



## EURASIAN ECONOMIC COMMISSION COUNCIL

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**Решение Совета ЕЭК от 9 октября 2014 года №94 «О Положении о едином порядке проведения совместных проверок объектов и отбора проб товаров (продукции), подлежащих ветеринарному контролю (надзору)**

### DECISION

«09» October 2014

№ 94

Minsk

#### **On Regulation on common system of joint inspections of objects and sampling of goods (products), subject to veterinary control (supervision)**

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

1. Approve attached Regulation on common system of joint inspections of objects and sampling of goods (products), subject to veterinary control (supervision).

2. Declare paragraph 1 of the Decision of the Commission of the Customs Union of 18 October 2011 No. 834 “On Regulation on common system of joint inspections of objects and sampling of goods (products), subject to veterinary control (supervision)” as terminated.

3. This Decision shall enter into force after 30 days from the date of its official publication, with the exception of paragraph 11 and subparagraph "g" of paragraph 48 of the Regulations approved by this Decision, which come into force from the date of accession of the Republic of Kazakhstan to the World Trade Organization.

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

**От Republic of Belarus**

**Republic of Kazakhstan**

**Russian Federation**

**S. Rumas**

**B. Sagintayev**

**I. Shuvalov**

APPROVED

by the Decision of Council the Eurasian Economic  
Commission of 9 October 2014, No. 94

**REGULATION ON COMMON SYSTEM OF JOINT INSPECTIONS (CONTROL)  
OF OBJECTS AND SAMPLING OF GOODS (PRODUCTS),  
SUBJECT TO VETERINARY CONTROL (SUPERVISION)**

**I. General Provisions**

1. This Regulation has been developed in order to implement the Agreement of the Customs Union on veterinary and sanitary measures of 11 December 2009.

2. This Regulation establishes general principles for ensuring safety of animals and products of animal origin which are included into the Common list of Goods, subject to veterinary control (supervision), approved by the Customs Union Commission Decision No 317 of 18 June 2010 (hereinafter – the Common list of goods) are imported into the customs territory of the Customs Union from the territory of third countries, and are moved from the territory of one member-state of the Customs Union (hereinafter – member state) to the territory of another member-state in their production (manufacture), processing, transportation and (or) storage, as well as arrangements for audit of official supervision systems of third countries and for joint inspections (control) of establishments and entities engaged in the production (manufacture), processing, transport and (or) storage of controlled goods (products), and acceptance of guarantees.

3. Joint inspections (controls) of the controlled objects shall be carried out in accordance with this Regulation in the following cases:

Inspection (control) of establishments of third countries where audit of the official systems of supervision has not been done or the result of such audit of the official systems of supervision is unsatisfactory with the goal to include these establishments into the register of establishments of third countries (see Section VI of this Regulation);

Inspection (control) of establishments of third countries where audit of the official systems of supervision has not been done or the result is unsatisfactory with the goal to confirm the presence of these establishments in the register of establishments of third countries (see Section VI of this Regulation);

Inspection (control) of establishments in third countries during the audit (re-audit) of the official system of supervision with the goal to confirm (re-confirm) that implementation of the measures and the official system of supervision in the third country results in a level of protection at

least equivalent to that established by the Customs Union requirements (see Section VI of this Regulation);

Inspection (control) of establishments of the member-states with the goal to include these establishments into the register of the establishments of the Customs Union (see Section VII of this Regulation);

Inspection (control) of establishments of the member-states listed in the register of the establishments of the Customs Union with the goal of regular veterinary control (supervision) (see Section VIII of this Regulation).

4. In conducting audit of third countries' official system of supervision and inspection (control) of controlled objects the authorized body of the member-states take into account the existing trade conditions considering the history of trade and the data of compliance with the Customs Union requirements by the third countries from which import of relevant goods (products) into the territory of the Customs Union occurred.

## II. Terms and Definitions

5. The following terms and definitions are used in this Regulation:

“audit of foreign official system of supervision” - a procedure for determining if a foreign official system of supervision is capable of providing a level of protection of controlled goods (products) equivalent at least to the level of safety established by the Customs Union requirements;

“on-site inspection (control)” - a form of veterinary control (supervision) which is carried out by inspector via visits to a controlled object;

“Common veterinary requirements” - Common veterinary (veterinary and sanitary) requirements for goods subject to veterinary control (supervision) approved by the Customs Union Commission Decision No 317 of 18 June 2010;

“zoning” - procedures carried out by a competent authority or an authorized body to determine on territory subpopulations of animals, which have a specific epizootic status defined mainly on the basis of the geographical criterion.

“inspector” - an authorized official of an authorized body of the member-state or a competent authority of a third country;

“Inspector-auditor – official of the state body or the government agency with relevant knowledge and experience in the field of audit and (or) inspection (control);

“quarantine” – a regime of special and organizational measures aimed at preventing the spread and elimination of quarantine and especially dangerous diseases of animals identified in accordance with the legislation of the member-states;

“compartmentalization” - procedures carried out by a competent authority or an authorized body in partnership with producers (manufacturers) of the product in the territory of the country to determine subpopulations of animals and establishments, handling products of animal origin from these subpopulations, which have a specific epizootic status defined by the management and animal husbandry practices related to biosecurity;

“competent authority” – a governmental authority of a third country which has legal power to draft legislation and (or) implement legislation (or to perform both functions) on inspections (controls);

“monitoring” - carrying out of planned and successive observations or measurements in order to get an overview of the safety of controlled goods (products) and their compliance with the established requirements;

“controlled object” – an establishment or entity engaged in production (manufacture), processing, transportation and (or) storage of controlled goods (products);

“controlled goods (products)” - animals and products of animal origin, included in the Common list of goods;

“register of establishments of the Customs Union” - a register of organizations and individuals which produce, process and (or) store controlled goods (products) transferred from the territory of one member-state to the territory of another member-state;

“register of establishments of third countries” – register of organizations and individuals producing, processing and (or) storing controlled goods imported to the customs territory of the Customs Union;

“raw material” - goods (products) intended for further processing;

“Customs Union requirements” - international standards, guidelines and recommendations within the meaning of the Customs Union Commission Decision No. 721 “On application of international standards, recommendations and guidelines” of 22 June 2011 related to the veterinary and sanitary requirements for controlled goods, technical regulations of the Customs Union, Common veterinary requirements and (or) other requirements that the member-states have agreed with third countries in the veterinary (imports) certificates in accordance with Chapter “Final and Transitional Provisions” of Common veterinary requirements and mandatory national requirements of the member-states for goods;

“authorized body” – a state body of the member-state which has legal power to draft legislation and/or implement legislation (or to perform both functions) on inspections (controls);

“expert” – official of the state body or the state agency assisting authorized bodies of the member-states in conducting inspection (control) of objects and sampling goods (products).

### III. General principles to ensure safety of controlled goods (products) in their production, processing, transportation and (or) storage

6. The basic principle used by the member-states to ensure safety of controlled goods (products) in their production, processing, transportation and (or) storage in a third country is an audit of a foreign official system of supervision.

7. In case if an audit of a foreign official system of supervision was successful, the inclusion of establishment (entities) into the register of establishments of third countries, if it is provided by

Customs Union legislations, shall be carried out in accordance with the list of establishments provided by the competent authority.

8. In case if an audit of a foreign official system of supervision was not carried out or is not completed or if, as a result of such audit, the foreign official system of supervision is not recognized as being capable to provide a level of protection at least equivalent to that provided by the Customs Union requirements, the member-states can agree the inclusion of an establishment (establishments) into the register of establishments of third countries on the basis of results of joint inspections (controls) or guarantees provided by the competent authority, when inclusion into the Register is required.

9. In the process of preparing and approving the results of joint inspections (control) of controlled objects and during an audit of a foreign official system of supervision the member-states ensure the availability (including the ability to preview) of these results to the competent authority of the third country and to the controlled objects.

In order to protect confidential information and to ensure absence of conflict of interests related to inspected (controlled) objects of control, the final report published by the authorized bodies shall not contain number (ID) and names of organizations and individuals involved in the production (manufacture), processing, transport and (or) storage of controlled goods.

10. During joint inspections (controls) of controlled objects the principles of zoning and compartmentalization shall be used as well as the data collected during monitoring of the controlled goods (products) produced at the controlled object (organization, establishment, entity) and, if it is located on the territory of a third country, - the data of the audit of a foreign official system of supervision.

11. During a joint inspection (control) of controlled objects in accordance with the present Regulation, an inspector shall check and evaluate the object of control in accordance with annex 3 as it is established in this Regulation and, if the controlled object is in compliance with the relevant international standards, guidelines and recommendations, it shall be considered to be in compliance with the relevant Customs Union requirements based on the principle of equivalence. In case the Customs Union or a mandatory requirement of the national legislation of the member-state is more stringent than the international standard in the absence of an appropriate scientific justification, the inspector shall evaluate compliance on the basis of the international standards, guidelines, and recommendations, as provided by the Agreement The WTO Agreement on the Application of Sanitary and Phytosanitary Measures of 15 April 1994 (further - WTO SPS Agreement) for the more stringent measures. In the presence of the mentioned act the inspector presents this act to the competent authority to provide the possibility to propose equivalent measures in accordance with the WTO SPS Agreement. If an establishment is included on the register of establishments of third countries based on guarantees from the competent authority, the inspector also checks and evaluates whether the guarantees applicable in the export certification are met.

12. Inspectors-auditors and experts of the authorized body should be impartial. Inspectors-auditors and experts of the authorized body should have appropriate qualifications, experience and must be trained in the relevant field of knowledge. In assessing the inspectors-auditors and experts of the authorized body should ensure security of confidential information.

#### IV. Audit of foreign official supervision systems

13. Inspectors-auditors carrying out an audit of foreign official system of veterinary supervision shall differentiate between the following two situations:

a) concerning countries from which the controlled goods (products) have not been imported to the customs territory of the Customs Union;

b) concerning countries from which import of the controlled goods (products) to the customs territory of the Customs Union has taken place.

14. To initiate an audit the competent authority shall send a request to the authorized body with indication of the scope of the audit, including a group of controlled goods (products) and types of activities of controlled objects.

15. Information on schedule of conducting audit of foreign official systems of supervision and joint inspection (control) of third country establishments by the authorized bodies that is provided by the authorized bodies, is published on the official website of Eurasian Economic Commission in information and telecommunication network "Internet" (hereinafter respectively - the official website of the Commission, the Commission) and updated at least twice a year.

16. In the assessment of the foreign official system of supervision, inspectors should take into account the history of trade and information that the authorized body currently has on the following issues:

- a) organisation, structure and powers of competent authority;
- b) human resources;
- c) material (including financial) resources;
- d) regulatory frameworks and functional capabilities;
- e) system of animal health control and system of public health protection;
- f) formal quality systems including quality management policy;
- g) system performance assessment and surveillance programs;

17. During the assessment of the foreign official system of supervision inspectors shall follow the principles presented in annex 2 of this Regulation and use the evaluation criteria as defined by the relevant articles of the Terrestrial Animal Health Code and Aquatic Animal Health Code of the World Organization for animal Health (hereinafter OIE), as well as documents of the Codex Alimentarius Commission, other international standards and guidance recognized by the World Trade Organization.

18. The first stage of the assessment is a documentary analysis. For this purpose, the authorized body requests the competent authority to provide the legal and other related documents needed to perform the assessment.

19. A questionnaire may be sent to the competent authority for gathering additional information on the structure, power and practices of the competent authority.

20. After the completion of documentary analysis, the authorized bodies of the member-states decide whether, based on the result of the analysis, a foreign official system of supervision with regard to relevant goods (products) is capable to provide, in the aggregate, a level of protection at least equivalent to the Customs Union requirements.

21. If this step is successfully completed, the authorized bodies of the member-states may plan inspections (controls) to verify the proper implementation of the relevant legislation of the third country.

22. The authorized body of the member-state, which planned the audit, no later than 2 months (unless a shorter period has been agreed by the member-states) before the beginning of the planned visit to the third country, which requested the audit, shall inform the authorized bodies of the other member-states of the forthcoming visit in order to form a group of inspectors and coordinate the timing of the visit.

23. The authorized bodies of the other member-states shall, no later than in 2 weeks after receiving the information on the upcoming visit, send a response that contains a rejection of participation in the visit or a consent to participate in the visit and the data on the officials of the member-state, who will participate in the visit. If the authorized body does not send a response within the specified period that means the refusal to participate in the visit.

24. The visit can be conducted by inspectors-auditors of one of the member-states if the other authorized bodies of the member-states do not respond or state that they will not participate. The authorized bodies of the member-states that do not participate in the audit recognize the decision, based on the results received by the visiting authorized body.

25. The initial audit is carried out by a group of inspectors-auditors.

26. The authorized bodies may engage experts who are the employees of state bodies and agencies (except for the interpreters) to assist inspectors-auditors on the matters below:

legislation of the relevant third country;

organization of the competent authority of the relevant third country, their powers and independence, their leadership and authority that they possess, in order to effectively implement and enforce the applicable law;

staff training on carrying out of inspections (controls);

resources, including diagnostic tools;

existence and implementation of documented procedures for control and monitoring systems;

animal health situation and procedure of notification to the member-states and relevant international bodies on outbreaks of OIE reportable animal diseases.

Experts are bound by the same obligations and responsibilities as the inspectors-auditors with regard to protection of confidential information and avoidance of conflict of interest in relation to the products of the establishments being inspected (controlled). The authorized body should ensure the impartiality and integrity of the experts.

27. The scope of the audit includes the confirmation of the system records, such as country's laws, regulations, directives, orders and other documents relating to the implementation of the audit program; records on activities of the enterprise, results of inspections (control) of establishments, and other activities to ensure implementation of the legislation; control of residues of chemical substances from farms to slaughterhouses; program of microbiological and chemical testing, laboratory support, program of sampling, methods of testing and other requirements related to exports into the customs territory of the Customs union including reduction in the level of pathogen and the implementation of the Hazard Analysis and Critical Control Points program.

28. During the on-site inspection (control) of an establishment that is part of the audit the inspectors-auditors of the member-state (member-states) correlate the documentation for the system

of control of third countries with observations in relation to the implementation of the control program.

29. The purpose of the visit to the establishment as part of the audit is to ensure that within the framework of the foreign system of supervision related to production, processing, transportation and (or) storage of the controlled goods (products) all of the laws, regulations and other requirements on inspection and certification, which the authorized body of the member-state (member-states) recognized as capable to provide a level of protection at least equivalent to that provided by the Customs Union requirements at the stage of analysis of documentation, are properly implemented.

30. After completion of the stage of documentary analysis and the stage of the on site inspections (control), the authorized body of the member-state prepares a preliminary report of the audit taking into account the provisions of Annex C of the WTO SPS Agreement and sends to the authorized bodies of all member-state a letter with the preliminary report attached. The report contains a preliminary conclusion on the presence or the absence of equivalence and identifies precisely the legal basis, in cases of insufficiencies of the official control system following the audit results, as well as recommendations to address such insufficiencies.

31. The authorized bodies (including those not participating in the audit) may send additional data and clarifications on the information and conclusions contained in the preliminary report within 2 months starting from the date of electronic notification on the receipt of preliminary report to the official electronic address.

32. The authorized body evaluates this additional data and clarifications and makes corrections of the preliminary report if needed within the 1 month after receipt additional data and information to the preliminary report.

33. The authorized body prepares the updated preliminary report of the audit taking into account the provisions of Annex C of the WTO SPS Agreement and sends to the competent authority a letter with its attachment.

34. The competent authority alongside with other interested entities of this third country may send additional data and clarifications on the information and conclusions of the preliminary report within 2 months after receipt of the preliminary audit report starting from the date of electronic notification on the receipt to the official electronic address of the authorized body.

35. The authorized body evaluates the received information, prepares, publishes and sends to the Commission the final report within 2 months after receipt of an official letter with comments on the preliminary report from the competent authority.

36. The final report prepared by the authorized body (authorized bodies) of the member-state (member states) who participated in conducting audit, shall contain the conclusion whether the foreign official system of supervision provides a level of protection at least equivalent to that in accordance with the Customs Union requirements (hereinafter – the conclusion about equivalence).

37. After the final report containing the conclusion about equivalence is presented to the Commission, the Commission shall without undue delay publish on the official website of the Commission report referred to in paragraph 36 of this Regulation. The authorized body publishes this information on its official web-site of information and telecommunication network “Internet”.

38. After the publication of information referred to in paragraph 37 of this Regulation the competent authority forms a list of establishments planning to export of the controlled goods to the CU Customs Union including for their inclusion in the register of establishments of third countries.

39. The competent authority, which prepares a list of establishments for inclusion in the register of establishments of third countries mentioned in paragraph 38 of this Regulation, shall send to the authorized body, who initiated the audit, a letter indicating the list of establishments.

40. The authorized body shall update the register of establishments of the third country by including of establishments from the updated list and publish updated Register of establishments of third countries within 10 working days after receiving the relevant letter from the competent authority.

41. The competent authority shall inform the Commission about changes in the legislation of its country affecting the official system of supervision regarding the relevant controlled goods (products). The Commission shall inform the authorized bodies about these changes without undue delays.

42. The authorized body of the member-state (member-states) may take a decision to re-audit the foreign official supervision system of a third country, but not more often than 1 time a year, except for the case as indicated in paragraph 44 of this Regulation. Decision on conducting re-audit shall be taken with respect to the reasonableness of reassessment and the necessity to reduce as much as possible the amount of information that shall be provided by the competent authority.

43. On the basis of the final report containing the conclusion about non-equivalence the member-states may consider issues to provide to the competent authority a right to provide the guarantees on compliance of the controlled goods (products) produced by a specific establishment (establishments) or to inform the competent authority that establishments of the third country can be listed in the register of establishments of third countries only on the basis of a successful on-site inspection (control) of production at these establishments by the Customs Union inspectors.

This decision shall be taken on the basis of the previous experience of trade with this country, and the knowledge about the structure and power of the competent authority of the third country and other relevant information.

44. In case if the official system of control of a third country is not recognized as capable of providing a level of protection at least equivalent to that provided by the Customs Union requirements, the competent authority of this country can reapply the authorized body to restart the audit at any time after taking corrective action. The authorized body shall accept this application and carry out the procedure of recognition of equivalence using the information collected during the previous audit to reduce the amount of work required as much as possible. In case of minor problems detected during the first audit, the analysis of the corrective actions may be so sufficient then the decision can be made without second audit. The procedure for conducting this second audit is the same as described above.

45. In case if the audit of a foreign official system of supervision has been started but not completed, or if the audit of a foreign system of supervision was not carried out, the member-states may consider to accept guarantees or conduct joint inspections (controls), when inclusion into the register of third country establishments is required.

## **V. Guarantees**

46. The competent authority may send a request to the authorized body for accepting its guarantee on compliance of controlled goods (products), produced by an establishment (establishments) enclosing information in accordance with subparagraphs “a”, “c”, “d”, “f”, “g” and “j” of paragraph 48 of this Regulation, that competent authority considers necessary for evaluation

of this request, including list of establishments with names of produced products by HS Code of Customs Union and types of activity. The guaranty of the competent authority is accepted on each group of goods (products) according to HS Code of Customs Union indicated in the request of the competent authority.

47. When receiving request listed in paragraph 46 of this Regulation authorized body considers information attached and other available information within reasonable time, but no longer 2 month.

Within this period, if necessary, authorized body may request additional information from the competent authority for assessment according to the criteria listed in paragraph 48 of this Regulation. In this case, the term of review of the request is extended by 15 working days from the date of receipt of additional information.

48. Evaluation of the request is held by the authorized body and is based on the following criteria, as relevant for the concerned commodity:

- a) a level of development of the competent authority;
- b) compliance to the guarantees that have been previously provided by the competent authority;
- c) risk of entry into the territory of the third country and further spread of pathogens of contagious animal diseases, including those common to humans and animals;
- d) epizootic situation in the third country;
- e) the results of monitoring tests performed by the member-states of the controlled goods (products), imported into the customs territory of the Customs Union from the third country (if available);
- f) data of monitoring of the controlled goods (products), carried out by the competent authority (if available). Absence of such data shall not be a reason for refusal to accept guarantees;
- g) confirmation that the competent authority has inspected (controlled) the establishments requested to be included into the Register of establishments of third countries, and has found them in compliance with the Customs Union requirements in accordance with Annex 3 to this Regulation;
- h) results of inspections (controls) by the authorized bodies of establishments on the territory of the third country (if available);
- i) experience of trade with the third country (if available);
- j) the list of establishments requested for inclusion into the Register of establishments of the third countries with type of products.

49. Upon completion of evaluation of the request, the authorized body prepares the draft final decision within 10 working days. Decision shall take into account the level of risk and must be based on the criteria listed in paragraph 48 of this Regulation.

50. The authorized body sends draft final decision including information provided by the competent authority to the authorized bodies of other member-states for approval.

The authorized bodies of other member-states receiving the draft final decision for approval may send a response to authorized body that prepared the draft final decision within 10 working days after its receiving. If the authorized bodies that received the draft final decision for approval will not send a response within indicated timeframe it means that it approves the draft final decision.

The response may represent itself an approval of the draft final decision or may contain comments and (or) proposal or objection.

51. In case of objection against conclusion made in draft final decision the authorized body shall include into its response the reasons. Those reasons shall be based on criteria listed in Paragraph 48 of this Regulation and shall explicitly specify which element was not met in those criteria taking into account the principle of proportionality to the risk. This timeframe will also be used to exchange additional information between the member-states to solve disagreements.

52. The authorized body that prepared the draft final decision upon receiving the responses from authorized bodies of other member-states shall prepare final decision within 10 working days.

53. Upon preparing the final decision, the authorized body shall send it in written form to the competent authority.

54. The final decision may contain a single (positive or negative) conclusion or different (positive or negative) conclusions with regard to groups of products produced by specific establishments.

55. If the decision is positive decision, authorized body updates registry of establishments of third countries within 10 working days from the date of the decision.

If the decision is negative decision, the reasons for refusal referred to in the final decision shall be based on the criteria listed in paragraph 48 of this Regulation, and reflect specific element that does not meet these criteria, taking into account the principle of proportionality to the risk. Such decision may be revised after giving by the competent authority additional information.

56. The competent authority, the guarantees of which have been accepted, can subsequently send a request to the authorized body to amend the list of establishments, including a request for the addition of new establishments to the Register of establishments of third countries.

57. The authorized body receiving such request shall evaluate it and prepare a draft decision in accordance with provisions of this Chapter.

58. The authorized body further may perform inspections (controls) of a representative part of establishments included ~~in~~ into the register of establishments of the third countries. In cases where unsatisfactory results are found during the inspection (control) of more than 60 percent of the inspected (controlled) establishments that indicates the significant deficiencies of official supervision, the authorized body may decide to refuse of accepting guaranties of the competent authority and require a mandatory joint inspection (control) of establishments of third country.

59. In case of taking corrective action with regard to the problem which was the reason for denying of the right to provide guarantees, the competent authority may apply to an authorized body to grant right to provide guaranties on compliance of establishments of this third country with Customs Union requirements. The Application will be considered in the order described above.

## **VI. Joint inspection (control) of establishments of third countries**

60. The joint inspection (control) of establishment (establishments) may be conducted with the following purposes:

1) to enlist establishment (establishments) into the register of establishments of third country (later in this chapter – case 1);

2) to joint inspection (control) of establishment (establishments) that previously were listed into the register of establishments of third country and import from which is allowed:

upon results of carrying joint inspections (control) (later in this chapter - case 2);

on the basis of acceptance of guarantees of competent authority (later in this chapter case 3);

upon results of satisfactory audit (later in this chapter – case 4);

on the basis of information about the non-compliance with Customs Union requirements (later in this chapter - case 5).

3) for joint inspection (control) of establishment (establishments) of third countries, which previously have been included into the Register of establishments of third countries and import of goods (products) from them have been temporary restricted (later in this chapter – case 6).

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

62. In Cases 1 and 6 the authorized body may postpone the joint inspection (control) by the reason of lack of resources (financial, human or others). In these situations, the authorized body shall take all possible measures to ensure that this postponement does not create an excessively prolonged impediment for exports to the customs territory of the Customs Union from the concerned establishment.

63. Expenses, connected with carrying out of joint inspections (controls) in Cases listed in paragraph 60 of this Regulation shall be covered by respective budgets of the member-states, unless in each case it is agreed otherwise.

64. Period of the joint inspection (control) of an establishment should not exceed the period agreed with the competent authority and shall not exceed 5 working days.

65. The authorized body planning the joint inspection (control) (later in this chapter – Initiator) no later than 3 months prior to joint inspection (control) (unless a shorter period is agreed

with the competent authority) shall send to the competent authority the list of legal acts where the relevant norms and requirements are set out and a list of documents, which the competent authority and (or) the inspected (controlled) establishment shall provide during the inspection (control) in Russian or another agreed language.

66. The Initiator no later than 3 months prior to the joint inspection (control) (unless a shorter period is agreed with the competent authority) may request the competent authority to provide preliminary information in Russian or another agreed language that is necessary for the inspection (control) or evaluation of its results, including:

- a) Data on the statutory powers of the competent authority;
- b) Data on the structure of central and local units of the competent authority responsible for the establishment to be inspected (controlled);
- c) Data on the training and retraining of the staff of the competent authority responsible for the establishment to be inspected (controlled);
- d) Data on the development and equipping of laboratory network of the third country, involved in the assessment of the safety of products, produced by the establishment to be inspected (controlled) and raw materials used by the establishment;
- e) Texts of legal acts of the third country, establishing mandatory requirements for products, manufactured by the establishment to be inspected (controlled), raw materials and methods of their control used by the establishment;
- f) National plan of the third country for control (supervision) in case of an emergency and spread of the pathogens of contagious diseases of animals, relevant for the products of the establishment to be inspected (controlled);
- g) Data on the presence and spread of the relevant animal and zoonotic diseases in the third country;
- h) National plan for monitoring of products subject to veterinary control (supervision);
- i) Results of control (supervision) procedures carried out by the competent authority with regard to the controlled goods (products) produced by the establishment to be inspected (controlled), aimed at control (supervision) of compliance with the Customs Union requirements if the establishment exported the controlled goods to the customs territory of the Customs Union in the past (this information can be provided before or during the joint inspection (control));
- j) Results of control (supervision) procedures carried out by the competent authority with regard to the controlled goods (products) produced by the establishment to be inspected (controlled), aimed at supervision of compliance with the requirements of the third country if the establishment did not export the controlled goods to the customs territory of the Customs Union in the past or there was no result of control (supervision) procedure listed in subparagraph "i" of this paragraph (this information can be provided before or during the joint inspection (control));

67. The Initiator no later than 2 months (unless a shorter period is agreed upon by the member-states) before the inspection (control), shall inform the authorized bodies of the other member-states on the forthcoming inspection (control) in order to form a group of inspectors and coordinate the timing of the joint inspection (control).

68. The authorized bodies of other member-states, no later than in 2 weeks after receiving from the Initiator of the information on the forthcoming inspection (control), may send a response

that contains a denial of participation in the inspection (control) or a consent to participate in the inspection (control) and the information on inspectors (experts), who will participate. Absence of such a response in the specified timeframe means the refusal to participate in the Inspection (control).

69. The joint inspection (control) can be conducted by inspectors of the Initiator only if other member-states do not respond or state that they will not participate. Non-participating member-states shall recognize the decision of Initiator made on the results of inspection.

70. The Initiator and other participating authorized bodies may engage experts who are employees of the governmental institutions or bodies (except for the interpreters) on the matters below:

- a) legislation of a third country;
- b) organization of the competent authority of a third country, their powers and independence, their leadership and authority with which they are endowed, in order to effectively implement and enforce the applicable law;
- c) staff training on carrying out of inspections (control);
- d) resources, including diagnostic tools;
- e) existence and implementation of documented procedures for control and monitoring systems;
- f) animal health situation and procedure of notification to the member-states and relevant international bodies on outbreaks of OIE reportable diseases.

71. Experts are bound by the same obligations and responsibilities as the inspectors with regard to protection of confidential information and avoidance of conflict of interest in relation to the products of the establishments being inspected (controlled). The authorized body should ensure the impartiality and integrity of the experts.

72. The Initiator shall no later than 2 months before the inspection (control) (unless a shorter period is agreed upon with the competent authority), send to the competent authority the following information:

- a) the purposes of the joint inspection (control);
- b) the member-states involved in the inspection (control);
- c) list of inspectors and experts;
- d) list of establishments to be inspected (controlled);
- e) list and quantity of the controlled objects supplying the relevant raw-materials to the establishments to be inspected (control);
- f) list and quantity of other establishments, involved in the production (manufacture) and (or) control of the relevant controlled goods (products) produced by the inspected (controlled) establishments;
- g) list of documents, which the competent authority and (or) the establishments to be inspected (controlled) shall provide in the course of the joint inspection (control) in Russian or another agreed language.

73. If the competent authority in Cases 2 - 5 refuses of inspection (control) of one or more of the selected establishments, it may serve as a ground for the Initiator to suspend exporting of products from those establishments if the Initiator does not consider the reasons for that provided by the competent authority as valid.

74. The inspectors on arrival to the establishment shall carry out examination of the following documents on:

- a) The type of activity;
- b) The layout of the establishment;
- c) The flow of production and production control;
- d) The structural and technological specifications of the establishment;
- e) The volumes of production and the output of controlled goods (products);
- f) The existence and implementation of official control and production control to ensure the safety of manufactured controlled goods (products);
- g) The epizootic situation on the administrative territory in the location of the establishment.

75. During the Inspection (control) the inspector shall:

- a) visit the buildings and other parts of the infrastructure of the inspected (controlled) establishment;
- b) study their compliance with the Customs Union requirements with respect to the principle of equivalence in Cases 1 - 3, 5 and 6 or ensure level of protection at least equivalent to the Customs Union requirements in Case 4;
- c) verify the methods and equipment used for the state and production control;
- d) conduct any other activities necessary to ensure achievement of the purposes of this Regulation.

76. During the Inspection (control) the inspectors shall study the compliance of technological processes in the establishment with the Customs Union requirements taking into account the relevant guidance recognized by WTO and the principle of equivalence as provided in paragraph 11 of this Regulation in Cases 1 - 3, 5 and 6 or ensure level of protection at least equivalent to the Customs Union requirements in Case 4.

77. During the Inspection (control) there may be visits to other establishments, which provide raw materials to the inspected (controlled) establishment, and (or) organizations involved in the official and (or) production control, if the competent authority agreed to such visits during the planning of the inspection (control).

78. Upon request of the competent authority during the Inspection (control) the Customs Union inspectors may do the sampling of the controlled goods (products) produced by the inspected (controlled) establishment and raw materials used by the establishment.

79. In the event of detecting during the inspection (control) of enlisted establishments to the register of establishments of third countries of incompliance if it represented a significant threat to human or animal life and health the group of inspectors (inspector) shall immediately inform the

Initiator on that and the Initiator may immediately suspend exports of goods (products) from this establishment.

80. In case of repeated unsatisfactory results of the joint inspection (control) of establishments, the authorized body may decide to suspend the export of goods (products) from these enterprises.

81. Upon request of representative of competent authority, or the company's executives, inspectors after visiting the establishment, shall provide information about identified incompliances, taking into account the principle of equivalence, as required by paragraph 11 of this Regulation. The company executives can inform participants of inspection (control) directly or through the competent authority prior to their departure from this third country on the implementation of measures taken to rectify identified incompliances. Participants of inspection (control) may take note of this information and take it into account before drawing up a preliminary report.

82. Upon completion of inspections (controls) initiator shall prepare the preliminary report. The preliminary report shall identify precisely the legal basis of inconsistencies that were detected during the Inspection (control), as well as include recommendations on corrective actions for the competent authority and (or) for the concerned establishment. Initiator no later than 2 months after completion of inspection (control) in a third country shall prepare and send to the authorized bodies of the member-states, participating in the inspection (control), draft preliminary report. Authorized bodies of other member-states no later than 2 weeks after receipt of the draft preliminary report (from the date of receipt of the notification email) shall send its feedback to the initiator. Absence of response within this period of time means consent with the draft of the preliminary report.

83. The initiator, taking into account the responses of the authorized bodies of other member-states, who participated in the inspection (control), shall send to the competent authority preliminary report on the joint inspection (control) within 3 months after completion of a joint inspection (control) in a third country. The competent authority within 2 months may send a response containing comments, additional information (including information on measures undertaken to remedy the identified deficiencies) and clarification to the Initiator. If the competent authority did not send a response within the indicated timeframe it means that it fully agreed with the preliminary report.

84. Upon receiving the response from the competent authority or ending of indicated timeframe if a response was not sent, the Initiator shall prepare and send within 1 month a draft final report to the authorized bodies of the member-states, participated in inspection (control). Authorized bodies of other member-states no later than 2 weeks after receipt of the draft final report (from the date of receipt of the notification email) send to the initiator reply. Absence of response within this period of time means consent with the draft of the final report.

The initiator, taking into account the responses of the authorized bodies of other member-states, participated in the inspections (controls), within 2 weeks after receiving the responses from the authorized bodies shall send to the competent authority final report of the joint inspections (controls).

85. The final report shall contain the conclusions regarding each of the inspected (controlled) establishments whether included in the register of establishments of third countries or not, and recommendations on corrective actions that shall be taken for the establishments to be included in the register of establishments of third countries.

86. The conclusion can be one of the following:

a) the establishment is listed to the register of establishments of third countries and can start the exporting;

- b) the establishment cannot be listed to the register of establishments of third countries;
- c) the establishment may continue exporting and it keeps current status in the register of establishments of third countries;
- d) the establishment may continue exporting and it keeps current status in the register of establishments of third countries, but corrective actions needed;
- e) the exporting from the establishment temporary restricted;
- f) the establishment may resume exporting, the status “temporarily restricted” cancelled;
- g) the establishment cannot resume exporting, the status "temporarily restricted" maintained;
- h) the establishment can continue export on condition of implement of “special requirements”, proposed by the initiator.

87. In Case 1 the establishments that were listed in register of establishments of third countries as a result of Inspection (control) can export the controlled goods to the customs territory of the Customs Union from the date of publishing of updated Register of establishments of third countries. The goods cannot be produced prior to the date of Inspection (control) unless otherwise specified in the conclusion.

88. The Initiator shall publish final report on official web-site in the information and telecommunications network "Internet" and send it to the authorized bodies and to the competent authority in 5 working days upon finishing the preparation of the final report.

89. Published final report shall not contain the official numbers, names and exact locations of the establishments of the third countries.

90. The Initiator shall update the register of establishments of third countries within 10 working days upon preparing the final report and send to the competent authority a notification on that.

## VII. Joint inspections (control) of establishments of the Customs Union with the purpose of their inclusion into the register of establishments of the Customs Union

91. The joint inspection (control) of an establishment (establishments) shall be conducted with the purpose to include them into the Register of establishments of the Customs Union except the case identified in paragraph 107 of this Regulation.

92. Joint inspection (control) shall be conducted upon request of the establishment.

93. The request of the establishment should be addressed to the authorized body. Expenses, connected with carrying out joint inspection (control), shall be covered by respective budgets of the member-states, unless otherwise prescribed by the legislation of the member-state in the territory of which the establishment is located.

94. The period of an on-site inspection (control) of an establishment should not exceed 5 working days.

95. The authorized body, planning the joint inspection (control), shall no later than 1 month prior to inspection (unless a shorter period is agreed with the authorized bodies, send to the authorized bodies of the other member-states the letter with notification about the forthcoming inspection (control) in order to form a group of inspectors and coordinate the timing of the joint inspection (control). The authorized bodies of the other member-states, shall no later than in 2 weeks after receiving the information on the forthcoming joint inspection (control), send a response that contains a denial of participation in the inspection (control) or a consent to participate in the inspection (control) and data on the inspectors (experts), who will participate, or does not send a response within the specified period, which means a refusal to participate in the inspection (control).

96. Establishments, located on the territory of the member-state may be included in the register of establishments of the Customs Union, without a joint inspection (control), according to the agreed decision of the authorized bodies of all member-states in the case where the risk associated with the supply of controlled goods (products) produced by the establishment, is assessed by them as acceptable risk.

97. A joint inspection (control) can be conducted by inspectors of one of the member-states if the authorized bodies of other member-states do not respond to the request on conducting the inspection or state that they will not participate in the inspection (control). Non-participating authorized bodies recognize the decision, based on the results of the inspection (control) conducted by the authorized body.

98. The inspector on arrival to the establishment shall carry out an examination of the following documents on:

- a) the type of activity,
- b) the layout of the establishment,
- c) the flow of production and production control,
- d) the structural and technological specifications of the establishment,
- e) the volumes of production and the output of controlled goods (products),
- f) existence and implementation of official control and self-control to ensure safety of the manufactured controlled goods,
- g) epizootic situation of the administrative territory in the location of the establishment.

99. During the on-site inspection (control) the inspectors shall:

- a) visit the buildings and other parts of the inspected (controlled) establishment infrastructure;
- b) study their compliance with the Customs Union requirements;
- c) verify the methods and equipment used for state control and self-control ;
- d) conduct any other activities necessary to ensure achievement of the purposes of this Regulation.

100. During on-site inspection (control) the inspectors shall study the compliance of technological processes in the establishment with the Customs Union requirements.

101.If it is agreed with the authorized body of the member-state during the planning of the joint inspection (control), there may be visits to other establishments, which supply raw-materials to the inspected (controlled) establishment, and (or) other organizations involved in official and (or) production control.

102.At the request of the authorized body, the inspectors may do the sampling of controlled goods (products) produced by the inspected (controlled) establishment and raw materials used by the establishment.

103.Upon completion of a visit to an establishment, inspectors upon request of the management of the establishment shall present the findings of non-compliances and recommendations for corrective actions.

104.After completion of a joint inspection (control), the authorized body, which conducted the inspection (control), published a report of the conducted inspection (control) and sends a letter to the authorized bodies of the member-states with the report attached to it.

105.The establishment may send additional data and clarifications on the information and conclusions of the preliminary report within 2 weeks.

106.The authorized body shall evaluate the received information and take a decision on the inclusion of the establishment into the register of establishments of the Customs Union, notify the establishment, the authorized bodies of the other member-states and the Commission about the decision within 1 month.

107.In case if the system of inspection (control) of the objects subject to veterinary control (supervision) of one of the member-states was recognized as equivalent, the establishments located on the territory of that member-state are included by the authorized body of the member-state in the register of establishments of the Customs Union without a joint inspection (control).

108.The Commission shall publish the updated register of establishments of the Customs Union based on information of the authorized body of the member-state without undue delay.

109.Establishments, newly listed in the register of establishments of the Customs Union, can supply the controlled goods (products) to the territory of the other member-states from the date of publication of the updated Register of establishments of the Customs Union. The goods shall be produced starting from the date of the start of the inspection (control) , and in case set out in paragraph 107 of this Regulation – from the date of submission to the Commission by the authorized body of the member-state of the information on inclusion of the establishment in the register of establishments of the Customs Union.

## VIII Joint inspections (control) of establishments included in the Register of establishments of the Customs Union on the territory of the member-states

110. A joint inspection (control) of an establishment (establishments) listed in the Register of establishments of the Customs Union may be conducted when necessary and subject to mutual agreement of the member-states in the following cases:

a) repeated detection of incompliance of the controlled goods (products) produced at the controlled objects with the Common veterinary requirements;

b) lifting of quarantine from the territory where the controlled object is located;

c) location of the controlled object on the territory bordering the territory (zone), where quarantine is established.

111. Expenses, related to carrying out a joint inspection (control), shall be covered by respective budgets of the member-states, unless otherwise provided by the legislation of the member-state in which territory the establishment is located.

112. Period of on-site inspection (control) at of an establishment should not exceed 5 working days.

113. The inspection (control) shall be conducted according to Section VII of this Regulation.

114. The authorized body maintaining the Register of establishments of the Customs Union of this member-state provides information that shall be contained in the register of establishments of the Customs Union to the Commission to make it available in the Integrated Information System of foreign and mutual trade of the CU (hereinafter - IISFMT) in the manner and format established by the Commission.

115. After including the establishment in the Register of establishments of the Customs Union, the authorized body may monitor the controlled goods (products) of the establishment. Monitoring is carried out in accordance with the legal act of the Customs Union and the national legislation of the member-state and shall include: laboratory monitoring, clinical monitoring (only in case of supplying of animals), monitoring of the adequacy of the accompanying veterinary documents and correct labeling of the controlled goods (products) in circulation on the customs territory of the Customs Union.

## IX. Sampling of controlled goods (products), produced on the customs territory of the Customs Union

116. Sampling of controlled goods (products), produced on the territory of the Customs Union, can be performed upon request of the producer or the owner of the goods or upon decision of a state veterinary inspector during:

a) implementation of a state program of random monitoring conducted within the framework of the state veterinary control (supervision) over safety of the controlled goods (products) that are in circulation on the customs territory of the Customs Union;

b) implementation of the state veterinary control (supervision) of the controlled goods (products) aimed at their certification for exports;

c) implementation of enhanced laboratory control of the safety of controlled goods (products), produced by an establishment in case of detection of a violation of the relevant Customs Union requirements (with regard to the controlled goods (products) for internal circulation on the customs territory of the Customs Union). Enhanced laboratory control in such cases is a measure applied as an alternative to a temporary ban on the transfer of goods (products) produced by the establishment to the territory of the other member-states or for exports.

d) state veterinary control (supervision) over the establishment.

117. The purpose of sampling is taking of samples for their subsequent laboratory testing.

118. Sampling shall be done by an inspector who has relevant knowledge and skills, allowing to properly implement the Customs Union requirements with regard to the procedures of sampling, packing and transportation of samples, to avoid their damage, substitution and contamination that may skew the results of the laboratory testing.

119. Sampling, recording and transportation of selected samples shall be arranged in the way to prevent their damage, spoilage, contamination, substitution or other types of violation of law ~~heat~~.

120. In cases referred to in subparagraphs a) (except in the case specified in paragraph 121 of this Regulation) and in subparagraph d) of paragraph 116 of this Regulation, sampling, transportation of taken samples to the laboratory and their laboratory testing shall be carried out at no charge to the owner of controlled goods.

121. In case of detection of violations of Common veterinary requirements during the documentary or physical control, the owner of the controlled goods (products) shall bear the costs for sampling of controlled goods (products), transportation of samples to the laboratory and laboratory study.

122. In the case referred to in subparagraph c) of paragraph 116 of this Regulation, the owner of controlled goods (products) shall bear the costs for sampling of controlled goods, transportation of samples to the laboratory and laboratory study.

123. In the case referred to in paragraph 121 of this Regulation, laboratory study of samples should be conducted against all safety parameters in order to determine the possibility of further use or destruction of a particular batch of goods (products) under control.

124. In case of sampling upon request of the producer or the owner, they have the right to determine the laboratory, regardless on the territory of which member-state it is situated. In other cases, the inspector in the decision on the sampling states laboratory unless it was identified in the order, upon which he conducted the sampling.

125. Sampling shall be documented by issuing of an act of sampling according to the form in annex 1. The first copy of the act shall be provided by the inspector to the producer or the owner of the controlled goods. The second copy shall be provided to the chief veterinary inspector of the territory where the sampling was done. The third copy shall be sent to the laboratory where the testing of the samples will be done. The fourth copy shall be kept by the inspector for at least 1 year.

126. Upon arrival of the samples to the laboratory they shall be checked by the laboratory staff to detect their suitability for the testing (absence of spoilage), adequacy of packaging and accuracy of the accompanying documents. In case of violations, the samples shall not be tested and a notification on the violations shall be sent to the inspector who did the sampling.

127. The laboratory shall be accredited by the accreditation authority of the member-state and have equipment that allows to properly implement laboratory testing, including as to the sensitivity of the results allowing to detect a maximum allowable concentration of an organism or a compound to be detected.

128. In case of incompliance of a sample with the Customs Union requirements, the laboratory shall keep the control samples until the expiry date of the lot of the controlled goods is over, but not longer than 3 months after notification of interested entities on the results of the laboratory testing.

129. In the case referred to in subparagraph c) of paragraph 116 of this Regulation, sampling should be taken from 10 batches of the goods (products) and for not more than 3 months. Sampling should be carried out only from goods (products) of the same type from which violations were

detected. Laboratory studies should be conducted only against safety indicator (s) on which discrepancy was previously detected.

130. The authorized body shall inform the owners of the controlled goods, the producers, the inspectors of the administrative territory and the authorized bodies of the other member-states about the violations detected during the monitoring or enhanced laboratory control as soon as possible but in any case no later than within 10 working days. The information shall contain the data on the sampling method, the site and purposes of the sampling, the analytical method if used, the laboratory where the laboratory testing took place, and the results of the testing.

131. The processing of documents on the results of the testing and notification on its results shall be carried out in accordance with the legislation normative legal acts of the Customs Union.

## X. Sampling on the customs territory of the Customs Union of the controlled goods (products), produced in a third country

132. Sampling on the customs territory of the Customs Union of controlled goods (products), produced in a third country, can be done upon request of the producer or the owner of the goods or upon decision of a state veterinary inspector during:

a) implementation of a state program of random monitoring as part of the state veterinary control (supervision) over the safety of controlled goods that are in circulation on the customs territory of the Customs Union;

b) implementation of the state border veterinary control (supervision) of the controlled goods (products) (except in case as indicated in subparagraph c) of this paragraph) at the state border checkpoint, in the places of complete customs clearance, or other places where imported animals are quarantined;

c) implementation of enhanced laboratory control of the safety of controlled goods (products), produced by an establishment (entity) of a third country, in case of detection of a violation of the relevant Customs Union requirements. The enhanced laboratory control in this case is a measure implemented as an alternative to temporary ban on imports of controlled goods (products) produced by the establishment;

d) control of batches of controlled goods (products) produced by an establishment that is under temporary restriction, if the product leaves the premise prior to the date of import restriction enforcement,

e) control of controlled goods (products) produced by an establishment that was included in the register of establishments of third countries under guarantees of the competent authority that had been under temporary restrictions after repeated violation and the temporary restrictions were removed after guarantees by the competent authority.

133. The purpose of sampling is taking samples for their subsequent laboratory testing.

134. Sampling shall be done by an inspector who has relevant knowledge and skills, allowing to properly implement the Customs Union requirements with regard to the procedures of sampling, packaging and transportation of samples, to avoid their damage, substitution and contamination that may skew the results of the laboratory testing.

135. Sampling, its documenting and transportation of the samples shall be arranged in the way to prevent their damage, spoilage, contamination, substitution and other types of violation of law.

136. In the cases referred to in subparagraphs a) and b) of paragraph 132 of this Regulation, sampling, transporting of samples to laboratory and laboratory tests shall be carried out at no charge to the owner of controlled goods.

137. With regard to cases mentioned in subparagraph b) of paragraph 132 of this Regulation, in case of violations of veterinary-sanitary requirements during the documentary or physical control of imported controlled goods (products) through the government border or places of full customs clearance, the owner of the goods can apply for laboratory control for those goods aimed to ensure its safety. In this case, the owner of the controlled goods (products) shall bear the costs for sampling of controlled goods (products), transportation of samples to the laboratory and laboratory study.

138. In the case referred to in paragraph 137 of this Regulation, laboratory testing of samples should be conducted against all safety parameters in order to determine the possibility of further use or destruction of a particular batch of controlled goods (products).

139. In the cases referred to in subparagraphs «c» - «e» of paragraph 132 of this Regulation, the owner of controlled goods shall bear the costs for sampling of controlled goods (products), transportation of samples to the laboratory and laboratory testing.

140. In the case referred to in paragraph subparagraph d) of paragraph 132 of this Regulation, sampling should be carried out for all batches of imported goods (products) and shipped prior to introduction of temporary restrictions for a certain manufacturer. Laboratory studies should be conducted only against safety indicator (indicators) on which discrepancy was previously detected.

141. In the case referred to in subparagraph e) of paragraph 132 of this Regulation, sampling should be carried out for the first 10 batches of imported goods (products) of appropriate manufacturer.

142. The laboratory shall be accredited by the accreditation authority of the member-state and have equipment that allows to properly implement laboratory testing, including as to the sensitivity of the results allowing to detect a maximum allowable concentration of an organism or a compound to be detected.

143. In case of incompliance of a sample with the Customs Union requirements the laboratory shall keep the control samples until the expiry date of the lot of the controlled goods is over, but not longer than 3 months after notification of interested entities on the results of the laboratory testing.

144. In case of sampling upon request of the producer or the owner, they have the right to determine the laboratory, regardless on the territory of which member-state it is situated. In other cases the inspector shall determine in the decision on the sampling unless it was identified in the order, upon which he conducted the sampling.

145. In case referred to in subparagraph c) of paragraph 132 of this Regulation, after a single detection of any violation, sampling should be taken from 10 batches of imported goods (products) and within not more than 3 months. Sampling should be carried out only from goods (products) of the same type from which violations were detected. Laboratory studies should be conducted only against safety indicator (indicators) on which discrepancy was previously detected.

146. The authorized body shall inform the competent authority of the country where the controlled goods were produced, and the competent authority of the country from which the

controlled product was exported to the customs territory of the Customs Union, the owner of the goods, manufacturer, inspectors of administrative territory, authorized bodies of other member-states on violations identified during monitoring and (or) intensive laboratory monitoring of controlled goods (products) as soon as possible, but not later than 10 working days after receipt of the laboratory results of testing from the laboratory. This information shall contain the data on the sampling method, the site and purposes of the sampling, the method used, if laboratory methods are used, the laboratory where the testing was performed, and the results of the testing.

147. The processing of documents on the results of the laboratory testing and notification on its results shall be carried out in accordance with the normative legal acts of the Customs Union.

## XI. Sampling on the territories of third countries as part of an audit of foreign official system of supervision or a joint inspection (control)

148. Sampling of controlled goods (products) for laboratory testing as part of an audit of foreign official system of supervision or a joint inspection (control) shall be conducted upon request of the competent authority and in accordance with the requirements set out by this Section.

149. Sampling shall be performed by an inspector of the member-state or a state (state approved) inspector (veterinarian) of the third country or by a representative of the producer or the owner of the controlled goods upon agreement between the competent authority and the authorized body.

150. With the agreement of the competent authority and the authorized body, sampling shall be performed in accordance with the legislation normative legal acts of the Customs Union or the legislation of the third country.

151. The person performing the sampling shall have relevant knowledge and skills, allowing to properly implement the requirements, as provided in paragraph 149 of this Regulation, of the Customs Union or the third country with regard to the procedures of sampling, packaging and transportation of samples to avoid their damage, substitution or contamination that may skew the results of the laboratory testing.

152. Sampling, its documenting and transportation of the samples shall be arranged in the way to prevent their damage, spoilage, contamination, as well as substitution or other types of violation of law.

153. The laboratory shall be accredited by the accreditation body of member-state, or the samples shall be tested in a laboratory of a third country proposed by the competent authority and agreed upon with the authorized body.

154. In case of incompliance of a sample with the Customs Union requirements, the laboratory shall keep the control samples until the expiry date of the lot of the controlled goods is over, but no longer than 3 months after notification of interested entities on the results of the laboratory testing.

155. The competent authority or the authorized body depending on where the laboratory is situated, shall inform, respectively, the authorized body or to the competent authority about the results of the laboratory testing of the controlled goods as soon as possible and in any case no later than within 10 working days after receiving the results of the laboratory testing from the laboratory. This information shall contain the data on the sampling method, the site and purposes of the sampling, the analytical method if used, the laboratory where the laboratory testing was performed, the results of the testing.

156. The processing of documents on results of laboratory testing and notification on its results shall be agreed by competent authority and authorized body.

## XII. Keeping the register of establishments of third countries

157. The Register of establishments of third countries shall be published at the official website of the Commission.

158. The internet-access to the Register of establishments of third countries is free of charge.

159. The Register of establishments of third countries contains the following information in the Russian language (unless otherwise stated below) about the establishments of third countries that export and (or) have the right to export controlled goods to the customs territory of the Customs Union:

- a) name of establishment in English and (or) other state language;
- b) number (identifier) of the establishment given by the competent authority;
- c) list of controlled goods (products) that the establishment has the right to export to customs territory the Customs Union;
- d) veterinary and sanitary status (hereinafter - status) of the establishment the register of establishments of third countries and the date of its changing;
- e) address of the establishment;
- f) region (oblast, province, land, state, etc.)

160. In cases specified by the annex No 1 to the Common veterinary requirements, establishments not listed in the register of establishments of third countries shall have no right to export such goods (products) to the customs territory of the Customs Union.

161. The status of an establishment in the Register of establishments of third countries can be one of the following:

- a) “unrestricted” - the establishment currently can export controlled goods to the customs territory of the Customs Union without any bans or additional encumbrances;
- b) “temporarily restricted” - exports of controlled goods (products) from the establishment is currently temporarily suspended;
- c) “enhanced laboratory control” - exports of controlled goods (products) are possible, but every shipment of exported goods shall be sampled for their laboratory control;
- d) “notified” - the competent authority was notified by the authorized body about violations detected with regard to the goods (products), produced by the establishment, but the violations have not currently lead to temporary restrictions or enhanced laboratory control;
- e) “special requirements” - the need to use substitutive (additional) measures to allow exports of controlled goods (products), produced by the establishment, to continue to the customs territory of the Customs Union, otherwise such exports shall be suspended. In this case the Register of establishments of third countries shall contain a link to the document explaining what kind of special requirements shall apply.

162. An establishment can be included in the register of establishments of third countries as a result of:

a) provision by the competent authority the data on the establishment in the notification about the permit to export controlled goods to the Customs Union issued by the competent authority in case of a successful audit of the foreign official system of supervision of this country as provided by Section IV of this Regulation;

b) provision by the competent authority of guarantees that controlled goods produced by the establishment and the processes of their production comply with the Customs Union requirements in case of granting to the competent authority of the right to provide guarantees in the order established by Section V of this Regulation;

c) decision of the authorized body made based on the results of an inspection (control) of the establishment in the order established by Section VI of this Regulation.

163. An establishment can be excluded from the register of establishments of third countries upon request of the establishment or upon request of the competent authority.

164. Except in emergency situations, a temporary restriction of imports from an establishment only can be imposed only in one of the following cases:

a) upon request of the establishment or the competent authority;

b) based on repeated findings of non-compliance with the Customs Union requirements either registered during an on-site inspection (control) of the establishment, or as a result of monitoring and enhanced laboratory control of the controlled goods (products), produced by the establishment, of which the competent authority has been notified, if the detected non-compliances represent a significant threat to human or animal life or health.

In extraordinary cases, the Commission can take a decision to imposed restrictions with regard to a group of establishments or all establishments of a third country, as a result of detection of serious violations in the official system of supervision of the third country, if corrective actions were not taken and such temporary restrictions of imports were proportionate to the risk to human or animal

165. A change of status of an establishment in the register of establishments of third countries can be made as a result of:

a) a request of the establishment;

b) a request of the competent authority;

c) a request of an importer willing import the controlled goods produced by the establishment;

d) an on-site inspection (control) of the establishment by the authorized body;

e) detection on the customs territory of the Customs Union of the violations of the Customs Union requirements related to the controlled goods (products) produced by the establishment;

f) expiration of the period of enhanced laboratory control of the controlled goods (products) produced by the establishment;

g) refusal to further accept guarantees from the competent authority;

- h) reinstatement of the right of the competent authority to provide guarantees;
- i) negative conclusion on equivalence upon results of a re-audit of the foreign official system of supervision;
- j) positive conclusion on equivalence upon results of a re-audit of the foreign official system of supervision of the third country.

166. The authorized body shall notify the competent authority and the authorized bodies of the other member-states of any change in status, the reason for the change, including relevant specific information related to the laboratory testing confirming noncompliance with the EU Customs Union requirements, if such laboratory testing caused the change in status.

167. Following receipt of a report of violations the competent authority shall investigate the situation and determine if corrective actions is necessary and, if necessary to confirm that the corrective actions have been taken. Following this investigation of the situation the competent authority may request a change in status for the establishment in the register of establishments of third countries.

168. Any changes in the register of establishments of third countries database shall be made without undue delay, but no longer than 10 working days after taking of a corresponding decision or receiving of a corresponding request in cases when no decision of the authorized body is required.

### XIII. Keeping the register of establishments of the Customs Union

169. The Register of establishments of the Customs Union represents a web-accessible database. The content of the register of Customs Union establishments is reflected on the official web-sites of the authorized bodies and Commission.

170. Internet - access to the register of establishments of the Customs Union is free of charge.

171. The register of establishments of the Customs Union contains the following information about the establishments of the member-states that have the right to transfer controlled goods from the territory of one member-state to the territory of another member-state:

- a) member-state
- b) registration number of the establishment given by the authorized body of the member-state;
- c) name of establishments;
- d) region (region, province, land, state, province, Aimak, district);
- e) address of the establishment;
- f) activity of the establishment;
- g) veterinary and sanitary status of the establishment;
- h) ground for listing of the establishment in the Register of establishments of the Customs Union.

The register of establishments of the Customs Union may contain other information about the listed establishments.

172. Establishments can have the following status in the register of establishments of the Customs Union:

a) “unrestricted” - the establishment currently can supply controlled goods (products) from the territory of one member-state to another member-state’s territory without any bans or additional encumbrances;

b) “temporary restricted” - the controlled goods (products) produced by the establishment cannot be currently transferred from the territory of one member-state to the other member-state’s territories;

c) “enhanced laboratory control ” - the controlled goods (products) produced by the establishment can be transferred from the territory of one member-state to the other member-state’s territories but every shipment shall be sampled for subsequent laboratory control;

d) “notified” - the authorized body of the member-state, where the establishment is located, has been notified by the authorized body of another member-state or the establishment has been notified by the authorized body of the member-state, where the establishment is situated, about violations related to the controlled goods produced by the establishment, but the violations have currently not lead to restrictions or additional encumbrances;

e) “special requirements” - the need to use substitutive (additional) measures to allow transfer of the controlled goods produced by the establishment to the other member-states’ territories. If no such measures are taken such transfer may be prohibited. In this case the register of establishments of the Customs Union shall contain a link to the document explaining what kind of special requirements shall apply.

173. An establishment can be listed in the Register of establishments of the Customs Union:

a) upon request of the authorized bodies in case identified in paragraph 107 of this Regulation;

b) as a result of a joint inspection (control) of the establishment.

174. An establishment can be delisted from the Register of establishments of the Customs Union upon request of the establishment.

175. Reasons for changing the status of establishments in the Register of establishments of the Customs Union can be as follows:

a) a request of the establishment;

b) a decision of the authorized body of the member-state;

c) an on site inspection (control) of the establishment;

d) detection of violations related to the controlled goods produced by the establishment on the territory of one of the member-states;

e) expiration of the period of enhanced laboratory control of the controlled goods (products) produced by the establishment.

176. Any change in the database on the Customs Union establishments shall be made without undue delay, but no longer than 10 working days, after taking of a corresponding decision or receiving of a request in cases when no decision of the authorized body is required.

#### XIV. Final and transitional provisions

177. Entry into force of this Regulation does not change the status of establishments of the member-states and establishments of third countries in the Register of establishments of the Customs Union and the Register of establishments of third countries, respectively.

178. Prior to the launch of the IISFMT, which should support the functioning of the registers, the authorized bodies shall publish the registers, stated in paragraph 177 of this Regulation, on their official websites in the Internet.

179. The competent authority may appeal the conclusions reached following the audit of official system of control or inspection (control), if this competent authority has comments to the procedures followed by the inspectors-auditors or to the way their conclusions were reached. Such appeal shall be submitted to the authorized body of the member-state (member-states) and to the Commission. The authorized body and the Commission shall evaluate the appeal and possibly amend the conclusions within a reasonably short time period, generally not to exceed 6 months.

ANNEX No 1

To the On Regulation on common system of  
joint inspections  
of objects and sampling of goods (products),  
subject to veterinary control (supervision)

(form)

**Statement of Sampling**

No. \_\_\_\_\_ dated \_\_\_\_\_, 20\_\_

Regional (city) territorial subdivision of the department of the authorized body for  
\_\_\_\_\_ region (city)

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

Name of the moveable (transportable) object \_\_\_\_\_

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

I (we) \_\_\_\_\_  
(full name, position of the representative (s) of the authorized body carrying out sampling)

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

(specify position, full name of the representative (s) of the owner of the moveable (transportable) object, legal entity or full name of natural person)

have carried out inspection

\_\_\_\_\_ (name of the moveable (transportable) object )  
Lot size \_\_\_\_\_, delivery date \_\_\_\_\_  
(net weight, number of packages)

\_\_\_\_\_ (specify name, number of units and number of vehicles)

Accompanying documents

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

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

Products were manufactured \_\_\_\_\_  
(country of origin)

Shelf life, manufacturer, date of manufacture \_\_\_\_\_

Inspection results

\_\_\_\_\_ (appearance, smell, packaging integrity, correspondence to marking, temperature inside the product, etc.)

The ground for laboratory examination of products and fodders

\_\_\_\_\_ (under the procedure of scheduled inspection and supervision; suspicion of danger in veterinary relation, obtaining information on poor quality, violation of storage terms and conditions, in case of the owner of moveable (transportable) object)

Samples are selected at \_\_\_\_ hours \_\_\_\_ minutes

In accordance with

\_\_\_\_\_ (specify name of the document)

to the amount of \_\_\_\_\_, numbered and sealed \_\_\_\_\_

is/are directed to \_\_\_\_\_  
(specify name of the veterinary laboratory)

for \_\_\_\_\_  
(specify type of laboratory examination)

Date of sending samples \_\_\_\_\_

State veterinary and sanitary inspector performing sampling: \_\_\_\_\_  
(signature) (full name)

Owner of products or its representative: \_\_\_\_\_  
(signature) (full name)

Marks concerning receipt of samples: \_\_\_\_\_

Samples are accepted by: \_\_\_\_\_  
(signature, specify position, name of the veterinary laboratory specialist)

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

**Guidelines for Inspectors on Determining the Equivalency of Veterinary Measures Applied by Third Countries when Conducting Inspections of Objects Subject to Veterinary Control and Audit of Official Systems of Control of Third Countries**

The Guideline establishes procedures on determining the equivalence of veterinary measures, applied by third countries when conducting inspections of objects subject to veterinary control and audit of the official systems of control of a third countries and principles of actions taken by inspectors and experts of the competent authorities of the exporting countries.

Principles of actions taken by the inspectors throughout the assessment process:

Principle A. Assessments should be outcome focused, transparent, evidence-based and conducted in a cooperative, ethical and professional manner, respecting confidential information (where appropriate).

Principle B. The importing and exporting countries should have an agreed process to address any issues that may arise throughout the assessment process.

Principle C. The importing and exporting countries should agree on an appropriate tool for the conduct of the assessment prior to its commencement based on the agreed scope and objectives.

#### Principles of the assessment process

Principle D. The assessment process should be planned, systematic, transparent, consistent, fully documented and well communicated.

Principle E. The plan incorporating rationale, objective, scope, assessment tools and, requirements against which the exporting country's official inspection and certification system assessed should be identified by the importing country, notified to and agreed by the exporting country's competent authority(s), within a reasonable period prior to the commencement of the assessment.

#### Principles of reporting on assessment

Principle F. Agreed corrective actions, timeframes and follow-up verification procedures should be clearly established and documented.

Principle G. The final assessment report should be accurate and transparent and may be published respecting confidentiality of information, where appropriate.

#### Principle A

Assessments should be outcome focused, transparent, evidence-based and conducted in a cooperative, ethical and professional manner, respecting confidential information (where appropriate).

1. Inspectors and experts of the importing country's competent authority should be able to demonstrate that its assessment findings, conclusions and recommendations are primarily focused on whether the required outcomes are likely to be achieved by the system and that they are supported by objective evidence or data which can be verified as accurate and reliable.

2. Throughout the course of the assessment, all issues arising should be dealt with in a cooperative, ethical and professional manner by inspectors and experts of the competent authorities.

3. The importing country's inspectors and experts of the competent authority should ensure the impartiality. Inspectors and experts should have the appropriate qualifications, experience.

4. In conducting an assessment inspectors and experts should ensure that confidential information is protected.

#### Principle B

The importing and exporting countries should have an agreed process to address any issues that may arise throughout the assessment process.

5. Prior to the commencement of the assessment the key elements of a process to address issues that may arise throughout an assessment should be agreed. The authorized body of the importing and the competent authority of the exporting country should aim to resolve any issues which may arise in the course of the assessment in an open, transparent and cooperative manner. If any issues remain outstanding they should be indicated in the assessment report with appropriate justification.

#### Principle C

The authorized body of the importing and the competent authority of the exporting countries should agree on an appropriate tool for the conduct of the assessment prior to its commencement based on the agreed scope and objectives.

6. The most efficient and effective tool that can assess the effectiveness of the exporting country's state official system of inspection and certification system including the exporting country's competent authority(s) ability to organize and maintain control and deliver the required assurances to the importing country should be selected.

7. In selecting the assessment tool, it is important to consider the reason the assessment is being undertaken. For example, assessments can be part of a risk analysis prior to commencement of trade, they can assess the state official system of inspection and certification system, or controls for a particular element (e.g. chemical residues) or specific exporting establishments.

8. The importing country's experience, knowledge and confidence (Paragraphs 9-14 of the Appendix to the Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (CAC/GL 53-2003) provides additional guidance relating to what constitutes experience, knowledge and confidence and expands on information presented in paragraph 9-12 of that Guideline) in an exporting country's official inspection and certification systems, should be considered in selecting an assessment tool. 

#### Audit Tools

9. The audit tool ('systems based audit') should focus on assessing whether the implementation of the state official system of inspection and certification system or components thereof in operation in the exporting country is capable of meeting its objectives.

10. In contrast to the systems-based audits rely on the examination of a sample of system procedures, documents or records and, where required, a selection of sites within the scope of the system under audit, as opposed to examining all procedures.

11. A system-based approach focuses on the control system(s) and recognizes that any compliances/non-compliances found must be viewed in the context of the over-all system.

12. In conducting a systems-based audit, the audit may involve examination of the elements the legislative framework, controls, procedures, facilities, equipment, laboratories, transportation, communications, personnel and training to support the objectives of the inspection and certification programme or other elements as appropriate.

#### Inspection Method

13. The inspection method may be used in some instances to confirm the effectiveness of controls by the competent authority(s) in the exporting country.

14. Inspections may include the examination of:

- a) how establishments meet requirements, including review of specific activities and product specifications, observation and review of establishment operations and appropriate operating records;
- b) establishment's personnel capabilities, when specified in requirements;
- c) inspectors' capability, if specified in requirements.

#### Principle D

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

15. Documents supporting findings, conclusions and recommendations should be standardised as much as possible in order to make the performance of the assessment and the presentation of its outcome uniform, transparent and reliable.

16. Consultation should occur between the competent authorities of the importing and exporting countries at all points in the process, from developing the assessment plan through to final reporting and resolution of any issues arising during the assessment. To ensure ongoing and transparent communication the competent

authorities of the importing and exporting country should designate responsible contact persons or contact points for assessments.

#### Principle E

The plan incorporating the rationale, objective, scope, assessment tools and requirements against which the exporting country's official inspection and certification system is assessed, should be clearly identified by the importing country, notified to and agreed by the exporting country's competent authority(s), within a reasonable period of time prior to the commencement of the assessment.

17. When establishing the rationale, objective, scope, frequency of assessment and assessment tools, the importing country's competent authority should take into account the established level of experience, knowledge and confidence together with the history of previous assessments, the period since the last assessment and any other relevant factors.

18. A systematic evaluation procedure for undertaking the assessment should be used based on a predetermined and structured program consistent with the purpose of the assessment.

#### Notification

19. The following information should be exchanged during the initial request and prior to commencing an assessment of the exporting country's official state inspection and certification system with the authorized bodies of the importing country and competent bodies of the exporting country :

a) The rationale or need to conduct an assessment may arise from a number of reasons including, an importing country's legal obligations or the need to understand the respective roles of the competent authorities in both importing and exporting countries or the need to verify the capability of an exporting country's system or food production (processing) facilities to meet requirements.

b) The objective of the assessment (for example is: to verify that measures of the exporting country achieve the appropriate level of safety of the importing country). The risk assessment component of an exporting country's food control system may be audited where it is necessary to support a risk management approach.

c) The scope of the assessment (whether the assessment is to cover a whole system or its sub-components, measures, technical requirements, or products should be defined).

d) The assessment tool intended to be used including the requirements against which the official inspection and certification system of the exporting country will be assessed should be identified.

20. In all cases, the authorized body of the importing country should provide the competent body of the exporting country with sufficient notice of the intended assessment, in order to enable it to make the necessary arrangements such as logistics and information gathering. If the rationale for the assessment is a critical public health issue the advance notice should reflect the urgency related to the public health risk.

#### Assessment Preparation

21. A plan for undertaking the assessments, including the assessment tool, timeframes and exchange of required information should be prepared and communicated to the exporting country's competent authority within a reasonable period of time. The plan should include the following:

- a) objective and scope of the assessment including whether it is a stand-alone assessment or related to another assessment (e.g. follow-up of previous assessment) or series of assessments;
- b) items (elements) to be reviewed (undertaken) which may include records and assessment checklists;
- c) the anticipated timeframe within which the assessment will be conducted and reported;
- d) criteria against which the assessment of the exporting country's official inspection and certification system will be carried out;
- e) a contact person for the assessment team who can negotiate the details of the assessment plan and if required, assessment team members including foreign auditors/inspectors, the lead auditor (inspector), technical experts and translators;
- f) the language that will be utilised during the assessment including, translation, availability of impartial and knowledgeable interpretation and resources.
- g) an indication of the type or where possible (relevant) the identity of locations to be visited (e.g. offices, laboratories or other facilities) and the timing and responsibility for the notification to the sites (where necessary);
- h) the dates for the conduct of the assessment, the dates of the opening and closing meeting and the anticipated date for reporting the observations of the assessment;
- i) travel schedules and other logistics, as necessary for an assessment visit;
- j) provisions to protect confidential information.

22. While efforts should be made to adhere to the assessment plan it should be designed to be flexible in order to permit changes in emphasis based on information

gathered prior to, or during the assessment. Proposed significant amendments to the assessment plan should only be made in extenuating circumstances and should be communicated by the proposing competent authority to the other competent authority as soon as possible.

23. Advanced agreement should be reached on the language that will be utilised during the assessment including, translation, availability of impartial and knowledgeable interpretation and resources.

24. To the extent possible documentary information required for planning, conducting and completing the assessment should be requested and provided in advance of the assessment, utilizing electronic means wherever possible.

The assessment preparation request should be focused and related to the stated scope and objectives.

If this is a follow-up assessment, then the exporting country should only need to provide any information that has changed since the previous assessment or that has not been requested during a previous assessment.

In case the purpose of an information-request is not clear to the exporting country and (or) it has some issues related to the requested information, it may seek clarification from the importing country as to the purpose and use of such information.

When an on-site visit is the assessment tool proposed a review of documents describing the system including legislative support should be conducted prior to commencement of the assessment visit.

25. In some cases the assessment may be suspended or concluded prior to an on-site visit depending on the nature of information provided by the competent authority of the exporting country and in which case the reason should be communicated clearly to the competent authority of the exporting country by the authorized body of the importing country. The competent authority of the exporting country should have the opportunity to clarify the information provided should they consider this necessary.

#### Assessment Opening (Entry) Meeting

26. In the case of an assessment involving a visit an opening (entry meeting) should be held.

The meeting should be held at a place designated by the competent authority of the exporting country.

The meeting should review all aspects of the assessment plan including any final adjustments and is intended to provide an overview of the state system of

inspection and certification system of the exporting country and to confirm the parameters and logistics of the assessment.

Agreement should be reached on the methods to ensure continuous liaison and communications between the parties during the assessment.

#### Assessment Closing (Exit) Meeting

27. In the case of an assessment involving a visit a closing (exit) meeting should be held.

The meeting should be held at a place designated by the competent authority of the exporting country.

The assessment team should summarize and provide main findings and preliminary conclusions. Any non-conformities should be identified and outline the objective evidence to support the conclusions. Correction of non-conformities should be left to the competent authority of the exporting country and verified by the authorized body of the importing country including a follow-up assessment (if required).

This meeting provides an opportunity for the competent authority of the exporting country to raise questions or seek clarification of the findings and observations provided at the meeting.

#### Principle F

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

#### Principle G

The final assessment report should be accurate and transparent and may be published respecting confidentiality of information, where appropriate.

28. The exporting country assessed should have the opportunity to review the draft report in an agreed timeframe, provide comments and correct factual errors before its finalization. The final report should incorporate, or be accompanied by, the comments provided by the competent authority of the exporting country.

29. The report of assessment should provide a balanced picture of the findings and include conclusions and recommendations that accurately reflect those findings. It should:

- a) describe the objective, scope, and outcome;

- b) describe the criteria and assessment process;
- c) include assessment findings with supporting evidence for each conclusion, along with any details of significance discussed during the closing meeting;
- d) be made available as agreed to between the importing and exporting country's competent authorities, including and addressing the comments made by the competent authority of the exporting country to enhance the accuracy of the report;
- e) take into account the **timeframe for the finalisation of the report and response procedures** agreed upon between the authorized body of importing and the competent authority of the exporting country;
- f) include how corrective actions will be communicated and agreed to, including how follow-up verification will be completed;
- g) include any checklists of elements evaluated, to support the findings (where required);
- h) include a summary of the assessment outcome;
- i) include **outstanding matters** and issues arising during the assessment in the report if there is no agreement on the conclusions and the corresponding corrective actions;
- j) include **uncertainties and/or any obstacles** encountered that could affect the reliability of the assessment conclusion; and
- k) indicate any areas not covered in the assessment process, though within the scope, and the reasons for such deviation from the agreed scope.

30. The timeframe and protocol for any follow-up verification should be clearly stated. Verification of corrective actions may include:

- a) review of assurances provided by the competent authority of the exporting country;
- b) review of documentation provided by the competent authority of the exporting country; or
- c) review of stated corrective action in a subsequent assessment.

31. Confidential information must be respected in the preparation and subsequent distribution of the assessment report.

32. Once an assessment report has been finalised the competent authorities of the exporting country and the authorized body of the importing country should

discuss and if possible agree if and how any or all of the report will be published respecting confidentiality of information where appropriate.

Annex No. 3

To the Regulation on common system of joint inspections of facilities and sampling of goods (products), subject to veterinary control (supervision)

**GUIDELINES FOR INSPECTION OF FACILITIES SUBJECT TO VETERINARY CONTROL (SUPERVISION)**

**Section A. Guidelines for inspection of facilities and vessels for harvesting and processing of aquatic animals, including fish**

## I. GENERAL PROVISIONS

1. Present Guidelines establish approaches and principles of assessment of facilities and vessels for harvesting and processing of aquatic animals, including fish operating on the customs territory of the Customs Union and the third countries used in implementing their inspection.

2. Inspectors and experts from competent authorities at carrying out inspection of facilities and vessels for harvesting and processing of aquatic animals, including fish of the member-states of the Customs Union (hereinafter member-states) and third countries should be guided by the present Guidelines.

3. Establishments, vessels for harvesting and processing of aquatic animals, including fish operating of the member-states and the third countries are inspected for the compliance with the Customs Union requirements including based on equivalence principles in respect of establishments of third countries.

4. Using the criteria established by the Guidelines on Inspection of Facilities and Vessels for Harvesting and Processing of Aquatic Animals, including fish, the inspector shall determine whether the facility producing the aquatic animals, including fish reaches the appropriate safety level, established by the requirements of the Customs Union (as defined in Annex 2 to the Regulation on common system of joint inspections of objects and sampling of goods (products), subject to veterinary control (supervision)) and veterinary requirements of the member States, in cases when such requirements is not sat by the Customs Union normative legal acts.

5. Present Guidelines published in order to ensure accessibility and to facilitate fair practice development.

6. In present Guidelines following terms are used:

Risk analysis	process of collecting and evaluating information on hazards and conditions leading to their appearance, to make decisions that are important for food safety and, therefore, to be considered in the HACCP plan (Hazard Analysis and Critical Control Point) (in English transcription HACCP - Hazard Analysis and Critical Control Points);
Hazard Analysis and Critical Control Points (HACCP)	system which identifies, evaluates and controls the risks that are important for food safety
Biotoxins	means the toxic substance which naturally present in fish and fish products or accumulated by animals feeding on seaweeds that produce toxins, or in water containing toxins produced by organisms of such level.
Disinfection	reducing by chemicals and/or physical methods, the number of microorganisms in the environment to a level that does not compromise food safety and suitability
Defect	condition found in a product that does not meet essential terms of the quality, composition, and/or labeling of product according to relevant standards of the Codex Alimentarius

Contamination	bringing in or occurrence of contaminant in fish and other aquatic animals and their products
Contaminant	any biological or chemical agent, foreign substances, or other substances not intentionally added to a food product which may compromise food safety and suitability
Corrective action	an action that should be taken when the results of monitoring at the CCP (Critical Control Point) indicate a loss of control
Critical control point (CCP)	a stage at which control can be applied and is essential to prevent or eliminate the risk for food safety or reduce it to an acceptable level
Control measures	means any actions and activities that may be used to prevent or eliminate the risk of contamination of food products or reduce it to an acceptable level
Monitoring	action on carrying out planned sequence of observations or measurements of control parameters to assess whether a CCP (Critical Control Point) under control.
Facility	any facility where fish, other aquatic animals and their products are prepared, processed, cooled, frozen, packaged or stored
Hazard	presence of biological, chemical or physical substance in food product, or condition of food product that can cause adverse consequences for health
Chilling	cooling process of fish and other aquatic animals to a temperature close to the melting of ice
Chilled water	pure water cooled by a suitable cooling system
Cleaning	cleaning from soil, food residue, dirt, grease and other undesirable substances
Potable water	fresh water suitable for human consumption
Cut	the part of fish that remained from the decapitation and evisceration
Decomposition	a deterioration of fish, other aquatic animals and their products, including the laceration of texture and causing persistent and various unpleasant odors or tastes
Fish	any of the cold-blooded (ectothermic) aquatic vertebrates, except for amphibians and reptiles
Shelf-life	period during which the product remains microbiologically and chemically safe and <del>sensory quality</del> organoleptic characteristics at a certain temperature of storage. It is based on the identified hazards of the product, heat treatment or other procedures for the preservation, methods of packaging and other obstacles or factors that may be used

Raw materials	fresh and frozen fish, and other aquatic animals and/or parts thereof that can be used for manufacture of products intended for human consumption
Clean water	water from any source, where there are no harmful microbial contaminations, substances and/or toxic planktons in such quantities that could influence the health of fish and other aquatic animals, as well as safety of the products of their processing

## **II. DESIGN AND CONSTRUCTION OF VESSELS FOR HARVESTING AND PROCESSING OF AQUATIC ANIMALS, INCLUDING FISH**

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

1) possibility of easy cleaning and disinfection. Vessels should be designed and constructed:

to minimize sharp inside corners and projections in order to avoid dirt traps;

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

construction should facilitate ample drainage, as well as exclude counter and cross flows of raw material and edible fish product, as well as exclude counter and cross flows of edible fish products with processing waste;

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

2) to minimize contamination:

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

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

the intake for clean water should be located to avoid contamination;

all plumbing and waste lines should be capable of working under parameters indicative of peak demand;

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

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

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

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

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

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

3) to minimize damage to aquatic animals during processing:

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

the fishing gear and its usage should minimize damage and deterioration to aquatic animals;

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

chutes and conveyors should be designed to minimize mechanical damage of aquatic animals caused by long drops or crushing, etc.

4) to minimize damage during harvesting of aquacultured and aquatic invertebrates (aquacultured objects):

when harvesting aquaculture objects using seines and nets or other means and when transported live to facilities fishing facilities should be carefully selected to ensure minimum damage during harvesting and harvesting areas and all equipment for harvesting, catching, sorting, grading, conveying and transporting of live products shall ensure their rapid and efficient handling without causing mechanical damage;

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

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

where fish are stored or transported live, care should be taken to maintain factors that affect fish health (e.g. CO<sub>2</sub>, O<sub>2</sub>, temperature and nitrogenous wastes and maintaining optimal temperature, etc).

### **III. FISH FACILITY DESIGN AND CONSTRUCTION**

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

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

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

Organization and facility planning should done in a way to prevent product contamination and isolate "dirty" and "clean" zones.

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

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

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

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

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

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

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

1) possibility of easy cleaning and disinfection:

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

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

walls and partitions should have a smooth surface;

floors should be constructed at the correct angle to allow adequate drainage;

ceilings and overhead fixtures should be constructed and finished to minimize the buildup of dirt and condensation, and mechanical contamination by the shedding of particles;

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

doors should have smooth, non-absorbent surfaces;

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

2) to minimize contamination:

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

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

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

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

suitable and adequate facilities should be provided for storage and (or) production of ice;

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

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

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

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

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

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

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

separate and adequate facilities (areas) should be provided for storage of poisonous or harmful substances, dry storage of materials, packaging, etc., offal and waste materials with the purpose to prevent contamination with them;

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

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

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

3) to provide adequate lighting:

adequate lighting should be provided to all work surfaces.

#### **IV. DESIGN AND CONSTRUCTION OF EQUIPMENT AND UTENSILS**

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

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

1) sanitary cleaning and disinfection:

equipment should be durable and movable and (or) capable of being disassembled to allow for maintenance, sanitary cleaning and disinfection;

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

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

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

2) to minimize contamination:

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

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

adequate drainage should be provided in storage containers and equipment;

drainage should not be permitted to contaminate products.

3) to minimize damage:

surfaces should have a minimum of sharp corners and projections;

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

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

## **V. HYGIENE MAINTENANCE PROGRAM**

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

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

prevent the buildup or timely removal of waste and debris;

protect aquatic animals and their products from contamination and dirt;

dispose of any rejected material in a hygienic manner;

monitor personal hygiene of staff and check whether they comply with hygiene norms;

monitor the pest control programme;

monitor cleaning and disinfecting programs;

monitor the quality and safety of water and ice supplies.

The hygiene maintenance program should take into consideration the following:

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

2) a sanitation and disinfecting process may involve the following steps:

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

Pre-rinse - a 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 matters;

rinse - a rinsing with potable water or clean water (as appropriate), in order to remove all soil and detergent residues;

disinfection - application of chemicals, approved by the official agency having jurisdiction, and (or) heat in order to destroy most micro-organisms on surface;

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 fashion that would prevent their contamination;

4) check of the efficiency of the cleaning - the efficiency of the cleaning should be controlled as necessary;

5) handlers or cleaning personnel, as appropriate, should be well trained in the use of special cleaning tools and chemicals, and in methods of dismantling equipment in order to clean and they should be knowledgeable in terms of the significance of contamination and the hazards involved with poor quality implementation of cleaning and disinfection;

#### Designation of personnel for cleaning

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

6) maintenance of premises, equipment and utensils:

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

equipment, utensils and other physical facilities of the vessel should be kept clean and in good repair;

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

7) pest control systems:

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

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

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

8) Supply of water, ice and steam:

Water - there must be an adequate supply of hot and cold potable water and (or) clean water where it necessary. This potable water must be used whenever necessary to ensure that foodstuffs are not contaminated;

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

steam - for operations that require steam, an adequate supply at sufficient pressure should be maintained. Steam used in direct contact with fish and 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 waste materials should be removed from the fish processing premises or vessel on a regular basis;

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

vessel waste discharge should not contaminate vessel water intake systems or catch.

## **VI. PERSONAL HYGIENE AND HEALTH**

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

1) Facilities and equipment should include:

Adequate means of hygienically washing and drying hands;

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

2) Personnel hygiene:

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

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

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

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

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

immediately after using the toilet.

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

smoking;

spitting;

eating;

sneezing or coughing over unprotected food;

the adornment of personal effects, such as jewellery, watches or pins, or other items that can get into the products and might pose a threat to the safety and suitability of the products.

## **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 skill to enable them to handle aquatic animals in accordance with hygienic rules.

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

Each aquatic animals facility and vessels processing aquatic animals and their products should ensure that individuals have received adequate and appropriate training in the design and proper application of an HACCP (Hazard Analysis and Critical Control Point) system and process control.

Training of personnel in the use of HACCP (Hazard Analysis and Critical Control Point) is fundamental to the successful implementation and delivery of the program in aquatic animals processing establishments (vessels).

The practical application of such systems will be enhanced when the individual responsible for HACCP (Hazard Analysis and Critical Control Point) has successfully completed a course.

Managers should also arrange for adequate and periodic training of relevant employees in the facility so that they understand properly the principles involved in HACCP (Hazard Analysis and Critical Control Point).

## **VIII. GENERAL PROVISIONS FOR THE HANDLING OF FRESH AQUATIC ANIMALS**

If it is known that the shipment of aquatic animals or its part: contain parasites,  
infected by undesirable micro-organisms, contaminated with pesticides and veterinary drugs,  
contain premises of toxins contain decomposed substances,  
contaminated with substances that are known to be harmful for human consumption.

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

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

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

## **IX. TIME AND TEMPERATURE CONTROL**

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

Chilling is the most effective method for ensuring food safety of food products from aquatic animals. Therefore, it is essential that aquatic animals and their products to be chilled as quickly as possible and should be stored permanently at a temperature as close as possible to 0°C.

Minimum time before processing - is a guarantee to mitigate probability of deterioration

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

Permanent temperature control - is a means for preventing deterioration.

In the objective to ensure temperature control:

Chilled or refrigerated water systems, where appropriate, should ensure that fish and other aquatic animals are kept chilled at a temperature as close as possible to 0°C;

Fish and other aquatic animals should be stored in shallow containers and surrounded by finely divided melting ice;

Live fish and aquatic animals are to be transported at lower temperatures according to their biological species;

Chilled or refrigerated water systems equipment and (or) cold storage systems should be designed and maintained in a manner to provide adequate cooling even during peak loads;

Fish should not be stored in refrigerated water systems to a density that impairs its working efficiency;

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

## **X. SPARE HANDLING PRACTICIES – AS THE WAY TO MINIMIZE DETERIORATION**

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

To minimize handling damage by using the following practices:

while aquatic animals are kept on the deck the impact of unfavorable factors should be minimized in order to prevent unnecessary dehydrating;

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

Where fish and aquatic invertebrates are stored or transported live, care should be taken to maintain optimal indicators of the parameters that can influence their condition (e.g. concentration of CO<sub>2</sub>, O<sub>2</sub>, temperature and presence and quantity value of nitrogenous substances and etc.).

Fish and other aquatic animals should not be trampled or stood upon;

Where boxes (containers) are used for storage of fish and other aquatic animals, they should not be too deep, or overfilled, or stacked in a way that the upper boxes overpress the contents lower boxes;

Finely divided ice should be used where possible as its small pieces can help minimize damage to fish and aquatic animals and increase cooling capacity;

In refrigerated storage areas, that are cooled by water, the density of the fish should be controlled to prevent damage.

## **XI. PROCESSING OF FRESH FISH**

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

Potential hazards: decomposition, parasites, physical contamination.

Technical specifications for raw fish material could include the following:

organoleptic indicators, such as appearance, odour, texture and etc.;

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

microbiological indicators of raw materia, foreign materials;

physical characteristics (for example, size of fish);

Homogeneity of species in the lot.

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

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

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

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

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

#### Organoleptic evaluation of fish

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

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

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

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

#### 1) Chilled storage

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

Potential defects: decomposition, mechanical damage.

Technical guidance:

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

The facility (vessel) should be capable of maintaining the temperature of the fish between 0°C and 4°C;

for refrigerating containers, refrigerators, refrigerating rooms the possibility to measure temperature within the required time interval shall be provided.

Stock rotation plans should ensure proper utilization of raw material, products and materials for processing; The fish should be stored in shallow layers and surrounded by sufficient finely divided ice or with a mixture of ice and water before processing;

Fish should be stored such that damage from overstacking or overfilling of boxes will be prevented;

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

## 2) Defrostation Control.

Potential hazards: microbiological pathogens, toxins and histamine.

Potential defects: decomposition.

Technical guidance:

the defrostation method should be clearly defined and address the time and temperature of defrostation, temperature measuring instrument used and placement of device for measurement in a suitable way. The defrostation schedule (time and temperature parameters) should be carefully monitored.

Selection of the thawing method should take into account:

thickness and degree of heterogeneity of the products to be thawed depending on its size .

thawing time, temperature and fish temperature critical limits should be selected so as to control the development of micro-organisms and histamine (where high-risk species are concerned) and prevent of persistent objectionable odors or flavors indicative of decomposition;

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

Where recycling of water is used, care should be taken to avoid the buildup of micro-organisms;

Where water is used, circulation should be sufficient to produce even thawing;

During thawing, according to the method used, products should not be exposed to excessively high temperatures; Particular attention should be paid to controlling condensation and drip from the fish. Effective drainage should be ensured;

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

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

## 3) Washing and gutting

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

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

Gutting is considered complete when the intestinal tract and internal organs have been completely removed.

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

Sorting of whole fish should be done before gutting to remove foreign debris and reduce bacterial load;

gutted fish, to remove blood and viscera from the belly cavity;

surface of fish, to remove any loose scales, if necessary;

gutting equipment and utensils to be used in a proper way to minimize buildup of slime, blood and offal;

separate and proper equipped rooms to ensure storage for fish, roe, milts and livers, in case these are stored for further utilization.

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

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

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

Technical guidance:

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

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

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

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

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

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

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

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

## **XII. PROCESSING OF MINCED FISH**

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

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

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

Technical guidance:

The separator should be fed continuously but not excessively;

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

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

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

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

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

The separated residual material should be carefully removed on a continuous or near-continuous basis to the next processing stage;

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

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

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

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

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

### **XIII. FISH PROCESSING PRODUCED IN VACUUM PACKAGING OR PACKAGING WITH MODIFIED GAS ENVIRONMENT**

#### **1 Weighing**

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

#### **2 Vacuum or modified gas packaging**

Packaging process should be strictly controlled, the control should be performed in regards:

Volume of gas to product mass unit;

Types and gas ratio in applied gas mixture;

Types of tape used for packaging;

Type and integrity of seal;

Temperature of production during storage;

Making proper vacuum and proper packaging;

Control over the fact that the product was not in contact with area of joints;

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

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

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

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

### **XIV. PROCESSING OF FROZEN FISH**

#### **1 Freezing process:**

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

An optimal time and temperature regime for freezing should be established and should be taken into consideration the necessary parameters of freezing in freezing equipment and capacity, the nature of the fish product including thermal conductivity, thickness, shape and temperature and the volume of production. This regime should ensure that the range of temperature of maximum

crystallization is passed through as quickly as possible in order to minimize deterioration level of product structure by ice crystals;

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

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

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

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

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

Accurate records of all freezing operations should be kept;

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

## 2 Glazing:

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

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

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

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

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

## 3 Wrapping and packaging

Potential hazards: microbiological pathogens

Potential defects: subsequent dehydration, decomposition

Technical guidance:

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

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

Products should meet appropriate standards for labeling and weights.

#### 4 Storing in frozen condition

Potential hazards: microbiological pathogens, toxins, viable parasites

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

Technical guidance:

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

The refrigerating store should be equipped with a calibrated indicating thermometer with thermo register or should be provided other methods that allow continuous monitoring and recording of temperature;

A systematic stock rotation plan should be developed and maintained;

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

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

## **XI. TRANSPORTATION**

1. Vehicles should be designed and constructed considering the following:

- 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 necessary);

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

2. Transport means should ensure:

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

to provide the fish or other aquatic animals with protection against contamination, exposure to extreme temperatures and the drying effects of the sun or wind;

to permit the free flow of chilled air around the load when fitted with mechanical refrigeration means.

Guidelines to transportation (transfer) apply to sections XI-XIV. They are steps of the flow diagram that needs specific skills. Transportation should be considered with the same care as the other processing steps. This section provides examples of potential hazards and defects and describes technological guidelines that can be used to develop control measures and corrective actions.

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

### 3 Fresh, refrigerated and frozen products

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

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

Technical guidance:

Check temperature of product before loading;

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

Load in order to ensure a good air flow between product and wall, floor and roof panels;

load stabilizer devices are recommended;

It is necessary to monitor air temperatures inside the cargo hold during transportation; the use of a recording thermometer is recommended;

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

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

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

Transportation of fresh fish in containers with dry freezer bags and not ice should be considered where appropriate.

Where there is need to transport fish in ice suspension, chilled seawater, chilled seawater or refrigerated seawater (ice) should be used to ensure veterinary and sanitary safety with regard to transported fish;

Temperature during transportation of chilled products should be maintained at the temperature specified by technological process, but generally should not exceed 4°C;

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

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

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

## **Section B. Guidelines for inspection of dairy industry establishments**

### **I. General provisions**

1. Present Guidelines establish approaches and principles of assessment of milk and milk production establishments operating on the territory of the Customs Union and the third country in implementing their inspection.

2. Inspectors and experts from competent authorities at carrying out inspection of dairy industry establishments of the member states and third countries should be guided by the present Guidelines.

3. Dairy industry establishments operating on the territory of the member states and the third country are inspected for the compliance with the Customs Union requirements including based on equivalence principles.

4. Using the criteria established by the guidelines the inspector shall determine whether the dairy industry establishments reach the appropriate safety level, established by the requirements of the Customs Union (as defined in Annex 2 of to the Regulation on common system of joint inspections of objects and sampling of goods (products), subject to veterinary control (supervision)) and veterinary requirements of member States in cases when a such requirement is not sat by the Customs Union normative legal acts.

5. Present Guidelines published in order to ensure accessibility and to facilitate fair practice development.

6. In present Guidelines following terms are used:

Analysis of risks	a process consisting of three interconnected components: risk assessment, risk management and risk transfer;
Risk communication	interactive exchange of information and opinions throughout risk analysis process in respect of hazards and risks, risk-related and risk perception factors, among risk assessor, risk managers, consumers, feed and food industry establishments, academia and other stakeholders, including explanations of risk assessment findings and rationale for decisions on risk management;
Final consumer	a consumer of food products, which will not use the food product as part of any operations or activities of the food industry.

Processing	any action that substantially alters the initial product, including heating, smoking, curing, aging, drying, marinating, extraction, extrusion or combination of these processes
Processed foods	means food products which are result of <del>such</del> processing of unprocessed foods. These products may contain components which are necessary to manufacture them or give them specific properties.
Hazard	the presence of biological, chemical or physical substance in products, or condition of food product or feed that can cause adverse consequences for health;
Operator of food sector	means physical or legal person responsible for ensuring that the requirements of food law carried by the subjects of food sector which are under its supervision;
Risk assessment	means a scientifically based process consisting of four steps: hazard identification, hazard properties identification, impact assessment, and risk characterization;
Facility of food sector	any facility for profit or not, public or private, carrying out activities related to any stage of production, processing and distribution of food
Traceability	means ability to trace food, feed, animals giving animal food products or substances intended or planned to be included in food, as well as <del>œ</del> feed at all stages of production, processing and distribution;
Placing on market	placing the food for sale, including offering for sale or any other form of transfer (whether free or not) and sales, distribution and other forms of transfer;
Risk	a probability of adverse effects on health and the degree of this impact, which can lead to danger;
Retail trade	catering, including restaurants and other such public catering establishments, shops, distribution centers on supermarkets and wholesale trade;
Shelf life	period during which the product retains its microbiological safety and suitability within the specified storage temperature and, if necessary, specified storage and handling conditions
Stages of production, processing and distribution	any stage, including import, from the primary production of food down to its storage, transportation, sale or supply to the final consumer and, where relevant, importation, production, manufacture, storage, transportation, distribution, sale and supply of feed;
Raw milk	milk that has not been subjected to thermal treatment at a temperature higher than 40°C or processing which results changes of its components

Risk management	the process, different from risk assessment, which consists in determining the policy alternatives in consultation with stakeholders, considering risk assessment and other significant factors, and, if necessary selecting appropriate prevention and control measures.
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## **II. TRACEABILITY**

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

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

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

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

## **III. GENERAL HYGIENE RULES FOR FACILITIES**

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

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

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

2) Wall surfaces are to be maintained in a sound condition and be easy to clean and disinfect. This will require the use of impervious, non-absorbent, washable and non-toxic materials and require a smooth surface.

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

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

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

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

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

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

#### **IV. MILK AND DAIRY PRODUCT STORAGE AREAS**

Milk and dairy product storage areas are to be kept clean and maintained in good condition. The premises for product storage shall:

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

be such as to protect against the accumulation of dirt, contact of raw materials and products with toxic materials, the shedding of particles from the ceiling and the formation of condensation or undesirable mould (mould, the presence of which is not provided by the technological process) on surfaces;

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

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

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

Lavatories

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

Lavatories are to have adequate natural or mechanical ventilation.

#### Handwash sinks

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

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

#### Ventilation

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

#### Lighting

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

#### Drainage

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

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

#### Locker rooms

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

Locker rooms should be separated from lavatories.

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

Locker rooms should have abundant and well-distributed light.

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

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

## **V. EQUIPMENT**

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

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

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

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

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

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

## **VI. WATER SUPPLY**

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

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

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

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

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

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

## **VII. PERSONAL HYGIENE**

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

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

Conditions which should be reported to management so that any need for medical examination and (or) possible suspension from handling (processing) of food products can be considered, include jaundice, diarrhea (scour), vomiting, fever (temperature), sore throat, chill (shiver), visibly infected skin lesions (boils, cuts, etc.), unnatural discharges from the ear, eye or nose.

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

Personnel must wash their hands when personal hygiene may affect food products safety, for example: at the start of food handling (processing) activities;

immediately after using the toilet;

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

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

smoking;

spitting;

chewing or eating;

sneezing or coughing over unprotected food.

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

## **VIII. TRAINING**

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

Training programs should:

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

provide practical training to the extent required;

where necessary, arrange for testing of personnel;

ensure that personnel involved in supervisory roles have appropriate skills;

be certified and built on professional qualification requirements;

provide for continuing education of competent persons.

## **IX. HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP)**

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

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

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

The competent authority may choose to approve HACCP or HACCP like-systems plans and stipulate verification frequencies.

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

## **X. SANITATION STANDARD OPERATING PROCEDURES**

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

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

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

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

Characteristics of sanitation standard operating procedures (SSOPs) are:

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

designation by order of establishment personnel responsible for implementing and monitoring

SSOPs;

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

corrective actions that include appropriate disposition of products;

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

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

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

## **XI. RODENT AND INSECT CONTROL SYSTEMS**

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

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

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

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

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

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

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

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

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

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

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

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

## **XII. PRINCIPLES OF PRIMARY PROCESSING OF MILK**

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

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

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

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

Contamination of milk from biological or chemical agent of animal and environmental sources during primary production should be minimized at the initial stages of production (contaminant is any biological or chemical agent, foreign matter, or other substances not intentionally added to food which may compromise food safety or suitability).

The content of microorganisms-contaminants in milk should be kept as low as achievable, using good milk production practices, taking into account the technological requirements for subsequent processing.

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

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

### **XIII. MANAGEMENT OF PRODUCTION AT ESTABLISHMENTS**

#### **1 Acceptance of milk**

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

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

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

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

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

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

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

#### **3 Distribution and location of finished products**

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

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

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

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

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

#### **XIV. MANAGEMENT OF CONTROL MEASURES DURING AND AFTER HANDLING (PROCESSING)**

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

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

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

Ensuring the microbiological food safety are implemented by using appropriate selection of safety measures applied during primary production in combination with control measures applied during and after processing.

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

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

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

Individual safety measures should be selected and applied in such combination as to achieve a sufficient performance as to result in end products with acceptable levels of hazards.

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

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

Specific measures of ensuring the microbiological safety can be grouped according to primary function as follows:

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

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

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

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

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

Combination of microbiological safety measures.

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

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

The combination of safety measures has two main objectives:

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

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

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

The microbiostatic safety measures used should be adapted to the need related to the particular product in a particular situation.

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

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

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

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

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

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

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

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

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

## **XV. MICROBIOLOGICAL AND OTHER SUITABILITY INDICATORS OF RAW MATERIALS**

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

Other criteria, such as temperature, acidity, level of microbial and chemical contamination should be used to detect raw milk unacceptable for production.

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

rejection of the particular milk shipment for the production of raw milk products;

corrective actions on the milking procedure (cleaning and sanitation procedures of the milking equipment, cleaning or sanitation procedures of the udder, etc.);

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

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

change in livestock management practices;

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

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

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

Depending on the hazard analysis performed by the manufacturer and the combination of safety measures applied during and after processing of milk products, specific microbiological criteria may need to be established.

## **XVI. MICROBIOSTATIC CONTROL MEASURES**

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

Microbial growth is dependent upon many conditions in the organism's environment such as: ingredients, nutrients, water activity, pH, presence of preservatives, competitive microorganisms, gas atmosphere, redoxpotential, storage temperature and time.

Control of these conditions can therefore be used to limit, retard, or prevent microbial growth.

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

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

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

Examples of typical microbiostatic measures:

Carbon dioxide (CO <sub>2</sub> ):	The addition and (or) formation of carbonic acid as part of processing to obtain a multiple microbiostatic effect, including the creation of anaerobic conditions by replacing oxygen therewith, reducing pH, inhibiting certain intracellular enzymes (decarboxylation), and inhibiting the transport of watersoluble nutrients across the membrane (by dehydrating the cellular membrane). The efficiency depends mainly on the point of application. In ripened cheese, the emission of carbon dioxide from the cheese to the outside environment is often utilized to provide anaerobic conditions in the headspace of cheese packaging.
Coatings	The introduction of a physical barrier against microbial contamination, with or without antimicrobial substances implemented into it (immobilized) to obtain a slow migration of these from the surface.
Freezing:	The lowering of temperature below the freezing point of the product combined with a reduction of the water activity. Freezing has microbiostatic as well as microbiocidal effects.
Lactoferrins:	Retardation through the utilization of naturally present glycoproteins (highest concentration in colostrum) to prolong the lag phases of bacteria for 12-14 hours, by binding iron in the presence of bicarbonates.
Lactoperoxidase system:	The activation of the lactoperoxidase or thiocyanate or hydrogen peroxide system (indigenous system in milk) to inactivate several vital metabolic bacterial enzymes, consequently blocking their metabolism and ability to multiply.
Modified atmosphere:	The establishing of a gaseous environment (either low in oxygen and (or) high in carbon dioxide or nitrogen) to limit growth of aerobic microorganisms by impairing of biochemical mechanisms for exchange of bacterial cells. Modified atmosphere packaging (MAP) means that a modification of the gas atmosphere in the packaging is created. It is important to take into account that establishing anaerobic environment to limit growth of aerobic microorganisms may proliferate certain anaerobic pathogenic microorganisms.
Packaging:	Packaging provides a physical barrier that protects products against access of micro-organisms from the surroundings.
pH reduction	The creation of extra-cellular acid conditions that enables hydrogen ions to be imported into the cytoplasm of micro-organisms, thus disturbing the mechanism for maintaining constant intracellular pH responsible for maintaining functionality of key cell components vital for continuing growth and viability. Low pH values are obtained by fermentation or addition of acids (inorganic or organic). The pH value which is low enough for preventing growth depends on the pathogen, but lies typically between pH 4.0-5.0. Microorganisms become more sensitive to other antimicrobial measures at lower pH. Synergy occurs with salt, water activity, organic acids, the LP-system, and antimicrobial substances
Use of preservatives:	The addition of certain additives to enhance keeping quality and stability through direct or indirect antimicrobial and (or) fungicidal activity. Most preservatives are rather specific and have effect only on certain microorganisms.

Redox potential control:	The redox potential (Eh) is a quantitative measure of the oxidizing or reducing potential of food systems that determines whether aerobic or anaerobic microorganisms are able to grow. Eh is influenced by removal of oxygen and/or addition of reducing substances (e.g. ascorbic acid, sucrose, etc.).
Refrigeration:	The lowering of product temperature to limit microbial activity.
Time:	The practice of applying very short collection/storage periods, limiting the shelf life of products, or immediate processing of raw milk to ensure that all micro-organisms present are in the lag phase, and therefore not active and more susceptible to other antimicrobial measures.
Water activity control:	<p>The control of the water activity (aw) in the product (the accessibility of water for microorganisms, not the water content in the food), expressed as the ratio of water vapour pressure of the food to that of pure water. The aw value for preventing growth depends on the pathogen, but lies typically between 0.90 and 0.96. Water activity can be controlled by:</p> <ul style="list-style-type: none"> <li>• concentration, evaporation and drying, which also increase the buffering capacity of milk (synergy);</li> <li>• salting (addition of sodium chloride), which also reduces the cell resistance against carbon dioxide and in the solubility of oxygen (synergy);</li> </ul> <p>and</p> <ul style="list-style-type: none"> <li>• sweetening (addition of sugars), which at aw below 0.90-0.95 also results in an antimicrobial effect, depending on the type of sugar(synergy).</li> </ul>

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

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

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

#### Examples of typical microbiocidal measures

Centrifugation:	<p>The removal of microbial cells of high density from milk using high centrifugal forces.</p> <p>Most efficient against microbial cells of high density, notably bacterial</p>
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	spores and somatic cells
Commercial sterilization:	The application of heat at high temperatures for a time sufficient to render milk or milk products commercially sterile, thus resulting in products that are safe and microbiological stable at room temperature.
Competitive microflora:	The reduction of the number of undesirable micro-organisms by lowering the pH, consumption of nutrients, and production of bacterial antimicrobial substances (such as nisin, other bacteriocins and hydrogen peroxide). Usually, this microbiological measure is applied by choice of starter cultures. The efficiency is determined by many factors, including the speed, level of pH-reduction and variations in the pH level.
"Cooking" of cheese curd:	The application of heat to cheese curd, mainly for technical purposes. The heat treatment has a lower intensity than thermization but stresses micro-organisms to become more susceptible to other microbiological measures.
Electromagnetic energy - treatment:	Electromagnetic energy results from high voltage electrical fields, which alternate their frequency millions of times per second (< 10 <sup>8</sup> MHz). Examples are microwave energy (thermal effect), radio-frequency energy (non-thermal effects) or high electric field pulses (10-50 kV/cm, non-thermal effects). The treatment destroys cells by establishing pores in the cell walls due to the build up of electrical charges at the cell membrane.
High-pressure treatment:	Application of high hydrostatic pressures to irreversibly damage the membranes of vegetative cells.
Microfiltration:	Removal of bacteria, clumps and somatic cells by recirculation over a microfilter. Normally, a pore size of ~0.6-1.4 $\mu$ m is sufficient to separate most bacteria. Synergy in combination with heat treatment.
Pasteurization:	The application of heat to milk and liquid milk products aimed at reducing the number of any pathogenic micro-organisms to a level at which they do not constitute a significant health hazard
Pulsed high intensity - light:	The application of (on e.g. packaging material, equipment and water) high intensity broadband light pulses of wavelengths in the ultraviolet, visible and infrared spectrum (~20 000 times sunlight) to destroy micro-organisms. Due to the inability to penetrate intransparent substances, the technology is only effective against surfaces, for instance, in the removal of biofilm and can therefore prevent cross contamination
Ripening (ageing):	The holding for such time, at such temperature, and under such conditions as will result in the necessary biochemical and physical changes characterizing the cheese in question. When applied as a microbiocidal control measure, the multifactoral, complex system developing in cheese (pH, antagonistic flora, decreased water activity, metabolism of bacteriocins and organic acids) is utilized to influence the microenvironment in and on the food and consequently the composition of

	the microflora present.
Thermization:	The application to milk of a heat treatment of a lower intensity than pasteurization that aims at reducing the number of micro-organisms. A general reduction of log 3-4 can be expected. Micro-organisms surviving will be heat-stressed and become more vulnerable to subsequent microbiological measures.
Ultrasonication:	The application of high intensity ultrasound (18-500 MHz) that cause cycles of compression and expansion as well as cavitation in microbial cells. Implosion of microscopic bubbles generates spots with very high pressures and temperatures able to destroy cells. More effective when applied in combination with other microbiological safety measures. When applied at highertemperatures, the treatment is often referred to as "thermosonication".
Warm sealed packaging:	The application of heat (80 to 95 °C) to a solid end product in connection with the packaging process, for instance to maintain the product at a viscosity suitable for packaging. Such process can be done in a continuous flow system or in batch processes. The product is sealed at the packaging temperature and chilled for storage (distribution) purposes afterwards. When combined with low pH in the product, e.g. below 4.6, the warm sealed product may be commercially sterile as any surviving micro-organisms may not be able to grow. A supplementary microbiostatic measures is to ensure adequate cooling rates of packaged products to minimize potential for <i>B. cereus</i> growth.

## XVII. PASTEURIZATION OF MILK AND FLUID MILK PRODUCTS

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

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

Processing times necessary rapidly decrease with minimal increase in temperature. Extrapolation to temperatures outside the range of 63 to 72 °C, in particular, processing at temperatures above 72 °C must be treated with the utmost caution as the ability for them to be scientifically [validated] is beyond current experimental techniques.

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

To ensure that each particle is sufficiently heated, the milk flow in heat exchangers should be turbulent.

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

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

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

#### Verification of process

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

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

## **Section C. Guidelines for inspection of animal slaughter facilities and meat industry establishments**

### **I. GENERAL PROVISIONS**

a) Present Guidelines establish approaches and principles of assessment of animal slaughter facilities and meat industry establishments that carry out their activities in the third country and customs territory of the Customs Union.

b) Inspectors and experts from competent authorities of the member states at carrying out inspection of meat industry establishments of the Customs Union and third countries should be guided by present Guidelines.

c) Animal slaughter facilities and meat industry establishments of the member states of the Customs Union and third countries are inspected for the purposes of compliance with the requirements of the Customs Union, on the basis of, among others, the equivalency principle.

d) Using the criteria established by the Guidelines the inspector shall determine whether the slaughter facilities and meat industry establishments reach the appropriate safety level, established by the requirements of the Customs Union (as defined in Annex 2 of this Regulation) and veterinary requirements of member States in cases when such requirement is not sat by the Customs Union normative legal acts.

e) Present Guidelines published in order to ensure accessibility and to facilitate fair practice development.

f) In present Guidelines following terms are used:

Meat	slaughter product in the form of carcass or part of carcass, representing set of muscle, fat, connective tissues, with the inclusion of bone tissue or without
Analysis of risks	a process consisting of three interconnected components: risk assessment, risk management and risk transfer;
Internal organs (offal)	organs in thoracic, abdominal and pelvic cavities, and trachea and esophagus and in birds, animals
Domestic hooved animals	means domestic cattle (including buffalo and bison species), pigs, sheep and goats, as well as domestic solipeds
Mechanically separated meat or “MSM”	deboned meat in a pasty mass with a mass fraction of bone particles not more than 0.8 percent, obtained by separating muscle, connective and (or) adipose tissue (residual muscle, connective and (or) adipose tissue) from the bone by mechanical means without addition of non-meat ingredients
Contamination	presence or introduction of hazardous substance;
Risk communication	interactive exchange of information and opinions throughout risk analysis process in respect of hazards and risks, risk-related and risk perception factors, among risk assessor, risk managers, consumers, feed and food industry establishments, academia and other stakeholders, including explanations of risk assessment findings and rationale for decisions on risk management;
Final consumer	a final consumer of food products, which will not use the food product as part of any operations or activities of the food industry.
Meat by-products	products of slaughter in the form of internal organs, head, tail, limbs (parts thereof), trim meat, stripped of bruising, without serous membrane and surrounding tissues as well as skin and parts of the pigs between nipples
Meat products	processed products, obtained as a result of processing of meat or as a result of further processing of such processed products, so that the cut surface shows that the product no longer has the characteristics of fresh meat
Processing	any action that substantially alters the initial product, including heating (except for freezing and chilling), smoking, curing, aging, drying, marinating, extraction, extrusion or combination of these processes
Processed foods	food products obtained as a result of processing of unprocessed foods. These products may contain components necessary to produce them or give them specific properties.

Hazard	the presence of biological, chemical or physical substance in product or feed, or condition of food product or feed that can cause adverse consequences for health;
Facility of food sector	any facility for profit or not, public or private, carrying out activities related to any stage of production, processing and distribution of food
Operator of food sector	physical or legal person responsible for ensuring that the requirements of food law carried by the subjects of food sector which are under its supervision;
Risk assessment	a scientifically based process consisting of four steps: hazard identification, hazard properties, impact assessment, and risk characterization;
Traceability	ability to trace food, feed, animals giving food products or substance intended or planned to be included in food or feed at all stages of production, processing and distribution;
Bird	farmed birds, including birds that are not considered as domestic but which are risen as domestic animals, except for ratites
Placing on market	placing the food for sale, including offering for sale or any other form of transfer, whether free or not, and sales, distribution and other forms of transfer;
Risk	a function of probability of adverse effects on health and the degree of this impact, which can lead to danger;
Retail trade	catering, including restaurants and other such public catering establishments, shops, distribution centers on supermarkets and wholesale trade;
Chopped meat	meat with bones that has been minced into fragments
Fresh meat	meat that has not undergone a preservation process except chilling, freezing or quick-freezing, including meat that is packed in vacuum or packed in controlled atmosphere.
Risk management	means the process, different from risk assessment, which consists in determining the policy alternatives in consultation with stakeholders, considering risk assessment and other significant factors, and, if necessary selecting appropriate prevention and control measures;
Stages of production, processing and distribution	any stage, including import, from the primary production of food down to its storage, transportation, sale or supply to the final consumer and, where relevant, importation, production, manufacture, storage, transportation, distribution, sale and supply of feed;
Carcass	body of an animal after slaughter and dressing
Packaging	placing food product into package or container in direct contact with

	food product, and wrapper or container itself;
Meat cutting workshop	means facility used for boning and / or cutting meat.

## **II. TRACEABILITY**

The traceability of meat and meat products shall be established at all stages of production, processing and distribution.

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

Slaughterhouses and meat industry establishments shall have in place systems and procedures to identify other entities, to which their meat and meat products have been supplied. This information shall be made available to the competent authorities on demand.

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

## **III. GENERAL RULES OF HYGIENE FOR PRODUCTION FACILITIES OF SLAUGHTERHOUSES AND MEAT INDUSTRY ESTABLISHMENTS**

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

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

### **FLOOR SURFACE**

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

### **DRAINS**

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

## **WALL SURFACES**

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

## **CEILINGS**

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

## **WINDOWS**

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

## **DOORS**

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

## **SURFACES**

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

## **WATER SUPPLY**

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

## **IV. PREMISES OF SLAUGHTERHOUSES AND MEAT INDUSTRY ESTABLISHMENTS**

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

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

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

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

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

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

### **LAVATORIES**

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

### **HANDWASH SINKS**

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

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

### **VENTILATION**

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

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

Sanitary conveniences are to have adequate natural or mechanical ventilation.

### **LIGHTING**

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

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

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

### **DRAINAGE**

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

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

### **LOCKER ROOMS**

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

Locker rooms should be separated from the toilet area.

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

Locker rooms should have good lightning.

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

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

## **V. EQUIPMENT**

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

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

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

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

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

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

## **VI. WATER SUPPLY**

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

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

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

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

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

## **VII. PERSONAL HYGIENE**

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

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

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

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

Management decides on the need for a medical examination and (or) possible removal of the patient from the treatment of food products on the basis of his health status.

Personnel shall always wash hands, if it can affect the safety of meat and meat products, for example:

Getting to the processing of meat and meat products;

immediately after using the restroom;

After contact with the raw food or any contaminated material, if it may lead to contamination of other foods, employees must be avoided the processing of ready to eat food.

During operation, the persons involved in the handling of meat and meat products must not:

smoke;

expectorate;

chew or eat food;

sneeze or cough near unprotected (uncovered) food.

It is prohibited to carry or wear personal items such as jewelry, watches, pins and other items in the places of meat and meat products processing.

## **VIII. PERSONNEL TRAINING**

The control points of animal slaughter and meat processing plants should provide supervision, instruction and (or) training in food hygiene to persons engaged in the processing of meat and meat products, depending on the nature of the work performed by them;

Training programs shall:

provide staff training, knowledge, skills and ability to perform specific tasks related to hygiene when working with meat products, for example, a post-mortem examination, verification of statistical process control, HACCP;

in the right amount to provide practical training;

organize a formal testing of employees, if necessary;

ensure that employees involved in the learning process, have the appropriate skills;

be directed to the recognition and professional development of staff;

## IX. HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP)

HACCP system for the production of meat and meat products are effective management scheme of processing for the safety of meat and meat products.

Checking the HACCP plan concerning meat and meat products must ensure the effectiveness of the execution of technical requirements and technical criteria, taking into account the degree of variability in the presence of risk factors that are usually associated with many different animals presented for study.

The frequency of inspections may vary depending on the operational aspects of process control, the historical indicators of the enterprise on the application of HACCP plan and the results of the inspection itself.

It is recommended to use microbiological tests to verify the HACCP system, for example, testing the critical limits and statistical process control are important features of HACCP in respect of many products.

Guidelines vary depending on the type of processing, for example:

Raw, chopped or shredded, such as pork sausage;

Meat with secondary inhibitors / not suitable for long-term storage, such as corned jerked beef;

Heat treated / not fully ready, not suitable for long-term storage, such as burgers, semi-finished products;

Fully ready / not suitable for long-term storage, such as cooked ham;

Not treated thermally / suitable for long-term storage, for example dry salami;

Heat treated / suitable for long-term storage, for example, beef jerky;

Thermally processed / commercially sterile, such as canned meat.

In the development of HACCP plans for thermally processed meat semi-products and meat products, managers of slaughter facility and meat processing plants must keep complete documentation, in accordance with the requirements for the process, with respect to all thermal parameters of the process, post-heat treatment, and additional canning, depending on the desired result of the process, such as pasteurized product. Technological parameters for cooling the heat-treated meat products may include fast, slow or intermittent cooling depending on the product. Previously heated meat products shall not be packaged at a temperature higher than the minimum, for example, 4 ° C, if there is no way to prove that cooling after packaging does not put a threat the safety of the product.

HACCP plans for meat semi-products and meat products that have undergone preparation should include the monitoring and documentation of the parameters with which the compliance with internal temperature is reached.

## **X. SANITATION STANDARD OPERATION PRUCEDURES**

Set of standard sanitary procedures (SSOP), relating to the activity and the preparation for it, is designed to minimize the direct and indirect contamination of the meat as possible from a practical point of view. A properly implemented SSOP system must provide cleaning and disinfection of equipment and material-technical base to start work, and good hygiene during work. SSSP aids are provided by competent authority, and may contain minimum regulatory requirements for general improvement of sanitary condition.

The characteristics of the SSOP are:

Improvement of SSOP written program by description of procedures and frequency of their use by slaughter facility or meat processing plants;

establishment of workers of slaughter facility and meat processing plants responsible for performance and control of SSOP;

record-keeping and monitoring corrective and (or) preventive actions that are not accessible to the competent authority conducting the inspection;

elimination of defects, including appropriate product placement;

periodic assessment of the effectiveness of the control points of animals slaughter and meat processing plants.

Microbiological testing of SSOP should provide a number of direct and indirect methods. The control points of slaughter or meat processing plants should apply statistical process control or other methods of monitoring sanitary state.

For products, ready-to-eat, microbiological testing SSOP of surfaces in contact or not in contact with food should be conducted with more care than for any other product.

## **XI. METHODS OF PEST CONTROL**

Rodents pose a greater threat to the safety and suitability of food. In their breeding and feeding places there is a high probability of infection. Maintaining hygiene at the proper level is designed to prevent the formation of an environment conducive to rodents.

Slaughter facility and meat processing plants must be maintained in a condition to prevent pest occurrence and breeding sites. All holes where rodents can enter, should be sealed. Wire netting installed on open windows, doors and ventilation systems designed to reduce the possibility of penetration of pests. If possible, exclude the possibility of pets' occurrence on the territory of slaughter facility or meat processing plants.

The presence of water and food increases the risk of pests and diseases caused by them. Potential sources of food shall be stored in containers protected from rodents and (or) away from the floor and walls. Premises related to food, must be kept clean, both inside and outside. If possible, food wastes shall be stored in closed containers, protected from rodents.

Points of animal slaughter, meat processing plants and the surrounding areas shall be regularly inspected for rodents. Rodents should be eliminated immediately, without causing harm to the safety and suitability of meat and meat products.

## **XII. INFORMATION CONCERNING THE FOOD CHAIN**

Managers of animal slaughter facility and meat processing plants are required, depending on the need, to request for information, collect, verify and process the information on the food chain as defined in this section, in respect of all animals, except game animals, sent or intended to send to slaughter facility or meat processing plants.

Managers of animal slaughter facilities and meat processing plants should be informed in advance – before the arrival of the animals to the slaughter facility without prejudice of the rules of slaughtering of the animals of this specie applied in the third country.

Relevant information concerning the food chain includes, in particular:

the status of the establishment of animal origin or the state of animal health in the region;  
animal health;

veterinary medicinal agents or other therapeutic agents that have been applied to animals in a relevant period, specifying the date of application and periods of expectation (for animal slaughter facilities);

presence of diseases that may affect the safety of meat;

if it is important for public health, the results of analyzes carried out on samples taken from animals or other samples taken to determine the diagnosis of diseases that may affect the safety of meat, including samples taken under monitoring and control of zoonoses and residues;

relevant reports relating to prior pre-slaughter and post-mortem studies of animals from the same establishment of origin, including, in particular, reports of an official veterinarian;

date of inspection, if it can indicate the presence of disease;

name and address of the private veterinarian who performs the daily control of the establishment of origin.

If the subject, managing slaughter point of animals already has this information (for example, as a result of a continuous contract or through a quality assurance system), then there is no need to provide a subject managing slaughter point of animals, the following information:

the status of the establishment of origin or the state of animal health in the region;  
animal health;

relevant reports relating to prior pre-slaughter and post-mortem studies of animals from the same establishment of origin, including, in particular, reports of an official veterinarian;

name and address of the private veterinarian who performs the daily control of the establishment of origin.

The information must not be provided in the form of a verbatim extract from the register of the establishment of origin of animals. It may be provided through exchange of information electronically or as a typical application, signed by the manufacturer.

Managers who make a decision on the admission of animals to slaughter facilities or meat processing enterprises, after making the assessment of relevant information concerning the food chain, are required to provide this information to the official veterinarian immediately, not later or in time before the arrival of the animal or batch of animals. Managers of animal slaughter facilities and meat processing plants before the slaughter of animals must provide the official veterinarian with all information that could be a cause of concern for health.

In case of the arrival of animal at the slaughter without information on the food chain, manager must immediately notify the official veterinarian. It is prohibited to expose the animal to slaughter without prior consent of official doctor.

If the competent authority has granted permission, information regarding the food chain, may accompany the animals to which it relates to slaughter facility or shall be delivered in advance – before arrival of animals to slaughter facility without prejudice to the rules of this type of slaughter in a third country. Managers of animal slaughter facility and meat processing plants must have access to any information relevant to the food chain, which could lead to serious problem in slaughter facility, in a sufficient period before the arrival of animals at slaughter facility to make appropriate adjustments to working plan. It is prohibited to expose animals to slaughter or gutting without the prior consent of official veterinarian.

The managers of animal slaughter facility and meat processing plants must check the veterinary documents accompanying animals bred in farms in order to make sure that the animal is intended for slaughter for human consumption. In case of accepting an animal for slaughter, the manager shall pass the passport to official veterinarian.

### **XIII. TRANSPORTATION OF LIVE ANIMALS TO ANIMAL SLAUGHTER FACILITY OR MEAT PROCESSING ENTERPRISES**

During the reception and transportation, animals shall be handled carefully without causing them undue physical pain.

Animals with symptoms of the disease or animals that originate from herds that have been infected by agents, important to public health, are admitted for transportation to slaughter facility or meat processing enterprises only with the approval of competent authority.

### **XIV. ANIMAL SLAUGHTER FACILITY AND MEAT PROCESSING ENTERPRISES**

Slaughter facility and meat processing plant must have hygienic places of animal stay or if the climate permits, pens for animals that can be easily cleaned and disinfected. These objects

should be provided with equipment for watering animals, and if necessary for feeding them. Sewage system should not pose a risk for meat and meat products.

Slaughter facility and meat processing plant must be equipped with separate space, and access to which shall be restricted for sick animals or suspected animals in order to prevent possible spread of an infection.

The size of animal stay must provide good conditions for animal welfare. Their layout shall facilitate pre - slaughter research, including the identification of animals or groups of animals.

In order to prevent contamination of meat, animal slaughter facility and meat processing enterprises shall:

have a sufficient number of premises suitable for the performance of certain actions;

have separate rooms for emptying, cleaning stomachs and intestines, if only the competent authority will not issue a permission for a specific enterprise to separate these activities by periods in the manner of individual cases;

provide separate places, and time division of the following actions:

stunning and bleeding;

scalding, dehairing, scraping, singeing (for pigs);

gutting and further purification;

processing of pure guts and scars;

pre-treatment and cleaning of other offal, particularly processing of dressed heads if it is not performed on slaughter line;

group packing of offal;

dispatch of meat;

availability of devices that prevent contact of the meat with the floor, walls and equipment;

have appropriately designed slaughter lines (where they are used), providing a constant advancement of slaughter process and prevention of cross-contamination of different parts of slaughter line. If the same premises have several slaughter lines, it is necessary to ensure proper separation of slaughter lines in order to prevent cross-contamination.

Slaughter facilities or meat processing plants must be equipped to carry out disinfection, with hot water, or with an alternative system.

Hand-washing facilities for workers who contact with unpackaged meat must be properly designed, in order to prevent the spread of contamination.

Slaughter facilities or meat processing plants must have the premises locked with key, cold rooms for storage of meat left and separate cold rooms for storage of meat declared as unsuitable for human consumption.

Slaughter facilities or meat processing plants must have the appropriate areas for washing and disinfection of vehicles carrying slaughter animals. This rule does not apply with the approval of the competent authority, if near the point of animal slaughter in official order act the appropriate equipment and special spaces for this purpose are provided.

Slaughter facilities or meat processing plants must have the a separate premises for the slaughtering of sick and suspected animals access to which shall be restricted unless another place (establishment) officially approved for slaughtering of such animals.

If in the slaughter facility or meat processing plants is stored manure or contents of gastrointestinal tract, for this purpose there shall be allocated a special place or area.

Slaughter facility or meat processing plants must have properly equipped, lockable place or, if necessary, a room for the exclusive use of veterinary services.

## **XV. ANIMAL SLAUGHTER HYGIENE**

Managers of animal slaughter facility and meat processing plants, on which the slaughter of ungulates bred in farms is carried out, shall ensure the compliance with the following requirements.

After the arrival of animals to animal slaughter facility, it is prohibited to delay their slaughter without justified reasons. However, prior to slaughter of animals there should be given time to rest, if such need arises for reasons of their well-being.

The meat of animals cannot be used for human consumption if such animals were not exposed to slaughter in animal slaughter facility or meat processing enterprises.

Slaughter facility or meat processing plants must accept only live animals, assigned for slaughter.

Meat of animals exposed to slaughter in slaughter facility or meat processing enterprises as a result of an accident can be used for human consumption, if the study did not identify serious injuries except occurred in the result of accidents.

Animals or, if necessary, each batch of animals to be slaughtered shall be identified in such a way as to allow determination of their origin.

Animals must be clean.

Managers of slaughter facility and meat processing plants are obliged to follow the directions given by a veterinarian and designated by a competent authority.

Animals entered in the slaughter facilities should be immediately subjected to slaughter.

Stunning, bleeding, dressing, gutting and cleaning shall be carried out without delays and in such a way as to prevent contamination of meat. In particular:

in the process of bleeding the trachea and esophagus shall not be damaged, except the cases where the slaughter is carried out in accordance with the ritual religious ceremony;

in the process of removal of hides and wool:

prevent contact between the outer cover of hides and carcasses of animal;

persons contacting with the outer cover of hides and wool of animal should not touch the meat;

it is necessary to take precautions to avoid pouring the contents of the gastrointestinal tract during and after evisceration and to ensure that evisceration is made as soon as possible after stunning;

upon removing the udder prevent contamination of carcasses with milk or fore milk.

Carcasses and other parts of the body intended for human consumption must be exposed to the full dressing, except pigs, as well as heads and legs of sheep, goats and calves.

Heads, including the lips and muzzle, feet must be treated in such a way as to prevent contamination of residual meat.

Undressed pigs shall be immediately dehaired. It is necessary to minimize the risk of contamination of the meat with water used for scalding. Then the pigs shall be washed thoroughly with potable water.

Carcasses shall not have visible contamination by wastes. Any kind of visible contaminations shall be immediately removed by boning or using alternative means giving equivalent results.

Carcasses and pelts must not contact with floors, walls or working places.

Managers of animal slaughter facility and meat processing plants must follow the directions of the competent authority in order to ensure appropriate conditions for carrying out post-mortem examination of all animals subjected to slaughter.

Prior to the date of the post-mortem study, parts of animals to be slaughtered and intended for such a study, must:

be identifiable as belonging to a given carcass;

must not contact with any other carcass, offal or purtenance, including those which have been subjected to post-mortem investigation.

however, the penis, in male animals, may be removed immediately, provided that it does not reveal any pathological changes.

Both kidneys must be removed from fat layer. As for cattle, pigs and one-hoofed animals, perirenal bag cannot be removed.

If blood or other wastes of several animals congregate in the same tank before the post-mortem studies, and the carcass of one or more of these animals have been declared as unsuitable for human consumption, the entire content of such tank is declared as unsuitable for human consumption.

After the post-mortem investigation:

tonsils of cattle and one-hoofed animals must be removed in accordance with hygiene requirements;

parts unsuitable for human consumption must be removed as quickly as possible from the clean sector of animal slaughter point and meat processing plant;

abandoned or declared as unsuitable for human consumption meat and inedible by-products must not contact with meat declared as suitable for human consumption;

viscera or parts of viscera remaining in the carcass, except kidneys, must be removed completely and as quickly as possible, unless the competent authorities will not give permission to do otherwise.

After the post-mortem studies the meat shall be immediately cooled in slaughter facility.

In case of destination for further processing:

stomachs must be scalded or cleaned;

intestines must be emptied and cleaned;

heads and feet must be dressed or scalded and remove them from the wool.

In case if animal slaughter point and meat processing plant received the approval in respect of the slaughter of different animal species or for processing carcasses of wild animals kept by a man, as well as game animals, it is necessary to take measures that prevent cross-contamination by provision of separate premises and time division of operations carried out in various forms. There shall be available separate equipment for receiving and storing undressed carcasses of wild animals kept by man that have been slaughtered in establishment, as well as the carcasses of game animals.

If slaughter facility has not locked with a key equipment provided for the slaughter of sick or suspected animals, the equipment used for the slaughter of such animals shall be cleaned, washed and identified under official supervision before proceeding to the slaughter of other animals.

It is allowed to hack the carcass of hoofed animals bred in farms to half or quarter carcasses, and half carcasses - no more than three parts. Further cutting and separation of bones from the carcass are permitted only on meat cutting.

## **XVI. DEVICES TO CUT MEAT**

All items, fittings and equipment with which products are in contact must be:

- effectively cleaned and , if necessary, disinfected. Cleaning and disinfection should take place at a frequency sufficient to avoid any risk of contamination;
- Constructed of materials and be kept in condition that minimize any risk of contamination;

- except for non-returnable packaging, constructed from materials and kept in condition, in which they can be kept clean and, if necessary, disinfecting;
- installed in such a manner as to allow adequate cleaning of the equipment and the surrounding area.

If necessary, equipment must be fitted with any appropriate control device.

In the case of the use of chemical additives to prevent corrosion of equipment and containers, they should be used in accordance with good practice (manufacturer's instructions).

## **XVII. COMPLIANCE WITH HYGIENE IN THE PROCESS OF CUTTING AND DEBONING**

Slaughter facility and meat processing plant must ensure the compliance with following requirements under cutting and deboning the meat of domestic ungulates:

the work with meat and meat products shall be organized in such a way as to prevent or minimize contamination.

there must be sufficient ventilation to prevent condensation of moisture on meat surface in the process of cooling.

meat intended for cutting is brought to workshops in consignments as needed;

all processes of cutting, deboning, trimming and packaging have to be under low temperature to prevent growth of microorganisms or have to be used another actions leading to the same result,

If the premises are approved for cutting of meat of different animal species, precautions must be taken to avoid cross-contamination by separating operations for different types on sites, and time.

Meat can also be dressed and sliced without intermediate cooling if the space for cutting is on the same site as space for slaughter. In this case, the meat must be transferred to cutting site directly after slaughter or after a waiting period in refrigeration chamber.

If the meat is packaged:

packaging material must be suitable for use, storage in accordance with hygiene standards;

wrappers or cartons shall have appropriate internal layer or other means to protect the meat, except the cases where the inner protective layer or other protection is not required if the pieces of meat, such as cuts are individually wrapped before packing.

Cooling and freezing is carried out in accordance with technological instructions.

## **XVIII. STORAGE AND TRANSPORTATION OF THE MEAT**

Due to the potential for growth of pathogenic and spoilage micro-organisms under conditions of inadequate temperature control, meat should be transported at temperatures that achieve safety and suitability objectives. Equipment for continuous monitoring and recording of temperatures should accompany transport vehicles and bulk containers wherever appropriate. Additionally, the conditions of transport should provide adequate protection from exogenous contamination and damage, and should minimize growth of pathogenic and spoilage micro-organisms. Moreover, the conditions of transportation shall provide adequate protection against external contamination and damage, and must reduce the growth of pathogenic and spoilage microorganisms.

Meat intended for freezing must be frozen without undue delay, taking into account stabilization period before freezing.

Unpackaged meat must be stored and transported separately from packaged meat, otherwise the packaging material and the method of storage or transportation shall not be source of meat contamination.

#### **XIX. MINCED MEAT, MEAT PREPARATIONS AND MECHANICALLY SEPARATED MEAT (MSM)**

Slaughter facility and food industry enterprises on production of minced meat, meat preparations or mechanically separated meat must ensure that they:

are constructed in such a way as to avoid contamination of meat and products, in particular allow continued change of operations;  
separation between the different production batches;

have separate storage premises for packaged and unpackaged meat and meat products only they are stored at different time or in such a way that the packaging material and the method of storage do not contaminate the meat;

have equipment for washing hands designed to prevent the spread of infection, used by personnel involved in processing of unpackaged meat and products;

have premises for disinfecting instruments with hot water supplied or an alternative system with the same effect.

Definition of mechanically separated meat (MSM) should be common, which covers all methods of mechanical deboning. Technological developments in this area mean that a flexible approach to this definition is required . Technical requirements for MSM shall differ depending on a risk assessment of the product by various methods.

When production of minced meat and meat preparations:

frozen or quick-frozen meat used for the preparation of minced meat or meat preparations must be boned before freezing. It can be stored for a limited period.

For MSM produced using methods which do not alter bone structure used in manufacturing MSM, and calcium in MSM which is not significantly higher than the minced meat, the following applies:

Raw materials for manufacturing of MSM It can be stored for a limited period to prevent growth of microorganisms.

Mechanical separation must be carried out immediately after deboning.

If MSM not used immediately after preparation, it has to be packaged and then cooled or frozen to prevent growth of microorganisms. Appropriate temperature requirements must be maintained during storage and transportation.

If the food industry enterprise has made an analysis, showing that MSM meets the microbiological criteria for minced meat, it can be used in meat preparations that are clearly not intended for consumption without prior heat treatment, and meat products. (MSM that does not meet these criteria can only be used for the production of heat-treated meat products in approved establishments).

Meat with bones obtained from the frozen carcasses shall not be re-frozen.

If not used within one hour after production, meat with bones shall be cooled.

If, after cooling MSM is not planned to be processed within 24 hours, it shall be frozen as soon as possible, but no later 12 hours, to prevent growth of microorganisms.

Frozen MSM shall be packaged before storage or transportation.

MSM is used only for the production of heat-treated meat products in approved establishments.

Minced meat, meat preparations and MSM shall not be re-frozen after thawing.

Packages intended for delivery to ultimate consumer, with minced of poultry or ne-hoofed animals or meat preparations containing MSM shall have a label that such products must be cooked before consumption.

Storage conditions of meat preparations and meat products must be clearly indicated on the package.

The work associated with meat shall be organized in such a way as to prevent or minimize infection.

Raw materials used to prepare minced meat must meet the following requirements:

it must comply with requirements for fresh meat;

it must be produced from skeletal muscle, including adipose tissue;

it must not be produced from:

wastes from cutting and trimming (except whole muscle cut);

MSM;

meat containing a bone or part of the skin;

meat of the head (except masticatory muscles), the muscle is not part of the white line of the abdomen, the wrist and the tarsus, bone scrapings and the muscles of the diaphragm (if serosa is not removed).

The following materials can be used for the preparation of meat preparations:

fresh meat;

meat that complies with requirements for raw materials used for minced meat.

If the meat products are not intended for consumption without prior heat treatment, for their production can be used:

meat obtained from cutting or grinding that comply with requirements for raw material used for minced meat, except wastes of cutting and trimming (other than a whole piece of muscle);

MSM, if food establishments analyzed that MSM in compliance with microbiological requirements for minced meat.

Raw materials used for the production of MSM must comply with requirements for fresh meat.

The following materials must not be used for the production of MSM:

Poultry: the legs, neck skin and head;

from other animals: the bones of the head, legs, tails, femur, tibias, humerus, radius and ulna.

## **XX. MEAT PRODUCTS**

The enterprise shall ensure that as a raw material derived from animals in the preparation of meat products are not used:

genitals of male or female animals, except testicles;

urogenital organs, except kidneys and the bladder;

cartilage of larynx, trachea and extralobar bronchi;

eyes and eyelids;

the external auditory meatus;

horn tissue;

the establishment shall ensure that in the preparation of meat products as raw material, obtained from poultry, are not used: the head (except the comb, the ears, earrings), esophagus, goiter, intestines and genitals.

All meat and meat products, including minced meat and meat preparations used to produce meat products must shall comply with requirements for fresh meat.

## **XXI. LABELING OF MEAT**

The labeling of meat shall be done only after animal have undergone ante-mortem inspection and meat post-mortem inspection and when there are no grounds for declaring the meat unfit for human consumption.

The labeling takes place on the external surface of the carcasses, by stamping the mark in ink or hot branding, and in such a manner that, if carcasses are cut into half carcasses or quarters, or half carcasses are cut into three pieces, each piece bears a health mark.

The colours used for health marking must be authorised in accordance with rules on the use of colouring substances in foodstuffs.

## **XXII. SPECIFIC RISK MATERIALS**

Specific risk materials must be denatured or painted immediately after the removal, with later disposal.

Specified risk materials must be disposed of animal slaughter facility, or if necessary in other places of slaughter or in enterprises on butchering, if it comes to the spines of cattle;

## **XXIII. FREQUENCY OF SAMPLING**

There is no single method for determining the frequency of sampling. For slaughter and dressing establishments frequency of sampling may be fixed in relation to the particular process or may be based on throughput of animals. In addition to ensuring randomness, variables to be taken into account at the establishment level include: source of raw materials, type and nature of the meat process, and volume of production.

Sampling frequency should be increased or decreased according to performance. Once results show that the HACCP-based procedures are providing a consistent level of acceptable performance, subsequent microbiological testing must be sufficient to ensure that process control is maintained.

## **XXIV. TRANSPORTATION OF LIVE POULTRY TO ANIMAL SLAUGHTER FACILITY OR MEAT PROCESSING ENTERPRISES**

During the reception and transportation the poultry must be handled carefully without causing undue physical pain.

Poultry with symptoms of disease or poultry that previously belonged to the groups infected by agents, affecting public health are allowed to transportation to points of poultry slaughter with the approval of competent authority.

Birdcages used for transportation of live poultry to slaughter facility or meat processing enterprises, as well as modules, if such are used must be made of metal that is resistant to corrosion and must be easily cleaned and disinfected. All the equipment intended for acceptance and delivery of live poultry must be cleaned immediately after voiding and, if necessary, before re-use.

## **XXV. POULTRY SLAUGHTER FACILITY OR MEAT PROCESSING ENTERPRISES**

Slaughter facility or meat processing enterprises must have premises or the area protected with shed for poultry delivery as well as for pre-slaughter studies.

In order to prevent contamination poultry slaughter facility or meat processing enterprises shall:

Have a sufficient number of premises suitable for the performance of certain actions;

have separate premises for evisceration and further processing, including the addition of spices in whole carcasses of poultry, if only the competent authority will issue a permission for a certain enterprise to separate these operations by periods in the manner of individual cases;

provide separate spaces, and time-sharing of the following operations:

stunning and bleeding;

plucking or dressing and scalding;

dispatch of meat;

availability of devices that prevent contact of the meat with the floor, walls and equipment;

have appropriately designed slaughter lines (where they are used), providing a constant advancement of poultry slaughter process and prevention of cross-contamination of different parts of slaughter line. If the same premises have several slaughter lines, it is necessary to ensure proper separation of slaughter lines in order to prevent cross-contamination.

Poultry slaughter facility or meat processing plants must be equipped to carry out disinfection, with hot water or with an alternative system ensuring the same result.

Hand-washing facilities for workers who contact with unpackaged meat must be properly designed, in order to prevent the spread of contamination.

Points of animal slaughter or meat processing plants must have the premises locked with key, cold rooms for storage of meat left and separate cold rooms for storage of meat declared as unsuitable for human consumption.

Points of poultry slaughter or meat processing plants shall have a dedicated place with appropriate equipment for cleaning, washing and disinfection of equipment used for transportation as the birdcages and vehicles.

Points of poultry slaughter or meat processing plants must have properly equipped, lockable premise or, if necessary a room for the exclusive use by veterinary services.

## **XXVI. POULTRY SLAUGHTER HYGIENE**

Poultry is not used for human consumption, if these poultry were not exposed to slaughter at poultry slaughter facility or meat processing enterprises.

Slaughter facility or meat processing enterprises shall accept only live poultry intended for slaughter.

Poultry entered the premises, where the slaughter is carried out, shall be exposed to slaughter without undue delay.

Stunning, bleeding, dressing or plucking, evisceration and further purification of poultry must be carried out without undue delay and in such a way as to avoid contamination of meat. In particular, it is necessary to take measures to prevent the spillage of digestive tract contents upon evisceration.

The Managers of slaughter facility or meat processing enterprises must comply with the instructions of the competent authority to ensure appropriate conditions for carrying out a post-mortem studies, and in particular, the proper study of poultry after slaughter.

After the post-mortem inspection:

parts unsuitable for human consumption must be removed as quickly as possible from the clean sector of the enterprise;

abandoned or declared as unsuitable for human consumption poultry, as well as non-edible by-products must not contact with meat declared as suitable for human consumption;

viscera or parts of viscera remaining in the carcass, except kidneys must be removed completely and as quickly as possible, if only the competent authorities will not give permission to do otherwise.

After study and gutting the poultry exposed to slaughter, must be cleaned and cooled as soon as possible, if only the meat is cut pair.

If poultry carcasses undergo the process of cooling by loading, it is necessary to pay attention to the observance of the following precautions.

It is necessary to take all precautions to prevent contamination of carcasses, taking into account parameters such as carcass weight, water temperature, volume and direction of water flow, and cooling period.

Equipment must be entirely emptied, cleaned and disinfected whenever the need arises, but at least once a day.

Slaughter facility and meat processing enterprises are prohibited to conduct the slaughter of sick or suspected poultry and poultry species exposed to slaughter under program of disease control or program of disease prevention of, except with the consent of the competent authorities. In such a situation, the slaughter shall be carried out under official supervision, and it is necessary to take all precautions to avoid contamination. Before re-use the premises shall be cleaned and disinfected.

## **XXVII. CUTTING DEVICES OF POULTRY MEAT**

Slaughter facility and meat processing enterprises must ensure that the facility is constructed in such a way as to avoid contamination of meat, in particular by:

Ensuring continuous changes of operation;

separation between different parties of products;

the availability of facilities for separate storage of packaged and unpackaged meat;

availability of equipment for washing hands with taps designed to prevent the spread of contamination, used by persons involved in work with unpackaged meat;

providing means for disinfecting instruments with hot water or an alternative system with similar result.

## **XXVIII. HYGIENE DURING AND AFTER CUTTING AND DEBONING POULTRY MEAT**

Work associated with poultry shall be organized in such a way as to prevent or minimize infection. For this purposes, slaughter facility or meat processing enterprises shall ensure that:

poultry meat intended for cutting is delivered in the production premise gradually as needed;

in the process of cutting, boning, trimming, filling and packaging the temperature of meat should be low enough, but not above 4°C.

in premises designed for cutting meat of different animal species, precautions are taken to avoid cross-contamination, where necessary by separation of operations for different types of meat on sections and time.

Poultry is separated from bones and cut until a temperature reaches no more than 4°C, if the premise for cutting is on the same area as slaughter area, provided that it is transmitted to the cutting area:

directly from the slaughter premises;

after cooling or freezing.

As soon as poultry is cut and, if necessary packaged, it cooled to a temperature to prevent growth of microorganisms.

Poultry must reach a temperature of not more than 4°C before transportation and maintain this temperature during transportation.

Poultry meat intended for freezing must be frozen as soon as possible.

Unpackaged meat shall be stored and transported separately from packaged meat, otherwise the packaging material and the method of storage or transportation do not cause contamination of meat.