

**EURASIAN ECONOMIC COMMISSION  
COUNCIL**

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**DECISION**

October 9, 2014

**No.94**

Minsk

**On the Regulation on the Harmonized Procedure of Joint On-Site Inspections and of  
Taking Samples of Goods (Products) Subject to Veterinary Control (Supervision)**

In accordance with Article 3 of the Treaty on the Eurasian Economic Commission of November 18, 2011, the Rules of Procedure of the Eurasian Economic Commission approved by Decision of the Supreme Eurasian Economic Council No.1 on November 18, 2001, and Article 7 of the Customs Union Agreement on Veterinary Measures dated December 11, 2009, the Council of the Eurasian Economic Commission decided as follows:

1. Approve the attached Regulation on the Harmonized Procedure of Joint On-Site Inspections and of Taking Samples of Goods (Products) Subject to Veterinary Control (Supervision).
2. Repeal Clause 1 of the Customs Union Commission Decision No. 834 dated October 18, 2011 “On the Regulation on the Harmonized Procedure of Joint On-Site Inspections and of Taking Samples of Goods (Products) Subject to Veterinary Control (Supervision).
3. This Decision shall come into force upon the expiration of 30 calendar days following its official publication, except for Clause 11 and Clause 48 “g” of the Regulation approved by the present Decision, which shall come into effect on the date of the accession of the Republic of Kazakhstan to the World Trade Organization.

**Members of the Council of the Eurasian Economic Commission:**

On behalf of the Republic of  
Belarus

S. Rumas

Stamp: For documents

On behalf of the Republic of  
Kazakhstan

B. Sagintaev

Stamp: For documents

On behalf of the Russian  
Federation

I. Shuvalov

Stamp: For documents

APPROVED BY:

Eurasian Economic Commission  
Council Decision No.94 dated  
October 9, 2014

## REGULATION

### **On the Harmonized Procedure of Joint On-Site Inspections and of Taking Samples of Goods (Products) Subject to Veterinary Control (Supervision)**

#### **I. General Provisions**

1. The present Regulation is developed to implement the Customs Union Agreement on Veterinary and Sanitary Measures of December 11, 2009.

2. This Regulation establishes general principles of (i) ensuring safety of animals and products of animal origin which are included in the Common List of Goods Subject to Veterinary Control (supervision) approved by the CU's Commission Decision No.317 dated June 18, 2010 (hereinafter "Common List of Goods"), when imported to the customs territory of the Customs Union from third countries or transported from the territory of one CU Member-State (hereinafter "Member-State") to another Member-State, during their production, processing, transportation and/or storage, as well as (ii) auditing of official control systems of third countries and joint check (inspection)s (audits) of organizations and individuals involved in production (manufacture), processing, transportation and/or storage of goods (products) subject to veterinary control, and (iii) acceptance of guarantees.

3. Joint on-site inspections (checks) shall be performed in accordance with this Regulation as follows:

inspections (checks) of third-country enterprises, where no audit of official control systems was performed, or where the official system audit results are not satisfactory, for the purpose of including these enterprises in the register of third-country enterprises (see Section VI of this Regulation);

inspections (checks) of third-country enterprises, where no audit of official control systems was performed, or where the official system audit results are not satisfactory, in order to verify the inclusion of such enterprises in the register of third-country enterprises (see Section VI of this Regulation);

inspections (checks) of third-country enterprises during the audit (follow-up audit) of the official control system to confirm (reconfirm) the fact that the official control system of a third country and measures taken thereby ensure at least the same level of safety as the one provided in the Customs Union (see Section VI of this Regulation);

inspections (checks) of Member-States' enterprises aimed at including such enterprises in the CU Register of Companies (see Section VII of this Regulation);

inspections (checks) of Member-States' enterprises included in the CU Register of Companies for the veterinary control (supervision) purposes (see Section VIII of this Regulation).

4. During the audit of a third-party official control system or on-site inspections (checks), the authorized bodies of the Member-States take account of the existing trading conditions, history of trade and data concerning compliance with the CU requirements to third countries which exported respective goods (products) to the territory of the Customs Union.

## **II. Terms and definitions**

5. For purposes of this Regulation, the definitions of the following terms apply:

“audit of a foreign official control system” means a procedure used to verify the ability of a foreign official control system to ensure that the safety of goods (products) is at least equivalent to the level of safety established by the CU requirements;

“on-site check (inspection)” is a form of the veterinary control (supervision) performed by the inspector visiting the facilities concerned;

“common veterinary requirements” means the common veterinary (veterinary and sanitary) requirements to the goods subject to the veterinary control (supervision) approved by the CU’s Commission Decision No. 317 dated June 18, 2010;

“zoning” means procedures implemented by the competent authority or authorized body with a view to defining animal subpopulations of distinct epizootic status within its territory primarily on a geographic basis;

“inspector” means an official authorized by a Member-State’s authorized body or a third-country’s competent authority;

“inspector/auditor” means an employee of a governmental body or institution who has the required knowledge and experience in audits and/or inspections;

“quarantine” means a special regime of activity and organizational measures focused on localization and liquidation of dangerous infectious and quarantine animal diseases defined in the Member-States’ legislation;

“compartmentalisation” means procedures implemented by the competent authority or authorized body jointly with producers/manufactures within the territory of the country to determine the subpopulations of animals and enterprises engaged into the circulation of products of animal origin, with specific epizootic status defined primarily by management and husbandry practices related to biosecurity;

“competent authority” means a public body of a third country empowered to develop and/or enforce legal acts (or performing both functions) related to checks/inspections;

“monitoring” means performance of planned and consistent observations or measurements with a view to defining general safety of goods (products) and their compliance with the relevant requirements;

“target unit” means a company or individual engaged in production (manufacture), processing, transportation and/or storage of controlled goods (products);

“controlled goods (products)” means animals and products of animal origin included in the Common List of Goods (Products);

“register of CU companies” means the register of enterprises and individuals engaged in production, processing and/or storage of controlled goods (products) transferred from the territory of one Member-State to the territory of another Member-State.

“register of companies from third countries” means the register of enterprises and individuals engaged in the manufacture, processing and/or storage of controlled goods (products) imported to the customs territory of the Customs Union;

“raw materials” means goods (products) intended for further processing;

“requirements of the Customs Union” means international standards, manuals and recommendations in the context of the CU Commission Decision No.721 “On Application of International Standards, Recommendations and Manuals” of June 22, 2011 related to the veterinary and sanitary requirements to the controlled goods; technical regulations of the Customs Union; Unified Veterinary Requirements and/or various requirements of the Member-States agreed upon with third countries in veterinary (import) certificates in accordance with the Section “Final Transitional Provisions” of the Unified Veterinary Requirements as well as mandatory national requirements of the Member-States to goods;

“authorized body” means the state body empowered to develop and/or enforce legal acts (or performing both functions) related to checks/inspections;

“expert” means an employee of a governmental body or institution who provides assistance to the authorized bodies of the Member-States during inspections (checks) and sampling of goods (products).

### **III.General principles to ensure safety of controlled goods (products) during production (manufacture), processing, transportation and/or storage**

6. Audit of a foreign official control system is a common practice used by the Member-States to ensure safety of the controlled goods (products) during production, processing, transportation and/or storage in third countries.

7. If the audit of a foreign official control system generates successful results, the enterprises (individuals) shall be included in the register of companies from third countries in accordance with the list provided by the competent authority in accordance with the relevant legal acts of the Customs Union.

8. If the audit of a foreign official control system was not conducted, or has not been completed, or the safety of the foreign official control system fails to be recognized equivalent to the level fixed by the CU requirements, the Member-States may negotiate the inclusion of the enterprise (individual) into the register of companies from third countries based on the results of the joint on-site inspection or the guarantees provided by the competent authority as required for the registration.

9. During the preparation and approval of the results of the joint on-site inspections and audit of the foreign official control system, the Member-States shall provide access to the results (including the possibility to preliminary study such results) for the third-country competent authority and the controlled facilities.

For the purposes of confidentiality and for the avoidance of the conflict of interest in respect of the facilities subject to check (inspection), the final version of the report published by the authorized bodies shall contain the number (identifier) and name of the enterprises and individuals engaged in the production (manufacture), processing, transportation and/or storage of controlled goods.

10. The principles of zoning and compartmentalisation shall be used together with the data obtained from the monitoring of controlled goods (products) conducted by the controlled company (organization, enterprise, individual) and, if the latter is located in a third country, the data of the audit of the foreign official control system shall be used during the joint on-site checks (inspections).

11. During joint on-site checks (inspections) in accordance with this Regulation, the inspector shall audit and assess the controlled facility in accordance with Annex 3, as defined in this Regulation, and, if found compliant with the international standards, manuals and recommendations, the facility shall be deemed compliant with the CU requirements based on the equivalence principle. In case a CU legal act or mandatory requirement of the national legislation

of any Member-State is of a limiting nature, the inspector, unless a respective scientific framework is available, shall assess the compliance based on international standards, manuals and recommendations stipulated by the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (hereinafter, the SPS Agreement) which entered into force on April 15, 1994, to impose tougher measures. With the respective legal act in place, the inspector shall provide it to the competent authority to afford grounds for equivalent measures in accordance with the SPS Agreement. In case an enterprise is included into the register of companies from third countries based on the guarantees of the competent authority, the inspector shall check and assess the performance of the guarantees issued for the purposes of the export certification.

12. The inspectors/auditors and experts of the authorized body shall be impartial. They shall have an adequate qualification, experience and insights into the respective field of knowledge. The inspectors/auditors and experts of the authorized body shall ensure the safety of the confidential information.

#### **IV. Audit of foreign official control systems**

13. The inspectors/auditors performing the audit of foreign official veterinary control systems shall distinguish the following two situations:

- a) countries from which no import of controlled goods (products) to the customs territory of the Customs Union has been performed;
- b) countries from which import of controlled goods (products) to the customs territory of the Customs Union has been performed.

14. In order to initiate an audit procedure, the competent authority shall send to the authorized body a request specifying the scope of the audit, including the groups of controlled goods (products) and types of activities of the controlled enterprises.

15. Information about the schedule of the audit of foreign official control systems and joint on-site inspections of thirty-country enterprises to be conducted by the authorized bodies are posted at the official website of the Eurasian Economic Commission (hereinafter – official website, the Commission, respectively) based on the data submitted by the authorized bodies and updated at least twice a year.

16. While assessing foreign official control systems, inspectors shall consider the history of trade with the respective country and information currently available to the authorized body concerning the following:

- a) Organization, structure and powers of the competent authority;
- b) Staffing;
- c) Material resources (including finance);
- d) Regulatory documents and functional abilities;
- e) Animal and human health control measures;
- f) Formal quality control systems, including quality management policy;
- g) Assessment of quality control system efficiency.

17. While assessing a foreign official control system, inspectors shall follow the principles specified in Annex 2 to this Regulation and make use of the assessment criteria specified in the OIE Aquatic & Terrestrial Health Codes, Codex Alimentarius, and any other international standards and manuals recognized by the World Trade Organization.

18. The first stage of the assessment comprises the documentary analysis. To this end, the authorized body makes a request to the competent authority to provide legislative and other related documents required for inspection purposes.

19. The competent authority may also receive a questionnaire to get additional information concerning the structure, powers or practical works thereof.

20. Once the documents are analyzed, the authorized bodies of the Member-States shall resolve whether the foreign official control system for the respective goods (products) is able to ensure the safety at least equivalents to the level required by the Customs Union.

21. Once this stage is successfully completed, the authorized bodies of the Member-States may schedule inspections to verify the duly implementation of the respective third country legislation.

22. The authorized body of a Member-State which planned to perform the audit shall, at least two months before (unless lesser period is agreed upon by the Member-States) the beginning of the planned visit to a third country requesting such audit, inform the authorized bodies of other Member-States about the forthcoming visit in order to organize inspector groups and coordinate the time of the visit.

23. The authorized bodies of other Member-States shall, no later than in two weeks after receiving the information on the forthcoming visit, provide a reply containing the refusal or consent to participate in the respective audit and information about the officials of such Member-State who will participate in the visit. The authorized body's failure to provide a reply within the set period shall be deemed a refusal to participate in the visit.

24. The visit shall be made by the inspectors/auditors from one of the Member-States if other authorized bodies of the Member-States fail to provide a reply or refused to participate. The authorized bodies of the Member-States not participating in the audit recognize the decision made by the visiting authorized body.

25. The primary audit is performed by a group of inspectors/auditors.

26. The authorized bodies may engage experts employed with the state authorities and institutions (except for translators) to assist to the inspectors/auditors concerning the following:

Legislation of the relevant third country;

The competent authority of the relevant third country, its structure, powers and independence, management and rights with respect to the effective application or enforcement of laws;

Training of personnel to conduct inspections;

Resources, including diagnostics;

Existence and implementation of procedures and monitoring systems reflected in the documents;

Animal health care and procedures applied to notify the Member-States and respective international organizations about outbreaks of animal diseases subject to OIE notification.

The experts shall be bound by the same liabilities and responsibilities as the inspectors/auditors concerning the protection of confidential information and ensuring the absence of the conflict of interests related to the products of the enterprises being inspected. The authorized body shall guarantee the experts' impartiality and fidelity to principles.

27. The audit includes verification of system data, such as national laws, rules, directives, instructions and other documents related to the audit programs; data concerning the enterprise activities, on-site checks (inspections) and other law enforcement activities; control of

residual chemicals at the technological sections from farms to slaughters; programs of microbiological and chemical research, laboratory support, sampling program, research methods and other requirements related to the export of products to the customs territory of the Customs Union, including reduction of pathogens, implementation of risk analysis methods and critical check points.

28. During on-site inspections as part of the audit, inspectors/auditors of the Member-States shall check and compare the control system documents of third countries to verify compliance thereof with the established control system.

29. The purpose of on-site visits as part of the audit shall be verification of the compliance, within the frameworks of the foreign official control system related to production, processing, transportation and/or storage of controlled goods (products), of all laws, rules and other requirements related to the safety analysis conducted by the authorized body of a Member-State to ensure the level of safety at least equivalent to the one established by the CU.

30. Once the documentary analysis and on-site visits (inspections) are completed, the authorized body of the Member-State shall prepare a preliminary audit report, including the provisions of the Annex C to the SPS Agreement and shall send the report to other Member-States. The report shall contain preliminary opinion on the equivalency and shall provide a clear legal basis for the instances when the foreign official control system is recognized incompliant based on the audit results and recommendations to rectify the incompliance.

31. The authorized bodies (including those not participating in the audit) shall provide additional data and clarifications concerning the information and the opinion contained in the preliminary report within two months from the date of the preliminary report received at the official email.

32. The authorized body shall assess the additional data and clarifications and shall make changes to the preliminary report, as required.

33. The authorized body shall prepare an updated preliminary audit report in terms of provisions of the Annex C to the SPS Agreement and shall attach it to the letter sent to the competent authority.

34. The competent authority jointly with other interested persons of such third country may provide additional data and clarifications concerning the information and the opinion contained in the preliminary report within two months from the date of notice of the preliminary report receipt at the official email.

35. The authorized body shall assess the additional data, and prepare, publish and send to the Commission a final report within two months from the date of the official letter from the competent authority with comments to the preliminary report.

36. The final report prepared by the authorized body (bodies) of a Member-State (Member-States) participating (participated) in the audit shall contain the opinion whether the foreign official control system ensures the safety level at least equivalent to that provided by the CU (hereinafter, opinion on equivalence).

37. Following the submission of the final audit report containing opinion on equivalence to the Commission, the latter shall publish at its official website the report specified in Clause 34 of this Regulation. The authorized body shall publish the information at its official website.

38. Once the information specified in Cause 37 of this Regulation is published, the competent authority shall make a list of enterprises which plan to import the controlled goods to the Customs Union, including those to be included in the register of companies from third countries.

39. The competent authority preparing the list of enterprises to be included in the register of companies from third countries as set forth in Clause 38 of this Regulation shall send the letter with the attached list to the relevant authorized body.

40. The authorized body shall update the register of companies from third countries by including the enterprises from the updated list and publish the updated register of companies from third countries within ten business days following the date of the respective letter from the competent authority.

41. The competent authority shall inform the Commission of the changes made in its national legislation affecting the official control system with regard to the controlled goods (products). The Commission shall inform the authorized bodies of such changes as soon as practical.

42. The authorized body of the Member-State (Member-States) has the right to conduct a follow-up audit of a foreign official control system of the third country but no oftener than once a year, except as specified in Clause 44 of this Regulation. The decision to conduct the follow-up audit shall be made in accordance with the expedience thereof and the need to reduce the scope of information to be provided by the competent authority.

43. Based on the final report containing a negative opinion on equivalence, the Member-States may consider whether the competent authority has the right to issue guarantees concerning the compliance of the controlled goods (products) produced by a particular enterprise or to inform the competent authority that the enterprises of the given third party may be included in the register of companies from third countries based solely on the positive results of the audit (inspection) performed by the CU inspectors.

The decision shall be made based on the trade history of the country, insights in the structure and powers of the competent authority of the given third country, and any other relevant information.

44. If the foreign official control system is not recognized as capable of ensuring safety at least equivalent to the level established by the CU, the competent authority of the country may file another request to the authorized body to hold an audit any time after rectification measures. The authorized body shall accept such request and, in order to reduce the scope of the required works to the minimum, to perform the equivalence verification procedure using the information received during the previous audit. In case insignificant issues arise during the first audit, the analysis of rectification measures may be sufficient, thus being the case, the decision may be adopted without repeating the audit. The follow-up audit is similar to the above procedure.

45. If the audit of the foreign official control system has been started but is not completed, or was not performed, the Member-States may consider acceptance of guarantees or conduct joint on-site checks (inspections) when inclusion to the register of companies from third countries is required.

## **V. Guarantees**

46. The competent authority may send to the authorized body a request to accept its guarantees concerning the compliance of controlled goods (products) produced by a particular enterprise, and attach the information according to subclauses "a", "c", "d", "g" and "j" of Clause 48 of this Regulation, which the competent authority deems necessary to assess the issue, including the list of enterprises as per the Nomenclature of Goods of Foreign Trade Activity of the Customs Union (hereinafter, the CU TNVED), and other types of activities. The guarantee of the competent authority shall be accepted for each group of goods (products) in accordance with the CU TNVED codes specified in the request of the competent authority.

47. Upon receipt of the request specified in Clause 46 of this Regulation, the authorized body shall consider the attached and other related information within the reasonable period, but no more than two months.

During the specified period, if necessary, the authorized body may request additional information from the competent authority in order to perform assessments according to the criteria specified in Clause 48 of this Regulation. Thus, the assessment period shall be extended by fifteen business days after receipt of additional information.

48. The request shall be reviewed by the authorized body based on the goods under consideration:

- a) Level of the competent authority development;
- b) Compliance with the guarantees previously provided by the competent authority;
- c) Risk of distribution at the territory of a third country and beyond of contagious disease agents, including animal and human diseases;
- d) Epizootic situation in the third country;
- e) Results of monitoring research of controlled goods (products) imported to the customs territory of the Customs Union from the third country performed by the Member-States (if any);
- f) Monitoring of controlled goods (products) performed by the competent authority (if any). Absence of these data shall not entail any waiver of such guarantees;
- g) Confirmation that the competent authority has inspected the enterprises requested for inclusion into the register of companies from third countries and recognized them compliant with the respective requirements of the Customs Union in accordance with Annex 3 of this Regulation;
- h) Results of on-site checks (inspections) by authorized bodies obtained in the territory of the third country (if any);
- i) Experience in trade with a third country (of any);
- j) List of enterprises requested to be included in the register of companies from third countries, including types of goods;

49. Once the request is assessed, the authorized body shall draft a final decision within ten business days. The decision shall consider the level of risk and shall be based on the criteria specified in Clause 48 of this Regulation.

50. The authorized body shall send the draft of the final decision, including information provided by the competent authority, to the authorized bodies of other Member-States to get an agreement.

The authorized bodies of other Member-States, which received the draft of the final decision, may reply to the competent authority within ten business days from the date of its receipt. If the authorized body fails to reply within the specified period, it shall be deemed agreed to the final decision.

The reply may contain agreement or arguments and/or suggestions or objections.

51. If there are any objections concerning the opinion made in the draft final decision, the authorized body shall specify the reasons thereof. The reasons shall be based on the criteria specified in Clause 48 of this Regulation and shall expressly name the elements failing to comply such criteria, given the risk proportionality principle. The same timeframes shall be used to share additional information between the Member-States to settle disputes.

52. Following the receipt of the replies from the authorized bodies of other Member-States, the authorized body that has prepared the draft final decision shall prepare the final decision within 10 business days.

53. Once the final decision is prepared, the authorized body sends it to the competent authority in writing.

54. The final decision may contain one (positive or negative) opinion or various (positive or negative) opinions concerning the groups of products of the particular enterprise.

55. In case of positive opinion, the authorized body shall update the register of companies from third countries within 10 business days from the date of the decision.

Otherwise, the reason for rejection specified in the final decision shall be based on the criteria specified in Clause 48 of this Regulation and shall reflect the specific element failing to comply with the criteria given the risk proportionality principle. The decision may be revised after provision of additional information by the competent authority.

56. The competent authority whose guarantees have been taken accordingly may further send to the authorized body a request to amend the list of enterprises, including a request to add new enterprises to the register of companies from third countries.

57. The authorized body which has received such a request performs an assessment and prepares a draft decision in accordance with the provisions of this Section.

58. The authorized body may carry out further checks (inspections) of significant enterprises included in the register of companies from third countries. In cases where unsatisfactory results are found during the inspection, more than 60 percent of enterprises from the subject to inspection, indicating a significant shortcomings official surveillance system, the authorized body may decide to refuse to accept the guarantees of the competent authority and to require mandatory joint on-site checks (inspections) of third-country enterprises.

59. In the case of corrective measures being taken with regard to guarantee problems, the competent authority may apply to the authorized body with a request for granting the right to provide a guarantee of compliance of the third country enterprises to the requirements of the Customs Union. The request shall be processed according to the above procedure.

## **VI. Joint checks (inspections) of third-country enterprises**

60. A joint on-site inspection may be conducted in order to:

1) include the enterprise in the register of companies from third countries (hereinafter in this Section, Case 1);

2) conduct joint checks (inspections) of an enterprise which has been previously included in the register of companies from third countries, and which got import permit:

based on the results of the joint checks (inspections) (hereinafter in this Section, Case 2);

based on the guarantees of the competent authority (hereinafter in this Section Case 3);

based on the successful audit results (hereinafter in this Section, Case 4);

based on the information about the non-compliance to the CU requirements (hereinafter in this Section, Case 5);

3) conduct joint checks (inspections) of third-country enterprises which have been previously included in the register of companies from third countries the import of goods (products) from which has been temporarily restricted (hereinafter in this Section, Case 6).

61. The joint check (inspection) in Cases 1 and 6 is carried out at the request of the competent authority, and in the Cases 2 to 5 - at the request of the authorized body.

62. In Cases 1 and 6, the authorized body may postpone a joint on-site inspection if there is a lack of resources (financial, human or other resources). Thus being the case, the authorized body shall take all possible measures to ensure that such delay should not lead to excessively long export problems to the customs territory of the Customs Union.

63. Any costs associated with joint on-site inspections referred to in Clause 60 of this Regulation shall be covered by the respective budgets of the Member-States, unless otherwise individually agreed upon.

64. The period of a joint check (inspection) shall not exceed a period agreed on with the competent authority, and shall not exceed five business days.

65. The authorized body planning to hold a joint check (inspection) (hereinafter, the initiator), shall no later than three months before the event (unless a shorter period agreed upon with the competent authority) send to the competent authority a list of legal acts stipulating relevant standards and norms, and a list of documents that should be submitted by the enterprise during inspection in the Russian or any other language agreed upon with the competent authority.

66. No later than in three months prior to the joint check (inspection) (unless a shorter period is agreed with the competent authority), the initiator may submit to the competent authority a request for preliminary information in Russian or other agreed language, as required, for checks (inspections) or assessment of results thereof, including:

- a) information on the statutory powers of the competent authority;
- b) information on the structure of the central office and regional offices of the competent authority responsible for the audited (inspected) enterprise;
- c) information concerning training and retraining of personnel of the competent authority responsible for the audited (inspected) enterprise;
- d) information concerning development and equipment of the laboratory network of the third country involved in the safety assessment of the products of the audited (inspected) enterprise and its raw materials;
- d) texts of normative legal acts of the third country, establishing mandatory requirements to the products of the audited (inspected) enterprise and its raw materials and methods of control;
- e) the third-country national plan to control (supervise) emergencies and distribution of agents of contagious animal diseases relevant to the products of the audited (inspected) enterprise;
- g) information on the existence and dissemination of appropriate animal diseases and zoonosis in a third country;
- h) national plan for monitoring of products subject to veterinary control (supervision);
- i) results of control procedures (supervision) conducted by the competent authority in respect of controlled goods (products) produced by the audited (inspected) enterprise, in terms of ensuring control (supervision) over the compliance to the requirements of the Customs Union, if the enterprise had previously supplied controlled goods to the customs territory of the Customs Union (this information can be provided either before or during the joint on-site inspection);

j) results of control procedures (supervision) conducted by the competent authority in respect of controlled goods (products) produced by the audited (inspected) enterprise to check compliance of the third country, if the enterprise had not previously supplied controlled goods into the customs territory of the Customs Union or if the control (supervision) referred to in subclause "i" gave no results (this information can be provided either before or during the joint check (inspection)).

67. No later than two months before the commencement of the audit (inspection) (unless Member-States agreed upon a shorter period), the initiator shall inform the authorized bodies of Member-States of the forthcoming audit (inspection) in order to form a group of inspectors and coordinate the timing of the joint check (inspection).

68. No later than two weeks after receipt of the initiator's information about the forthcoming audit (inspection), the authorized bodies of Member-States can provide a reply containing a refusal or consent to participate in the audit (inspection) and information about inspectors (experts) who are going to participate. No reply within the set timeframe means refusal to participate in the joint check (inspection).

69. The joint check (inspection) can be conducted by inspectors from one Member-State if other Member-States failed to submit a reply or declared that they will not participate in the joint on-site check (inspection). The Member-States not participating in the joint on-site check (inspection), shall recognize the decision based on the results obtained by the initiator.

70. The initiator and the other participating authorized bodies may invite experts employed by the state authorities and institutions (except for translators), on the following issues:

- a) legislation of the respective third country;
- b) Organizational structure of the competent authority of the respective third country, its powers and independence, management and rights with respect to the effective application or enforcement of laws;
- c) training of personnel to conduct inspections;
- d) resources, including diagnostics;
- e) existence and implementation of documented procedures and monitoring systems;
- f) animal health care and procedures applied to notify the Member-States and respective international organizations about outbreaks of animal diseases subject to OIE notification.

71. The experts shall be bound by the same liabilities and responsibilities as the inspectors/auditors concerning the protection of confidential information and ensuring the absence of the conflict of interests related to the products of the enterprises being checked (inspected). The authorized body shall guarantee impartiality and fidelity principles of experts.

72. No later than two months before the check (inspection) (unless a shorter period is agreed upon with the competent authority), the initiator shall provide the competent authority with the following information:

- a) purposes of the joint on-site check (inspection);
- b) Member-States participating in the check (inspection);
- c) list of inspectors and experts;
- d) list of enterprises subject to check (inspection);

- e) list and the number of controlled facilities supplying the appropriate raw materials to the enterprises subject to check (inspection);
- f) list and the number of other enterprises involved in manufacturing (production) and/or control of the relevant controlled goods (products) produced by the enterprises subject to check (inspection);
- g) list of documents that the competent authority and/or the enterprise subject to check (inspection) must provide during the joint on-site check (inspection) in the Russian or other agreed language.

73. If the competent authority in Cases 2 to 5 refuses to perform check (inspection) of one or several selected enterprises, it may be grounds for the initiator to suspend exports from these enterprises unless the initiator believes that the reasons for the rejection provided by the competent authority are acceptable.

74. Upon arrival at the enterprise, the inspector shall review the documents concerning the following:

- a) type of activity;
- b) project of the enterprise;
- c) production flows and products control;
- d) structural and technological characteristics of the enterprise;
- e) production volumes and output of controlled goods (products);
- f) existence and implementation of the official controls and production control to ensure safety of controlled goods (products) manufactured;
- g) epizootic situation at the premises of the enterprise.

75. During the check (inspection), the inspector shall:

- a) visit the buildings and other infrastructure facilities of the enterprise being checked (inspected);
- b) examine compliance with the requirements of the Customs Union with regards to the equivalence principle in Cases 1 - 3, 5 and 6, or ensure the level of safety at least equivalent to the requirements of the Customs Union, in Case 4;
- c) verify methods and equipment used in the state control and production control;
- d) carry out other actions necessary to achieve the objectives of this Regulation.

76. During the on-site check (inspection), inspectors shall examine the compliance of technological processes of the enterprise with the requirements of the Customs Union, taking into account relevant instructions recognized by the WTO, and the principle of equivalence, as required by Clause 11 of this Regulation, in Cases 1 - 3, 5 and 6, or ensure the level of safety at least equivalent to the requirements of the Customs Union, in Case 4.

77. During the on-site check (inspection), inspectors may visit other enterprises that supply raw materials to the enterprise under inspection, and/or organizations involved in the official and/or production control, if the competent authority consents to such a visit in accordance with the agreed upon inspection schedule.

78. At the request of the competent authority, during the on-site check (inspection), inspectors of the Customs Union may take samples of the controlled goods (products) produced by the enterprise, as well as raw materials used thereby.

79. If during the on-site check (inspection) of enterprises included in the register of companies from third countries, incompliances be identified that pose a significant threat to life and health of humans or animals, the group of inspectors (or an inspector) shall immediately inform the initiator thereof and the initiator shall immediately suspend exports of goods (products) from this enterprise.

80. In case unsatisfactory results of the follow-up joint check (inspection) repeat, the authorized body may decide to suspend the export of goods (products) from such enterprises.

81. After their visit to the enterprise, at the request of the authorized body or the enterprise's management, inspectors shall report the noncompliance with the equivalence principle, as required by Clause 11 hereof. The enterprise's management shall inform the participants of the inspection, directly or through the competent authority, before their departure from that third country on the measures taken to address the identified deficiencies. Participants of the on-site check (inspection) shall take note of such information before drawing up a preliminary report.

82. Once the on-site checks (inspections) are completed, the initiator prepares a preliminary report. The preliminary report shall disclose a specific legal framework in respect of the discrepancies that were identified during the checks (inspections), and shall include recommendations to the competent authority and/or a particular enterprise to address such inconsistencies. No later than in two months after the completion of checks (inspections) in the third country, the initiator shall prepare and submit to the authorized bodies of the Member-States participating in the inspection a draft preliminary report. No later than two weeks after receiving the draft preliminary report (starting from the date of receiving the electronic notice), the authorized bodies of other Member-States shall reply to the initiator. Failure to reply after the deadline shall mean acceptance of the draft preliminary report.

83. Given the replies of the authorized bodies of other Member-States participating in the on-site check (inspection) and within three months after completion of the joint check (inspection) in the third country, the initiator shall send to the competent authority a preliminary report on the joint check (inspection) results. The competent authority shall within two months provide a reply with comments, additional information (including information about the measures to correct the identified deficiencies), as well as explanations for the initiator. Failure of the competent authority to reply within the set timeframe shall mean full consent with the preliminary report.

84. After receiving a reply from the competent authority or in case no reply was sent within the set timeframe, the initiator shall prepare and submit to the authorized body of the Member-States participating in the inspection a draft final report within one month. No later than in two weeks after the receipt of the draft final report (starting from the date of the electronic notification), the authorized bodies of other Member-States shall reply to the initiator. Failure to reply after the deadline shall mean the acceptance of the draft preliminary report.

Given the replies of the authorized bodies of other Member-States participating in the on-site check (inspection) and within two weeks after receiving the replies of the authorized bodies, the initiator shall send to the competent authority a final report on the joint checks (inspections).

85. The final report shall contain opinions concerning each checked (inspected) enterprise, whether included or not in the register of companies from third countries, and recommendations for the corrective measures to be taken by the enterprises to be included in the above register.

86. The opinion can be as follows:

- a) the enterprise is included in the register of companies from third countries and may start export operations;

- b) the enterprise may not be included in the register of companies from third countries;
- c) the enterprise can continue exporting and maintain its current status in the register of companies from third countries;
- d) the enterprise can continue exporting and maintain its current status in the register of companies from third countries, but corrective actions are needed;
- d) exports from the enterprise are temporarily restricted;
- e) the enterprise can resume exports; the status of “temporarily restricted” is cancelled;
- g) the enterprise cannot resume exports; the status of “temporarily restricted” is maintained;
- h) the enterprise can continue to export subject to fulfilment of “special requirements” proposed by the initiator.

87. In Case 1, enterprises included in the register of companies from third countries as a result of the inspection, shall be entitled to export controlled goods into the customs territory of the Customs Union from the date of publication of the updated register of companies from third countries. Goods cannot be manufactured before the date of check (inspection) unless otherwise stated in the opinion.

88. The initiator shall publish the final report on its official Internet website and shall send it to the authorized bodies and competent authorities within five business days after the completion of the final report.

89. The published final report shall not contain the official numbers, names and exact location of the enterprises from third countries.

90. The initiator shall update the register of companies from third countries within 10 business days after preparation of the final report and send a notification to the competent authority.

## **VII. Joint on-site checks (inspections) of the CU enterprises for the purposes of their inclusion in the register of CU companies**

91. Joint checks (inspections) shall be carried out in order to include them in the CU register, except as referred in Clause 107 hereof.

92. A joint check (inspection) shall be carried out at the request of the enterprise.

93. An enterprise shall address its request to the authorized body. Costs associated with joint checks (inspections) shall be covered by the respective budgets of the Member-State, unless otherwise stipulated by the legislation of the Member-State where such enterprise is located.

94. An on-site check (inspection) of the enterprise shall not exceed 5 business days.

95. The authorized body planning to hold a joint check (inspection) shall send to the authorized bodies of the Member-States a one month prior notice (unless a shorter period with the authorized bodies is not agreed upon) in order to inform the groups of inspectors and coordinate the date of such joint check (inspection). No later than in two weeks after receiving the information about the forthcoming joint check (inspection), the authorized bodies of other Member-States shall reply refusing or consenting to participate in the check (inspection), and provide data about the inspectors (experts) who are going to take part in the check (inspection). Failure to reply within the specified period shall mean a refusal to participate in the check (inspection).

96. Enterprises located in the territory of a Member-State may be included in the register of CU companies without a joint check (inspection) if agreed by the authorized bodies of all Member-States, and if the risk associated with the supply of controlled goods (products) manufactured by the enterprise has been assessed as acceptable.

97. The joint check (inspection) can be carried out by the inspectors from one Member-State if authorized bodies of other Member-States failed to submit a reply or announced that they will not participate in the check (inspection). The authorized bodies not participating in the joint check (inspection) shall recognize the decision based on the check (inspection) conducted by the authorized body.

98. Upon arrival to the enterprise, the inspector shall review all documents concerning:

- a) type of activity;
- b) project of the enterprise;
- c) production flows and products control;
- d) structural and technological characteristics of the enterprise;
- e) production volumes and output of controlled goods (products);
- f) existence and implementation of the official controls and production control to ensure safety of controlled goods (products) manufactured;
- g) epizootic situation at the premises of the enterprise.

99. During the on-site check (inspection), the inspector shall:

- a) visit the buildings and other infrastructure facilities of the enterprise;
- b) examine their compliance with the requirements of the Customs Union;
- c) verify methods and equipment used in the state control and self-inspection;
- d) perform any other actions necessary to achieve the objectives of this Regulation.

100. During the on-site check (inspection), inspectors shall examine the compliance of technological processes of the enterprise with the requirements of the Customs Union.

101. If agreed with the competent authority of the Member-State, during the planning of the joint check (inspection), visits may be made to other enterprises supplying raw materials to the enterprises under inspection and/or organizations involved in the formal and/or production control.

102. At the request of the authorized body, inspectors can take samples of controlled goods (products) produced by the enterprise, as well as samples of raw materials.

103. After the visit to the enterprise and at the request of the enterprise's management, inspectors shall provide information concerning deficiencies identified and recommendations concerning corrective measures.

104. Once the joint check (inspection) is completed, the responsible authorized body shall publish a report on the check (inspection) and provide it to the authorized bodies of the Member-States.

105. The enterprise may submit additional information and clarification on the information contained in the preliminary report and its conclusions within two weeks.

106. The authorized body shall review the information and decide on the inclusion of the enterprise in the register of CU companies, and inform thereof the enterprise, other Member-States and the Commission within one month.

107. If the decision of the CU Commission recognizes the veterinary control system of a Member-State is in conformity with the requirements, the enterprises located within the territory of such Member-State shall be included by the authorized body in the register of CU companies without joint check (inspection).

108. The Commission shall publish an updated register of CU companies based on the information of the authorized body of a Member-State without undue delays.

109. Enterprises included in the register of CU companies shall supply controlled goods (products) to the territory of other Member-States from the date of publication of the updated register of CU companies. The products shall be manufactured after the date of commencing the on-site check (inspection) and as stipulated in case referred to in Clause 107 of this Regulation - the date of submission of the information concerning the inclusions into the register of CU companies to the Commission by the competent authority of the Member-State.

### **VIII. Joint on-site checks (inspections) of enterprises included in the register of CU companies conducted in the territory of the Member-States**

110. A joint check (inspection) of an enterprise (enterprises) included in the register of CU companies shall be performed as needed or as mutually agreed upon by the Member-States in the following cases:

- a) repeated noncompliance of controlled goods (products) produced by the enterprise with the common veterinary requirements;
- b) remove quarantine from the territory where the inspected enterprise is located;
- c) the inspected enterprise is located within the territory bordering on the quarantine area (zone).

111. The costs associated with the joint check (inspection) shall be covered by the respective budgets of the Member-States, unless otherwise provided for by the legislation of the Member-State wherein the enterprise is located.

112. The term of the on-site check (inspection) shall not exceed five business days.

113. A check (inspection) shall be conducted in accordance with Section VII hereof.

114. The authorized body which maintains the register of CU companies of the given Member-State, shall provide information to be included in the register of CU companies to the Commission in order to make it available as part of an integrated information system of foreign and mutual trade within the Customs Union (hereinafter - IISVVT), in the manner and format established by the Commission.

115. Once the enterprise is included in the register of CU enterprises, the authorized body can monitor the controlled goods (products) of the enterprise. Monitoring is carried out in accordance with the regulations of the Customs Union and the legislation of the Member-State and shall include laboratory monitoring, clinical monitoring (only in case of supply of animals), monitoring the validity of veterinary documents and correct labelling of controlled goods (products) in circulation in the customs territory of the Customs Union.

### **IX. Sampling of controlled goods (products) manufactured in the customs territory of the Customs Union**

116. Sampling of controlled goods (products) produced in the customs territory of the Customs Union may be performed at the request of the manufacturer or owner of the goods or by the decision of the State Veterinary Inspector during:

a) implementation of the public monitoring program carried out under the state veterinary control (supervision) over the safety of controlled goods (products) in circulation in the customs territory of the Customs Union;

b) state veterinary control (supervision) of controlled goods (products) for the purpose of export certification;

c) enhanced laboratory control of goods (products) produced by the enterprise in case of violation of the relevant requirements of the Customs Union (with respect to controlled goods (products) intended for circulation in the customs territory of the Customs Union) or a third country (with respect to controlled goods (products) intended for export). Enhanced laboratory control in these cases is a measure introduced as an alternative to a temporary ban on the movement of goods (products) produced by the enterprise on the territory of other Member-States, or for export;

d) the state veterinary control (supervision) in respect of the enterprise.

117. The purpose of sampling is to obtain samples for subsequent laboratory analysis.

118. Sampling shall be performed by an inspector who has appropriate knowledge and experience in compliance with the requirements of the Customs Union to the sampling procedures, their packaging and transportation in order to avoid damage, substitution or contamination that may skew the results of laboratory tests.

119. Sampling, documentation and transportation of samples shall be organized so as to prevent damage, deterioration, contamination, and the substitution of other types of offenses.

120. In the cases referred to in subclauses "a" (except as in the case referred to in Clause 121 hereof) and "d" of Clause 116 of this Regulation, sampling, transport of samples to the laboratory and laboratory research shall be carried out free of charge for the owner of the controlled goods.

121. In case during the documentary or physical control violations are identified concerning the common veterinary requirements, the owner of the controlled goods (products) shall bear the costs of the sampling of controlled goods (products), transportation of samples to the laboratory and laboratory studies.

122. In the case referred to in subclause "a" of Clause 116 hereof, the owner of the controlled goods shall bear the costs of sampling of the controlled goods (products), transportation of samples to the laboratory and laboratory studies.

123. In the case referred to in Clause 121 of this Regulation, laboratory samples shall be conducted concerning all safety indicators to identify opportunities for further use or disposal of a particular batch of controlled goods (products).

124. In case sampling is performed at the request of the manufacturer or the owner, they shall be entitled to determine the lab regardless its location (whether within the territory of a Member-State or not). In other cases, the inspector shall name the sampling lab in its decision, if it was not identified in the request underlying the sampling.

125. Sampling shall be documented by making a sampling report according to the form provided in Annex 1. The first copy of the report shall be provided to the manufacturer or owner of the controlled goods. The second copy shall be provided to the Chief State Veterinary Inspector of the territory where the samples are taken. The third copy shall be sent to the laboratory where the samples shall be analyzed. The fourth copy the inspector shall hold in his/her custody for at least one year.

126. Upon arrival of the samples to the laboratory, the laboratory personnel shall check the samples to determine their suitability for the study (absence of damages), the correct

packaging and supporting documents. In case of any violations, the sample shall not be subjected to the study, and a notice of violation shall be directed to the inspector who performed sampling.

127. The laboratory must be accredited by the accreditation body of the Member-State and shall have equipment enabling correct laboratory research, including provision of detection sensitivity, allowing identifying the maximum allowable concentration of the organisms or compounds being detected.

128. In case samples fail to comply with the requirements of the Customs Union, the laboratory shall maintain control samples before the expiration of the useful life of the controlled goods batch, but not more than three months after notification of stakeholders about the results of laboratory tests.

129. In the case referred to in subclause "a" of Clause 116 of this Regulation, sampling shall be carried out on ten batches of manufactured goods (products) and within maximum three months. Sampling shall be made only of the same type of goods (products) that were identified as noncompliant. Laboratory studies shall be conducted only concerning the indicator (indicators) which showed incompliance.

130. The authorized body shall inform the owners of the controlled goods, the manufacturer, inspectors in the administrative territory and the authorized bodies of other Member-States concerning the violations identified during monitoring or enhanced laboratory control as soon as possible, but no later than within ten business days. This information shall contain details of the method of sampling, location and purpose of the analytical method used, if any, and the laboratory where the tests were made and the results obtained.

131. Documentary registration of the results of the research and notification of their results shall be carried out in accordance with the regulations of the Customs Union.

## **X. Sampling of controlled goods (products) manufactured in a third country within the customs territory of the Customs Union**

132. Sampling of controlled goods (products) manufactured in a third country within the customs territory of the Customs Union shall be made at the request of the manufacturer or owner of the goods or by decision of the state veterinary inspector during:

- a) implementation of the public monitoring program carried out for the state veterinary control (supervision) over the safety of controlled goods (products) circulated in the customs territory of the Customs Union;
- b) state border veterinary control (supervision) in respect of controlled goods (products) (except in the case referred to in subclause "b" of this Clause) at checkpoints across the state border, in points of full customs clearance or in other places where imported animals are subject to quarantine;
- c) enhanced security controls of laboratory controlled goods (products) manufactured by an enterprise (individual) from a third country in case of violation of the relevant requirements of the Customs Union. Enhanced laboratory control in these cases is a measure introduced as an alternative to a temporary ban on the import of controlled goods (products) manufactured by the enterprise;
- d) monitoring of batches of controlled goods produced by manufacturers, whose import is temporary restricted, but shipped before the date of the introduction of such restrictions;
- e) monitoring of controlled goods (products) manufactured by the enterprises included in the register of companies from third countries under the guarantee of the competent authority, which were under a restriction after repeated violations and temporary restrictions were removed under the guarantee of the competent authority.

133. The purpose of sampling is to obtain samples for subsequent laboratory analysis.

134. Sampling shall be performed by an inspector with appropriate knowledge and experience in compliance with the requirements of the Customs Union to the sampling procedures, their packaging and transportation in order to avoid damage, substitution or contamination that may skew the results of laboratory tests.

135. Sampling, documentation and transportation of samples shall be organized so as to prevent damage, deterioration, contamination, and the substitution of other types of offenses.

136. In the cases referred to in subclauses “a” and “b” of Clause 132 of this Regulation, sampling, transport of samples to the laboratory and laboratory research shall be carried out free of charge for the owner of the controlled goods.

137. With regard to the cases referred to in subclause “b” of Clause 132 of this Regulation, in case during the documentary or physical control violations are identified concerning the common veterinary requirements at checkpoints across the state border or in a place of full customs clearance, the owner of controlled goods (products) may request laboratory tests for such goods (products) in order to confirm their safety. In this case, the owner shall bear the costs for the sampling of controlled goods (products), transportation of samples to the laboratory and laboratory analysis.

138. In the case referred to in Clause 137 of this Regulation, laboratory samples shall be conducted concerning all safety indicators to identify opportunities for further use or disposal of a particular batch of controlled goods (products).

139. In the cases referred to in subclauses “a”–“d” of Clause 132 of this Regulation, the owner of the controlled goods shall bear the costs of sampling of the controlled goods (products), transportation of samples to the laboratory and laboratory studies.

140. In the case referred to in subclause “d” of Clause 132 of this Regulation, sampling shall be made from all batches of the imported goods (products) shipped before the date of the introduction of temporary restrictions in respect of a particular manufacturer. Laboratory studies shall be conducted only concerning the indicator which was previously identified as noncompliant.

141. In the case referred to in subclause “d” of Clause 132 of this Regulation, sampling shall be made from the first ten batches of imported goods (products) of a particular manufacturer.

142. The laboratory must be accredited by the accreditation body of the Member-State and shall have equipment enabling correct laboratory research, including provision of detection sensitivity, allowing identifying the maximum allowable concentration of the organisms or compounds being detected.

143. In case samples fail to comply with the requirements of the Customs Union, the laboratory shall maintain control samples before the expiration of the useful life of the controlled goods batch, but not more than three months after notification of stakeholders about the results of laboratory tests.

144. In the case of sampling, the manufacturer or the owner shall be entitled to determine the laboratory for tests regardless of whether or not it is within the territory of the Member-State. In other cases, the inspector shall name the sampling lab in its decision, if it was not identified in the request underlying the sampling.

145. In the case referred to in subclause “a” of Clause 132 hereof, after a single violation was identified, the sampling shall be carried out on ten batches of manufactured goods (products) and within no more than three months. Only the same type of goods (products)

identified as noncompliant shall be sampled. Laboratory studies shall be conducted only based on the indicator which was identified as noncompliant.

146. The authorized body shall inform the competent authority of the country where the controlled product was manufactured, the competent authority of the country from which the controlled product has been exported to the customs territory of the Customs Union, the owner of the goods, the manufacturer, inspectors of the relevant administrative territory, and the authorized bodies of other Member-States about violations identified during the monitoring and/or enhanced laboratory tests of controlled goods (products), as soon as possible, but no more than in ten business days after receipt of the laboratory tests. This information shall contain details of the method of sampling, location and purpose of the analytical method used, if any, and laboratory where the tests were made, and the results received.

147. Documentary registration of the laboratory results and notification thereof shall be carried out in accordance with the regulations of the Customs Union.

## **XI. Sampling in third countries as part of the audit of foreign official control system or joint check (inspection)**

148. Sampling of controlled goods (products) for laboratory testing in third countries as part of the audit of foreign official control system or joint check (inspection) shall be carried out at the request of the competent authority and in accordance with the requirements of this Section.

149. Sampling shall be carried out by an inspector of the Member-State, or public inspector/veterinarian of a third country (as defined by this state), or representative of the manufacturer or owner of controlled goods by an agreement between the competent authority and the authorized body.

150. As agreed by the competent authority and the authorized body, the sampling shall be carried out in accordance with the regulations of the Customs Union or the law of a third country.

151. The person performing the sampling must have an appropriate knowledge and experience to apply the correct requirements set forth in Clause 149 of the present Regulation, the requirements of the Customs Union or a third country with respect to sampling procedures, packaging and transportation thereof in order to prevent any damage, substitution or contamination that may skew the results of laboratory tests.

152. The sampling, documentation and transportation of samples shall be organized so as to prevent damage, deterioration, contamination, substitution or any other violations.

153. The laboratory must be accredited by the accreditation body of the Member-State or samples shall be examined in the laboratory of a third country by the competent authority as agreed by the authorized body.

154. In case of non-compliance of the sample requirements of the Customs Union, the laboratory shall maintain control samples before the expiration of the use of the controlled batch of goods, but not more than 3 months after notification of stakeholders about the results of laboratory tests.

155. Depending on where the laboratory is located, the competent authority or authorized body shall notify the authorized body or competent authority, accordingly, of the results of laboratory tests of controlled goods as soon as possible and within maximum 10 business days after receipt of the laboratory tests. This information shall contain details of the method of sampling, its place and purpose of the analytical method used, if any, and the laboratory and test results.

156. Rules for documents on the results of laboratory tests must be agreed upon by the competent authority and the authorized body.

## **XII. Maintaining the register of companies from third countries**

157. The register of companies from third countries shall be published on the official website of the Commission.

158. Internet access to the register of companies from third countries is provided free of charge.

159. The register of companies from third countries shall contain the following information in Russian (unless otherwise specified below) concerning third-country enterprises that export and/or have the right to export, controlled goods into the customs territory of the Customs Union:

- a) name of the enterprise in English and/or other official language;
- b) number (ID) of the enterprise assigned by the competent authority;
- c) list of controlled goods (products) which is an enterprise has the right to export to the customs territory of the Customs Union;
- d) veterinary and sanitary status (hereinafter, the status) of the enterprise in the register of companies from third countries and the last updated date;
- e) address of the enterprise;
- f) region (oblast, province, land, state, etc.).

160. In the cases specified in Annex 1 to the common veterinary requirements, the enterprises not included in the register of companies from third countries have no right to export goods (products) into the customs territory of the Customs Union.

161. The status of the enterprise in the register of companies from third countries may be as follows:

- a) "without limitations" means that currently the enterprise is able to export controlled goods to the customs territory of the Customs Union without any restrictions and additional burdens;
- b) "temporarily restricted" - export of controlled goods (products) from this enterprise is temporarily suspended;
- c) "enhanced laboratory control" - export is possible, but each batch of exported goods shall be subject to sampling and laboratory tests;
- d) "warning" means that the competent authority is informed by the authorized body of violations revealed in respect of goods (products) manufactured by this enterprise, but currently these violations have not led to the introduction of time limits or enhanced mode of laboratory control;
- e) "special requirements" means the need to use replacement (additional) measures to ensure that the export of controlled goods (products) manufactured by the enterprise to the customs territory of the Customs Union could continue, but without the use of these measures, it shall be suspended. In this case, the register of companies from third countries shall contain reference to the documents explaining what kind of special requirements shall apply.

162. An enterprise may be included in the register of companies from third countries as follows:

- a) provision by the competent authority of data about this enterprise in its notice allowing the export of controlled goods (products) into the customs territory of the Customs Union, issued by the competent authority, - in case the country has successfully passed the audit procedure of the foreign official control system established by Section IV of this Regulation;
- b) provision by the competent authority of guarantees that the controlled goods manufactured by the enterprise and the process technology comply with the requirements of the Customs Union, - if the competent authority was given the right to provide guarantees in the manner prescribed by Section V of this Regulation;
- c) the decision of the authorized body taken as a result of joint check (inspection) of the enterprise in the manner prescribed by Section VI of this Regulation.

163. An enterprise may be excluded from the register of companies from third countries at the request of the enterprise or the competent authority.

164. Except in an emergency, temporary restriction of entry to the enterprise may be used only in one of the following cases:

- a) at the request of the enterprise or by the competent authority;
- b) based on the repeated non-compliances with the requirements of the Customs Union registered either during the on-site check (inspection) or as a result of monitoring and enhanced laboratory monitoring of controlled goods (products) manufactured by this enterprise, which was previously informed by the competent authority, if the discrepancies pose a significant threat to life and health of humans or animals.

In exceptional cases, the Commission may decide to impose restrictions on a group of enterprises or all enterprises of the third country in case serious violations are identified in the official control system of such third country and if corrective measures are not taken; these temporary restrictions shall be proportional to the risk to human and animal health.

165. Changing the status of the enterprise in the register of companies from third countries is possible as a result of:

- a) request of the enterprise;
- b) request of the competent authority;
- c) request of the importer wishing to import controlled goods produced by the enterprise;
- d) on-site check (inspection) of the enterprise carried out by the authorized body;
- e) identification (within the customs territory of the Customs Union) of violations of the requirements of the Customs Union in respect of controlled goods (products) produced by the enterprise;
- f) end of the period of enhanced laboratory monitoring of controlled goods (products) manufactured by the enterprise;
- g) refusal to receive guarantees of the competent authority;
- h) restoration of the right of the competent authority to provide guarantees;
- i) unfavourable opinion on the equivalence of the follow-up audit of the official control system of the third country;
- j) favourable opinion on the equivalence of the follow-up audit of the official control system of the third country.

166. The competent authority and the authorized bodies of other Member-States shall be informed by the authorized body of any changes in status and reasons for such changes,

including information relating to the confirmed non-compliance of the Customs Union laboratory studies, if laboratory tests have caused the status change.

167. Upon receipt of the report on violations, the competent authority shall conduct a study of the situation and identify measures to correct it, if necessary, and confirm implementation of such measures. According to the results of the examination of the situation, the competent authority may make a request to change the status of the enterprise in the register of companies from third countries.

168. Any changes shall be made in the register of companies from third countries without undue delay, but not more than in ten business days following the resolution on the request or when a decision by the authorized body is not required.

### **XIII. Maintaining the register of CU companies**

169. The register of CU companies is a database with access to the Internet. Content of the register of CU companies is presented on the official websites of the authorized bodies and the Commission.

170. Internet access to the register of CU companies is provided free of charge.

171. The register of CU companies provides the following information about the enterprises of the Member-States entitled to transport the controlled goods from the territory of one Member-State to the territory of another Member-State:

- a) name of the Member-State;
- b) registration number issued by the competent authority of the Member-State;
- c) name of the enterprise;
- d) region (oblast, province, land, state, voivodship, aimak, county);
- e) address of the enterprise;
- f) type of activity;
- g) veterinary and sanitary status of the enterprise;
- h) basis for the inclusion of the enterprise in the CU register.

Register of CU companies may contain other information about enterprises included therein.

172. Enterprises may have the following status in the CU register:

- a) "without limitations" means that currently the enterprise is able to export controlled goods into the customs territory of the Customs Union without any restrictions and additional burdens;
- b) "temporarily restricted" means that export of controlled goods (products) from this enterprise is temporarily suspended;
- c) "enhanced laboratory control" - export is possible, but each batch of exported goods shall be subject to sampling for laboratory control;
- g) "warning" means that the competent authority is informed by the authorized body of violations revealed in respect of goods (products) manufactured by this enterprise, but currently these violations have not led to the introduction of time limits or enhanced mode of laboratory control;
- e) "special requirements" means the need to use replacement (additional) measures to ensure that the export of controlled goods (products) manufactured by the enterprise to the customs territory of the Customs Union could continue, but without the use of these

measures, it shall be suspended. In this case, the register of companies from third countries shall contain reference to the documents explaining what kind of special requirements shall apply.

173. An enterprise may be included in the register of CU companies:

- a) by request of the authorized body - as specified in Clause 107 of this Regulation;
- b) as a result of a joint check (inspection) of the enterprise.

174. An enterprise may be excluded from the register of CU companies at its request.

175. The reasons for changing the status of the enterprise in the register of CU companies are as follows:

- a) request of the enterprise;
- b) decision of the authorized body of the Member-State;
- c) on-site check (inspection) of the enterprise;
- d) violations revealed in the territory of one Member-State with respect of controlled goods manufactured by the enterprise;
- e) the end of the period of enhanced laboratory monitoring of controlled goods (products).

176. Any changes shall be entered into the database of CU enterprises without undue delay, but not more than in ten business days after the corresponding decision or receiving a request in cases where a decision by the authorized body is not required.

#### **XIV. Final and transitional provisions**

177. The enactment of this provision does not change the status of the Member-States and third countries' enterprises in the register of CU companies and in the register of companies from third countries, respectively.

178. Prior to the enactment of the IISVVT module supporting the operation of registries, the authorized bodies shall publish the registers referred to in Clause 177 of the present Regulation on their official websites.

179. The competent authority may challenge the results of the audit opinion on the formal system of supervision or inspection, if that competent authority has comments on the procedure to be followed by the inspectors, auditors, or the method of compiling the report. Such a complaint may be forwarded to the competent authority of the Member-State (Member-States) and the Commission. The authorized body and the Commission shall evaluate the complaint and amend the opinion within a reasonably short period of time, usually not exceeding 6 months.

Stamp: Eurasian Economic Commission; For documents

ANNEX 1

to the Regulation on the Harmonized Procedure of  
Joint On-Site Inspections and of Taking Samples  
of Goods (Products) Subject to  
Veterinary Control (Supervision)

(form)

**Sampling Report**

No. dated \_\_\_\_ / 20 \_\_\_\_

Regional (municipal) territorial subdivision of the authorized body for \_\_\_\_\_  
city (town)

Name of enterprise \_\_\_\_\_

Name of transported goods \_\_\_\_\_

Place of sampling \_\_\_\_\_  
(name and address)

I, \_\_\_\_\_  
(full name, position of the authorized body representative in charge of sampling)

in presence of \_\_\_\_\_

(title, full name of the representative of the owner of transported goods, legal entity or full name of the individual  
have inspected \_\_\_\_\_  
(name of transported goods) \_\_\_\_\_

Size of the batch \_\_\_\_\_ date of arrival \_\_\_\_\_  
(name, q-ty and number of transporting vehicles)

Supporting documents \_\_\_\_\_  
(types of documents, No. and date of issue)

Absence of documents \_\_\_\_\_  
(please specify)

The goods are manufactured \_\_\_\_\_  
(country of origin)

Expiry date, manufacturers, date of manufacture \_\_\_\_\_

Results of the inspection \_\_\_\_\_

(appearance, smell, packaging, compliance of labelling, internal temperature, etc.)

Basis for laboratory analysis of products and feeds:

(subject to planned control and supervision; suspicion for dangerous veterinary status; information about bad  
quality; violation of storage conditions; upon request of the owner of transported goods)

Samples were taken at \_\_\_\_\_ (specify time)

According to \_\_\_\_\_  
(specify the document)

In the amount \_\_\_\_\_ numbered and sealed \_\_\_\_\_

Directed to \_\_\_\_\_  
(specify veterinary laboratory)

For \_\_\_\_\_  
(specify types of laboratory tests)

Public veterinary-sanitary inspector in charge of sampling: \_\_\_\_\_  
(signature) \_\_\_\_\_ (name)

Marks of acceptance of samples^

Samples are accepted by \_\_\_\_\_  
(signature, title, name of the lab expert)

to the Regulation on the Harmonized Procedure of  
Joint On-Site Inspections and of Taking Samples  
of Goods (Products) Subject to  
Veterinary Control (Supervision)

## INSTRUCTION

### **For the inspectors to determine the equivalency of veterinary measures used in third countries during inspections of enterprises subject to veterinary control and audit of official control systems of third countries**

This instruction sets out the procedures for assessing the equivalence of veterinary measures applied by third countries in conducting inspections of facilities subject to veterinary control, and audit official control systems of third countries, as well as the principles of action of inspectors and experts authorized bodies of the importing countries and the authorized bodies of the exporting countries.

Principles of actions by the inspectors during the assessment process:

Principle A. Assessment procedures shall focus on the result and shall be transparent, constructive and shall be carried out consistently, ethically and professionally, with respect to confidential information (if such information is necessary).

Principle B. Importing and exporting country must agree to consider issues arising in the course of assessment.

Principle C. Importing and exporting country agree on the method of assessment before it starts, based on the agreed scope and objectives.

The principles of the assessment process:

Principle D. Process of assessment shall be laid out, it shall be systematic, transparent, consistent, fully documented, including news coverage.

Principle E. Plan shall include the rationale, objectives, scope, assessment methods and requirements for evaluating the system of state inspection and certification shall be determined by the importing country, reported to the authorized bodies of the exporting country and agreed with them within a reasonable period of time to beginning the assessment.

The principles of assessment reporting:

Principle F. Agreed corrective actions, timeframes and procedures for verification must be clearly identified and documented.

Principle G. Final assessment report shall be accurate and transparent and may be published with the confidentiality of information, where applicable.

Principle A

Assessment procedures shall focus on the result; they shall be transparent, constructive and shall be carried out consistently, ethically and professionally, with respect to confidential information (if such information is necessary).

1. Inspectors and experts of the authorized body of the importing country shall be able to confirm that the results of the assessment, conclusions and recommendations reflect the likelihood of the desired results system, and confirmed by objective evidence or data that have been approved to be accurate and reliable.

2. Matters arising during the assessment must be resolved by the inspectors and experts of authorized bodies in unison, ethically and professionally.

3. Inspectors and experts authorized bodies of the importing country shall observe impartiality. Inspectors and experts shall have appropriate qualifications and experience.

4. Inspectors and experts of the importing country shall guarantee the protection of confidential information in the assessment.

#### Principle B

The importing country and the exporting country must agree to address issues that arise during the assessment.

5. Prior to the assessment, the responsible parties shall agree on the key elements of the process that may arise in the course of consideration. Authorized bodies of the importing country and the competent authorities of the exporting country shall seek to resolve any issues that arise in the course of the assessment together, in a consistently open and transparent manner. If any issues remain unresolved, they shall be included in the assessment report with appropriate explanations.

#### Principle C

The authorized body of the importing country and the competent authority of the exporting country shall agree on the method of assessment before it starts, based on the agreed scope and objectives.

6. The most efficient and effective method shall be selected to assess the effectiveness of the system of state control and certification of the exporting country, including the ability of the authorized bodies of the exporting country to organize and carry out the control, as well as to provide the necessary guarantees for the importing country.

7. When choosing a method of assessment, it is important to consider the reason. For example, estimates may be part of the risk analysis conducted before the start of trading; they can evaluate the system of state inspection and certification or control of a single element (e.g. chemical residues) or specific exporting enterprises.

8. When choosing a method of assessment, the account shall be taken of the experience, knowledge and reliability (Clauses 9 - 14 of the Annex to the Guidelines for assessing the equivalence of sanitary measures associated with the system of inspection and certification of food (CAC / GL 53-2003) contains definitions of "experience", "knowledge" and "reliability", as well as expand the information provided in Clauses 9-12 of these Guidelines), which the importing country has regarding the system of state inspection and certification of the exporting country.

#### Audit techniques

9. The method of audit ("system audit") shall focus on the assessment as to whether the system of state inspection and certification or its components complies with its objectives.

10. In contrast to the study of all procedures, system audit is based on a study of the example system procedures, documents or records and, if required, a number of sites in the scope of the system subject to audit.

11. The system approach focuses on the system of control and according to its all the identified (non)compliances shall be considered in the context of the whole system.

12. The ongoing systematic audit may include the study of elements of the legislative framework, controls, procedures, facilities, equipment, laboratories, vehicles, communications

equipment, personnel and training processes to achieve the objectives of the program for the inspection and certification or, if necessary, other elements.

### **Method of inspection**

13. The inspection method may be used in some cases to confirm the effectiveness of inspections carried out by the competent authority in the exporting country.

14. Inspections may include examination of the following:

a) how the enterprise complies with the requirements, including consideration of specific activities and product specifications, monitoring and review activities of the enterprise and the relevant records of the activity;

b) number of employees at the enterprise, particularly if it is specified in the request;

c) capabilities of inspectors, if this is particularly specified in the requirements.

### **Principle D**

The assessment process must be laid out, it shall be systematic, transparent, consistent, fully documented, including news coverage.

15. Documents confirming the results, conclusions and recommendations shall be made out so that the assessment and its results were uniform, transparent and reliable.

16. In order to prepare and assess between the authorized bodies of the importing country and the authorized bodies of the exporting country shall be consulted on all points of the process, from the development of an assessment plan to the final report and decisions on all matters arising in the course of the assessment. To ensure regularity and transparency of communication interaction, the authorized bodies of the importing country and the competent authorities of the exporting country shall appoint responsible contact persons or contact points for assessment.

### **Principle E**

Plan including the rationale, objectives, scope, assessment methods and requirements for evaluating the system of state inspection and certification shall be determined by the importing country, reported to the authorized bodies of the exporting country and agreed with them within a reasonable time prior to the assessment.

17. In determining the rationale, objectives, scope, frequency of assessment and assessment methods, the authorized body of the importing country shall take into account the established level of experience, knowledge, reliability, along with a history of previous estimates for the period since the last inspection, as well as all other relevant factors.

18. The assessment procedure, if carried, must be applied on the basis of pre-defined and structured program in accordance with the purpose thereof.

### **Notification**

19. In the initial request and before the current assessment of the state inspection and certification systems existing in the exporting country, the authorized bodies of the importing country and the competent authorities of the exporting country shall share the following information:

a) rationale for the assessment. Reasons may include legal obligations of the importing country, the need to understand the respective roles of the authorized bodies of the importing country and the competent authorities of the exporting country, the need to confirm the ability of

the exporting country or enterprises for the production (processing) of food products to ensure compliance, or other reasons;

b) purpose of the assessment (e.g., confirmation that measures used by the exporting country provide an adequate level of protection for the importing country). If necessary, components of the risk assessment of food safety control system of the exporting country may be audited to support risk management techniques;

c) application assessment area (whether the assessment of the whole system or only to its individual components, stages, or specifications of products);

d) intended method of assessment, including the requirements against which the state of the system of inspection and certification of the exporting country will be assessed.

20. In all cases, the authorized body of the importing country must notify the competent authority of the exporting country of the proposed assessment to the competent authority to arrange all the necessary measures, such as logistics and information gathering. If the rationale for the assessment is a health issue, the notice shall reflect the urgency associated with the risk to human health.

### **Preparation for assessment**

21. It is necessary to prepare the assessment plan, including assessment methods, 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 shall include the following:

a) purpose and scope of the assessment, including information on whether it is a separate assessment or related to another assessment (e.g., control of previous assessment) or a series of assessments;

b) area (cells) for review of research (analysis), which may include recording and evaluating checklists;

c) expected period during which the assessment will be performed and the report will be made;

d) criteria used to assess the system of state inspection and certification of the exporting country;

e) contact person for members of the assessment team that can negotiate the details of the assessment plan and, if necessary, members of the assessment team, including foreign auditors (inspectors), Chief Auditor (Inspector), technical experts and translators;

f) language to be used during the assessment, including translation, accessibility of disinterested and competent interpretation and resources.

g) indication of the type or, if possible/necessary places of visits (e.g., offices, laboratories or other facilities); the timing and responsibility for the notification (if necessary);

h) date of assessment, date of admission and outcome of the meeting and the expected date posts comments on the assessment;

i) route and activities related to the logistics required by persons conducting the assessment;

j) how to protect confidential information.

22. Whereas it is necessary to enforce the assessment plan, we shall make it flexible to make changes based on the information collected prior to or during the assessment. The proposed significant changes to the assessment plan shall be made only in extenuating circumstances and as soon as possible to report them to the competent authority, as required.

23. It is necessary to agree in advance upon the language to be used during the assessment, including translation, availability of disinterested and competent interpretation and resources.

24. To the extent possible, the documentary information required for planning, performing and completion of the assessment, shall be requested and provided prior to the assessment using possible means of electronic communication.

The request for the preparation of the assessment shall contain the area of assessment and its purpose.

If a control assessment is scheduled, the exporting country shall provide only the information that has changed since the previous assessment or has not been requested in the previous assessment.

In case the purpose of the request for information is not clear, and/or there are problems associated with the provision of the requested information, the exporting country may require the importing country to provide clarification on the purpose of the request and the intended use of such information.

If a visit is suggested as a method of assessment, before such a visit an analysis of the documents describing the system, including legislation, shall be performed.

25. In some cases, assessment can be suspended or terminated prior to the visit to the facility depending on the nature of the information provided by the competent authority of the exporting country, in which case the authorized body of the importing country shall clearly inform the competent authority of the exporting country. The competent authority of the exporting country shall be able to get clarification on the information provided, if deemed necessary.

### **Opening assessment meeting**

26. If the assessment includes a visit, it is necessary to hold an opening meeting.

The meeting shall be held at the venue designated by the competent authority of the exporting country.

The meeting shall consider all aspects of the assessment plan, including final adjustments; purpose of the meeting - to review the system of state inspection and certification in the country and to confirm the parameters and logistics assessment.

It is necessary to agree the ways to ensure continuous interaction and communication between the teams during the assessment.

### **Closing meeting**

27. If the assessment includes a visit, it is necessary to conduct a closing meeting.

The meeting shall be held at the venue designated by the competent authority of the exporting country.

The assessment team shall summarize the results of the visit and present the main findings and preliminary results of the assessment. It is necessary to specify any inconsistencies and provide objective evidence to support the conclusions. Correcting inconsistencies shall be entrusted with the competent authority of the exporting country and verified by the authorized body of the importing country, including the follow-up assessment (if necessary).

At the meeting, the competent authority of the exporting country shall have an opportunity to ask clarification and require the comments made at the meeting.

## **Principle E**

Agreed corrective actions, timeframes and verification procedures shall be clearly identified and documented.

### **Principle F**

The final assessment report shall be accurate and transparent and may be published with the confidentiality of information, where applicable.

28. The exporting country which assessed, shall be given the opportunity to review the draft report within the agreed period, provide comments and correct factual errors before compiling the final report. The final report shall include or be accompanied by a commentary by the competent authority of the exporting country.

29. The assessment report shall present objective results and conclusions and recommendations based on these results. The report shall:

- a) state the purpose, scope and results;
- b) contain criteria and process of assessment;
- c) contain results of the assessment with supporting evidence for each opinion, along with the importance of discussion at the final meeting;
- d) be available by prior agreement with the competent authority of the exporting country, including comments from the competent authority of the exporting country to improve the accuracy of the report;
- e) take into account the timeframe to finalize the report and take adequate measures as agreed between the authorized body of the importing country and the competent authority of the exporting country;
- f) include a description of how the corrective actions, as well as follow-up checks (inspections) should be communicated and agreed upon;
- g) include a checklist of elements to be evaluated to support the conclusions (if necessary);
- h) include the transfer of assessment results;
- i) include the main issues and problems encountered during the assessment, if there is no agreement on the findings and corrective actions;
- j) include the uncertainty arising, and/or any obstacles that could affect the objectivity of the conclusion of the assessment;
- k) contain a description of the areas not covered in the assessment report, although falling under the scope of, and the reasons for such a deviation from the agreed scope.

30. It is necessary to specify the timing and protocol for verification. Confirmation of corrective actions may include:

- a) guarantees provided by the competent authority of the exporting country;
- b) documents submitted to the competent authority of the exporting country; or
- c) the alleged corrective action, followed by assessment.

31. In drawing up the final assessment report and its subsequent publication due consideration shall be given to the confidential information.

32. Once the final version of the report is made, the authorized body of the importing country and the competent authority of the exporting country must agree on whether the published report, and how it shall be done, taking into account the confidentiality of the information, if available.

## **ANNEX 3**

to the Regulation on the Harmonized Procedure of  
Joint On-Site Inspections and  
of Taking Samples of Goods (Products)  
Subject to Veterinary Control (Supervision)

# **G U I D E L I N E S**

## **for the inspection of facilities subject to veterinary control (supervision)**

### **Section A. Guidelines for the inspection of enterprises and vessels engaged in harvesting and processing of aquatic animals, including fish**

#### **I. General Provisions**

1. These Guidelines cover assessment approaches and principles applied in the course of inspection of enterprises and vessels engaged in harvesting and processing of aquatic animals, including fish, and performing their activities within the customs territory of the Customs Union and third countries.

2. Inspectors and experts of competent authorities should be governed by these Guidelines when inspecting enterprises and vessels of the Member-States of the Customs Union (hereinafter — "Member-States") and third countries engaged in harvesting and processing of aquatic animals, including fish.

3. Enterprises and vessels of the Member-States and third countries engaged in harvesting of aquatic animals, including fish, shall be inspected to verify compliance with the requirements of the Customs Union based on the principle of equivalent treatment granted to third-country enterprises.

4. Using criteria established by the Guidelines for the inspection of enterprises and vessels engaged in harvesting and processing of aquatic animals, including fish, the inspector should determine whether the enterprise ensures proper protection level in accordance with the requirements of the Customs Union (as specified in Annex 2 to the Regulation on the Harmonized Procedure of Joint On-Site Inspections and of Taking Samples of Goods (Products) Subject to Veterinary Control (Supervision)) and veterinary requirements of the Member-States where such requirements are not prescribed by regulatory and legal instruments of the Customs Union.

5. The present Guidelines are published to ensure availability to public and to promote good practices.

6. The terms and expressions used in these Guidelines shall have the following meaning:

"hazard analysis" means the process of collecting and evaluating information on hazards and conditions leading thereto in order to decide which are significant for food safety and, therefore, should be addressed in the HACCP plan (Hazard Analysis and Critical Control Points);

"Hazard Analysis and Critical Control Points (HACCP)" means a system that identifies, evaluates and controls hazards that are significant for food safety;

"biotoxins" are poisonous substances naturally present in fish and fishery products or accumulated by the animals feeding on toxin-producing algae or in water containing toxins produced by such organisms;

"disinfection" means the use of chemical agents and/or physical methods to reduce the number of microorganisms in the environment to a level that does not compromise food safety or suitability;

"defect" is a condition found in a product which does not comply with the essential quality, composition and/or marking requirements of the appropriate Codex Alimentarius product standards;

"contamination" means the introduction or occurrence of a contaminant in fish and other aquatic animals and products thereof;

"contaminant" means any biological or chemical agent, foreign matter, or any other substances not intentionally added to food that may compromise food safety or suitability;

"corrective action" means any action to be taken when the results of monitoring at the CCP (critical control point) indicate a loss of control;

"critical control point (CCP)" means a step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level;

"control measure" means any action and activity that can be used to prevent or eliminate a food contamination hazard or reduce it to an acceptable level;

"monitoring" means the act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP (critical control point) is under control;

"facility" means any premises where fish and other aquatic animals as well as products thereof are prepared, processed, chilled, frozen, packaged or stored;

"hazard" means a biological, chemical or physical agent in, or condition of, food products with the potential to cause an adverse health effect;

"chilling" means a process by which the temperature of fish and other aquatic animals is reduced to the desired holding temperature approaching that of melting ice;

"refrigerated water" means clean water cooled by a suitable refrigeration system;

"cleaning" means the removal of soil, food residues, dirt, grease or other objectionable matter;

"potable water" means freshwater fit for human consumption;

"dressed" means that portion of fish remaining after heading and gutting;

"decomposition" means the deterioration of fish and aquatic animals as well as products thereof, including texture breakdown, causing a persistent and distinct objectionable odour or flavour;

"fish" means any of the cold-blooded (ectothermic) aquatic vertebrates. Amphibians and aquatic reptiles are not included;

"shelf-life" means the period during which the product maintains its microbiological and chemical safety and organoleptic qualities at a specific storage temperature. It is based on identified hazards for the product, heat or other preservation treatments, packaging method and other hurdles or inhibiting factors that may be used;

"raw materials" mean fresh and frozen fish, aquatic animals and/or their parts that may be utilized to produce fish and fishery products intended for human consumption;

"clean water" means water from any source where harmful microbiological contamination, substances and/or toxic plankton are not present in such quantities that may affect the safety of fish, aquatic animals and their products.

## **II. Design and construction of vessels used to harvest and process aquatic animals, including fish**

The design and construction of fishing vessels and vessels used to harvest and process fish and aquatic animals should take into consideration the following:

- 1) For ease of cleaning and disinfection, vessels should be designed and constructed:
  - to minimize sharp inside corners and projections in order to avoid dirt traps;
  - to provide an adequate supply of clean water or potable water at relevant pressure;

Construction should facilitate ample drainage and eliminate the risk of counter-current or cross-current flows of raw materials and finished fish products as well as those of finished fish products and production wastes;

Inner surfaces of holds and containers should be impervious, made of smooth material or be smoothly painted, and should be easy to wash and disinfect. Coatings shall not contaminate fish products with substances harmful to human health;

- 2) To minimize contamination:

All surfaces in fish handling areas should be non-toxic, smooth, impervious and easily accessible in order to minimize the buildup of 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 should have an adequate supply of cold potable water or clean water for that purpose. Adequate facilities should be fitted with washing and disinfecting equipment, where appropriate;

The intake for clean water should be located so as to avoid contamination;

All plumbing and waste lines should be capable of coping with peak load;

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 wastes, should not contaminate the aquatic animals and their products;

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

Separate and adequate areas (facilities) should be provided for the storage of poisonous or harmful substances, dry storage of materials, packaging, etc., and storage of offal and waste materials;

Adequate hand washing and toilet facilities, isolated from the fish and shellfish handling areas, should be available where appropriate;

The entry of birds, animals, insects or other pests should be prevented.

- 3) To minimize damage to the aquatic animals when handling:

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

The fishing gear and its usage should minimize damage and quality deterioration of the aquatic animals;

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

Chutes and conveyors should be designed to prevent or minimize mechanical damage caused by long drops, or breakage, crushing, etc.

4) To minimize damage during harvesting of fish and aquatic invertebrates (aquaculture products):

When aquaculture products are caught and harvested using seines, nets or other means and are transported live to processing facilities, catching/gathering gear should be carefully selected to ensure minimum damage during catching/harvesting; while 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;

All surfaces, equipment and materials that come into contact with the fish, aquatic invertebrates and their products should be constructed of suitable corrosion-resistant material that should be smooth and easily cleanable and disinfectable. Surface coatings should be durable and should be made of materials intended to come into contact with food;

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

Where fish is held or transported live, care should be taken to maintain factors that affect fish health (e.g. CO<sub>2</sub>, O<sub>2</sub>, nitrogenous wastes, optimum temperature, etc.).

### **III. Fish processing facility design and construction**

Fish processing facility shall be fitted with transportation routes, pedestrian walkways and production sites with hard impervious coating, storm-water drainage preventing atmospheric precipitations from stagnation, and fencing, and should meet requirements to amenity planting, natural illumination, ventilation, and groundwater level.

Location of fish processing facility should eliminate the possibility of adverse impacts from other enterprises.

Production areas should be adequate to allow processing operations to be performed under proper hygienic conditions.

Facility layout and arrangement should enable prevention of product contamination and separation of "dirty" and "clean" areas.

Fish processing facilities should be designed and constructed to:

prevent counter-current or cross-current flows of raw materials and finished fish products;

prevent counter-current or cross-current flows of finished fish products and production wastes;

minimize process delays likely to result in degradation of quality of fish, shellfish and their products.

Aquatic animals are highly perishable food products and should be handled carefully and chilled without undue delay.

Therefore, facilities 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) For ease of 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 materials that should be light-colored, smooth and easily cleanable;

Walls and partitions should have a smooth surface;

Floors should be constructed with the slope to allow adequate drainage;

Ceilings and overhead fixtures should be constructed and finished to minimize the buildup of dirt and condensation, and the mechanical contamination with foreign particles;

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

Doors should have smooth, non-absorbent surfaces;

Joints between floors and walls should be designed and constructed to ensure ease of cleaning;

2) To minimize contamination:

Facility layout should be designed to minimize cross-contamination of finished product from raw materials, which may be accomplished through physical or time separation of the flows thereof;

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 fish, shellfish 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 should be chemically inert to fish, shellfish and their products as well as detergents and disinfectants under normal operating conditions;

Adequate facilities should be provided for the handling and washing of fish, shellfish and their products and an adequate supply of cold potable water or clean water shall be ensured for that purpose;

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

Ceiling lights should be covered or otherwise properly protected to prevent contamination of products by glass or other foreign matter;

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 the storage of detergents and disinfectants intended for washing and cleaning of premises and equipment;

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

All plumbing and waste lines should be capable of coping with peak loads;

Accumulation of solid, semi-solid or liquid wastes should be reduced to prevent product 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 for the storage of poisonous or harmful substances, dry storage of materials, packaging, etc., and storage of offal and waste

materials in order to prevent contamination thereby;

Adequate hand washing and toilet facilities, isolated from handling area, should be available as well as equipment designed to prevent the entry of birds, insects or other pests and animals, and water supply lines fitted with back-flow devices where appropriate;

Amenity premises for the employees of production sections shall be fitted similar to decontamination stations with hand washing and boot-washing and disinfectant facilities at the entrance;

3) To ensure appropriate lighting:

All work surfaces shall be adequately illuminated.

#### **IV. Design and construction of equipment and utensils**

The condition of the equipment and utensils should be such as to minimize and prevent the contamination thereof.

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

1) For decontamination and disinfection:

Equipment should be durable and movable and/or capable of being disassembled to enable maintenance, decontamination, and disinfection;

Equipment, containers and utensils coming into contact with fish, shellfish and their products should be designed to provide for adequate drainage and assembled to ensure that they can be properly cleaned, disinfected and maintained to avoid contamination;

In handling areas, surfaces should have a minimum of sharp corners and projections in order to avoid physical damage to products being processed and to reduce the chance of contamination buildup;

An adequate supply of suitable washing utensils and detergent agents approved by the competent official agency should be provided.

2) To minimize contamination:

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;

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

Storage containers and equipment should be provided with adequate drainage;

A threat of product contamination from drainage should be eliminated.

3) To minimize damage:

Surfaces should have a minimum of sharp corners and projections;

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

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

## V. Hygiene Control Programme

The 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 should be taken into consideration in the Hygiene Control Programme.

In particular, the Programme should involve exercising control at all points where contamination or infestation 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 scope of operations and the nature of activities.

Hygiene control measures should be implemented to:

- prevent the build-up, or ensure the timely disposal, of waste and debris;
- protect the fish, shellfish and their products from infestation and contamination;
- dispose of any rejected material in a hygienic manner;
- monitor the personal hygiene and health standards in the workplace;
- monitor the pest control programme;
- monitor the decontamination and disinfection programme;
- monitor the quality and safety of water and ice supplies.

The Hygiene Control Programme should take into consideration the following:

- 1) An ongoing decontamination and disinfection schedule.

An permanent decontamination 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 revised whenever structural modifications are made to the vessel, processing facility and/or equipment. Part of this schedule should include a “clean as you go” policy;

- 2) A typical decontamination and disinfection process may include the stages as follows:

Pre-cleaning (preparation of area and equipment for cleaning) involves steps such as removal of all aquatic animals and their products from the area, protection of sensitive components and packaging materials from moist, removal by hand or squeegee of fish offal, garbage, etc.

Pre-rinse: Rinsing with water in order to remove remaining large pieces of loose material;

Cleaning: The removal of soil, food residues, dirt, grease or other objectionable matter;

Rinse: Rinsing with potable water or clean water, as appropriate, to remove all contaminating material and detergent residues;

Disinfection: Application of disinfectant chemicals approved by the competent official agency and/or heat to destroy micro-organisms on surfaces;

Post-rinse: As appropriate, a final rinse with potable water or clean water in order to remove all disinfectant residues;

- 3) Storage: Cleaned and disinfected equipment, container and utensils should be stored in a such a fashion as to prevent their contamination;

- 4) Check of the efficiency of cleaning: The efficiency of cleaning should be controlled

as appropriate;

5) Handlers or cleaning personnel, as appropriate, should be well trained in the use of special cleaning utensils and chemicals, and in methods of dismantling equipment for cleaning and they should be knowledgeable in terms of the significance of proper contamination and disinfection and the hazards involved.

Designation of personnel for cleaning: In each processing plant or vessel, a properly trained individual should be designated to be responsible for the sanitation of the processing facility or vessel and the equipment therein;

6) Maintenance of premises, equipment, and utensils:

Buildings, materials, utensils and all equipment at the processing plant or vessel, 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. For each type of equipment, these procedures should specify the methods used, the persons in charge of their application, and the frequency of performance;

7) Pest control system:

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

Pest control programmes could include preventing access, eliminating pest harbourage at the production site, and establishing detection and eradication systems;

Physical, chemical and biological agents intended for pest control should be properly applied by appropriately qualified personnel in accordance with the applicable rules;

8) Supply of water, ice and steam:

Water: Where appropriate, a sufficient supply of cold and hot potable water and (or) clean water at an adequate pressure should be provided. Wherever possible, potable water should be used to avoid contamination;

Ice: Ice should be produced using potable water or clean water and should be protected from contamination;

Steam: For operations that require steam, an adequate supply at relevant pressure should be maintained. Steam used in direct contact with fish or other aquatic animals or food contact surfaces should not constitute a threat to the safety or suitability of the food;

9) 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 collection, removal, and disposal of offal and waste materials should be maintained in a proper manner;

Vessel waste discharge should not contaminate vessel water intake systems or the harvest.

## **VI. Personal hygiene and health**

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

1) Facilities and equipment should include:

Adequate facilities for hygienically washing and drying hands;

Adequate toilet and changing facilities for personnel should be located and designated in an appropriate manner;

2) Personnel hygiene:

No 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 be engaged in preparation, handling or transportation processes;

Where necessary, adequate and appropriate protective clothing, headwear and footwear should be worn;

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

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

at the start of fish or shellfish handling activities and upon re-entering a processing area;  
immediately after using the toilet.

In handling and processing areas, smoking, spitting, hawking, eating, sneezing or coughing over uncovered food should be prohibited.

The adornment of personal belongings, such as jewellery, watches or pins, or other items that, if dislodged, might pose a threat to the safety and suitability of products should not be permitted either.

## VII. 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 skills to enable them to handle aquatic animals in accordance with the applicable hygiene rules.

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

Each handling facility (vessel) engaged in processing of aquatic animals and their products should ensure that all individuals involved have received adequate and appropriate training in the design and proper application of an HACCP (hazard analysis and critical control points) system and flow process control.

Training of personnel in the use of HACCP (hazard analysis and critical control points) system is of fundamental importance to the successful implementation and delivery of the programme in aquatic animals processing establishments.

The practical application of HACCP principles is more likely to be successful where the individual responsible for HACCP has successfully completed an appropriate training course.

Managers should also arrange for appropriate initial training and periodic training of all involved employees in the facility so that they understand HACCP principles.

## **VIII. General considerations for the handling of fresh aquatic animals**

Unless they can be reduced to an acceptable level by normal sorting and/or processing, no aquatic animals should be accepted for further processing if they are known to contain parasites, undesirable micro-organisms, pesticides, veterinary drugs or toxic, decomposed or extraneous substances known to be harmful to human health.

When aquatic animals determined as unfit for human consumption are found, they should be removed and stored separately from the catch and either reworked or disposed of in a proper manner.

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

## **IX. Time and temperature control**

Temperature is the most important factor affecting the rate of deterioration of aquatic animals and their products and the intensity of multiplication of microorganisms.

Chilling is the most effective method for ensuring safety of food products derived from aquatic animals. Therefore, it is essential that fresh aquatic animals and their products are chilled promptly and kept at a temperature as close as possible to 0 °C.

Minimum time before processing to minimize deterioration.

To minimize the likelihood of deterioration it is important that chilling commences as soon as possible and fresh aquatic animals are kept chilled on a continuous basis. Fresh aquatic animals should be kept chilled, processed and distributed with no delay.

Temperature control to prevent deterioration.

Where temperature control is concerned:

Where appropriate, chilled water systems should be employed to ensure that aquatic animals are kept chilled at a temperature as close as possible to 0 °C;

Aquatic animals should be stored in shallow containers and surrounded by finely divided melting ice;

Live aquatic animals are to be transported at low temperatures tolerable for the species;

Chilled or refrigerated water systems and/or cold storage systems should be designed and maintained in such a way as to provide adequate cooling capacities even during peak loads;

Fish should not be stored in chilled 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.

## **X. Gentle handling techniques to prevent deterioration**

Poor handling practices can lead to substantial mechanical damage to fresh aquatic animals. Such damages can accelerate the rate of deterioration and decomposition and increase unnecessary post-harvest losses.

To minimize handling damage, the following techniques shall be used:

While on deck, exposure to adverse effects should be kept to a minimum in order to prevent unnecessary dehydration of aquatic animals;

Aquatic animals should be handled and conveyed with care particularly during transfer and sorting in order to avoid physical damage such as puncture, mutilation, etc.;

Where aquatic animals are held or transported live, care should be taken to maintain parameters that can influence fish health (such as CO<sub>2</sub> and O<sub>2</sub> concentrations, temperature, presence and amount of nitrogenous substances, etc.);

Aquatic animals should not be trampled or stood upon;

Where boxes (containers) are used for storage of aquatic animals, they should not be overfilled or stacked too deep in such a way that upper boxes press too heavily against the contents of the lower ones;

Finely divided ice should be used for chilling where possible for it can help minimize damage to aquatic animals and maximize cooling capacity;

In refrigerated water storage chambers, the density of the fish should be controlled to prevent damage.

## XI. Processing of raw materials

Potential hazards: pathogenic microorganisms, viable parasites, biotoxins, chemicals (including veterinary drug residues) and physical contamination.

Potential defects: decomposition, parasites, physical contamination.

For raw fish material, product specifications could include the following characteristics: organoleptic characteristics, such as appearance, odour, texture, etc.;

chemical indicators of decomposition and/or contamination, for example, trimethylamine, total volatile basic nitrogen (TVBN), histamine (for histidine-containing fish species), heavy metals, pesticides, nitrates, etc.;

microbiological criteria of raw material, foreign matter;

physical characteristics, such as size of fish;

batch homogeneity in terms of species composition.

Training in species identification and communication of product specification should be provided to fish handlers to ensure a safe source of incoming fish where written protocols exist. Warranting special consideration are the methods and techniques for reception and sorting of fish species that pose a risk of biotoxins such as ciguatoxin in large carnivorous tropical and subtropical reef fish or histamine in histidine-containing fish species, and parasite identification techniques.

Skills should be acquired by fish handlers and appropriate personnel in visual inspection techniques for identification of indicators of fish kill to ensure the appropriate safety level of raw material.

Fish requiring prompt 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 if it is known to contain harmful or extraneous substances or decomposed material that will not be eliminated or reduced to an acceptable level by normal procedures of sorting or preparation.

Organoleptic (sensory) evaluation of fish

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

It is recommended that appropriate sensory evaluation criteria be used to evaluate the acceptability of fish and to eliminate fish showing loss of quality.

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

Scale/slime: dull, gritty colours, yellow-brown dotting slime;

Eyes: concave, opaque, sunken, discoloured;

Gills: gray-brown or bleached;

Slime: opaque yellow, thick or clotting;

Odour: rotting flesh, ammonia, meat, lactic, sulphide, faecal, putrid, rancid.

1) Chilled storage.

Potential hazards: microbial pathogens, biotoxins, histamine (for histidine-containing fish species).

Potential defects: Decomposition, physical damage.

Technical guidance:

Fish should be moved to the chilled storage facility or placed in chilled storage containers without undue delay;

The processing plant (vessel) should be fitted with facilities capable of maintaining the temperature of the fish within the range of 0°C to 4°C;

Cold storage containers, refrigerators and refrigerator rooms should be equipped with a thermometer to control temperature at appropriate intervals;

Stock rotation plans should ensure prompt utilization of the raw fish material intended for processing;

The fish should be stored in shallow containers and surrounded by sufficient amount of finely divided ice, or a mixture of ice and water, or refrigerated water before processing;

Fish should be stored in such a fashion that damage caused by overstacking or overfilling of boxes (containers) is prevented;

As necessary, ice supply on the fish should be replenished or temperature in the storage room shall be adjusted accordingly.

2) Controlled thawing.

Potential hazards: microbial pathogens, biotoxins and histamine .

Potential defect: decomposition.

Technical guidance: The thawing method should be clearly defined and should address the time and temperature of thawing as well as the use and suitable placement of the temperature measuring instrument. Fitting a system for recording thawing time and temperature is highly recommended. The thawing schedule (time and temperature parameters) should be thoroughly reconciled.

Selection of the thawing method should take into account:

The 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 microorganisms and histamine (where high-risk species are concerned) and to prevent the occurrence of persistent and distinctive objectionable odours or

flavours indicative of decomposition or rancidity;

Where water is directly used as the thawing medium, it should be of potable quality;

Where recycle water is used, care should be taken to avoid the buildup of microorganisms;

Where water is used in the course thawing, circulation should be sufficiently intensive to ensure even thawing;

During thawing, according to the method used, products should not be exposed to excessively high temperatures;

Special attention should be paid to controlling formation of condensation and aerosols. Effective drainage should be ensured;

After thawing, fish should be immediately processed or refrigerated and kept at the appropriate temperature;

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

### 3) Washing and gutting.

Potential hazards: microbial pathogens, biotoxins, histamine (for histidine-containing fish species).

Potential defects: presence of viscera, bruising, objectionable odour, cutting faults.

Technical guidance:

Gutting is considered complete when the intestinal tract and internal organs have been removed entirely;

A sufficient supply of clean water or potable water should be available for washing;

Prior to gutting, whole fish should be sorted to remove foreign debris and reduce bacterial load;

Gutted fish should be handled and washed to remove blood and viscera residues from the belly cavity;

Surface of fish should be handled to remove any loose scales where appropriate;

Gutting equipment and utensils should be available and used properly to minimize the buildup of slime, blood and offal;

Separate and adequately equipped storage premises should be provided for the fish, fish roe, milt and livers, if these are saved for later utilization.

### 4) Filleting, skinning, trimming and candling.

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

Potential defects: parasites, presence of bones, objectionable matter (e.g., skin, scales, etc.), 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 constant and uniform flow without stoppages or slowdowns and removal of waste;

A sufficient supply of clean water or potable water should be available for washing of products being processed, including fish prior to filleting or cutting, especially fish that have

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

Filleting equipment and utensils should be washed on a regular basis to minimize the buildup of slime and blood;

For fillets intended for marketing or further processing as boneless, fish handlers should be provided with appropriate inspection techniques and the necessary tools to remove bones;

For candling of skinless fillets from certain fish species, skilled personnel should be provided with the necessary candling equipment to be used in a suitable location that is optimum in terms of illumination parameters and conditions. This technique is effective in removing parasites from 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 and products caused by lamp-generated heat.

## **XII. Processing of minced fish**

Mincing fish using mechanical meat/bone separation process

Potential hazards: pathogenic microorganisms, biotoxins, histamine, physical contamination (metal, bones, rubber from separator belts, etc.).

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

Technical guidance:

The separator should be fed continuously but not excessively;

Candling is recommended for those fish species or batches that are suspected of high infestation with parasites;

Split fish or fillets should be fed into the separator in such a fashion that the cut surface contacts the perforated surface;

Fish should be fed to the separator in a 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 of 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 ensure that they do not get through to the next processing stage;

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

The core temperature of the fish being frozen should be monitored on a regular basis to ensure completeness of the freezing process;

Frequent checks should be conducted to ensure correct flow of a freezing procedure;

Where appropriate, monitoring should ensure that spray nozzles do not become clogged;

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

### **XIII. Processing of fish to be marketed in vacuum or modified atmosphere packaging**

#### **1. Weighing**

Weigh scales should be periodically calibrated using a standard weight to ensure accuracy.

#### **2. Vacuum or modified atmosphere packaging**

Packaging process should be strictly controlled. Control should be ensured by:

monitoring the gas–product ratio;

types and ratio of gas mixtures used;

type of packaging film used;

control of product temperature during storage;

generating adequate vacuum and adequate packaging;

Fish flesh should not come into contact with the seam area;

Packaging material should be inspected prior to use to ensure that it is not damaged or contaminated;

Packaging integrity of the finished product should be inspected periodically by appropriately trained personnel to verify the effectiveness of the seal and the proper operation of the packaging machine;

Following sealing, modified atmosphere packed (MAP) or vacuum-packed products should be transferred carefully and without undue delay to refrigerated storage rooms;

It should be ensured that adequate vacuum is attained, and the package seals are intact.

### **XIV. Frozen fish production**

#### **1. Freezing process**

The fish products 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 thus increasing the rate of quality deterioration and reducing shelf-life owing to the action of micro-organisms and undesirable chemical reactions;

An optimum time and temperature regime for freezing should be established and should take into consideration the freezing equipment properties and capacity and the necessary freezing parameters attributable to the nature of the fish product, including thermal conductivity, thickness, shape and initial temperature and the volume of production. Such regime should ensure that the range of temperatures of maximum crystallization is passed through as quickly as possible in order to minimize damage to product structure caused by ice crystals;

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

The rate of utilization of production line capacity should be geared to the capacity of freezers;

Frozen product should be moved to the refrigerated storage rooms as quickly as possible;

The core temperature of the fish products being frozen should be monitored on a continuous basis till completion of the freezing process;

Frequent checks should be conducted to ensure correct flow of the freezing procedure;

Accurate records of all freezing operations should be kept;

For killing parasites harmful to human health, requirements to the freezing temperature and monitoring of freezing duration should match equipment specifications to ensure appropriate cold treatment.

## 2. Glazing:

Glazing is considered complete when the entire surface of the frozen fish product is covered with a suitable protective coating of ice. Glazed fish product should have no exposed areas left uncoated where sublimation dehydration can occur as a result of freezer burn;

If additives are used in the water for glazing, care should be taken to ensure their proper proportions and application with due regard to product specifications;

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

Where appropriate, monitoring should ensure that nozzles do not become clogged;

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 in the glazing solution, which can hamper freezing performance.

## 3. Wrapping and packaging

Potential hazards: pathogenic microorganisms.

Potential defects: subsequent dehydration, decomposition.

Technical guidance:

Packaging material should be clean, sound, durable, sufficient for its intended use and of food-grade to enable its use in direct contact with food products;

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

Products should meet applicable standards for marking and weights.

## 4. Frozen storage

Potential hazards: microbial pathogens, toxins, viable parasites.

Potential defects: dehydration, rancidity, loss of nutritional properties.

Technical guidance:

The enterprise (vessel) should be equipped with the appropriate facilities capable of maintaining the temperature of the fish at or colder than  $-18^{\circ}\text{C}$ , and with minimum temperature fluctuations;

The refrigerated storage room should be equipped with a calibrated recording thermometer (or alternative temperature control and recording means should be provided);

A systematic stock rotation plan should be developed and observed;

Products should be glazed and/or wrapped using a wrapping film to protect it from dehydration;

Fish batch should be rejected if found to contain defects that subsequently cannot be eliminated or reduced to an acceptable level by repeated handling, sorting and preparing procedures.

## XV. Transportation

1. Vehicles should be designed and constructed with the following taken into consideration:

Walls, floors and ceilings, where appropriate, should be made of a suitable corrosion-resistant material with smooth, non-absorbent surfaces;

Floors should be adequately drained (where appropriate);

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

2. Vehicles should be designed and constructed to ensure that:

live fish and other aquatic animals are transported at temperatures tolerable for the species;

fish or other aquatic animals being transported are protected against contamination, exposure to extreme temperatures and the drying effects of the sun or wind;

the free flow of chilled air is permitted around the load (where the vehicle is fitted with mechanical refrigeration means).

Handling (transportation) guidelines apply to Sections XI—XIV. Transportation (handling) is a step of the flow diagram. Transportation personnel should possess 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 offers technological guidelines that can be used to develop control measures and corrective actions.

Transportation of fresh, refrigerated or frozen fish, shellfish and their products is of particular importance in all respects. During transportation of the above, care should be taken to minimize the risk of any rise in product temperature and to maintain it within the established limits. Moreover, appropriate measures should be applied to minimize damage to products and their packaging.

3. Fresh, refrigerated and frozen products

Potential hazards: objectionable biochemical processes (histamine), population growth of microorganisms, contamination.

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

Technical guidance:

Temperature of the product should be checked before loading;

Unnecessary exposure to elevated temperatures during loading and unloading of aquatic animals and their products should be avoided;

Loading should be performed in such a fashion as to ensure good air flow between products and walls, floor and roof panels; the use of load stabilizer devices is recommended;

Air temperatures inside the cargo hold should be monitored during transportation; the use of a recording thermometer is recommended;

During transportation, frozen products should be maintained at a temperature of –18°C or colder ( $\pm 3^\circ\text{C}$  fluctuations are permissible);

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

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

Transportation of fresh fish in containers with dry freezer agents instead of ice should be considered where appropriate;

Should the need arise for the transportation of fish in ice slurry, chilled seawater or refrigerated seawater, chilled seawater or refrigerated seawater (ice) should be used in such a manner as to ensure veterinary and sanitary safety of fish being transported;

Refrigerated processed products should be transported at the temperature maintained at the levels specified by the processor (but generally transportation temperature should not exceed 4 °C);

Fish, shellfish and their products shall be ensured adequate protection against contamination, dust, exposure to elevated temperatures and the drying effects of the sun or wind.

Before loading, the cleanliness, suitability and sanitation condition of the vehicle should be verified. Loading and transportation should be conducted in such a way as to avoid damage and contamination of products and to ensure integrity of the packaging.

## **Section B. Guidelines for the Inspection of Dairy Enterprises**

### **I. General Provisions**

1. These Guidelines specify the approaches to and principles for the assessment of enterprises producing milk and milk products on the customs territory of the Customs Union and third countries to be carried out during inspection.
2. Inspectors and experts of authorized bodies should inspect dairy enterprises of the Member-States and third countries in compliance with these Guidelines.
3. Dairy enterprises of the Member-States and third countries shall be inspected as to their compliance with the requirements of the Customs Union based, *inter alia*, on the equivalence principle as regards third countries.
4. Using the criteria of these Guidelines, the inspector should determine whether a dairy enterprise achieves the safety level set by the requirements of the Customs Union (as defined in Annex 2 to the Regulation on the Harmonized Procedure for Joint On-Site Inspections and of Taking of Samples of Goods (Products) Subject to Veterinary Control (Supervision)), and by the veterinary requirements of the Member-States in cases when such requirements are not stipulated in regulatory legal acts of the Customs Union.
5. These Guidelines shall be published to ensure general availability and promote good practice.
6. The terms used herein shall have the following meaning:

“Risk analysis” means a process consisting of three interconnected components: risk assessment, risk management, and risk transfer.

“Risk communication” means an interactive exchange of information and opinions concerning hazards, risks, risk-related factors, and risk perception carried out throughout the risk analysis process among risk assessors, risk managers, consumers, enterprises of the feed and food

industries, scientific community, and other interested parties and aimed, *inter alia*, at clarifying the risk assessment results and forming the grounds for risk management decisions;

“Final consumer” means a food consumer who will not use a food product as part of any transaction or business of a food industry enterprise;

“Processing” means any operation that significantly modifies the initial product, including heating, smoking, air drying, ageing, drying, pickling, extraction, extrusion, or a combination thereof;

“Processed products” means food products resulting from the processing of crude food products. They may contain components necessary for their production or attributing specific properties;

“Hazard” means the presence in the products of a biological, chemical, or physical factor, or a condition of food or feed products capable of causing adverse health effects;

“Food sector operator” means a natural person or a legal entity responsible for the fulfillment of food legislation requirements by food sector entities under its supervision;

“Risk assessment” means a scientifically based process consisting of four stages: hazard identification, hazard characterization, exposure assessment, and risk characterization.

“Food sector enterprise” means a state or private enterprise whose operation carried out with or without the purpose of profiting relates to any stage of production, processing, and distribution of food products;

“Traceability” means the ability to trace food products, feed, food-producing animals, and substances intended for or planned to be included in food or feed, at all stages of production, processing, and distribution;

“Placing on the market” means marketing the food products for the purpose of sale, including sales offers or other forms of transfer (free of charge or otherwise) and sale, distribution, and other forms of transfer;

“Risk” means the probability of an adverse health effect and its potential hazard;

“Retail trade” means stores, supermarket distribution centers, and wholesale trading centers, as well as public catering facilities including restaurants and other similar facilities;

“Shelf life” means the period of time during which the product remains microbiologically safe and edible under specified storage temperature and, where appropriate, under specified storage and handling conditions;

“Production, processing, and distribution stages” means any stage including import, from primary production of a food product up to its storage, transportation, sale, or delivery to the final consumer and, where applicable, import, production, manufacture, storage, transportation, distribution, sale, and delivery of feed;

“Raw milk” means milk that was not subjected to heat treatment at temperatures exceeding 40°C or to other treatment changing its ingredients;

“Risk management” means a process, different from risk assessment, that determines political alternatives in consultations with interested parties taking into account risk assessment and other significant factors and, where necessary, selection of appropriate preventive and control measures.

## **II. Traceability**

The traceability of dairy products for people should be ensured at all stages of production and circulation of such products.

An enterprise producing dairy products or involved in their circulation should at the same time provide the possibility for identifying any raw-material supplier and the origin of any component of the product, as well as all recipients of its products.

Enterprises engaged in circulation of products should possess systems and procedures to give competent authorities access to such information at the request of the latter.

Food products placed or prepared to be placed on the market should be marked or identified in a way that facilitates their traceability through documents, or should contain information in accordance with the requirements imposed on specific types of food products.

### **III. General Hygiene Rules for Enterprises**

Milk collection and processing should be conducted so as to minimize the possibility of contaminating the products.

The following requirements are necessary for proper sanitation of the production process:

- 1) The floor surface should be kept clean and be easily washed and disinfected. Waterproof, nonabsorbent, washable, and nontoxic materials should therefore be used as the flooring. Where appropriate, the floor should be provided with drains. The floor surface should be washed at the end of each workday (or shift).
- 2) The wall surface should be kept clean and be easily washed and disinfected. Waterproof, nonabsorbent, washable, and nontoxic materials should therefore be used as the wall lining. The wall surface should be smooth.
- 3) Other surfaces (including those of the equipment) in areas where food products are treated (processed), and in particular surfaces contacting the food products, should be kept clean and be easily washed and disinfected. Smooth, washable, corrosion-resistant, and nontoxic materials should be used for this purpose. All surfaces should be washed at the end of each workday (or shift).
- 4) To remove production waste liquids, the building should be provided with blown-through drains of appropriate size, properly located and equipped with lids. The floor surface in all premises should be inclined towards the drains.
- 5) The ceiling (or the inside surface of the roof when there is no ceiling) and the top brackets should be designed so as to prevent fouling and reduce the likelihood of condensation, growth of undesirable mold (the presence of which is not provided for by the production process), and falling of particulate materials from the ceiling.
- 6) Windows and other apertures should be designed so as to prevent fouling. Windows opening on the outside should be equipped with mosquito nets easily removable for cleaning. Windows through which contaminants may penetrate the premises should remain closed during the production.
- 7) Doors should be easily cleaned and disinfected. Smooth and nonabsorbent materials should be used for this purpose. Wooden doors and doorframes should be coated with metal having tightly soldered seams.
- 8) Water supply: independently of the water source used (boreholes, wells, streams, public water supply, etc.), water should meet the requirements imposed on potable water. All production areas should be supplied with cold and hot water in sufficient amounts.

### **IV. Storage Premises for Milk and Milk Products**

Storage premises for milk and milk products should be kept clean and in good condition.

Storage premises for the products should:

allow effective maintenance, cleaning, and disinfection, prevent or minimize air pollution, and have workspace sufficient for sanitary and hygienic cleaning;

prevent fouling, any contact of raw materials and products with toxic materials, falling of particulate materials from the ceiling, formation of condensation or undesirable mold (the presence of which is not provided for by the production process) on the surfaces;

ensure proper hygiene activities including protection of premises against contamination, rodents, and insects;

ensure, as appropriate, proper thermal control for processing and storage of the products with thermal control systems continuously monitoring and, where required, recording the temperatures;

provide conditions for the personnel to change clothing and, as appropriate, take decontamination showers before entering the production premises.

#### Water Closets

The enterprise should have a sufficient number of water closets connected to the sewerage system. They should be located away from premises where milk products are treated (processed).

The water closets should be equipped with appropriate natural or mechanical ventilation systems.

#### Washbasins

The enterprise should have a sufficient number of properly positioned and marked washbasins for washing hands. They should be supplied with hot and cold water and fit with hand washing and hygienic drying (wiping) sets. Washbasins should be provided in water closets, changing rooms, and production premises. Their design should allow switching the water on and off without the use of hands.

Washbasins for washing the products should be separated from hand washbasins.

#### Ventilation

The premises should be equipped with proper natural or mechanical ventilation systems to prevent air from a non-clean (raw material) area (environment) from entering a clean area (area of production and storage). The design of the ventilation system should ensure prompt removal of filters and other parts that need regular cleaning or replacement.

#### Lighting

The light intensity should allow the personnel of the enterprise and the technical control service to evaluate the sanitary conditions and product contamination.

#### Drainage

The drainage systems should function properly. They should be developed and designed to minimize the risk of product contamination.

In places where the drainage channels are completely or partially opened, their design should guarantee that the wastewater from a non-clean area would not enter a clean area, in particular a clean area where food products presenting a high health hazard to final consumers are treated (processed).

#### Changing Rooms

The changing rooms should be located separately from premises where food products are prepared, stored, or treated (processed).

The changing rooms should be located separately from water closets.

Separate changing rooms should be provided for men and women, if men and women work at the enterprise.

The changing rooms should have sufficient and properly distributed lighting.

Separate changing rooms for those working in “non-clean” and “clean” areas are advisable.

A container for dirty clothing should be adjacent to the changing rooms.

## **V. Equipment**

All parts, tools, and equipment contacting food products should:

be thoroughly cleaned and, if necessary, disinfected. The regularity of cleaning and disinfection of the equipment should eliminate any risk of product contamination;

be designed in such a way, made from such materials, and maintained through regular repair in such condition that minimize any risk of contamination;

with the exception of nonreturnable containers and packaging, be designed in a such a way, made from such materials, and maintained through regular repair in such condition that they remain clean and are disinfected only as the need arises;

be installed in such a way that allows for proper cleaning of the equipment and the surrounding area.

If required, the equipment should be provided with suitable control devices. If chemical substances are necessary to prevent corrosion of the equipment and containers, such substances should be used according to safety procedures.

## **VI. Water Supply**

Water including potable water should be supplied to the enterprise continuously with a guaranteed prevention of food contamination.

Non-potable (industrial) water used, for example, in fire extinguishing, steam generation, and cooling systems, as well as for other purposes should circulate in an individual supply system. It should not mix with potable water or penetrate the potable water system.

Water used in processing of raw materials or products or as an essential component of production should not introduce any risk of product contamination. It should comply with potable water standards, unless a competent authority decides that its quality cannot affect the sanitary conditions of food products.

Ice contacting or capable of contaminating food products should be produced from potable water. It should be produced, treated, and stored under conditions preventing its contamination.

Vapor contacting food products should be free of any substances dangerous to health or capable of contaminating food products.

When raw materials or products are heat treated in sealed containers, water used for cooling the containers after the heat treatment should not be the source of food contamination.

## **VII. Personal Hygiene**

Personal hygiene activities are needed to prevent general and cross contamination of food products with causative microorganisms that can lead to food-borne diseases.

Each employee processing food products should maintain an appropriate level of personal hygiene and wear clean and, where necessary, protective clothing. An employee who falls ill should immediately inform his/her superior about the disease and its signs.

The list of diseases and symptoms that should be reported to the superior for considering the need for a medical check-up and (or) for removal of food products from treatment (processing)

includes jaundice, diarrhea, vomiting, high temperature, angina, fever (shivers), apparent skin damage (abscess, cut, etc.), and unusual ear, eye, or nasal discharge.

The personnel directly processing milk should also maintain an appropriate level of personal hygiene and, where necessary, use protective clothing, headwear, and footwear. A waterproof bandage should be applied to cuts and wounds when the injured employee is allowed to continue work.

The personnel should wash hands in all cases when personal hygiene can affect the safety of food products, for example:

at the beginning of work related to treatment (processing) of food products;

immediately after using the water closet;

after treating raw food products or any contaminated material. This may contaminate other products, so employees of this category should avoid contacting any finished products.

During their working hours, employees involved in processing of food products should avoid smoking, spitting, chewing, eating, sneezing, or coughing in proximity to unprotected food products.

The employees should not wear any jewelry, watches, pins, etc. or bring such articles to food processing areas.

## **VIII. Training**

The management of a food producing enterprise should check the personnel involved in processing food products and conduct briefings and (or) trainings on issues of food safety and hygiene, the program of which corresponds to the basic areas of their work.

The training programs should:

provide the personnel with knowledge, skills, and habits aimed at fulfilling certain tasks of dairy production hygiene, checking the statistical process control, HACCP or similar systems;

ensure the required level of practical training;

provide for testing of the personnel, when required;

guarantee due skills to personnel involved in process control;

be certified and based on vocational training requirements;

provide for further education of competent persons.

## **IX. Hazard Analysis and Critical Control Points (HACCP)**

HACCP or similar systems in dairy production are a tool of process control applied to guarantee food safety.

The verification of a plan for HACCP or similar system in dairy production should ensure the compliance of such plan with objectives or criteria of manufacturing safe products, from the veterinary and sanitary standpoint, taking into account the degree of variability of hazards and risks that is normally associated with different health conditions of animals providing raw materials to be processed.

The verification frequency according to the plan of a HACCP or similar system may vary depending on the operational aspects of process control and on the results of previous verifications.

A competent authority may personally approve the plan for a HACCP or similar system and determine the frequency of verifications.

Microbiological study aimed at verification within the framework of a HACCP or similar system (for example, to verify critical limits and statistical process control) for many food products is the major efficiency characteristic of the plan for a HACCP or similar system.

## **X. Sanitation Standard Operating Procedures (SSOP)**

Sanitation standard operating procedures (SSOP) applied in and before the production serve to minimize any direct and indirect contamination of milk.

A properly implemented SSOP system should guarantee that all tools and equipment are cleaned and disinfected prior to the beginning of work and that hygiene requirements are met during the production.

A competent authority may provide SSOP guidelines that cover minimum obligatory requirements for general sanitation.

The SSOP specifics include:

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

appointment, from among the enterprise personnel, of persons responsible for SSOP implementation and monitoring;

documentation on monitoring and any corrective and (or) preventive measures taken, the access to which is provided to the competent authority for inspection purposes;

corrective measures including appropriate disposition of the products;

periodic evaluation of the system efficiency carried out by the manager of the enterprise.

In sanitation control of a production area where finished food products intended for human consumption are treated, microbial limit tests of surfaces contacting or not contacting the food products within the SSOP framework should have a higher intensity than those in other cases and for other types of products.

## **XI. Rodent and Insect Control**

Rodents and insects are the major threat to safety and suitability of food products. Pest infestation may occur in places that create conditions for their reproduction and abundant nutrition.

To prevent the formation of environment favorable to rodents and insects, proper sanitation methods are required.

Effective preventive measures, visual inspection of the delivered materials, and strict control can minimize infestation probability and thus reduce the need for rodenticides and insecticides.

Buildings should be renovated, as this will help to block the access for rodents and insects and eliminate their potential reproduction areas.

Openings, drains, and other places through which rodents and insects can penetrate the premises should be closed mechanically. Adequate screens on open windows, doors, and vent panes will reduce the pest threat.

All animals except working dogs should be removed from the territory of any milk processing enterprise wherever possible.

Accessibility to food and water facilitates the invasion and occupation of the enterprise territory by rodents and insects.

Potential food sources should be kept in containers reliably protected against pests and (or) be located above the ground and away from the walls.

The enterprise and the territory around it should be regularly inspected for traces of rodents and insects. If such traces are detected, the response should be immediate, without affecting the safety and suitability of food products.

The premises and the territory should be properly and regularly sanitized with the help of chemical, physical, or biological agents.

The efficiency of sanitation systems should be checked by periodic preoperational inspections or, where applicable, by collecting microbial samples from the surrounding environment and surfaces that contact food products, with regular revision and adaptation of such systems to changing circumstances.

## **XII. Principles of Primary Processing of Milk**

Milk delivered to consumers should be free of contaminants creating hazard to human health.

As the primary stages of dairy production significantly influence the safety of milk products, the potential microbial contamination of any origin should be absolutely minimized.

To ensure proper health condition of dairy animals, they should be taken care of, and relevant livestock breeding techniques should be applied.

Unsatisfactory stock-keeping, insufficient or poor-quality feed, veterinary shortcomings, inadequate hygiene of milkers and their equipment, and improper milking techniques may cause food contamination with chemical substances and other contaminants at the primary stages of dairy production.

Contamination of milk by biological and chemical agents originating from the animals and the environment should be minimized at the primary stages of production (a contaminant is a biological or chemical agent, a foreign matter, or another substance unintentionally introduced into a food product and compromising its safety and suitability).

The content of contaminant microorganisms in milk should be kept at the lowest possible level by applying high-quality milk production techniques and taking into account process requirements imposed on further milk processing.

In order to increase the safety at the primary stages of production, measures should be taken to reduce to a permissible level the initial concentration of contaminant microorganisms in milk including pathogens and microorganisms affecting the safety and suitability of food products.

The safety and suitability of the products can be ensured by means of such milk preparation technology that allows for less stringent microbial control measures as compared to other technologies.

## **XIII. Production Management at the Enterprise**

### **1. Receipt of Milk**

Milk received at a milk processing plant (when further treatment does not provide for other measures) should be cooled and kept, as necessary, at lower temperatures to minimize any possibility of propagation of the microbes it contains.

A principle should be used according to which milk received first is treated first.

### **2. Intermediate products of processing stored until further treatment (processing) should be kept under conditions that limit (prevent) the microbial growth, or should be treated (processed) in the shortest possible time.**

The maximum safety and suitability of milk and milk products and the intensity of control measures to be applied in processing depend not only on the initial microbial content of raw

materials received at a milk processing plant, but also on the effective prevention of microbial growth within such materials.

The primary factors for microbial growth reduction include proper storage temperatures and appropriate handling of raw materials.

The compliance of products with specified purposes of safe food products and (or) associated purposes and criteria depends on properly applied control including that of time and temperature.

The enterprise should ensure adequate turnover of raw materials and products based on the “first in, first out” principle.

### 3. Storage and Disposition of Finished Products

Milk and milk products should be stored at a temperature that provides their safety and suitability from the moment of packaging until consumption or cooking.

The storage temperature should ensure safety and suitability of milk and milk products during the entire shelf life set by the manufacturer. The storage temperature may vary depending on perishability of the product.

A distribution system should be developed for perishable products to ensure low-temperature storage and thus their safety and suitability.

When treating food products meant for long storage at ambient temperatures, extreme temperatures should be avoided to guarantee proper storage conditions.

Anticipated temperature abuse should be taken into account in the development of standard distribution and treatment models.

## **XIV. Safety Measures during and after Treatment (Processing)**

It is important to apply safety measures both during the primary production stages and during treatment. This will minimize or prevent microbial, chemical, or physical contamination of milk. Additional attention should be paid during treatment of milk products to avoiding negligent cross contamination, *inter alia*, by components potentially containing allergens.

Note: Clear distinction may be drawn between two types of safety measures: those applied against microbial contaminants and those of chemical and physical nature.

Safety measures applied against chemical and physical contaminants of food products are primarily preventive. They are aimed at preventing contamination of food products by chemical or physical contaminants. At the same time, there are several exceptions, such as the use of filters, protective screens, and metal detectors to remove specific physical contaminants.

Microbiological safety of food products is provided by appropriate measures applied at the primary production stages in combination with safety measures applied during and after treatment.

The result of any antibacterial safety measure largely depends on the microbial content and on the concentration of microbial contaminants in the contaminated product.

It is therefore important to apply preventive measures both at the primary production stages, to reduce the initial pathogen content, and during processing, to prevent contamination in the course of production.

The initial microbial content significantly influences the characteristics critical for the microbiological safety measures applied during and after processing, as well as the characteristics necessary for identifying a food product as suitable for human consumption. The safety and suitability of the final product depend not only on the initial microbial content and

process efficiency, but also on further growth of surviving organisms and contamination at the following production and circulation stages.

Individual safety measures should be selected and applied in a combination that ensures appropriate characteristics and reduces the hazard of the final product down to an acceptable level.

Acceptable contamination levels of the final product should be identified based on the purpose of ensuring safe food products, as well as on the criteria of suitability of final products and similar criteria.

Specific microbiological safety measures may be classified in the following way according to their primary functions:

Antibacterial measures are aimed at reducing the microbial content, for example, by elimination, growth inhibition, or physical removal of microbes. These measures may be applied during processing in the course of a relevant process (for example, during microfiltration, thermostating, pasteurization) and used after processing as the internal factors (for example, during oxidation);

Microbiostatic measures prevent, limit, or inhibit microbial growth with the help of chemical or physical agents. These measures render food products stable against pathogens and saprogenic microflora. They may be applied after the production of milk, as well as during (for example, as intermediate stages) and after processing.

Though the microbiostatic measures make the microbial re-growth less probable, such probability still remains. Such measures, which are effective after treatment, may be applied to products as external factors (temperature and time control) or introduced into products as internal factors (preserving agents, pH value).

The microbiostatic measures preventing direct product contamination are aimed at physical prevention or reduction of microbial contamination of products. They are implemented, for example, by using a closed production cycle, special technologies, or appropriate packaging designed to protect the products.

A single-step treatment may have significant consequences for the microbial contamination level (for example, lower pH or lower water content), while other microbiological safety measures only reduce the number of microorganisms contaminating the product (or the environment where the product is manufactured) at a specific stage of the production where they are applied.

### Combination of Microbiological Safety Measures

Several microbiological safety measures are typically required to control the microbial content and inhibit or prevent decay and food-borne diseases.

Combination of measures may be developed to reduce the number of specific hazardous organisms and (or) make the product unfit for their further growth (activity). Such combinations are sometimes referred to in the dairy industry as “a barrier technology”.

The combination of safety measures pursues two major objectives:

- during treatment, to guarantee that the content of hazardous pathogens and (or) saprogenic flora will remain at or be reduced to an acceptable level;
- after treatment (packaging, distribution, and storage), to guarantee that the acceptable content of hazardous pathogens and (or) saprogenic flora achieved during treatment will remain under control through the shelf life of the product.

Guarantees may be required to indicate that the microbial growth is minimized before treatment, between its stages, and after treatment.

The microbiostatic measures should be adapted to demands associated with a specific product in a specific situation.

The result of ensuring safety and suitability of the final product depends not only on the initial microbial content and the efficiency of safety procedures, but also on the success of implementing methods for further prevention of growth of surviving microorganisms and on the effective prevention of new contamination stages.

Therefore, all combinations of microbiological safety measures should be accompanied by relevant preventive measures applied before and after the process, when their joint use is considered to be necessary.

Depending on the source and possible ways of microbial contamination, the hazard may be controlled with the help of preventive measures implemented at the primary production stages and (or) in the production environment.

When assessing the efficiency of measures aimed at preventing microbial contamination, it is especially important to know which hazards can be addressed by such measures and to which degree the measures reduce the probability of contamination of milk during milking and of milk products during their treatment and (or) sales.

Microbial hazards resistant to preventive and microbiostatic measures should be prevented with the help of relevant antibacterial measures combined with other activities.

Measures preventing microbial contamination that are effective only at the stage of their application should be combined with other microbiological measures.

The combination of measures is most effective when it is multipurpose, i.e. when different individual measures are selected in order to influence different factors determining the microbial survival, for example, pH value, water activity, nutrient availability, etc.

As a rule, a multipurpose combination of measures is more effective than any individual measure applied with high intensity.

Using several measures that inhibit the growth or reduce the number of microorganisms may have a synergistic effect, when the cumulative result of their joint use is much higher than the result expected from applying such measures separately.

## **XV. Microbiological and Other Indicators of Suitability of Raw Materials**

Milk delivered for processing should be subject to organoleptic inspection.

Other criteria, such as temperature, acidity, microbial and chemical contamination levels should also be used to identify raw milk unsuitable for production.

Any incompliance of the delivered milk with the specified criteria (especially related to pathogens) should necessitate changes to be immediately introduced at the farm and the processing enterprise. The examples of such changes include:

refusal to use a given lot of milk in the production of raw milk products;

changes in the milking routine (cleaning procedures for milking equipment, udder, etc.);

improved feeding of animals at the farm that has delivered the milk;

improved hygienic quality of water for animals;

changes in animal management techniques;

individual inspection of animals to identify an animal (animals) that may be a vector of disease; isolation of such animal from the herd where necessary.

The changes should be specified and implemented, and the dairy farms may in addition need specialized assistance.

Where a wider range of measures is applied to ensure safety and suitability of milk, for example, when raw milk is intended for the production of raw milk products, it may become necessary to classify farms into two groups, those fit and unfit for the production of raw milk, and to impose additional requirements on milk used in the production of milk products not subject to heat treatment.

Depending on the results of the hazard analysis performed by the producer and on the combination of safety measures applied during and after the treatment of milk products, a need may arise in additional special criteria of microbial purity.

## XVI. Microbiological Safety Measures

Note: The safety measures are presented in this section as descriptive examples only and require validation prior to use with respect to their effectiveness and safety.

Microbial growth is dependent upon many environmental factors, such as ingredients, nutrients, water activity, pH, presence of preservatives, competitive microorganisms, gas atmosphere, redox potential, storage temperature, and shelf life.

Control over these factors can be used to limit, inhibit, or prevent microbial growth.

Microbiological safety measures, as well as measures protecting the product against direct microbial contamination from the environment perform microbiostatic functions.

Many microbiostatic measures interfere with homeostasis mechanisms of microorganisms, which them to reproduce and remain viable in order to survive environmental stresses.

Maintaining the homeostasis requires significant energy and material resources of a microorganism. Therefore, when a microbiological measure disturbs the homeostasis, the microorganism lacks enough energy to reproduce and remains in the lag phase. Some microbial cells may even die out before their homeostasis is reestablished.

Examples of typical microbiostatic measures include the following:

Carbon dioxide (CO <sub>2</sub> )	Addition and (or) formation of carbon dioxide during processing to obtain a long-term microbiostatic effect, including the creation of anaerobic conditions by replacing oxygen, pH reduction, inhibition of certain intracellular enzymes (decarboxylation), and suppression of the transport of water-soluble nutrients through the membrane (by dehydrating the cellular membrane). The efficiency primarily depends on the point of application. Carbon dioxide emission from ripened cheese to the outside environment is often utilized to provide anaerobic conditions within the headspace of cheese packaging.
Coating	Creation of a physical barrier to protect food products against microbial contamination. Antibacterial substances may be introduced into the coating to gradually eliminate the microorganisms from the surface.
Freezing	Lowering the temperature below the freezing point of the product with a simultaneous water activity reduction. The effect of freezing is both microbiostatic and microbiocidal.

Lactoferrin	Microbial growth inhibition by natural glycoproteins (highest concentration in colostrum) to extend the lag phases of bacteria by 12-14 hours due to binding of iron ions in the presence of bicarbonates
Lactoperoxidase system	Activation of the lactoperoxidase, or thiocyanate, or hydrogen peroxide system (indigenous system of milk) to inactivate a number of metabolic enzymes vital to bacteria and thus cause multi-point blocking of their metabolism and reproducibility
Modified atmosphere	Creation of a gas environment (either low in oxygen and (or) high in carbon dioxide or nitrogen) to inhibit the growth of aerobic microorganisms by impairing biochemical pathways of bacterial cells. Modified atmosphere packaging (MAP) is a technique that modifies the gas environment inside the packaging. It should be taken into account that anaerobic environment created to inhibit the growth of aerobic microorganisms may cause proliferation of certain anaerobic pathogens.
Packaging	Packaging provides a physical barrier to protect products against microorganisms from the environment.
pH reduction	Creation of an acidic medium to enable an additional amount of hydrogen ions to penetrate the cytoplasm of microorganisms, thus disturbing the consistency mechanism of intracellular pH responsible for the functionality of key cell components vital for further growth and viability. Low pH values may be obtained through fermentation or addition of acids (organic or inorganic). The pH value low enough to prevent microbial growth depends on the pathogen, but typically falls within the range of 4.0-5.0 pH. At lower pH, microorganisms become more sensitive to other antibacterial measures. Synergy may occur with salt, water activity, organic acids, lactoperoxidase system, and antibacterial substances.
Use of preservatives	Introduction of certain additives into the product to extend its shelf life and enhance stability through direct or indirect antibacterial and (or) antiseptic activity. Most preservatives are rather specific and can affect only specific microorganisms.
Redox potential control	The redox potential is a quantitative measure of the oxidizing or reducing potential of a nutrient medium that determines which microorganisms (aerobic or anaerobic) are able to grow in given conditions. It may be influenced by removal of oxygen and (or) addition of reducing substances (e.g. ascorbic acid, sucrose, etc.).
Chilling	Reducing the temperature of the product to inhibit microbial activity
Time	The practice of using very short collection (storage) periods that limit the shelf life of products, or immediate processing of raw milk to ensure that all microorganisms present are in the lag phase

	and thus inactive and more susceptible to other antibacterial measures
Water activity control	<p>The control of water activity (aw) in the product (meaning accessibility of water for microorganisms rather than the water content of products), expressed as the ratio of the pressure of water vapor in the product to that of pure water vapor. The aw value for preventing microbial growth depends on the pathogen, but typically falls within the range of 0.90-0.96. Water activity can be controlled by:</p> <p>concentration, evaporation, and drying, which also enhance the buffering capacity of milk (synergy);</p> <p>salting (addition of sodium chloride), which also reduces the cell resistance to carbon dioxide and influences the solubility of oxygen (synergy);</p> <p>sweetening (addition of sugar), which at aw values below 0.90-0.95 also results in an antibacterial effect depending on the type of sugar (synergy).</p>

Antibacterial or practical elimination measures reduce the microbial load, for example, through killing, inactivation, or removal of microbes.

Many microbiological safety measures have multiple functions. Such measures as pH reduction, refrigeration, freezing, and the use of preservatives and indigenous antimicrobial systems also have antibacterial effects the degree of which often depends on the intensity of their application.

Pasteurization and other heat treatments of milk having at least equivalent efficiency are applied at such intensities (with appropriate time and temperature combinations) that they practically eliminate some of the pathogens. Such techniques have therefore been traditionally used in the manufacture of milk products as key antibacterial measures. Non-thermal antibacterial measures of similar efficiency are not yet applied at intensities that can ensure the safety of milk products at the stage of application.

Examples of typical antibacterial measures include the following:

Centrifugation	Removal of high-density microbial cells from milk by centrifugal forces. This measure is most effective against high-density microbial cells, especially bacterial spores and somatic cells.
Commercial-scale sterilization	High-temperature treatment of milk and milk products long enough to render them commercially sterile, and thus safe and microbiologically stable when kept at room temperature
Competitive microflora	Reduction of the number of undesirable microorganisms by lower pH, consumption of nutrients, and production of antibacterial substances (such as nisin, other bacteriocides, and hydrogen peroxide). This microbiological measure is typically applied when starter cultures are selected. Its effectiveness depends on a number of factors including the pH reduction rate and level, as well as variations at a

	given pH level.
Preparing cheese curd	High-temperature treatment of cheese curd, primarily for technical purposes. The heat treatment is less intensive than thermization but renders microorganisms more susceptible to other microbiological measures.
Electromagnetic energy treatment	Electromagnetic energy is generated by high-voltage electric fields the frequency in which varies millions of times per second (< 108 MHz), for example, microwave energy (thermal effect), radio-frequency energy (non-thermal effects), and high-voltage electric pulses (10-50 kV/cm, non-thermal effects). Such treatment destroys cells by forming pores in their walls due to the buildup of electrical charges in the cell membrane.
High-pressure treatment	Application of high hydrostatic pressures to cause permanent damage to the membranes of vegetative cells
Microfiltration	Removal of microbes, their clumps, and somatic cells by passing the product through a microfilter. The filter pore size is typically about 0.6-1.4 µm, which is sufficient to filter off most of the bacteria. This method may be combined with heat treatment.
Pasteurization	High-temperature treatment of milk and liquid milk products aimed at reducing the number of any pathogens to a level at which they do not present a high health hazard
Pulsed high-intensity light	Application (for example, to packaging materials, equipment, and water) of high-intensity broadband light pulses in the ultraviolet, visible, and infrared spectrum (approximately 20 000 times the sunlight intensity) to destroy microorganisms. Due to the inability to penetrate nontransparent substances, this technology is only effective for exposed surfaces (for example, after the removal of a bio-film), preventing their cross contamination.
Ripening (ageing)	Holding a product for such time, at such temperature, and under such conditions that cause biochemical and physical changes required in the production of cheese. When this process serves as an antibacterial measure, the multiple-factor and complex system developing in cheese (acidity, antagonistic flora, lower water activity, metabolism of bacteriocides and organic acids) is used to influence the microenvironment in food products and, consequently, the composition of their microflora.
Thermization	High-temperature treatment of milk, less intensive than pasteurization, aimed at reducing the number of microorganisms. A general 3-4 log reduction in the number of bacteria may be expected. High temperatures

	make the surviving microorganisms more vulnerable to subsequent microbiological measures.
Ultrasonication	Application of high-intensity ultrasound (18-500 MHz) causing compression, expansion, and cavitation cycles in microbial cells. Implosion of microscopic gas bubbles generates spots of very high pressures and temperatures able to destroy the cells. This method can be more effective when combined with other microbiological safety measures. When applied at higher temperatures, the treatment is often referred to as thermosonation.
Heat-sealed packaging	High-temperature (80-95 °C) treatment of a solid final product associated with the packaging process and aimed, for example, at keeping the product viscous for proper packaging. The process can be carried out both in a continuous flow system and in batch operations. The product is sealed at packaging temperatures and cooled for subsequent storage (distribution). When combined with low pH (for example, below 4.6), the heat-sealed product may be commercially sterile because surviving microorganisms are likely to lose their ability to grow. Additional microbiostatic measures should ensure adequate cooling standards for the packaged products so as to minimize the growth potential for <i>Bacillus cereus</i> bacteria.

## **XVII. Pasteurization of Milk and Liquid Milk Products**

Minimum pasteurization conditions are those having bactericidal effects equivalent to heating of milk to 72 °C for 15 seconds (continuous pasteurization) or to 63 °C for 30 seconds (batch pasteurization). Similar conditions can be obtained following the line that joins these points in a time versus temperature graph.

The required processing time rapidly decreases with a minimum increase in temperature. The temperature extrapolation beyond the 63-72 °C range and, particularly, processing at temperatures above 72 °C should be performed with utmost caution because this technique has not yet been studied experimentally.

For example, it would be very difficult (if possible at all) to determine the pasteurization efficiency at 80 °C as in this case the extrapolated processing time would be about 0.22 seconds to achieve at least a 5 log reduction in the number of bacteria.

The milk flow in heat exchangers should be turbulent to ensure sufficient heating for each particle.

When changes in the composition, processing, and use of the product are suggested, the scheduled heat treatment should be respectively altered and its efficiency evaluated by a competent person.

For example, the fat content of cream necessitates minimum conditions that exceed those for milk, minimum 75 °C for 15 seconds.

Liquid milk products having high sugar or high viscosity also require pasteurization conditions in addition to the minimum conditions defined for milk.

## Process Verification

In accordance with an acceptable method, pasteurized products should demonstrate a negative alkaline phosphatase reaction immediately after the heat treatment. Other methods may also be employed to show that appropriate heat treatment has been conducted.

Alkaline phosphatase can be reactivated in many milk products (cream, cheese, etc.). In addition, microorganisms used in the production process may generate microbial phosphatase and other substances capable of distorting the results of residual phosphatase tests. This specific verification method should therefore be applied immediately after heat treatment to produce valid results.

## **Section C. Guidelines for the Inspection of Slaughterhouses and Meat Enterprises**

### **I. General Provisions**

1. These Guidelines specify the approaches to and principles for the assessment of slaughterhouses and meat enterprises operating on the customs territory of the Customs Union and third countries to be carried out during inspection.
2. Inspectors and experts of authorized bodies of the Member-States should inspect enterprises of the Customs Union and third countries in compliance with these Guidelines.
3. Slaughterhouses and meat enterprises of the Customs Union Member-States and third countries shall be inspected as to their compliance with the requirements of the Customs Union based, *inter alia*, on the equivalence principle as regards third countries.
4. Using the criteria of these Guidelines, the inspector should determine whether a slaughterhouse and meat enterprise achieve the safety level set by the requirements of the Customs Union (as defined in Appendix No. 2 hereto), and by the veterinary requirements of the Member-States in cases when such requirements are not stipulated in regulatory legal acts of the Customs Union.
5. These Guidelines shall be published to ensure general availability and promote good practice.
6. The terms used herein shall have the following meaning:

“Risk analysis” means a process consisting of three interconnected components: risk assessment, risk management, and risk transfer;

“Viscera” means thoracic, abdominal, and pelvic cavity organs, as well as trachea and esophagus of poultry and animals;

“Domestic ungulates” means cattle (including buffalos and bison), pigs, sheep, goats, and domestic solipeds;

“Contamination” means the presence or introduction of a hazard substance;

“Risk communication” means an interactive exchange of information and opinions concerning hazards, risks, risk-related factors, and risk perception carried out throughout the risk analysis process among risk assessors, risk managers, consumers, enterprises of the feed and food industries, scientific community, and other interested parties and aimed, *inter alia*, at clarifying the risk assessment results and forming the grounds for risk management decisions;

“Final consumer” means a food consumer who will not use a food product as part of any transaction or business of a food industry enterprise;

“Meat products” means products resulting from meat processing or subsequent treatment of such processed products, when the surface of a cut shows that the product no longer has any characteristics of fresh meat;

“Meat by-products” means slaughter products such as viscera, heads, tails, legs (their parts), and trimmings cleaned of bruises and free of serosa and adherent tissues, as well as pig skin and inter-mammary parts;

“Meat” means a slaughter product in the form of a carcass or part of a carcass that includes muscle, fatty, and connecting tissues, with or without bone tissue;

“Mechanically separated meat” (MSM) means boneless meat having a paste form and the weight content of bone inclusions of 0.8% or less, obtained by mechanical separation of the muscle, connecting, and (or) fatty tissues from the bones without additional non-meat ingredients;

“Processed products” means food products resulting from processing of crude food products. They may contain components necessary for their production or attributing specific properties;

“Processing” means thermal treatment (except freezing and chilling), smoking, preservation, ripening, souring, salting, drying, pickling, concentration, extraction, extrusion, or a combination thereof;

“Hazard” means the presence in products of a biological, chemical, or physical factor, or a condition of food or feed products capable of causing adverse health effects;

“Food sector operator” means a natural person or a legal entity responsible for the fulfillment of food legislation requirements by food sector entities under its supervision;

“Risk assessment” means a scientifically based process consisting of four stages: hazard identification, hazard characterization, exposure assessment, and risk characterization;

“Food sector enterprise” means a state or private enterprise whose operation carried out with or without the purpose of profiting relates to any stage of production, processing, and distribution of food products;

“Traceability” means the ability to trace food products, feed, food-producing animals, and substances intended for or planned to be included in food or feed, at all stages of production, processing, and distribution;

“Poultry” means farmed poultry including fowl not considered as domestic but raised as domestic, with the exception of cursorial birds;

“Placing on the market” means marketing the food products for the purpose of sale, including sales offers or other forms of transfer, free of charge or otherwise, and sale, distribution, and other forms of transfer;

“Risk” means the probability of an adverse health effect and its potential hazard;

“Retail trade” means stores, supermarket distribution centers, and wholesale trading centers, as well as public catering facilities including restaurants and other similar facilities;

“Chopped meat” means boned meat ground into fragments;

“Fresh meat” means meat not subject to any preservation process except chilling, freezing, or fast freezing, including vacuum-packed meat or meat packed in a controlled atmosphere;

“Production, processing, and distribution stages” means any stage including import, from primary production of a food product up to its storage, transportation, sale, or delivery to the final consumer and, where applicable, import, production, manufacture, storage, transportation, distribution, sale, and delivery of feed;

“Carcass” means the body of an animal after slaughter and dressing;

“Packaging” means placing a food product into a wrapping or container directly contacting the food products, as well as such wrapping and such container;

“Risk management” means a process, different from risk assessment, that determines political alternatives in consultations with interested parties taking into account risk assessment and other significant factors and, where necessary, selection of appropriate preventive and control measures.

“Meat cutting shop” means premises where meat is deboned and (or) cut.

## **II. Traceability**

Traceability of meat and meat products should be ensured at all stages of production, processing, and distribution.

Slaughterhouses and meat enterprises should provide the possibility for identifying the suppliers of animals, raw materials, or substances intended for food purposes. Thus, they should have systems and procedures for submitting such information at the request of competent authorities.

Slaughterhouses and meat enterprises should have systems and procedures for identifying persons to whom they supply meat and meat products. This information should be available at the first request of competent authorities.

Meat and meat products that are or can be placed on the market should be marked or identified in a way that facilitates their traceability through relevant documents or information in accordance with the requirements of more specific provisions.

## **III. General Hygiene Rules for Production Premises of Slaughterhouses and Meat Enterprises**

It is important to perform meat processing, dressing, or subsequent treatment in clean areas and to protect meat products against contamination of any origin, as far as practicable.

When meat is processed at facilities constructed and maintained specifically for meat processing, contamination sources should be controlled. Proper sanitation requires the following.

### **Floor Surface**

Floor surfaces in slaughterhouses and meat enterprises should be kept in good condition and easily cleaned and, where necessary, disinfected. Impermeable, moisture-proof, washable, and nontoxic materials should be used for this purpose. Where appropriate, the floor should be provided with surface drainage.

### **Drains**

A sufficient number of properly located, fixed, and ventilated drains of appropriate size should be provided to remove waste liquids. All floors should be inclined towards the drains.

### **Wall Surfaces**

The wall surfaces in slaughterhouses and meat enterprises should be flat, kept in good condition, and easily cleaned and, where necessary, disinfected. Impermeable, moisture-proof, washable, and nontoxic materials should be used for this purpose.

### **Ceilings**

The ceilings in slaughterhouses and meat enterprises (or the inside surface of the roof when there is no ceiling) and the suspended structures should be designed and installed so as to prevent fouling and reduce condensation, growth of undesirable mold, and falling of particulate materials.

### **Windows**

The windows and other apertures in slaughterhouses and meat enterprises should be designed so as to prevent fouling. Windows opening on the outside should be equipped, where necessary, with mosquito nets easily removable for cleaning. Windows that may cause contamination should remain closed during the production.

#### Doors

The doors in slaughterhouses and meat enterprises should be easily cleaned and, where necessary, disinfected. Materials having smooth and nonabsorbent surface should be used for this purpose. Wooden doors and doorframes should be impermeable, moisture-proof, washable, and made on nontoxic materials.

#### Surfaces

The surfaces (including those of the equipment) in areas where meat and meat products are processed, particularly surfaces contacting meat and meat products, should be kept in good condition and easily cleaned and, where necessary, disinfected. Smooth, washable, corrosion-resistant, and nontoxic materials should be used for this purpose. All surfaces should be cleaned at the end of each day.

#### Water Supply

Independently of the source (boreholes or public water supply systems), the water supplied should be potable, and all working areas of slaughterhouses and meat enterprises should be provided with hot and cold water in sufficient amounts.

### **IV. Premises of Slaughterhouses and Meat Enterprises**

The premises of slaughterhouses and meat enterprises should be clean and kept in proper condition.

The layout, design, and dimensions of the premises should:

- be suitable for appropriate maintenance, cleaning, and (or) disinfection, prevent or minimize airborne contamination, and have enough space for hygienic performance of all types of work;

- protect against dirt buildup, contacts with toxic substances, introduction of any particles into food products, and formation of condensate or undesirable mold on the surfaces;

- allow for appropriate hygiene practices with respect to meat and meat products, including contamination prevention and, particularly, pest control;

- ensure, where necessary, conditions suitable for temperature-controlled processing and storage of meat and meat products at appropriate temperatures, and be designed to provide monitoring and, where required, recording of temperature changes.

#### Water Closets

The enterprise should have a sufficient number of water closets connected to the sewerage system. They should not open directly to the premises where meat and meat products are processed. The water closets should be equipped with appropriate natural or mechanical ventilation systems.

#### Washbasins

A sufficient number of properly positioned washbasins for washing hands should be provided and supplied with hot and cold water. Hand washing and hygienic drying sets should be placed near the washbasins. The washbasins should be installed in water closets, changing rooms, and production premises. Their design should allow switching the water on and off without the use of hands.

Where required, the appliances for washing meat and meat products should be separated from hand washbasins.

#### Ventilation

The ventilation systems in slaughterhouses and meat enterprises should be designed, constructed, and maintained to guarantee continuous welfare of animals taking into account weather conditions.

There should be appropriate and sufficient means of natural or mechanical ventilation. Air from contaminated areas should be prevented from entering clean areas. The design of the ventilation systems should ensure accessibility of filters and other parts that need regular cleaning or replacement.

Natural or mechanical ventilation should be provided in water closets.

#### Lighting

The lighting equipment in premises of slaughterhouses and meat enterprises where meat and meat products are processed should ensure maximum safety to prevent broken glass from getting into meat and meat products, as well as dirt and debris buildup on the surface of the lamps.

The light intensity should be sufficient for the personnel and inspectors to see the sanitary conditions and detect product contamination.

The premises where meat is processed should have adequate natural and (or) artificial lighting.

#### Drainage System

The drainage systems in slaughterhouses and meat enterprises should serve their purpose. Their design and structure should prevent infection of animals and contamination of meat and meat products.

The drainage channels should be completely or partially opened and designed to remove waste from contaminated areas, in particular, from places of processing meat and meat products that are potentially hazard to final consumers.

#### Changing Rooms

The changing rooms for the personnel of slaughterhouses and meat enterprises should be separated from premises or units where products are prepared, stored, or processed.

The changing rooms should be separated from water closets.

Separate changing rooms should be provided for men and women.

The changing rooms should have adequate lighting.

Separate changing rooms for those handling raw products and workers of other shops help to prevent cross contamination of products.

Baskets for dirty clothing should be provided near the changing rooms.

### **V. Equipment**

All parts, tools, and equipment contacting meat and meat products at slaughterhouses and meat enterprises should be:

thoroughly cleaned and, if necessary, disinfected regularly enough to eliminate any risk of product contamination;

designed in such a way, made from such materials, and maintained in such condition that minimize any risk of contamination;

designed in a such a way, made from such materials, and maintained in such condition that they may be cleaned and, if necessary, disinfected, with the exception of nonreturnable containers and packaging;

installed in such a way that allows for cleaning of the equipment and the surrounding area.

Where required, the equipment should be provided with suitable control devices. If chemical substances are necessary to prevent corrosion of the equipment and containers, such substances should be used according to relevant hygiene practice.

## **VI. Water Supply**

Slaughterhouses and meat enterprises should be supplied with potable water to be used, where necessary, to prevent contamination of meat and meat products. Non-potable water used, for example, in fire extinguishing, steam generation, and cooling systems, as well as for other purposes should circulate in a properly identified individual system. It should not mix with or be discharged into the potable water system.

Recycled water used in processing or as a component of production should not present any risk of contamination. It should comply with potable water standards, unless a competent authority decides that its quality does not affect the quality of meat and meat products.

Ice contacting or capable of contaminating meat products should be produced from potable or clear water, when used to chill undressed meat. It should be produced, treated, and stored under conditions preventing its contamination.

Vapor contacting meat and meat products should be free of any hazard substances and should not contaminate food products.

When meat products are heat treated in sealed packaging, the cooling water should not be the source of their contamination.

## **VII. Personal Hygiene**

Processing and inspection of meat present a wide range of possibilities for cross contamination. Personal hygiene activities at slaughterhouses and meat enterprises are intended to prevent excessive general contamination, as well as human infection by causative agents that can lead to food-borne diseases.

Persons moving from storage areas for raw meat to those for meat preparations and finished meat products should change or thoroughly wash their protective clothing and, where necessary, carry out disinfection, or otherwise minimize the possibility of cross contamination.

Persons processing meat and meat products should maintain an appropriate level of personal hygiene and use protective clothing, headwear, and footwear. A waterproof bandage should be applied to cuts and wounds when the injured employee is allowed to continue work.

Persons who fall ill should immediately inform the management of the slaughterhouse or meat enterprise about the disease and its signs.

The management shall decide on a medical checkup and (or) possible suspension of the affected person from processing food products, depending on his/her health condition.

The personnel should wash hands in all cases when personal hygiene can affect the safety of meat and meat products, for example:

at the beginning of work related to processing of meat and meat products;

immediately after using the water closet;

after contacting raw products or any contaminated material, when this may contaminate other food products, employees should avoid processing food products ready for consumption.

During their working hours, persons involved in processing of meat and meat products should avoid smoking, spitting, eating, sneezing, or coughing in direct proximity to exposed products.

In areas where meat and meat products are processed such personal belongings as jewelry, watches, pins, and other articles are prohibited.

### **VIII. Personnel Training**

The management of slaughterhouses and meat enterprises should provide supervision, briefings, and (or) training on issues of food hygiene to persons processing meat and meat products depending on the type of their work.

The training programs should:

- provide the personnel with knowledge, skills, and habits aimed at fulfilling certain tasks of hygiene in meat production, such as postmortem examination, checking the statistical control, HACCP;
- ensure the required level of practical training;
- provide for formal testing of the personnel, when required;
- guarantee due skills to personnel involved in training;
- be aimed at assessing and upgrading the professional skills of the personnel.

### **IX. Hazard Analysis and Critical Control Points (HACCP)**

HACCP systems in the production of meat are an efficient tool of process control applied to guarantee safety of meat and meat products.

Verification of a HACCP plan for meat and meat products should ensure the efficiency of meeting the technical requirements and criteria, taking into account the degree of variability in the presence of hazards normally associated with different lots of animals presented for testing.

The verification frequency may vary depending on the operational aspects of process control, the historical performance of the establishment in applying the HACCP plan, and on the results of verification itself. Microbiological tests are recommended to verify the HACCP systems, for example, to verify the critical limits and statistical process control, which are an important component of HACCP for many products.

Guidelines should distinguish between and take into account the processing categories, for example:

- raw, minced or comminuted, for example, pork sausage;
- meat with secondary inhibitors – non-shelf stable, for example, cured corned beef;
- heat treated – not fully cooked, non-shelf stable, for example, partially cooked cutlets;
- fully cooked – non-shelf stable, for example, cooked ham;
- not heat treated – shelf stable, for example, dry salami;
- heat treated – shelf stable, for example, jerked beef;
- heat treated – sterile, for example, canned meat.

When developing HACCP plans for heat treated meat preparations and meat products, the management of slaughterhouses and meat enterprises should fully document, as appropriate to the process, all temperature parameters of the process, post-heating treatment, and additional preservation processes depending on the desired process outcome, for example, a pasteurized product. Process parameters for chilling of heat treated meat products may include rapid, slow, or interrupted chilling depending on the product. Previously heated meat products should not be

packaged at a temperature above a minimum, for example, 4°C, unless it can be proven that chilling after packaging does not compromise the product safety.

HACCP plans for meat preparations and meat products subjected to cooking should include monitoring and recording of parameters that ensure appropriate internal temperatures.

## **X. Sanitation Standard Operating Procedures (SSOP)**

Sanitation standard operating procedures (SSOP) applied in and before the production serve to minimize any direct and indirect contamination of meat to the greatest possible extent. A properly implemented SSOP system should ensure that the equipment and facilities are cleaned and disinfected prior to the beginning of operations, and that hygiene requirements are met during the work. SSOP guidelines are provided by a competent authority and may include minimum obligatory requirements for general sanitation.

The SSOP specifics include:

development by the slaughterhouse or meat enterprise of a written SSOP program that describes the involved procedures and the frequency of their application;

identification of personnel of the slaughterhouse or meat enterprise responsible for SSOP implementation and monitoring;

documentation on monitoring and corrective and (or) preventive measures unavailable to the inspecting competent authority;

corrective measures including appropriate disposition of the products;

periodic evaluation of the system efficiency carried out by managers of slaughterhouses and meat enterprises.

Microbiological verification of SSOP should provide a range of direct and indirect methods. Managers of slaughterhouses and meat enterprises should apply statistical process control or other methods to monitor sanitation.

For ready-to-eat products, the SSOP microbial limit tests of surfaces contacting or not contacting the food products should have a higher intensity than those for other types of products.

## **XI. Rodent Control**

Rodents are a major threat to safety and suitability of food products. Infestation is highly probable in areas of their reproduction and feed. Proper sanitation is aimed at preventing the formation of environment favorable to rodents.

Buildings of slaughterhouses and meat enterprises should be maintained in a state that prevents the access for rodents and eliminates their reproduction areas. All openings through which rodents can enter the premises should be sealed. Screens on open windows and doors and in ventilation systems should reduce the possibility of penetration for pests. The territory of slaughterhouses and meat enterprises should be secured against penetration of any animals wherever possible.

Accessibility to food and water increases the risk of pest proliferation and related diseases. Potential food sources should be kept in containers protected against pests and (or) be located away from the floors and walls. Premises related to food products should be kept clean both on the inside and on the outside. Where possible, food waste should be kept in closed containers protected against rodents.

Slaughterhouses, meat enterprises, and the surrounding territories should be regularly inspected for the presence of rodents. Rodent invasion should be eliminated immediately, without affecting the safety and suitability of meat and meat products.

## **XII. Food Chain Information**

Managers of slaughterhouses and meat enterprises, when necessary, should request, collect, check, and process food chain information specified in this section in respect of all animals, except game, delivered or meant to be delivered to slaughterhouses or meat enterprises.

Managers of slaughterhouses or meat enterprises should receive such information before the animals are delivered to the slaughterhouse without prejudice to slaughter rules applied to such animals species in a third country. The food chain information includes, in particular, the following:

- the status of the farm of origin of animals or the health condition of animals in the region;
- health condition of the animals;
- veterinary drugs or other medications administered to animals during a respective period, with specified dates of administration and withdrawal period (for slaughterhouses);
- diseases that may affect the safety of meat;
- when critical to the public health, test results of samples taken from the animals or other samples taken to diagnose diseases that may affect the safety of meat including samples taken within the framework of monitoring and controlling zoonoses and residues;
- relevant reports on previous antemortem and postmortem examinations of animals from the same farm of origin including, in particular, reports by the official veterinarian;
- date of inspection, when indicating disease;
- name and address of a private veterinarian who takes daily care of the farm of origin.

If a party keeping a slaughterhouse already has such information (for example, due to a permanent contract or a quality assurance system), there is no need to provide such party with the following information:

- the status of the farm of origin or the health condition of animals in the region;
- health condition of the animals;
- relevant reports on previous antemortem and postmortem examinations of animals from the same farm of origin including, in particular, reports by the official veterinarian;
- name and address of a private veterinarian that takes daily care of the farm of origin.

The information need not be submitted in the form of a word-for-word abstract from the register of the farm of origin. It may be delivered through electronic data exchange or as a standard form signed by the producer.

After assessing the food chain information, the managers making decisions as to the acceptance of animals at slaughterhouses or meat enterprises should provide the veterinarian with such information immediately, before or during the arrival of the animal or the lot of animals. The manager of the slaughterhouse or meat enterprise shall provide the official veterinarian, prior to antemortem inspection, with full information regarding health concerns.

If an animal delivered to a slaughterhouse is not accompanied by food chain information, the manager should immediately notify the official veterinarian. Slaughter of the animal may not take place until the official veterinarian so permits.

When a competent authority issues the permit, the food chain information may accompany the animals to the slaughterhouse or should be delivered before the animals arrive at the slaughterhouse, without prejudice to slaughter rules applied to animals of the given species in a third country. In reasonable time before the animals arrive, managers of slaughterhouses and

meat enterprises should have access to any food chain information that may seriously disturb the operation of the slaughterhouse in order to adjust their work plan.

Slaughter and evisceration of the animals may not take place until the official veterinarian so permits.

The manager of a slaughterhouse or meat enterprise should check the veterinary documents accompanying farm-bred animals to make sure that the animals are intended for slaughter for the purpose of human consumption.

### **XIII. Transportation of Live Animals to Slaughterhouses and Meat Enterprises**

Animals being loaded and transported should be treated with care, without causing them unreasonable suffering.

Animals showing symptoms of a disease or animals from herds previously infected with agents critical to the public health may be transported to slaughterhouses or meat enterprises only with the permission of the competent authority.

### **XIV. Slaughterhouses and Meat Enterprises**

Slaughterhouses and meat enterprises should have hygienic lairages or, where the climate permits, outdoor pens easy to clean and disinfect. These facilities should be provided with equipment for drinking and, if necessary, feeding of animals. Sewage disposal systems should not compromise the safety of meat and meat products.

Slaughterhouses and meat enterprises should include separate wards for animals affected or suspected of being affected, with restricted access preventing any spread of possible infection.

The lairages should be large enough to ensure proper conditions for the animals. Their layout should facilitate antemortem inspection including identification of animals or groups of animals.

To avoid meat contamination, slaughterhouses and meat enterprises should:

- have enough premises suitable for specific operations;
- have individual premises for emptying stomachs and intestines, unless in specific cases the competent authority permits a certain enterprise to separate these operations in time;
- provide separate areas for the following operations separated in time:
  - stunning and bleeding;
  - scalding, dehairing, scraping, singeing (pigs);
  - evisceration and subsequent cleaning;
  - treatment of cleaned viscera and paunch;
  - preliminary treatment and cleaning of other offals, specifically treatment of skinned heads when such operation is not carried out at the slaughter line;
  - grouped packaging of offals;
  - shipment of the meat;
  - be fit with appliances to prevent meat from contacting floors, walls, and equipment;
  - have properly designed slaughter lines (in the areas of usage) to ensure constant progress of operation and prevent cross contamination between different sections of the slaughter line. Several lines operated in the same room should be separated to prevent cross contamination.

Slaughterhouses and meat enterprises should be equipped for disinfection with hot water supply or an alternative system having an equivalent effect;

Hand-washing appliances for personnel who contact exposed meat should be designed to prevent any spread of contamination.

Slaughterhouses and meat enterprises should have lockable rooms, cooling chambers to store the remaining meat, and separate cooling chambers to store meat identified as unsuitable for human consumption.

Slaughterhouses and meat enterprises should have special areas to wash and disinfect vehicles used for transporting animals. This rule shall not apply with the permission of the competent authority when near the slaughterhouse there is a special area properly equipped for this purpose.

Slaughterhouses and meat enterprises should have separate premises for animals affected or suspected of being affected, the access to which should be restricted, unless another place (enterprise) is officially approved for slaughtering such animals. If manure or digestive tract contents are stored at a slaughterhouse or meat enterprise, a special place or territory should be provided for this purpose.

Slaughterhouses and meat enterprises should have a properly equipped lockable area or premises for the exclusive use of the veterinary service.

## **XV. Hygiene of Animal Slaughter**

Slaughtering of animals delivered to the slaughterhouse should be carried out without undue delay. However, the animals should be adequately rested when this is required by their condition.

Meat from animals cannot not be used for human consumption if they die otherwise than by being slaughtered in the slaughterhouse or meat enterprise.

Only live animals intended for slaughter should be delivered to slaughterhouses and meat enterprises.

Meat from animals slaughtered at slaughterhouses or meat enterprises as a result of an accident may be used for human consumption, provided the inspection find no other serious damages expect those caused by the accident.

Slaughter animals or, where necessary, each lot of the slaughter animals should be identified as to the place of origin.

The animals should be clean.

The managers of slaughterhouses or meat enterprises should follow the instructions of the veterinarian appointed by the competent authority.

Animals brought into the slaughter room should be slaughtered without delay.

Stunning, bleeding, skinning, evisceration, and cleaning should be carried out without undue delay in such a way that contamination of the meat is avoided, in particular:

the trachea and esophagus should remain intact during bleeding, except in the case of ritual slaughter;

during skinning and dehairing:

contact between the external skin and the carcass should be avoided;

persons contacting the external skin and hair of the animals should not touch the meat;

measures should be taken to prevent the spillage of digestive tract contents during and after evisceration and to carry out evisceration in the shortest possible time after stunning of the animals;

during udder removal, milk and colostrums should not contaminate the carcass.

Carcasses and other parts intended for human consumption should be totally skinned, except pigs, and heads and legs from sheep, goats, and calves.

Heads including lips and snouts, and legs should be handled in such a way as to avoid contamination of the rest of the meat.

Pigs should be dehaired before dressing. Any risk of meat contamination by scalding water should be minimized. Then pigs should be thoroughly cleaned with potable water.

Carcasses should be free of visible soiling with waste. Any visible soiling should be immediately removed by boning or other methods of the same effect.

Carcasses and offals should not contact floors, walls, or workplaces.

The managers of slaughterhouses or meat enterprises should follow the instructions of the competent authority in order to ensure adequate conditions for postmortem examination of all slaughtered animals.

Prior to postmortem examination, parts of animals subject to slaughter and such inspection should be identifiable as belonging to a specific carcass and should not contact other carcasses, offals, or viscera including those already subjected to postmortem examination.

Reproductive organs of male animals may be removed initially provided there are no pathological changes.

Both kidneys should be removed from the fat layer. The perirenal sac should not be removed in the case of cattle, pigs, and solipeds.

If blood or other waste from several animals is accumulated in the same reservoir prior to postmortem examination, and the carcass of one or more of such animals is identified as unsuitable for human consumption, the entire contents of such reservoir is declared unsuitable for human consumption.

After postmortem examination:

tonsils of cattle and solipeds should be removed in compliance with hygiene requirements;

parts unsuitable for human consumption should be removed from the clean sector of the slaughterhouse or meat enterprise as soon as possible;

meat detained or identified as unsuitable for human consumption and inedible by-products should not come into contact with meat declared suitable for human consumption;

viscera or parts of viscera remaining in the carcass, except for the kidneys, should be removed entirely as soon as possible, unless otherwise permitted by the competent authority.

After postmortem examination, the meat should immediately be chilled at the slaughterhouse. When meant for further processing:

stomachs should be scalded and cleaned;

intestines should be emptied and cleaned;

heads and legs should be skinned or scalded and dehaired.

When a slaughterhouse or meat enterprise is permitted to carry out slaughter of different animal species or to process carcasses of farmed or wild game, measures should be taken to prevent cross contamination by providing individual areas for and separating in time of operations intended for different species. There should be separate equipment to receive and store undressed carcasses of farmed game slaughtered at the farm, as well as carcasses of wild game.

When a slaughterhouse does not have lockable equipment intended for slaughtering animals affected or suspected of being affected, the equipment used for slaughtering such animals should

be cleaned, washed, and disinfected under official supervision before being used to slaughter other animals.

Carcasses of farmed ungulates may be cut into halves or quarters, and half carcasses into three parts maximum. Only a meat-cutting establishment may carry out further cutting and deboning.

## **XVI. Meat Cutting Equipment**

All parts, tools, and equipment contacting products should:

be thoroughly cleaned and, if necessary, disinfected. The regularity of cleaning and disinfection of the equipment should eliminate any risk of contamination;

be made from such materials and maintained in such condition that minimize any risk of contamination;

with the exception of non-returnable containers and packaging, be made from such materials and maintained in such condition that they remain clean and, when necessary, are disinfected;

be installed in such a way that allows for proper cleaning of the equipment and the surrounding area.

If required, the equipment should be provided with a suitable control device.

Chemical substances used to prevent corrosion of the equipment and containers should be used in compliance with good practice (manufacturer's instructions).

## **XVII. Hygiene of Meat Cutting and Deboning**

In cutting and deboning of meat from domestic ungulates, slaughterhouses and meat enterprises should ensure compliance with the following requirements:

operations with meat should be arranged in such a way as to avoid or minimize contamination;

adequate ventilation should be provided for chilling operations to avoid moisture condensation on the surface of meat;

meat intended for cutting should be brought into the workrooms progressively as needed;

all cutting, deboning, trimming, and packaging processes should be carried out at low temperatures to prevent microbial growth, or other measures of an equivalent effect should be applied;

where the premises are used for cutting meat of different animal species, precaution measures should be taken to avoid cross contamination, where necessary, by separating operations on different species in space and time.

Meat may as well be cut and packaged without intermediate chilling when the cutting area is on the same site as the slaughter premises. In this case, the meat may be moved to the cutting area immediately after slaughter or after being held in a cooling chamber.

Where meat is packaged or wrapped:

the packaging material should be suitable for use and storage in compliance with hygiene standards;

the wrapping and cartons should have a suitable inner liner or other means of protecting the meat, except that the liner or other protection may be unnecessary if pieces of meat (such as cuts) are individually wrapped before packaging.

Chilling and freezing should be performed in compliance with the operating procedure.

## **XVIII. Storage and Transportation of Meat**

Due to the potential for pathogen growth and product spoilage under inadequate temperature control, meat should be transported at temperatures ensuring its safety and suitability. Transport vehicles and bulk containers should be equipped for continuous monitoring and recording of temperature, where possible. In addition, the vehicles should provide adequate protection from external contamination and damage, thus reducing the growth of pathogens and spoilage microorganisms.

If meat is inadvertently exposed to an adverse temperature or contamination source that may affect its safety and suitability, a competent person should inspect the meat before further transportation and distribution is permitted.

Additionally, the transportation conditions should provide adequate protection from external contamination and damage and reduce the growth of pathogens and spoilage microorganisms.

Meat intended for freezing should be frozen without undue delay taking into account stabilization period prior to freezing, where necessary.

Exposed and packaged meat should be stored and transported separately, unless the packaging material and the manner of storage or transportation cannot be a source of contamination for the meat.

## **XIX. Minced Meat, Meat Preparations, and Mechanically Separated Meat (MSM)**

Slaughterhouses and meat enterprises producing minced meat, meat preparations, and mechanically separated meat should:

- be designed so as to prevent contamination of meat and meat products, with the help of:
  - continuous rotation of operations;
  - separate production of different batches of products;
  - premises for separate storage of packaged and exposed meat and meat products, unless they are stored at different times or in such way that the packaging material and the manner of storage cannot be a source of contamination for the meat;
  - hand-washing appliances for employees engaged in processing of exposed meat and meat products, aimed at preventing contamination spread;
  - appliances for equipment disinfection with hot water or alternative systems having an equivalent effect.

The definition of mechanically separated meat (MSM) should be general and applied to all mechanical separation techniques. The technological development in this sphere implies flexible approach to this definition. MSM specifications should be different depending on risk assessment and different techniques.

In the production of minced meat and meat preparations:

frozen or fast-frozen meat used to produce minced meat or meat preparations should be deboned prior to freezing and can be stored only for a limited period of time.

The following applies to MSM obtained using techniques that do not alter the structure of bones and are used in the production of MSM, and the calcium content of which is not significantly higher than that of minced meat:

- raw materials for MSM may be stored for a limited period of time so as to prevent microbial growth;
- mechanical separation should take place immediately after deboning;

unless used immediately after being obtained, MSM should be wrapped or packaged and then chilled or frozen to prevent microbial growth. Appropriate temperatures should be maintained during storage and transportation;

when an analysis conducted by the meat enterprise demonstrates the compliance of MSM with microbiological criteria for minced meat, MSM may be used in meat preparations that are clearly not meant for consumption without preliminary heat treatment, and in meat products (MSM not complying with such criteria may be used only to produce heat treated meat products in approved establishments).

Boned meat obtained from frozen carcasses should not be refrozen:

unless used within one hour after being obtained, MSM should be chilled;

unless MSM is to be processed within 24 hours after chilling, it should be frozen as soon as possible, but no later than 12 hours, to avoid microbial growth. Frozen MSM should be packaged or wrapped until storage or transportation.

MSM may be used only to produce heat treated meat products in approved establishments.

Minced meat, meat preparations, and MSM should not be refrozen after thawing.

Packages containing minced meat from poultry or solipeds or meat preparations containing MSM to be supplied to final consumers should bear a notice indicating that such products should be cooked before consumption.

Storage conditions for meat preparations and meat products should be clearly indicated on the packaging.

Work related to meat should be arranged so as to prevent or minimize any risk of contamination.

Raw materials for producing minced meat should:

comply with the requirements for fresh meat;

be obtained from skeletal muscles including adherent fatty tissues;

should not be obtained from:

scrap cuttings and scrap trimmings (other than whole muscle cuttings);

MSM;

meat containing bone or skin fragments;

meat of the head (except masseter muscles), non-muscular part of the abdominal line, carpus and tarsus area, bone scrapings, and diaphragm muscles (unless the serosa has been removed).

Raw materials for meat preparations may include:

fresh meat;

meat that complies with the requirements for raw materials used to produce minced meat.

Meat preparations intended for consumption only after preliminary heat treatment may be produced from:

chopped or ground meat that complies with the requirements for raw materials used for minced meat, except scrap cuttings and scrap trimmings (other than whole muscle cuttings);

MSM, when an analysis conducted by the meat enterprise demonstrates the compliance of MSM with microbiological criteria for minced meat.

Raw materials for producing MSM should comply with the requirements for fresh meat.

The following raw materials should not be used to produce MSM:

feet, neck skin, and heads of poultry;  
head bones, feet, tails, femur, tibia, humerus, radius, and ulna bones of other animals.

## **XX. Meat Products**

The enterprise should guarantee that the following items are not used in the production of meat products:

reproductive organs of female or male animals, except testicles;  
urinary organs, except kidneys and bladder;  
cartilage of larynx, trachea and extralobular bronchi;  
eyes and eyelids;  
external auditory meatus;  
horn tissue.

The enterprise should guarantee that the following poultry raw materials are not used in the production of meat products: heads (except combs, ears, and wattles), esophagus, crops, intestines, and reproductive organs.

Meat and meat products including minced meat and meat preparations used to produce meat products should comply with the requirements for fresh meat.

## **XXI. Marking of Meat**

Meat should be provided with marking only after the antemortem inspection of the animal and after the postmortem examination of the meat, unless there are grounds to consider the meat unsuitable for human consumption.

Marking is provided by stamping a mark in ink to or hot branding of the external surface of a carcass in such manner that all pieces are marked when the carcass is cut into halves or quarters, or when half-carcasses are cut into three parts.

The marking ink should be approved in compliance with the rules on the use of coloring substances in food products.

## **XXII. Specific Risk Materials**

Specific risk materials should be denatured or colored immediately after removal and disposed of later on.

The specific risk materials should be removed at slaughterhouses or, where appropriate, other slaughter or dressing establishments in the case of backbones of cattle.

## **XXIII. Sampling Frequency**

There is no single method for determining the sampling frequency. At slaughtering and dressing establishments, it may depend on the process employed or on the number of animals received. In addition to ensuring the random character of sampling, variables to be taken into account at the establishment level include the source of raw materials, the type and nature of the process, and the volumes of production.

Sampling frequency should be increased or decreased depending on test results. When the results of HACCP-based measures demonstrate a consistently acceptable level of performance, the scope of subsequent microbiological testing should be sufficient to ensure that the process control is maintained.

## **XXIV. Transportation of Live Poultry to Slaughterhouses or Meat Enterprises**

Birds being loaded and transported should be treated with care, without causing them unreasonable suffering.

Birds showing symptoms of a disease or birds from groups previously infected with agents critical to the public health may be transported to slaughterhouses only with the permission of a competent authority.

Crates and, where appropriate, modules used to transport live poultry to slaughterhouses or meat enterprises should be made of corrosion-resistant metal and be easily cleaned and disinfected. When emptied and prior to being used again, any equipment intended for loading and delivery of live poultry should be cleaned, washed, and disinfected.

## **XXV. Poultry Slaughterhouses and Meat Enterprises**

Poultry slaughterhouses and meat enterprises should have premises or sheltered areas to keep the birds and to conduct antemortem inspection.

To avoid meat contamination, poultry slaughterhouses or meat enterprises should:

- have enough premises suitable for specific operations;
- have individual premises for evisceration and subsequent treatment including the addition of spices to whole carcasses, unless in specific cases the competent authority permits a certain enterprise to separate these operations in time;
- provide individual areas for the following operations separated in time:
  - stunning and bleeding;
  - defeathering or skinning and scalding;
  - shipment of the poultry meat;
- be fit with appliances to prevent poultry meat from contacting floors, walls, and equipment;
- have properly designed slaughter lines (in the areas of usage) to ensure constant progress of operation and prevent cross contamination between different sections of the slaughter line. Several lines operated in the same room should be separated to prevent cross contamination.

Poultry slaughterhouses and meat enterprises should be equipped for disinfection with hot water supply or an alternative system having an equivalent effect;

Hand-washing appliances for personnel who contact exposed meat should be designed to prevent any spread of contamination.

Poultry slaughterhouses and meat enterprises should have lockable rooms, cooling chambers to store the remaining poultry meat, and separate cooling chambers to store poultry meat identified as unsuitable for human consumption.

Poultry slaughterhouses and meat enterprises should have special areas to clean, wash, and disinfect the equipment used for transporting animals, such as crates and vehicles.

Poultry slaughterhouses and meat enterprises should have a properly equipped lockable area or premises for the exclusive use of the veterinary service.

## **XXVI. Hygiene of Poultry Slaughter**

Poultry meat cannot be used for human consumption if the poultry die otherwise than by being slaughtered in the slaughterhouse or meat enterprise.

Only live poultry intended for slaughter can be accepted at slaughterhouses and meat enterprises.

Poultry brought into the slaughter room should be slaughtered without undue delay.

Stunning, bleeding, skinning or defeathering, evisceration, and subsequent cleaning of poultry should be carried out without undue delay in such a way that contamination of the poultry meat is avoided. In particular, measures should be taken to prevent the spillage of digestive tract contents during evisceration.

The managers of slaughterhouses or meat enterprises should follow the instructions of the competent authority in order to ensure adequate conditions for postmortem examination of slaughtered poultry.

After postmortem examination:

parts unsuitable for human consumption should be removed from the clean area as soon as possible;

poultry meat detained or identified as unsuitable for human consumption and inedible by-products should not come into contact with poultry meat declared suitable for human consumption;

viscera or parts of viscera remaining in the carcass, except for the kidneys, should be removed entirely as soon as possible, unless otherwise permitted by the competent authority.

Inspected and eviscerated poultry should be cleaned and chilled as soon as possible, unless the poultry meat is cut warm.

The following precaution measures are required when poultry carcasses undergo immersion chilling.

Precaution measures should be taken to prevent soiling of carcasses; and such parameters as the weight of the carcasses, the temperature, volume, and flow direction of water, and the time of chilling should be taken into account.

The equipment should be completely emptied, cleaned, and disinfected at least once a day and whenever necessary.

Poultry affected or suspected as affected, as well as poultry subject to slaughter under a disease control program may not be slaughtered at slaughterhouses and meat enterprises, unless so permitted by the competent authority. In this case slaughtering should take place under official supervision with measures taken to prevent infection. Prior to further use, the premises should be cleaned and disinfected.

## **XXVII. Poultry Slaughterhouse Equipment**

Poultry slaughterhouses and meat enterprises should be designed so as to prevent contamination of poultry meat, with the help of:

continuous rotation of operations;

separation of different batches of products;

premises for separate storage of packaged and exposed poultry meat;

hand-washing appliances for employees engaged in processing of exposed poultry meat, with taps designed to prevent contamination spread;

appliances for equipment disinfection with hot water or alternative systems having an equivalent effect.

## **XXVIII. Hygiene during and after Dressing and Deboning of Poultry**

Handling poultry meat should be arranged so as to prevent or minimize any risk of contamination. Slaughterhouses and meat enterprises should therefore ensure the following:

meat to be cut should be brought into the workroom progressively as needed; during cutting, deboning, trimming, slicing, wrapping, and packaging, the temperature of the poultry meat should be maintained rather low, at no more than 4°C; in premises intended for cutting meat of different animal species, precaution measures should be taken to avoid cross contamination, where necessary, by separating operations on different types of poultry meat in space and time.

Poultry meat may be deboned and cut before reaching the temperature of no more than 4°C, if the cutting area is on the same site as the slaughter premises, provided that the meat is moved to the cutting area:

- directly from the slaughter premises;
- after being chilled or frozen.

As soon as the poultry meat is cut and, where necessary, packaged, it is chilled to prevent microbial growth.

The temperature of poultry meat before and during transportation should not exceed 4°C.

Poultry meat intended for freezing should be frozen in the shortest possible time.

Exposed and packaged poultry meat should be stored and transported separately, unless the packaging material and the manner of storage or transportation cannot be a source of contamination for the meat.