaughter according to a religious custom;

during the removal of hides and fleece:

contact between the outside of the skin and the carcass must be prevented;

operators and equipment coming into contact with the outer surface of hides and fleece must not touch the meat;

measures must be taken to prevent the spillage of digestive tract content during and after evisceration and to ensure that evisceration is completed as soon as possible after stunning;

removal of the udder must not result in contamination of the carcass with milk or colostrum.

Carcasses and other parts of the body intended for human consumption must be completely skinned, except in the case of porcine animals, the heads of ovine and caprine animals and calves, the muzzle and lips of bovine animals and the feet of bovine, ovine and caprine animals.

Heads, including muzzle and lips, and feet must be handled in such a way as to avoid contamination.

When not skinned, porcine animals must have their bristles removed immediately. The risk of contamination of the meat with scalding water must be minimized. Only approved additives may be used for this operation. Porcine animals must be thoroughly rinsed afterwards with potable water.

The carcasses must not contain visible fecal contamination. Any visible contamination must be removed without delay by trimming or alternative means having an equivalent effect.

Carcasses and offal must not come into contact with floors, walls or work stands.

Management of slaughterhouses and meat industry establishments must follow the instructions of the competent authority to ensure that post-mortem inspection of all slaughtered animals is carried out

under suitable conditions.

Until post-mortem inspection is completed, parts of a slaughtered animal subject to such inspection must:

remain identifiable as belonging to a given carcass;

come into contact with no other carcass, offal or viscera, including those that have already undergone post-mortem inspection.

however, provided that it shows no pathological lesion, the penis may be discarded immediately.

Both kidneys must be removed from their fatty covering. In the case of bovine and porcine animals, and solipeds, the peri-renal capsule must also be removed.

If the blood or other offal of several animals is collected in the same container before completion of post-mortem inspection, the entire contents must be declared unfit for human consumption if the carcass of one or more of the animals concerned has been declared unfit for human consumption.

After post-mortem inspection:

The tonsils of bovine animals, porcine animals and solipeds must be removed hygienically;

Parts unfit for human consumption must be removed as soon as possible from the clean sector of the slaughterhouse or meat industry establishment;

Meat detained or declared unfit for human consumption and inedible by- products must not come into contact with meat declared fit for human consumption;

Viscera or parts of viscera remaining in the carcass, except for the kidneys, must be removed entirely and as soon as possible, unless the competent authority authorizes otherwise.

Post-mortem inspection must be followed immediately by chilling in the slaughterhouse to ensure a temperature throughout the meat of not more than 3°C for offal and 7°C for other meat along a chilling curve that ensures a continuous decrease of the temperature.

When destined for further handling:

Stomachs must be scalded or cleaned;

Intestines must be emptied and cleaned;

Heads and feet must be skinned or scalded and depilated.

Where the slaughterhouse or meat industry establishment is approved for the slaughter of different animal species or for the handling of carcasses of farmed game and wild game, precautions must be taken to prevent cross-contamination by separation either in time or in space of operations carried out on the different species. Separate facilities for the reception and storage of unskinned carcasses of farmed game slaughtered at the farm and for wild game must be available.

If the slaughterhouse does not have lockable facilities reserved for the slaughter of sick or suspect animals, the facilities used to slaughter such animals must be cleaned, washed and disinfected under official supervision before the slaughter of other animals is resumed.

Carcasses of domestic ungulates may be cut into half-carcasses or quarters, and half carcasses into no more than three wholesale cuts, in slaughterhouses. Further cutting and boning must be carried out in a cutting plant.

15. SPECIAL REQUIREMENTS FOR MEAT CUTTING PLANTS

Management of slaughterhouses and meat industry establishments must ensure that facilities for handling meat of domestic ungulates:

are constructed so as to avoid contamination of meat, in particular by allowing constant progress of the operations or ensuring separation between the different production batches;

have rooms for the separate storage of packaged and exposed meat, unless stored at different

times or in such a way that the packaging material and the manner of storage cannot be a source of contamination for the meat;

have equipment for washing hands with taps designed to prevent the spread of contamination, for use by staff engaged in handling exposed meat;

have facilities for disinfecting tools with hot water supplied at not less than 82°C, or an alternative system having an equivalent effect.

16. HYGIENE DURING CUTTING AND BONING

Slaughterhouses and meat industry establishments must ensure that cutting and boning of meat of domestic ungulates takes place in accordance with the following requirements:

the work on meat must be organized in such a way as to prevent or minimize contamination.

during the chilling operations, there must be adequate ventilation to prevent condensation on the surface of the meat.

meat intended for cutting is brought into the workrooms progressively as needed;

during cutting, boning, trimming, slicing, dicing, wrapping and packaging, the meat is maintained at not more than 3°C for offal and 7°C for other meat, by means of an ambient temperature of not more than 12°C or an alternative system having an equivalent effect;

where the premises are approved for the cutting of meat of different animal species, precautions are taken to avoid cross-contamination, where necessary by separation of the operations on the different species in either space or time.

Meat may also be boned and cut prior to reaching the temperature 7°C when the cutting room is on the same site as the slaughter premises.

In this case, the meat must be transferred to the cutting room either directly from the slaughter premises or after a waiting period in a chilling or refrigerating room. As soon as it is cut and, where appropriate, packaged, the meat must be chilled to the temperature 7°C

Where meat is packaged or wrapped:

packaging material should be suitable for use, stored and used in a hygienic manner;

cases or cartons should have a suitable inner liner or other means of protecting the meat, except that the liner or other protection may not be required if pieces of meat, such as cuts, are individually wrapped before packing.

17. MEAT STORAGE AND TRANSPORT

Due to the potential for growth of pathogenic and spoilage micro-organisms under conditions of inadequate temperature control, meat must attain the temperature not more than 3°C for offal and 7°C for other meat before transport, and remain at that temperature during transport.

Equipment for continuous monitoring and recording of temperatures should accompany transport vehicles and bulk containers wherever appropriate.

Additionally, the conditions of transport should provide adequate protection from exogenous contamination and damage, and should minimize growth of pathogenic and spoilage micro-organisms.

If meat is inadvertently exposed to adverse temperature conditions or sources of contamination that may affect safety and suitability, an inspection should be carried out by a competent person before further transport or distribution is allowed.

Meat must attain the temperature not more than 3°C for offal and 7°C for other meat and remain at that temperature during storage.

Meat intended for freezing must be frozen without undue delay, taking into account where necessary a stabilization period before freezing.

Exposed meat must be stored and transported separately from packaged meat, unless stored or transported at different times or in such a way that the packaging material and the manner of storage or transport cannot be a source of contamination for the meat.

18. MINCED MEAT, MEAT PREPARATIONS AND MECHANICALLY SEPARATED MEAT (MSM)

18.1. REQUIREMENTS FOR SLAUGHTERHOUSES AND MEAT INDUSTRY ESTABLISHMENTS

Slaughterhouses and meat industry establishments producing minced meat, meat preparations or MSM must ensure that they:

are constructed so as to avoid contamination of meat and products, in particular by:

allowing constant progress of the operations;

ensuring separation between the different production batches;

have rooms for the separate storage of packaged and exposed meat and products, unless stored at different times or in such a way that the packaging material and the manner of storage cannot be a source of contamination for the meat or products;

have rooms equipped to ensure compliance with the temperature of not more than 4°C for poultry, 3°C for offal and 7°C for other meat;

have equipment for washing hands used by staff handling exposed meat and products with taps designed to prevent the spread of contamination;

have facilities for disinfecting tools with hot water supplied at not less than 82°C, or an alternative system having an equivalent effect.

The definition of mechanically separated meat (MSM) should be a generic one covering all methods of mechanical separation. Rapid technological developments in this area mean that a flexible definition is appropriate. The technical requirements for MSM should differ, however, depending on a risk assessment of the product resulting from different methods.

18.2. PRODUCTION OF MINCED MEAT AND MEAT PREPARATIONS

The following requirements apply to the production of minced meat and meat preparations.

frozen or deep-frozen meat used for the preparation of minced meat or meat preparations must be boned before freezing. It may be stored only for a limited period.

when prepared from chilled meat, minced meat must be prepared in the case of poultry, within no more than three days of their slaughter;

in the case of animal other than poultry, within no more than six days of their slaughter;

within no more than 15 days from the slaughter of the animals in the case of boned, vacuum-packed beef and veal.

immediately after production, minced meat and meat preparations must be wrapped or packaged and be:

chilled to an internal temperature of not more than 2°C for minced meat and 4°C for meat preparations;

frozen to an internal temperature of not more than -18°C.

These temperature conditions must be maintained during storage and transport.

18.3. PRODUCTION OF MSM

The following requirements apply to the production and use of MSM produced using techniques that do not alter the structure of the bones used in the production of MSM and the calcium content of which is not significantly higher than that of minced meat.

raw material for deboning from an on-site slaughterhouse must be no more than seven days old; otherwise, raw material for deboning must be no more than five days old. However, poultry carcasses must be no more than three days old.

mechanical separation must take place immediately after deboning.

if not used immediately after being obtained, MSM must be wrapped or packaged and then chilled to a temperature of not more than 2°C or frozen to an internal temperature of not more than –18°C. These temperature requirements must be maintained during storage and transport.

if the food business operator has carried out analyses demonstrating that MSM complies with the microbiological criteria for minced meat it may be used in meat preparations that are clearly not intended to be consumed without first undergoing heat treatment and in meat products. (MSM not shown to comply with this may be used only to manufacture heat-treated meat products in approved establishments)

raw material for deboning from an on-site slaughterhouse must be no more than seven days old; otherwise, raw material for deboning must be no more than five days old. However, poultry carcasses must be no more than three days old.

if mechanical separation does not take place immediately after deboning the flesh-bearing bones must be stored and transported at a temperature of not more than 2°C or, if frozen, at a temperature of not more than - 18 °C.

Flesh-bearing bones obtained from frozen carcasses must not be refrozen.

if not used within one hour of being obtained, MSM must be chilled immediately to a temperature of not more than 2°C.

if, after chilling, MSM is not processed within 24 hours, it must be frozen within 12 hours of production and reach an internal temperature of not more than –18°C within six hours.

frozen MSM must be wrapped or packaged before storage or transport, must not be stored for more than three months and must be maintained at a temperature of not more than –18°C during storage and transport.

MSM may be used only to manufacture heat-treated meat products in establishments approved in accordance with this Regulation.

Minced meat, meat preparations and MSM must not be re-frozen after thawing.

Packages intended for supply to the final consumer containing minced meat from poultry or solipeds or meat preparations containing MSM must bear a notice indicating that such products should be cooked before consumption.

The conditions of storage of meat preparations and manufactured meat should be clearly presented on the packaging.

19. HYGIENE DURING AND AFTER PRODUCTION OF MINCED MEAT, MEAT PREPARATIONS AND MSM

The work on meat must be organized in such a way as to prevent or minimize contamination. To

this end, food business operators must ensure in particular that the meat used is: at a temperature of not more than 4°C for poultry, 3°C for offal and 7°C for other meat, brought into the preparation room progressively as needed.

20. REQUIREMENTS FOR RAW MATERIALS

20.1. RAW MATERIALS FOR MINCED MEAT

The raw material used to prepare minced meat must meet the following requirements:
It must comply with the requirements for fresh meat;
It must derive from skeletal muscle, including adherent fatty tissues;
It must not derive from:
scrap cuttings and scrap trimmings (other than whole muscle cuttings);
MSM;
meat containing bone fragments or skin;
meat of the head with the exception of the masseters, the non- muscular part of the *linea alba*, the region of the carpus and the tarsus, bone scrapings and the muscles of the diaphragm (unless the serosa has been removed).

20.2. RAW MATERIALS FOR MEAT PREPARATIONS

The following raw material may be used to prepare meat preparations:
fresh meat;
meat meeting the requirements of raw material used for minced meat.
If the meat preparation is clearly not intended to be consumed without first undergoing heat treatment may be used:
meat derived from the mincing or fragmentation of meat meeting the requirements of raw material used for minced meat other than scrap cuttings and scrap trimmings (other than whole muscle cuttings);
MSM if the food business operator has carried out analyses demonstrating that MSM complies with the microbiological criteria for minced meat adopted in accordance with Regulation (EC) No 852/2004 it may be used in meat preparations that are clearly not intended to be consumed without first undergoing heat treatment.

20.3. RAW MATERIALS FOR MSM

The raw material used to produce MSM must comply with the requirements for fresh meat.
The following material must not be used to produce MSM:
or poultry, the feet, neck skin and head;
for other animals, the bones of the head, feet, tails, femur, tibia, fibula, humerus, radius and ulna.

21. MEAT PRODUCTS

The establishment must ensure that the following items are not used in the preparation of meat products:
genital organs of either female or male animals, except testicles;

urinary organs, except the kidneys and the bladder;

the cartilage of the larynx, the trachea and the extra-lobular bronchi;

eyes and eyelids;

the external auditory meatus;

horn tissue;

in poultry, the head — except the comb and the ears, the wattles and caruncles — the oesophagus, the crop, the intestines and the genital organs.

All meat, including minced meat and meat preparations, used to produce meat product must meet the requirements for fresh meat.

If the food business operator has carried out analyses demonstrating that MSM complies with the microbiological criteria for minced meat adopted in accordance with Regulation (EC) No 852/2004 it may be used in meat preparations that are clearly not intended to be consumed without first undergoing heat treatment and in meat products.

22. MARKING OF MEAT

Marking of meat is applied only after meat was subjected to ante-mortem and post-mortem inspection and when there are no grounds for declaring the meat unfit for human consumption.

The marking label for meat and meat products derived from the meat should have barcodes containing following information:

letter code of a Customs Union member-state;

reference number of the certified slaughterhouses and meat processing establishments of a Customs Union member-state;

reference number of the premises from which the animal was shipped to slaughter;

individual number of the animal;

net weight;

date of production including date and time;

expiration date;

code of the good.

Marking takes place on the external surface of the carcass, by stamping the mark in ink or hot branding, and in such a manner that, if carcasses are cut into half carcasses or quarters, or half carcasses are cut into three pieces, each piece bears a health mark.

The marking sign must be an oval mark at least 6.5 cm wide by 4.5 cm high.

The letters on the marking sign must be at least 0.8 cm high and figures - at least 1cm high. The dimensions and characters of the mark may be reduced for health marking of lamb, kids and piglets.

The colors used for marking must be authorized in accordance with rules on the use of coloring substances in foodstuffs.

23. SPECIFIED RISK MATERIAL

The following tissues shall be designated as specified risk material:

as regards bovine animals:

the skull excluding the mandible and including the brain and eyes, and the spinal cord of animals aged over 12 months;

the vertebral column excluding the vertebrae of the tail, the spinous and transverse processes of the cervical, thoracic and lumbar vertebrae and the median sacral crest and wings of the sacrum, but

including the dorsal root ganglia, of animals aged over 30 months;

the tonsils, the intestines from the duodenum to the rectum and the mesentery of animals of all ages.

as regards ovine and caprine animals:

the skull including the brain and eyes, the tonsils and the spinal cord of animals aged over 12 months or which have a permanent incisor erupted through the gum;

the spleen and ileum of animals of all ages.

Specified risk material shall be stained with a dye or, as appropriate, otherwise marked, immediately on removal, and disposed.

Specified risk material shall be removed at slaughterhouses, or, as appropriate, other places of slaughter, or at cutting plants, in the case of vertebral column of bovine animals;

Tongues of bovine animals of all ages intended for human or animal.

24. EMERGENCY SLAUGHTER OUTSIDE SLAUGHTERHOUSES OR MEAT INDUSTRY ESTABLISHMENTS

Management of slaughterhouses and meat industry establishments must ensure that meat from domestic ungulates that have undergone emergency slaughter outside the slaughterhouse may be used for human consumption only if it complies with all the following requirements.

An otherwise healthy animal must have suffered an accident that prevented its transport to the slaughterhouse for welfare reasons.

A veterinarian must carry out an ante-mortem inspection of the animal.

The slaughtered and bled animal must be transported to the slaughterhouse hygienically and without undue delay. Removal of the stomach and intestines, but no other dressing, may take place on the spot, under the supervision of the veterinarian. Any viscera removed must accompany the slaughtered animal to the slaughterhouse and be identified as belonging to that animal.

If more than two hours elapse between slaughter and arrival at the slaughterhouse, the animal must be refrigerated. Where climatic conditions so permit, active chilling is not necessary.

A declaration by the owner who reared the animal, stating the identity of the animal and indicating any veterinary products or other treatments administered to the animal, dates of administration and withdrawal periods, must accompany the animal to the slaughterhouse or meat industry establishment.

A declaration issued by the veterinarian recording the favorable outcome of the ante-mortem inspection, the date and time of, and reason for, emergency slaughter, and the nature of any treatment administered by the veterinarian to the animal, must accompany the slaughtered animal to the slaughterhouse.

The slaughtered animal must be fit for human consumption following post- mortem inspection carried out in the slaughterhouse.

Management of slaughterhouses and meat industry establishments must follow any instructions that the official veterinarian may give after post-mortem inspection concerning the use of the meat.

25. SAMPLING RULES FOR CARCASES OF CATTLE, PIGS, SHEEP, GOATS AND HORSES

Five carcasses shall be sampled at random during each sampling session. Sample sites must be selected taking into account the slaughter technology used in each slaughterhouse or meat industry

establishment.

When sampling for analyses of Enterobacteriaceae and aerobic colony counts, four sites of each carcass shall be sampled. Four tissue samples representing a total of 20 cm2 shall be obtained by the destructive method. When using the nondestructive method for this purpose, the sampling area shall cover a minimum of 100 cm2 (50 cm2 for small ruminant carcasses) per sampling site.

When sampling for Salmonella analyses, an abrasive sponge sampling method shall be used. Areas most likely to be contaminated shall be selected. The total sampling area shall cover a minimum of 400 cm2. When samples are taken from the different sampling sites on the carcass, they shall be pooled before examination.

Management of slaughterhouses and meat industry establishments shall take samples for microbiological analysis at least once a week. The day of sampling shall be changed each week to ensure that each day of the week is covered.

As regards the sampling of carcases for Enterobacteriaceae and aerobic colony count analyses, the frequency may be reduced to fortnightly testing if satisfactory results are obtained for six consecutive weeks.

In the case of sampling for *Salmonella* analyses of minced meat, meat preparations and carcases, the frequency may be reduced to fortnightly if satisfactory results have been obtained for 30 consecutive weeks.

26. SAMPLING FREQUINCIES FOR MINCED MEAT, MEAT PEPARATIONS AND MECHANICALLY SEPARATED MEAT

Slaughterhouses and meat industry establishments producing minced meat, meat preparations or mechanically separated meat shall take samples for microbiological analysis at least once a week. The day of sampling shall be changed each week to ensure that each day of the week is covered.

As regards the sampling of minced meat and meat preparations for *E. coli* and aerobic colony count analyses the frequency may be reduced to fortnightly testing if satisfactory results are obtained for six consecutive weeks.

In the case of sampling for *Salmonella* analyses of minced meat, meat preparations the frequency may be reduced to fortnightly if satisfactory results have been obtained for 30 consecutive weeks.

27. TRANSPORT OF LIVE POULTRY TO POULTRY SLAUGHTERHOUSES OR MEAT INDUSTRY ESTABLISHMENTS

Persons and entities transporting live poultry to slaughterhouses must ensure compliance with the following requirements.

During collection and transport, poultry must be handled carefully without causing unnecessary distress.

Poultry showing symptoms of disease or originating in flocks known to be contaminated with agents of public-health importance may only be transported to the slaughterhouse when permitted by the competent authority.

Crates for delivering live poultry to poultry slaughterhouses or meat industry establishments, as well as modules, where used, must be made of non-corrodible material and be easy to clean and disinfect. Immediately after emptying and, if necessary, before re-use, all equipment used for collecting and delivering live poultry must be cleaned, washed and disinfected.

28. REQUIREMENTS FOR POULTRY SLAUGHTERHOUSES OR MEAT INDUSTRY ESTABLISHMENTS

Management of poultry slaughterhouses or meat industry establishments must ensure that the construction, layout and equipment of slaughterhouses in which poultry or lagomorphs are slaughtered meet the following requirements.

Poultry slaughterhouses or meat industry establishments must have a room or covered space for the reception of poultry and for their inspection before slaughter.

To avoid contaminating meat, poultry slaughterhouses or meat industry establishments must:

have a sufficient number of rooms, appropriate to the operations being carried out;

have a separate room for evisceration and further dressing, including the addition of seasonings to whole poultry carcasses, unless the competent authority authorizes separation in time of these operations within a specific slaughterhouse on a case-by-case basis;

ensure separation in space or time of the following operations:

stunning and bleeding;

plucking or skinning, and any scalding;

dispatching meat;

have installations that prevent contact between the meat and the floors, walls and fixtures;

have slaughter lines (where operated) that are designed to allow a constant progress of the poultry slaughter process and to avoid cross-contamination between the different parts of the slaughter line. Where more than one slaughter line is operated in the same premises, there must be adequate separation of the lines to prevent cross-contamination.

Poultry slaughterhouses or meat industry establishments must have facilities for disinfecting tools with hot water supplied at not less than 82°C, or an alternative system having an equivalent effect.

The equipment for washing hands used by the staff engaged in handling exposed meat must have taps designed to prevent the spread of contamination.

Slaughterhouses for poultry, animals, or meat industry establishments must have lockable facilities for the refrigerated storage of detained meat and separate lockable facilities for the storage of meat declared unfit for human consumption.

Poultry slaughterhouses or meat industry establishments must have a separate place with appropriate facilities for the cleaning, washing and disinfection of:

transport equipment such as crates;

means of transport.

Poultry slaughterhouses or meat industry establishments must have an adequately equipped lockable facility or, where needed, room for the exclusive use of the veterinary service.

29. POULTRY SLAUGHTER HYGIENE

Management of poultry slaughterhouses or meat industry establishments in which poultry are slaughtered must ensure compliance with the following requirements.

Meat from poultry must not be used for human consumption if the poultry die otherwise than by being slaughtered in a poultry slaughterhouse or meat industry establishment.

Only live poultry intended for slaughter may be brought into poultry slaughterhouses or meat industry establishments.

Poultry brought into the slaughter room must be slaughtered without undue delay.

Stunning, bleeding, skinning or plucking, evisceration and other dressing of poultry must be

carried out without undue delay in such a way that contamination of the meat is avoided. In particular, measures must be taken to prevent the spillage of digestive tract contents during evisceration.

Management of poultry slaughterhouses or meat industry establishments must follow the instructions of the competent authority to ensure that the post-mortem inspection is carried out under suitable conditions, and in particular that slaughtered poultry can be inspected properly.

After post-mortem inspection:

parts unfit for human consumption must be removed as soon as possible from the clean sector of the establishment;

poultry meat detained or declared unfit for human consumption and inedible by- products must not come into contact with meat declared fit for human consumption;

viscera or parts of viscera remaining in the carcase, except for the kidneys, must be removed entirely, if possible, and as soon as possible, unless otherwise authorised by the competent authority.

After inspection and evisceration, slaughtered poultry must be cleaned and chilled to not more than 4°C as soon as possible, unless the meat is cut while warm.

When poultry carcasses are subjected to an immersion chilling process, account must be taken of the following.

Every precaution must be taken to avoid contamination of carcases, taking into account parameters such as carcase weight, water temperature, volume and direction of water flow and chilling time.

Equipment must be entirely emptied, cleaned and disinfected whenever this is necessary and at least once a day.

Sick or suspect poultry, and poultry slaughtered in application of disease eradication or control programmes, must not be slaughtered in poultry slaughterhouses or meat industry establishments except when permitted by the competent authority. In that event, slaughter must be performed under official supervision and steps taken to prevent contamination; the premises must be cleaned and disinfected before being used again.

30. REQUIREMENTS FOR POULTRY MEAT CUTTING MACHINERY

Poultry slaughterhouses or meat industry establishments must ensure that the facilities are constructed so as to avoid contamination of meat, in particular by:

allowing constant progress of the operations;

ensuring separation between the different production batches;

have rooms for the separate storage of packaged and exposed meat, unless stored at different times or in such a way that the packaging material and the manner of storage cannot be a source of contamination for the meat;

have equipment for washing hands used by staff handling exposed meat with taps designed to prevent the spread of contamination;

have facilities for disinfecting tools with hot water supplied at not less than 82 °C, or an alternative system having an equivalent effect.

31. HYGIENE DURING AND AFTER CUTTING AND BONING OF POULTRY MEAT

Poultry slaughterhouses or meat industry establishments must ensure that cutting and boning of poultry meat takes place in accordance with the following requirements.

The work related to poultry meat must be organized in such a way as to prevent or minimize

contamination. To this end, poultry slaughterhouses or meat industry establishments must ensure that:

poultry meat intended for cutting is brought into the workrooms progressively as needed;

during cutting, boning, trimming, slicing, dicing, wrapping and packaging, the temperature of the meat is maintained at not more than 4°C;

where the premises are approved for the cutting of meat of different animal species, precautions are taken to avoid cross-contamination, where necessary by separation of the operations on the different species in either space and/or time.

Poultry meat may be boned and cut prior to reaching the temperature not more than 4°C when the cutting room is on the same site as the slaughter premises, provided that it is transferred to the cutting room either:

directly from the slaughter premises;

after chilling or refrigerating room.

As soon as poultry meat is cut and, where appropriate, packaged, it must be chilled to a temperature of not more than 4°C.

Poultry meat must attain a temperature of not more than 4°C before transport, and be maintained at that temperature during transport. Meat derived from poultry intended for freezing must be frozen without undue delay.

Exposed meat must be stored and transported separately from packaged meat, unless stored or transported at different times or in such a way that the packaging material and the manner of storage or transport cannot be a source of contamination for the meat.

32. SAMPLING RULES FOR POULTRY CARCASES

For the Salmonella analyses, a minimum of 15 carcasses shall be sampled at random during each sampling session and after chilling. A piece of approximately 10 g from neck skin shall be obtained from each carcass. On each occasion the neck skin samples from three carcasses shall be pooled before examination in order to form 5 x 25 g final samples.

END UNOFFICIAL TRANSLATION.