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Draft Rules of Veterinary Testing-Examination and Regionalization

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Approved By:
Christopher Riker

Prepared By:
Staff

Report Highlights:
Three new draft SPS regulations covering laboratory testing rules, rules of veterinary and sanitary examination, and veterinary regionalization were posted on the Russian Government website for public review at http://regulation.gov.ru/. According to the regulation.gov.ru, it is planned that all three documents will come into effect as of September 1, 2015. Interested U.S. parties are encouraged to share their comments and/or concerns with USDA via the point of contact specified below.

As of the date of publication of this report, FAS/Moscow does not believe these measures have been notified to the World Trade Organization.

General Information
Three new draft SPS regulations covering laboratory testing rules, rules of veterinary and sanitary examination, and veterinary regionalization were posted on the Russian Government website for public review at http://regulation.gov.ru/:

- Draft Veterinary Rules for Regionalization of Animal Contagious Diseases in the Russian Federation;
- Draft Laboratory Testing Assignment Procedures for the Purposes of Veterinary Certification, State Veterinary Surveillance, State Veterinary Control, and State Monitoring of the Biological and Food Safety;
- Draft Order Concerning the Approval of Veterinary and Sanitary Examination Assignment Procedures.

According to the regulation.gov.ru, it is planned that all three documents will come into effect as of September 1, 2015.

An unofficial English translation of the above draft documents can be found below.

Interested U.S. parties are encouraged to share their comments and/or concerns with USDA at AgMoscow@fas.usda.gov by June 19, 2015.

As of the date of publication of this report, FAS/Moscow does not believe these measures have been notified to the World Trade Organization.

BEGIN UNOFFICIAL TRANSLATION:

Attachment to the Decree of MinAg of Russia
dated «___»_____, 2015

Veterinary Rules for regionalization of animal contagious diseases in the Russian Federation

I. General provisions.

1. The present rules for regionalization of animal contagious diseases in the Russian Federation (hereinafter – Rules) have been developed in accordance with the Law of the Russian Federation from May 14, 1993, No. 4979-1 "On Veterinary Medicine" and the Decision of the Customs Union Commission from June 18, 2010, No. 317 "On the Application of Veterinary and Sanitary Measures in the Customs Union", taking into account the recommendations of the Office International des Epizooties (hereinafter – OIE). The Rules shall establish the procedures for determining the disease-free or disease-affected status of the Russian Federation or her administrative territory with respect to animal contagious diseases.

2. Freedom (non-freedom) of the Russian Federation or parts of its territory from a contagious disease (regionalization) shall be established to identify a population of livestock in this region with status of the disease different from population of livestock in the remaining territory of the Russian Federation, and the level of food safety of products manufactured in this region from the subpopulation of animals susceptible to the disease (those that are sick or may be vectors or carriers including latent carriers), excluding products that have been treated to ensure their freedom from the disease agents.

3. Federal Veterinary and Phytosanitary Surveillance Service (hereinafter – VPSS) shall determine the status of freedom from animal diseases for territories of the constituent entities of the Russian Federation, develop a map of regionalization for territories of the Russian Federation and submit information to the Ministry of Agriculture of the Russian Federation, which shall use this information to update the consolidated program of diagnostics, preventive veterinary and anti-epizootic measures on the territory of the Russian Federation.

4. In accordance with the regionalization of territories of the Russian Federation, territories not free from animal diseases may implement the following:

- additional anti-epizootic measures in compliance with the consolidated program of diagnostics, preventive veterinary and anti-epizootic measures on the territory of the Russian Federation;
- the present Rules can establish the special business rules for livestock breeding, grazing, housing, transportation, circulation and slaughter; production, processing, transportation and marketing of other regulated goods, the biological and farm animal waste;
- introduction of certain restrictive measures in accordance with the existing legislation.

5. During the implementation of regionalization, VPSS shall adhere to the standards of the OIE Terrestrial Animal Health Code or Aquatic Animal Health Code. If there are no applicable OIE Code directives – to the EEC legislation, if there are no applicable EEC directives – to the Russian Federation legislation, if the latter is not available – VPSS shall make decisions independently. While the status is being established, if one of its goals is to promote exports of the regulated goods produced in the region in question to a country (countries), VPSS shall establish the status of the region taking into account the specific legal requirements of the importing country.

6. The status of diseases in subpopulations of livestock existing in the region can be different for the following reasons:

- natural (in particular, climatic zone free from the disease agent or its carrier);
- artificial (in particular, the appropriate conditions are maintained to eliminate circulation of the disease agent in the subpopulation).

7. Description of status of a specific contagious disease in the animal subpopulation existing in the region requires a review of the diagnostics data, disease monitoring records, methods of preventing the disease, methods of animal identification and traceability, and their application in practice.

8. Regionalization shall be used jointly with compartmentalization, or separate from compartmentalization.

9. Disease-free region may include the exclusion zone, inside which the appropriate anti-epizootic measures shall be implemented to prevent the spread of the disease (or pathogen) beyond its border by controlling the traffic of all goods and vehicles across the border, which might contribute to the spread of the pathogen outside the zone limits. In the event that at the end of the activities in this zone the disease is not spreading beyond its limits, the region can maintain the disease-free status, except for the territory of the exclusion zone.

10. Disease-free region may include the protection zone to separate it from territories with different status.

11. The status of the region may be established based on the following:

a) presence of the disease agent:

- Disease-free region;
- Affected region;
- Region with undetermined status.

b) the use of vaccination:

- Region without vaccination;
- Region with vaccination,

d) levels of disease (disease agent) risk:

- High risk region;
- Region with undetermined risk;
- Low risk region;
- Negligible risk region.

The status of the region with respect to presence of the disease agent, the use of vaccination and risk associated with introduction of the disease agent shall be established independently.

II. General terms and definitions

12. The following terms and definitions shall be used for the present Rules:

Susceptible animals – species of animals, which can reproduce (proliferate) pathogens of contagious diseases. As a result of infection, such animals can display clinical signs of varying severity or show no clinical signs of the disease however can be latent carriers.

Protection zone – territory established to protect animal health in the disease-free region and to ensure safety of products of animal origin manufactured and/or traded on the territory of the region, which separates it from territories with different status. Protection zone may differ from the disease-free region with respect to levels of risk associated with pathogen introduction, the use of vaccination, availability of special monitoring programs, which are not in place in the disease-free zone.

Exclusion zone – territory established inside the disease-free region or region with undetermined status that includes the epizootic hotbed and (or) infected facility, within the limits of which the infection is contained.

Infected facility – site, building, farm, production unit, transport vehicle or other facility where corpses of infected livestock, other biological waste from infected animals, contaminated products of animals origin, pathogens can be found in the external environment.

Region – part of the territory of a country with a subpopulation of animals, which status of any contagious disease differ from other subpopulations, and there are measures in place to control, prevent and eradicate the disease in this subpopulation and/or to comply with the biological and/or food safety requirements.

Regionalization – establishing freedom or lack thereof of the Russian Federation or its administrative territory (Republic, Oblast, Krai, Rayon etc.) from contagious animal diseases.

Subpopulation – the established part of population of definite species of animals inhabiting or existing in a certain territory or a certain compartment of a particular territory of the Russian Federation.

Epizootic hotbed – premises or territory where the source of disease agent (sick animals, animals recovered from disease or healthy carriers) and risk factors associated with pathogen transmission to susceptible animals (environmental factors relevant to transmission of contagious disease agents) can be found.

III. Definition and description of boundaries of the region

13. Boundaries of the region may be natural (rivers, sea, mountains, forest areas, etc.) and artificial (motorways, canals, hedges, etc.) objects and obstacles, administrative borders of any level (borders of the Russian Federation, Federal Districts, constituent entity of the Russian Federation, rayon, municipal entity), or any combination thereof.

14. VPSS shall establish the territorial boundaries of the disease-free region when information referred to in paragraph 18 of the present Rules becomes available, or when requested by the executive body of the constituent entity of the Russian Federation on veterinary matters of at least one constituent entity, the whole territory of which, or only one part, is located inside the disease-free region.

15. VPSS shall establish the territorial boundaries of the affected region when information referred to in paragraph 19 of the present Rules becomes available, or when requested by the executive body of the constituent entity of the Russian Federation on veterinary matters of at least one constituent entity, the whole territory of which, or only one part, is located inside the affected.

16. VPSS shall establish the territorial boundaries of the region with undetermined status if no information referred to in paragraphs 18 and 19 of the present Rules is available.

17. If the executive body of the constituent entity of the Russian Federation on veterinary matters of at least one constituent entity takes the initiative to determine a status (e.g. disease-free region) with respect to a contagious disease in the region, it shall lead to regionalization with respect to this disease across the whole of the Russian Federation. In such case, VPSS shall review the boundaries of the region declared as “disease-free region”, boundaries of other regions declared with respect to the same contagious disease by the executive bodies of the constituent entity of the Russian Federation in the field of animal health, while the territory of the remaining constituent entities of the Russian Federation shall be classified as:

a) affected regions if outbreaks of the relevant contagious disease have been registered on their territory, or there is evidence that proves circulation of the disease agent;

b) regions with:

- undetermined status;
- undetermined status with vaccination (vaccination against the disease is under way in this region), if outbreaks of the relevant contagious disease were registered in those regions but no evidence of the disease agent circulation was found;

- undetermined status without vaccination (there is no vaccination against the disease in this region), if no outbreaks of the relevant contagious disease were registered in those regions and no evidence of the disease agent circulation was found.

18. When the executive body of the constituent entity of the Russian Federation on veterinary matters initiates the process of establishing boundaries of the disease-free region, it shall provide to VPSS the review of the disease diagnostics data, disease monitoring records, methods of preventing the disease, methods of animal identification and traceability and their application in practice. In reviewing the listed materials, VPSS shall also take into account the materials available from other sources.

19. VPSS shall consider the materials provided by the executive body of the constituent entity of the Russian Federation on veterinary matters in accordance with paragraphs 19, 20 of the present Rules within 6 months from the day of receipt of the materials.

20. Review of the materials to establish the boundaries of the disease-free region will bring the following results:

- region will be established within the boundaries presented, and as presented;
- refusal to establish the boundaries of the disease-free region as presented;
- refusal to establish the status of "disease-free region" within the boundaries presented;

The basis for the refusal to review the materials may be such as:

- presented documents contain invalid data or false information;
- presented documents do not contain sufficient information to make a decision.

VI. Establishing and changing the status of the region

21. The status of the region's level of disease freedom shall be established with respect to a specific contagious disease.

"Disease-free region" with respect to a specific contagious disease shall be established for a particular region on condition that one of the following criteria is met:

a) there were no outbreaks of this contagious disease or instances where circulation of the disease agent was detected in the region; it is not possible for the disease agent to spread due to the specific natural and climate conditions, lack of vectors of disease or other natural reasons; also the monitoring program is in place in the region to control products in the production stage or in circulation on the territory of the region received from sensitive domestic or wild (if any) animals;

b) in the region:

- there were no outbreaks of this contagious disease or instances where circulation of the disease agent was detected ever or within the time specified in accordance with the pathogenicity of the disease agent and its resistance in the external environment established by the OIE Terrestrial Animal Health Code of Aquatic Animal Health Code. In the absence of the related directives in the OIE Codes, the time limit shall be established by the EurAsEC laws, in the absence of the relevant EurAsEC regulations – by the laws of the Russian Federation, and in the absence of such – VPSS shall decide independently;
- monitoring activities are in place to control:

circulation of the disease agent among sensitive (if any) and wild (if any) animals,

products in circulation on the territory of the region from sensitive and wild (if any) animals to detect the viable disease agent,

products (including raw materials and finished products) from sensitive domestic and wild (if any) animals that were (are) kept on the territory of the region to detect the genome of the disease agent, its anitgens or other evidence of its presence on the territory of the region;

- group or individual (depending on the animal species and type of housing) identification of animals sensitive to this disease is in place;

- the program is being implemented to ensure biosecurity with respect to this disease including measures to clean and disinfect transport vehicles arriving from regions with a different status, import restrictions or any additional procedures ensuring safe imports of sensitive animals and other regulated goods (products), which may pose a threat of importing the disease agent;

- the outreach (educational) program is being implemented to raise the disease awareness of the general population, owners of sensitive animals, legal entities and individual entrepreneurs who have entered into the hunting agreements, and also manufactures of products from sensitive animals.

"Affected region" with respect to a specific contagious disease shall be established for a particular region on condition that one of the following criteria is met:

- the spread of the contagious animal disease has been established on the territory of the region;

- circulation of the contagious animal disease agent has been established on the territory of the region;

- in the course of monitoring of products originated from sensitive domestic (if any) or wild (if any) animals that were kept on the territory of this region, genetic material of the disease agent, its antigens or antibodies have been detected therein.

"Region with undetermined status" shall be established for a particular region with respect to a specific contagious disease if this region has not been classified as disease-free region or affected region during regionalization.

22. Status reflecting the disease freedom level and the use of vaccination or lack of vaccination against a specific contagious disease shall be established for this disease, where:

"Disease-free region without vaccination" status with respect to a specific contagious disease shall be assigned to the region that meets the following two criteria: the region was classified as disease-free, and there is no vaccination of domestic and/or wild (if any) animals against the contagious disease is used in this region.

"Disease-free region with vaccination" status with respect to a specific contagious disease shall be assigned to the region that meets the following two criteria: the region was classified as disease-free, and there is vaccination of domestic and/or wild (if any) animals against the contagious disease is used in this region.

"Affected region without vaccination" status with respect to a specific contagious disease shall be assigned to the region that meets the following two criteria: the region was classified as affected, and there is no vaccination of domestic or domestic and wild animals against the contagious disease is used in this region.

"Affected region without vaccination" status with respect to a specific contagious disease shall be assigned to the region that meets the following two criteria: the region was classified as affected, and there is vaccination of domestic or domestic and wild animals against the contagious disease is used in this region.

"Region with undetermined status without vaccination" with respect to a specific contagious disease shall be assigned to the region that meets the following two criteria: the region was classified as region with undetermined status, and there is no vaccination of domestic or domestic and wild animals against the contagious disease is used in this region.

"Region with undetermined status with vaccination" with respect to a specific contagious disease shall be assigned to the region that meets the following two criteria: the region was classified as region with undetermined status, and there is vaccination of domestic or domestic and wild animals against the contagious disease is used in this region.

23. Risk level status shall be established with respect to regions that are disease-free from a specific contagious disease, where:

“Disease-free region, but high risk, without vaccination” status shall be assigned to the region that meets the following three criteria:

- the region is free from the disease but is adjacent to the affected region;
- biosecurity measures on the borders of the region have limitations;
- there is no vaccination of domestic or wild animals against this contagious disease is used in the region.

“Disease-free region, but high risk, with vaccination” status shall be assigned to the region that meets the following four criteria:

- the region is free from the disease;
- the region is adjacent to the affected region;
- biosecurity measures on the borders of the said region have limitations;
- there is no vaccination of domestic or wild animals against this contagious disease is used in the region.

“Disease-free region, but low risk, with vaccination” status shall be assigned to the region on two conditions:

1) The region is free from the disease, domestic animals are vaccinated against this contagious disease, and it is not adjacent to the affected region,

2) The region is adjacent to the affected region however when sensitive animals and regulated goods (products) are imported into the disease-free region which puts the disease-free region at risk of introducing the disease agent, a set of measures necessary to ensure maintenance of the disease-free status is in place, and vaccination of domestic animals against the contagious disease is used in the region.

“Disease-free region, but low risk, without vaccination” status shall be assigned to the region on two conditions:

1) The region is free from the disease, domestic animals are not vaccinated against this contagious disease, and it is not adjacent to the affected region;

2) The region is adjacent to the affected region however when sensitive animals and regulated goods (products) are imported into the disease-free region which puts the disease-free region at risk of introducing the disease agent, a set of measures required to ensure maintenance of the disease-free status is in place,

“Disease-free region with negligible risk” status shall be assigned to the region that meets the following four criteria: the region is free from the disease; the region is not adjacent to the affected regions; the region does not support any business relations with the affected regions, so that sensitive animals and regulated goods (products) can be imported to the disease-free region, which would put the disease-free region at risk of introducing the disease agent; there is no vaccination against the disease used in the region.

“Disease-free region with undetermined risk with vaccination” status shall be assigned to the region that meets the following three criteria: the region is free from the disease; vaccination is used against the disease in the region; the region has not been classified as region with high, low or negligible risk.

24. The status and borders of a particular region shall be established simultaneously.

25. Upon receipt of information that a particular region is no longer in compliance with the status it received earlier, VPSS shall change the status of the region.

V. The criteria and procedures for establishing protection zone and exclusion zone

26. VPSS shall establish protection zone on condition that the zone is adjacent to:

- the State Border of the Russian Federation;

- transport infrastructure facilities of high biological risk (seaports, airports, railway stations), where animals and products of animal origin get loaded/unloaded, or;

- other high biological risk facilities (e.g. research and other institutions working with the disease agent, pathological samples and so on).

In other cases, protection zone shall be established by the executive authority of the constituent entity of the Russian Federation on veterinary matters in consultation with VPSS.

27. Boundaries of protection zone can include territories of one or several constituent entities of the Russian Federation.

28. Approaches specified in Chapter VI of the present Rules shall be used to determine boundaries of the protection zone.

Boundaries of the protection zone can be the limits around the area where a series of anti-epizootic measures is implemented in the protection zone but not implemented in the disease-free zone that the protection zone is adjacent to.

29. VPSS shall identify the range and regimes of anti-epizootic measures in the protection zone that separates the disease-free region from region(s) with other status in the following cases:

- zone is adjacent to the State Border of the Russian Federation;

- zone is adjacent to transport infrastructure facilities of high biological risk (seaports, airports, railway stations), where animals and products of animal origin get loaded/unloaded;

- zone is adjacent to other high biological risk facilities (e.g. research and other institutions working with the disease agent, pathological samples and so on);

- it includes the territory larger than one constituent entity of the Russian Federation.

In other cases, the range and regimes of anti-epizootic measures in protection zone shall be established by the executive authority of the constituent entity of the Russian Federation on veterinary matters in consultation with VPSS.

30. Exclusion zone shall be established by decision made by VPSS or the executive authority of the constituent entity of the Russian Federation on veterinary matters, or by their mutual decision.

31. The reason for establishing exclusion zone is the detection of epizootic hotbed or infected facility inside the disease-free region or region with undetermined status on condition that there is no spreading of infection from the epizootic hotbed outside the limits of the infected facility. If such spread occurs, it will lead to a change of the status of the region as a whole.

32. The same public authority that has established the exclusion zone shall define the range and regimes of anti-epizootic measures in the exclusion zone. However, the executive authority of the constituent entity of the Russian Federation on veterinary matters shall inform VPSS about it immediately after the exclusion zone has been established and the range of anti-epizootic measures to be implemented inside the zone has been defined.

VI. Measures to maintain the status of the region

33. In the event of a threat posed by the spread of infectious animal diseases, VPSS alone or on the proposal by the executive body of the constituent entity of the Russian Federation on veterinary matters can make a decision to impose a ban on imports (exports), restrict imports (exports) or establish conditions for imports (exports) of animals susceptible to the disease and regulated goods (products), importing which to the region may put it at risk of introducing the disease agent, for the following types of movement and trade logistics:

- imports from affected region to region with undetermined status;
- imports from affected region to the disease-free region;
- imports from region with undetermined status to the disease-free region;
- imports from region with vaccination to region without vaccination;

- imports from high risk region to low risk region;
- imports from high risk region to region with undetermined risk;
- imports from high risk region to negligible risk region;

- exports from region with undetermined risk to low risk region;
- exports from region with undetermined risk to negligible risk region;
- exports from low risk region to negligible risk region, exports from exclusion zone, exports from protection zone.

If such a decision is made, veterinary certification of cargo or their transportation shall be forbidden.

34. It is prohibited to impose a ban on transportation of animals or other regulated cargo (commodities), which cannot be carriers of the disease agent, however limitations and conditions can be established for their transportation to eliminate or lower the risk of spreading the disease agent by means of mechanical carry-over including contamination of transport vehicles and transport containers.

35. When exercising measures aimed at maintaining the status of the region, VPSS should proceed from the need to ensure biosecurity and maintain the status reached by the regions while minimizing harm to physical and legal persons living in this or other regions.

VII. Reporting the outcomes of regionalization

36. VPSS shall be responsible for communicating the outcomes of regionalization on the territory of the Russian Federation by posting the information on the official VPSS website under section “Regionalization” at: http://www.fsvps.ru.

37. Any changes in the regionalization information shall be published no later than 12 hours after VPSS makes a decision to amend it.

38. Information about the outcomes of regionalization shall be publicly available and free of charge.

END UNOFFICIAL TRANSLATION.

BEGIN UNOFFICIAL TRANSLATION:

Attachment to the Order of MinAg of Russia
dated «___» _____ No. ___

Lab testing assignment procedures for the purposes of veterinary certification, the state veterinary surveillance, the state veterinary control, and state monitoring of the biological and food safety

I. General provisions

1. The present lab testing assignment procedures for the purposes of veterinary certification, the state veterinary surveillance, the state veterinary control, and state monitoring of the biological and food safety (hereinafter – Procedures) shall establish the sampling methodology for the regulated products (cargo) (hereinafter – products), the sample test techniques for the purposes of veterinary certification, the state veterinary monitoring and veterinary control (surveillance), as well as determine their sources of funding.

The present Procedures have been developed in accordance with the Law of the Russian Federation dated May 14, 1993 No. 4979-1 "On Veterinary Medicine", Resolution of the Government of the Russian Federation dated October 29, 1997 No. 1263 "Concerning the Approval of the Examination Procedure for Poor Quality or Dangerous Food Raw Materials and Foodstuffs, their Use and Destruction" and for the purpose of ensuring veterinary and sanitary safety of products regulated by the state veterinary service.

2. Compliance with the present Procedures shall be obligatory for all legal and physical entities on the territory of the Russian Federation.

II. Terms and definitions.

The following terms and definitions shall be used for the present Procedures:

Veterinary and sanitary examination – a comprehensive assessment of products of animal origin to verify if they fit for any potential applications (human consumption or animal feed) performed by veterinary experts with the appropriate background and work skills.

In the course of the veterinary and sanitary examination, it is required to carry out organoleptic testing, or lab testing in instances stipulated by the current law.

Lab testing means testing performed by various methods (physical, chemical, gravimetrical, or other technical, biochemical, clinical, pathoanatomical, physiological and others) in the specially designated and properly equipped premises (building, facility) – laboratory (veterinary or other).

For the purpose of the present Procedures, organoleptic testing shall not be referred to as lab testing, even if such testing is carried out inside a lab including if combined with any other lab testing.

Lab testing may be carried out during the veterinary and sanitary examination if it is required by the veterinary and sanitary examination regulations for such type of products.

Organoleptic testing means an examination (usually, a comprehensive examination) carried out with the help of the sensory organs, without using any lab equipment, tools or devices, helping to identify a set of the product's properties (color, smell, taste, texture, juiciness and other), and also their combinations or alterations during simple processing of this type of product, for example cooking, slicing and so on. Organoleptic testing may be carried out during the veterinary and sanitary

examination or during any comprehensive lab studies.

Persistent threat is any hazard the product in question is exposed to that comes from the raw material used for its manufacturing or, given that the product were live animals at any stage of their life cycle it may be pathogens, parasites and their toxic metabolic by-products, drug residues and toxic substances that the animals were exposed to from the environment through air, feed or water, and other relevant agents of organic and non-organic origin.

Variable threat is any hazard the product is exposed to that does not come from the raw material of animal origin but developing when the product gets contaminated during the production process (e.g. processing contaminants, toxic elements), or any hazard that accumulates during storage or transportation of the product (e.g. opportunistic or pathogenic saprophytes propagating in the product during spoilage) or develops in the product during storage or transportation (e.g. histamine in certain fish species).

Threat is any substance or live organism, which presence in the product of this kind is banned or regulated.

III. Laboratory certification

3. Lab testing of samples selected from the product for the purposes of veterinary certification, the state veterinary monitoring and the state veterinary control (surveillance) may be carried out in the laboratories included in the Register of Laboratories Certified for Testing for the Purposes of Veterinary Certification, the State Veterinary Monitoring and the State Veterinary Control (Surveillance) (hereinafter – Register).

4. The Register is supported by GIS Vesta while the federal executive body in the field of veterinary surveillance acts as its operator.

5. The following information about a laboratory shall be shown in the Register:

5.1. Address;

5.2. Name;

5.3. Contact information;

5.4. List of individuals including the lab supervisor authorized to confirm the test findings;

5.5. Description of possible ways of delivering samples to the lab;

5.6. Lab cartographic information;

5.7. Description of the premises describing the biosafety level provided;

5.8. Lab equipment capability passport and calibration records for the equipment in use;

5.9. List of tests the lab has been certified for;

5.10. Competence validation records for every method of testing,

5.11. List of tests the lab may perform at the present time,

5.12. Background information on participation in the inter-laboratory comparison tests;

5.13. Information about professional training of personnel involved in testing;

5.14. List of the lab personnel involved in testing,

5.15. Background information on the lab personnel involved in testing,

5.16. Records of the lab participation in cross testing;

5.17. Background information on the lab participation in the cross testing;

5.18. Price-list.

Information in paragraphs 5.3 - 5.5, 5.7 - 5.8, 5.11, 5.13 - 5.14, 5.18 shall be updated, when needed.

Information in paragraphs 5.7 - 5.8, 5.13 shall be verified no more than once every quarter but at least once every 2 years in the course of a field audit organized by VPSS without any prior notification

of the lab personnel or supervisor.

6. Labs shall be added to the Register based on the application submitted by the lab supervisor of a facility that falls under the jurisdiction of the veterinary government authority or any other lab of any type of ownership, and provided that the lab fulfills the following conditions:

6.1. The lab has been certified in accordance with the established procedure;

6.2 - 6.3. The lab has confirmed its consent to:

- carry out tests referred to in paragraph 6;
- participate in cross testing;

6.4. In accordance with the established procedure, the lab has confirmed its technical competence of implementing a minimum of one of the methods of lab testing included in the List of Methods of Lab Testing Approved for the Purposes of Veterinary Certification, the State Veterinary Monitoring, State Veterinary Control and State Veterinary Surveillance (hereinafter – List);

6.5. The lab has the equipment required for the tests, which the lab has confirmed or is willing to confirm its technical competence to perform;

6.6. The lab has the satisfactory equipment capability passport, which mentions the equipment referred to in paragraph 5;

6.7. The lab operates GIS Vesta in accordance with the set standards for the purpose of keeping records of tests performed as part of the state veterinary surveillance.

6.8. The lab participates in the cross testing system arranged by VPSS, in accordance with the established procedure.

7. The lab listed in the Register being a production lab of the plant involved in production and/or circulation of products may test those products, in production or circulation of which the plant is involved, for any purpose. For any other case, in order to perform lab testing, such lab must maintain the coding system for test samples established by VPSS.

8. Any lab listed in the Register must use the VPSS coding system for test samples, except as provided in paragraph III.7.

VI. Technical competence validation

9. Lab technical competence may be validated:

9.1. in reference to any specific lab method of testing given that the lab participates in comparison testing arranged by one of the international systems of competence validation, see their list posted on VPSS website;

9.2. by way of participating in the lab comparison testing system arranged by VPSS.

10. Lab technical competence must be validated on a periodic basis according to the procedure established by the international system or VPSS.

11. In the event that technical competence has been validated by one of the above-mentioned international systems, the lab must submit to VPSS in a timely fashion the copies of documents provided by the international system.

V. Maintenance of the coding system for test samples.

12. Product samples selected for testing for the purposes of:

12.1. product state monitoring of the food and biological safety parameters;

12.2. cross tests;

12.3. reference tests;

12.4. the state veterinary control at the state border,

12.5. the state veterinary surveillance;

12.6. they are subject to encryption (except as set forth in III.7) during the sample selection process in accordance with one of the GIS Mercury active protocols.

13. The selected sample shall be placed in the tamper-evident strongbox, its type and properties determined by VPSS, that carries a code assigned during the encryption process. The sampling protocol and its code shall be stored with GIS Mercury.

14. Using GIS Vesta interface, the test material receiving department at the lab shall import the encrypted sample collection report from GIS Mercury to GIS Vesta.

15. The receiving department shall run the follow-up in-house sample encryption process using GIS Vesta and send the samples to the lab divisions for testing. It is prohibited to hand over the cipher from the receiving department to any unauthorized persons inside or outside the lab.

16. The sample may be deciphered on two occasions:

16.1. upon receipt of the first positive test result (non-compliance with one of the regulated parameters has been established) from the test assigned for this sample. In such case, the sample receiving department staff at the lab shall run the decoding with the help of GIS Vesta and GIS Mercury interface. Once the sample collection report has been deciphered, the receiving department staff shall send a report with their findings via GIS Vesta interface to GIS Mercury and a notification to GIS Cyrano.

16.2. given that the results of every test assigned for this sample were negative (no instances of non-compliance with any of the regulated parameters have been established). In such case, GIS Vesta shall run the decryption by default, and GIS Vesta shall automatically send the sample test protocol to GIS Mercury.

VI. Cross testing.

17. Periodic cross testing of the test samples shall be performed to monitor the competence and prevent corrupt practices during lab testing.

18. Cross testing is testing of one and the same sample in two labs. GIS Mercury automatically assigns those cases, for which cross testing shall be applied, unless it is requested by the product owner in instances stipulated in the present Procedures.

19. In the event that cross testing has been ordered by GIS Mercury, payment of costs associated with sample selection, delivery of samples to the lab and the analysis shall be covered by that budget, which funds are used to pay for the analysis in this instance. Should cross testing be ordered at the request of the product owner, the product owner shall be responsible for those expenses.

20. In the event that the cross testing results are conflicting, i.e. one lab gets a positive result (the product does not meet the established requirements) while the other lab gets a negative result (the product complies with the established requirements), VPSS shall order a reference test at one of the VPSS authorized establishments or any other properly certified lab facility not otherwise involved in the dispute and selected by the contestant parties by mutual agreement.

21. The reference test result shall be considered final. Based of the result, the lab, which findings have not been confirmed through the reference test shall lose its certification to perform this test by the said method. The lab may reinstate the right in no event sooner than 6 months given that during that time it will have successfully confirmed its technical competence of this lab technique.

22. In the event that it is impossible to arrange for the reference test (collection of additional samples is not possible, and so on), the Central Veterinary Laboratory shall hold an unscheduled round of technical competence validation for both labs, in the meantime both labs shall lose their right to use this method of testing until this unscheduled round is completed.

VII. Lab testing assignment procedures for the purposes of state monitoring of food safety and epizootology monitoring.

23. Lab testing shall be ordered by an official from the federal authority in the field of veterinary surveillance.

24. Official responsible for the lab testing assignment procedure shall identify a lab certified for such purpose.

25. Expenses associated with taking samples, their transportation to the lab and the lab research shall be paid by the relevant budget funds (federal budget or the budget of the Russian Federation constituent entity) allocated to the government authority for that purpose.

26. Product owner shall have the right to request the unscheduled cross testing for this batch of products to include several or all of the tests assigned by the official. In such case, the product owner can independently identify the second lab certified for such tests that will participate in cross testing, and he/she must cover for any expenses associated with taking samples, their transportation to the lab of his/her own choice, and the lab research. Should this happen, the tests shall be conducted in accordance with the cross testing procedure described in section IV.

VIII. Lab testing assignment procedures for the purposes of the state veterinary border control.

27. Lab testing shall be ordered by an official from the federal authority in the field of veterinary surveillance.

28. Official responsible for the lab testing assignment procedure shall identify a lab certified for such purpose.

29. Expenses associated with taking samples, their transportation to the lab and the lab research shall be paid by the relevant budget funds unless otherwise provided for by the import requirements for such type of regulated products.

30. Product owner shall have the right to request the unscheduled cross testing in accordance with paragraph 26.

XI. Lab testing assignment procedures for the purposes of enhanced lab monitoring.

31. Enhanced lab monitoring may be initiated for products manufactured by plants from the third countries and for products manufactured by the domestic establishments as an alternative measure on condition that:

31.1. In the course of the state lab monitoring, it has been determined that the product from this establishment does not comply with the established standards and requirements;

31.2. Conditions of release of product at this foreign plant do not meet the requirements established in the Russian Federation;

31.3. Epizootic situation in the third country where imports come from and/or the products have been manufactured does not ensure their safety at the level required by the Russian laws, while such lab testing will provide for the necessary safety level, in conjunction with a set of safety measures implemented at the plant.

31.4. Epizootic situation in the Russian Federation region or region of any other EurAsEC member state where imports come from does not ensure their safety at the level required by the Russian laws, while such lab testing will provide for the necessary safety level, in conjunction with a set of safety measures implemented at the plant.

32. Enhanced lab monitoring procedures shall be implemented in the same lab that has determined that products from this plant do not comply with the established requirements.

33. Expenses associated with taking samples, their transportation to the lab and lab research shall

be paid by the product owner or importer, if he or she is not the product owner at the time of importation.

34. In the event that it is impossible to conduct such tests in the lab for the reasons including: it has lost its certification for such method of testing, the lab itself or its division are in temporary state of non-operability, the lab is overbooked with work to the extent that makes it impossible to run these tests within a short timeframe, or other force majeure circumstances, the official responsible for sample collection shall identify another lab from the list of certified for such purpose.

35. Product owner shall have the right to request the unscheduled cross testing in accordance with paragraph 26.

X. Lab testing assignment procedures for the purposes of veterinary certification.

36. It is not permitted for government officials to order lab testing provided that:

36.1. there are no requirements on such mandatory lab testing for every batch of products for the purpose of their veterinary certification in the laws of the Russian Federation and EurAsEC (in relation to products in circulation on the EurAsEC territory) and in the laws of the importing country (in relation to the exported products), and

36.1. testing is ordered to detect (measure) a persistent threat, and

36.3. GIS Vesta has details of similar tests done earlier in one of the certified labs on the production batch or any of the shipments made from this production batch, and

36.4. setting the tests would force the product owner to cover the costs associated with testing and/or samples transportation, and/or the product circulation must be suspended.

37. Lab testing for the purpose of veterinary certification for products intended for circulation on the territory of EurAsEC, resulting in the need for the product owner to cover the costs associated with testing and/or sample transportation, and/or the need to suspend the product circulation, can be ordered by government officials in the cases provided for in the current laws of the Russian Federation and EurAsEC except in cases established in paragraphs 37 and 38.

38. Government officials shall be allowed to order lab testing not required by the current laws of the Russian Federation and EurAsEC for the purpose of veterinary certification for products that have no clear signs of damage or contamination and are intended for circulation on the territory of EurAsEC on condition that payment for testing and sample transportation shall be made at the expense of the government authority or the government facility that falls under the jurisdiction of such government authority. In such case, the product circulation shall not be suspended until the test results are received.

39. Government officials shall be allowed to order lab testing not required by the current laws of the Russian Federation and EurAsEC for the purpose of veterinary certification for products that have clear signs of damage or contamination or any other non-compliance and are intended for circulation on the territory of EurAsEC. In such case, the product circulation shall be suspended until the test results are received, and their description shall be sent to the product owner or accompanying person. In the event that the test results have confirmed that the product does not comply with one of the tests, description of which has been sent to the product owner or accompanying person, the product owner shall be responsible for covering the cost of testing and sample transportation, otherwise any payments for testing and sample transportation shall be made at the expense of the government authority or the government facility that falls under the jurisdiction of such government authority.

40. Lab testing for the purpose of veterinary certification for products intended for export to a third country, resulting in the need for the product owner to cover the costs associated with testing and/or sample transportation and/or the need to suspend the product circulation, can be ordered by government officials in the cases provided for in the current laws of the third country, except in cases

established in paragraphs 40 and 41.

41. Government officials shall be allowed to order lab testing of exported products not required by the current laws of the third importing country for the purpose of veterinary certification for those products that have no clear signs of damage or contamination on condition that payment for testing and sample transportation shall be made at the expense of the government authority or the government facility that falls under the jurisdiction of such government authority. In such case, the product circulation shall not be suspended until the test results are received.

42. Government officials shall be allowed to order lab testing of exported products not required by the current laws of the third importing country for the purpose of veterinary certification for those products that have clear signs of damage or contamination or any other non-compliance. In such case, the product circulation shall be suspended until the test results are received, and their description shall be sent to the product owner or accompanying person. In the event that the test results have confirmed that the product does not comply with one of the tests, description of which has been sent to the product owner or accompanying person, the product owner shall be responsible for covering the cost of testing and sample transportation, otherwise any payments for testing and sample transportation shall be made at the expense of the government authority or the government facility that falls under the jurisdiction of such government authority.

43. In the event that a government official has refused to complete the veterinary certification for the reason that in his/her opinion the product does not comply with the established requirements to the threat presence (exceeded levels of a regulated substance or organism) in the product, while at the same time the product owner has expressed his/her interest to perform the product test to confirm its compliance with the requirements established for the parameter(s), the government official must request the lab test(s) of the sample and the product owner shall have the right to select any of the certified labs for testing. In the event that the test results have confirmed that the product is non-compliant the product owner shall be responsible for covering the cost of testing and sample transportation, otherwise payments for testing and sample transportation shall be made at the expense of the government authority or the government facility that falls under the jurisdiction of such government authority.

X. Lab testing assignment procedures for the purposes of the state veterinary surveillance.

44. Government officials shall be allowed to order lab testing of products at any time and for any reason. In such case, payment of costs associated with the delivery of samples to the lab and the analysis shall be covered at the expense of the government authority or the government facility that falls under the jurisdiction of such government authority.

45. In the event that the product has clear signs of damage or other non-compliance with the established requirements and lab testing has been ordered for this product, its circulation shall be suspended until the test results are received.

46. In the event that the product does not have any clear signs of damage or any other non-compliance with the established requirements and lab testing has been ordered for this product, its circulation shall not be suspended until the test results are received.

XI. Assignment procedures for the follow-up lab testing.

47. The follow-up lab testing for any part of the production batch (e.g. any product shipment made of this production batch) of the regulated products (excluding live animals) for the presence of persistent threat given that such test for the threat presence has been already performed earlier with the negative result (threat not detected) for any part of the same production batch (e.g. any other shipment of the product made of this production batch) of the regulated products (excluding live animals) in the

certified lab and in accordance with the established procedure cannot be ordered on condition that this testing must be performed at the expense of the owner of the regulated products or circulation of this production batch or its part must be suspended before the test results are received.

48. The follow-up lab testing for any part of the production batch (e.g. any product shipment made of this production batch) of the regulated products (excluding live animals) for the presence of variable threat given that such test for the threat presence has been already performed earlier with the negative result (threat not detected) for any part of the same production batch (e.g. any other shipment of the product made of this production batch) of the regulated products (excluding live animals) in the certified lab and in accordance with the established procedure can be ordered on condition that this testing must be performed at the expense of the owner of the regulated products or circulation of this production batch or its part must be suspended before the test results are received only in those instances when the data becomes available directly suggesting that the product has changed its properties (spoilage, oxidation, contamination, and so on).

END UNOFFICIAL TRANSLATION.

BEGIN UNOFFICIAL TRANSLATION:

MINISTRY OF AGRICULTURE
OF THE RUSSIAN FEDERATION
(MinAg of Russia)

O R D E R

dated **No.**

Moscow

Concerning the Approval of the Veterinary and Sanitary Examination Assignment Procedures

In accordance with the Law of the Russian Federation from May 14, 1993 No. 4979-1 "On Veterinary Medicine" (Bulletin of the Congress of Peoples Deputies of the Russian Federation and the Supreme Council of the Russian Federation, 1993, No. 24, art. 857; Compilation of Laws of the Russian Federation, 2002, No. 1, art. 2; 2004, No. 27, art. 2711; No. 35, art. 3607; 2005, No. 19, art. 1752; 2006, No. 1, art. 10; No. 52, art. 5498; 2007, No. 1, art. 29; No. 30, art. 3805; 2008, No. 24, art. 2801; 2009, No. 1, art. 17, art. 21; 2010, No. 50, art. 6614; 2011, No. 1, art. 6; No. 30, art. 4590), as well as paragraph 5.2.9, Charter of the Ministry of Agriculture of the Russian Federation approved by the Provision of the Government of the Russian Federation from June 12, 2008, No. 450, (Compilation of Laws of the Russian Federation, 2008, No. 25, art. 2983; No. 32, art. 3791; No. 42, art. 4825; No. 46, art. 5337; 2009, No. 1, art. 150; No. 3, art. 378; No. 6, art. 738; No. 9, art. 1119, art. 1121; No. 27, art. 3364; No. 33, art. 4088; 2010, No. 4, art. 394; No. 5, art. 538; No. 16, art.1917; No. 23, art. 2833; No. 26, art. 3350; No. 31, art. 4251, art. 4262; No. 32, art. 4330; No. 40, art. 5068; 2011, No. 6, art. 888; No. 7, art. 983; No. 12, art. 1652; No. 14, art. 1935; No. 18, art. 2649; No. 22, art. 3179; No. 36, art. 5154; 2012, No. 28, art. 3900; No. 32, art. 4561; No. 37, art. 5001; 2013, No. 10, art. 1038; No. 29, art. 3969; No. 33, art. 4386; No. 45, art. 5822; 2014, No. 4, art. 382; No. 10, art.1035; No.12, art.1297; Official Internet portal of legal information: http://www.pravo.gov.ru, 20.01.2014, No. 0001201403200009), I hereby order:

to approve the Veterinary and sanitary examination assignment procedures attached.

Minister A.N. Tkachev

Attachment to the Decree of MinAg of Russia
dated «___»_____, 2015

Veterinary and sanitary examination assignment procedures

I. General provisions

1. The present veterinary and sanitary examination assignment procedures, for the purposes of the veterinary certification, state monitoring of the food quality and safety, state veterinary surveillance, and state veterinary control (hereinafter – Procedures), have been developed in accordance with the Law of the Russian Federation dated May 14, 1993, No. 4979-1 "On Veterinary Medicine", Resolution of the Russian Federation Government dated September 29, 1997, No. 1263 "On the Approval of the Examination Procedure for Poor Quality or Dangerous Food Raw Materials and Foodstuffs, Their Use and Destruction", and for the purpose of ensuring veterinary and sanitary safety of products regulated by the state veterinary service.

2. The present Procedures define the general requirements to the process of ordering the veterinary and sanitary examination, sources for its financing, and are subject to compulsory implementation on the territory of the Russian Federation by legal and physical entities, citizens, individual entrepreneurs who operate with the regulated products.

II. Terms and definitions

3. The following terms and definitions shall be used for the present Procedures:

Veterinary and sanitary examination (hereinafter – VSE) – comprehensive evaluation designed to verify whether the regulated products of animal origin fit for their specific intended usage, and to ensure protection of people from diseases common to man and animals, carried out by veterinary experts with the appropriate background and work skills. In the course of VSE, it is required to review the information about the product and raw materials of animal origin used for its manufacturing, to perform the organoleptic testing, and also lab testing if required by the current law;

Lab testing – testing performed by various methods (physical, chemical, gravimetrical, or other technical, biochemical, clinical, pathoanatomical, physiological and others) in the specially designated and properly equipped premises (building, facility) – laboratory (veterinary or other). For the purpose of the Procedures, organoleptic testing shall not be referred to as lab testing, even if such testing is carried out inside a lab or if also combined with any other lab testing.

Organoleptic testing – an assessment (usually, a comprehensive assessment) made with the help of the sensory organs, without using complex devices or tools, helping to identify a set of the product's properties such as visual appearance (shape, color, surface condition, integrity, consistency of the package, fat quality), smell, taste, texture, clarity, glitter, presence of mold or slime, surface or crosscut texture patterns, presence of any foreign inclusions, and many other properties, their combinations or alterations during simple processing of this type of product (e.g. cooking, slicing).

III. Lab and VSE lab certification

4. For the purposes of the veterinary certification, food quality and safety state monitoring, state veterinary surveillance, and state veterinary control (hereinafter – for the purposes of the state veterinary surveillance), VSE may be performed at VSE labs, VSE stations, and VSE posts (hereinafter – VSE labs) listed in the Register of VSE Labs certified for VSE procedures (hereinafter – Register).

The Register is supported by the federal information system Vesta (hereinafter – GIS Vesta) while the Federal Executive Body in the field of veterinary surveillance acts as its operator.

5. The following information about VSE laboratory shall be shown in the Register:

5.1. Address and the address change record;

5.2. Name and the name change record;

5.3. Relevant contact information,

5.4. List of individuals authorized to carry out VSE,

5.5. List of individuals authorized to validate the VSE findings,

5.6. Description of possible ways of delivering samples to the VSE lab,

5.7. VSE lab cartographic information;

5.8. Description of the premises describing the biosafety level provided, and such description change record;

5.9. VSE lab equipment list, and its calibration records;

5.10. List of tests the VSE lab has been certified for, and its change record;

5.11. List of products of animal origin that this lab may conduct VSE of, and its change record;

5.12. Competence validation records for every method of testing, and their change record;

5.13. List of tests the VSE lab may perform as VSE at the present time, and their change record;

5.14. Background information on participation in the inter-laboratory comparison tests;

5.15. Information about professional training of personnel involved in VSE;

5.16. List of VSE lab personnel involved in testing, and its change record;

5.17. Information about retraining of the VSE lab personnel involved in research, and its change record;

5.18. Price list (if any chargeable VSE services are offered to any external physical and/or legal entities), and its change record.

6. Information in paragraphs 4.8 and 4.9 shall be verified no more than once every quarter but at least once every 2 years by the officials of the state veterinary service of the constituent entity of the Russian Federation with or without VPSS officials in the course of a field audit organized by VPSS without any prior notification of the VSE lab personnel or supervisor.

7. Data entries into the Register shall be made by the VSE lab supervisor or his/her authorized agent. Any data entries regarding the VSE lab audits shall be made by the state veterinary surveillance officials authorized by the agency head who have conducted the audit.

8. Access to the Register shall be granted in accordance with the procedure established by VPSS.

9. Labs shall be added to the Register based on the application submitted by the VSE lab supervisor, and provided that the lab fulfills the following conditions:

10. VSE lab has confirmed its consent to perform audits referred to in paragraph 4 of the present Procedures;

10.1. VSE lab has confirmed its technical competence of implementing testing of a minimum of one type of products subject to VSE.

10.2. VSE lab has the equipment required for the tests, which the lab has confirmed or is willing to confirm its technical competence to perform;

10.3. VSE lab has the satisfactory equipment capability passport, which mentions the equipment referred to in paragraph 4.9 of the present Procedures;

10.4. VSE lab operates GIS Vesta in accordance with the set standards for the purpose of keeping records of VSE tests performed as part of the state veterinary surveillance.

11. VSE lab listed in the Register being a production lab of the plant involved in production and/or circulation of products may test those products, in production or circulation of which the plant is involved, for any purpose. For any other case, in order to perform VSE, such VSE lab must maintain the coding system for test samples established by VPSS.

12. Any VSE lab listed in the Register must use the VPSS coding system for test samples, except as provided in paragraph 6 of the present Procedures.

IV. Technical competence validation

13. VSE lab technical competence must be validated through its participation in the inter-laboratory comparison tests carried out by VPSS.

VSE lab technical competence must be validated on a periodic basis according to the procedure established by VPSS.

14. Technical competence of the experts who perform VSE shall be validated during advanced professional training at the premises of the higher veterinary education establishments, VSE laboratories, and relevant research establishments. Technical competence of experts involved in the VSE research may be validated by keeping records of VSE research projects carried out by the experts and their teaching activities on the VSE subject.

V. VSE assignment procedures for the purpose of the food quality and safety state monitoring

15. VSE shall be ordered by an official from the executive branch of the government who identifies a VSE lab certified for such testing.

16. Expenses associated with taking samples, their transportation to the lab and the VSE procedure shall be paid by the relevant budget funds (federal budget or the budget of the Russian Federation constituent entity) allocated to the government authority for that purpose.

VI. VSE assignment procedures for the state veterinary border control purposes.

17. VSE shall be ordered by an official from the federal authority in the field of veterinary surveillance who identifies a VSE lab certified for such testing.

18. Expenses associated with taking samples, their transportation to the lab and the VSE procedure shall be paid by the federal budget funds unless otherwise established by the import requirements for this type of regulated products.

VII. VSE assignment procedures for the veterinary certification purposes.

19. Based on the type of products of animal origin, the decision may be made for the VSE to include organoleptic or other testing of every product unit (carcass, half carcass, internal organs, etc.) established by the VSE procedures for such product type, or random testing of a certain portion of product units that comprise this batch, as is provided by the VSE procedures for such product type.

20. Owner of products of animal origin shall be responsible for any costs associated with the VSE performed for the veterinary certification purposes.

21. In relation to the products of animal origin received from non-mammals, reptiles and amphibian aquatic animals harvested at sea or ocean, VSE shall be performed on the basis of the fishing area monitoring data and veterinary surveillance records of the biologic species of aquatic animals fishing and processing operations, and no organoleptic or other testing shall be ordered given that:

- fishing vessels engaged in the marine animals fishing, fish processing vessels or on-shore fish processing plants processing such products have been certified in accordance with the established procedure,

- the fishing area monitoring data show that the harvested biologic species of aquatic animals in the fishing grounds are free from pathogens of animal and human diseases, and no natural or artificial harmful or regulated substances have been detected;

- the fishing area monitoring data show that the harvested biologic species of aquatic animals in the fishing grounds are free from natural or artificial harmful or regulated substances as well as infectious human or animal diseases, however not free from the invasive human or animal diseases, which pathogens lose their viability due to the applied method of processing or storage of the finished product, moreover the current legislation does not establish any mandatory requirements that restrict or regulate the presence of the devitalized invasive disease pathogens in the product.

VIII. VSE assignment procedures for the state veterinary surveillance purposes.

22. Authorized individuals shall be allowed to order VSE for the regulated products for the purpose of the implementation of the state veterinary surveillance at any time and for any reason.

23. Expenses associated with taking samples, their transportation to the lab and the VSE procedure shall be paid by the relevant budget funds (federal budget or the budget of the Russian Federation constituent entity) allocated to the government authority for that purpose.

24. If any regulated products with clear signs of damage or other non-compliance with the established requirements are detected in the course of the state veterinary surveillance, those signs shall be documented in accordance with the VPSS established procedure, and VSE of such product shall be ordered. In such case, the product circulation shall be suspended until the VSE results are received.

25. If in the course of the state veterinary surveillance the decision is made to order VSE of the regulated products that have no clear signs of damage or other non-compliance with the established requirements, the product circulation shall not be suspended until the VSE results are received.

IX. VSE assignment procedures for products manufactured from raw materials that have been or have not been subjected to VSE

26. If raw materials of animal origin have been subjected to VSE in accordance with the established procedure and the VSE findings were registered in GIS Vesta in accordance with the established procedure, and the raw materials were considered fit for the intended purpose, the product may be scheduled for VSE only in the following circumstances:

- at request of the product owner;

- during the implementation of the food quality and safety state monitoring, the state epizootic monitoring;

- during the implementation of the state veterinary border control;

- during the implementation of the state veterinary surveillance of products, which origin has not been properly established, in the event that such products are allowed for circulation in accordance with the current statutory requirements;

- for products manufactured from the raw material, which origin has not been properly established, in the event that such raw material and products are allowed for circulation in accordance with the current statutory requirements;

- if the raw material was subjected to VSE with the purpose of establishing its fitness for a specific application while the owner is willing to use or sell it to be used for different purposes, if that is allowed by the current law.

27. The product shall be subjected to VSE before its release for circulation provided that the raw material of animal origin used to manufacture the product of animal origin has not been subjected to VSE in accordance with the established procedure and using such raw material for the intended purpose is in compliance with the current statutory requirements.

X. The follow-up VSE assignment procedures

28. The follow-up VSE (VSE of the product or raw material used for its manufacturing that have already been passed VSE) shall be ordered by a government veterinary official for products of animal origin that show clear signs of damage or other non-compliance with the established requirements.

29. The follow-up VSE shall be ordered by a government veterinary official to verify that the product complies with the importing country's requirements to the exported Russian regulated product given that the earlier VSE of the product tested only its compliance with standards and requirements of the Russian Federation while the importing country's requirements were more stringent or different from the list of parameters tested in the course of the VSE in the Russian Federation.

30. Also, the follow-up VSE may be ordered by a government veterinary official as the food quality and safety state monitoring measure.

31. The follow-up VSE may be ordered at request of the owner of regulated products at any time or for any reason including: challenging the results of the earlier VSE; extending the shelf life of the consignment of regulated products if that is allowed by the current law; change of the intended use of the product.

32. If the follow-up VSE has been ordered at the request of the product owner or to test products that show clear signs of damage or other non-compliance with the established requirements, the owner shall be responsible for all costs incurred. Otherwise, expenses associated with taking samples, their transportation to the lab and the follow-up VSE procedure shall be paid by the relevant budget (federal budget or the budget of the Russian Federation constituent entity) allocated to the government authority for that purpose.

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