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Draft EAEU SPS Measure on Feed Additives Notified to WTO

Report Categories:

WTO Notifications

Grain and Feed

Sanitary/Phytosanitary/Food Safety

FAIRS Subject Report

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Report Highlights:

On September 14, 2015, Russia notified the World Trade Organization (WTO) of draft EAEU [1] rules for circulation of feed additives via [G/SPS/N/RUS/108](#). According to the notification, the document introduces common requirements for safety and registration procedures, quality assurance system, and inspection of feed additives for the EAEU member-states. The 60-day public comment period for the draft will close on November 13, 2015. Interested U.S. parties are encouraged to share their comments and/or concerns with USDA's enquiry point (us.spsenquiry@fas.usda.gov). For potential inclusion in the U.S. official position, please send your comments by November 1, 2015.

^[1] Current members are Armenia, Belarus, Kazakhstan, Kyrgyzstan, and Russia.

General Information:

The Eurasian Economic Commission (EEC), which is the regulatory body of the Armenia-Belarus-Kazakhstan-Russia [Eurasian Economic Union](#) (EAEU), published the following draft document on its website:

- [On Approval of the Rules Regulating Circulation of Feed Additives in the Customs Territory of the Eurasian Economic Union](#)

On September 14, 2015, Russia notified the World Trade Organization (WTO) of draft EAEU rules for circulation of feed additives via [G/SPS/N/RUS/108](#). According to the notification, the document introduces common requirements for safety and registration procedures, quality assurance system, and inspection of feed additives for the EAEU member-states. It also provides the measures for mutual harmonization and unification of legislation in the field of feed additives for member-states of the Eurasian Economic Union.

The 60-day public comment period for the draft will close on November 13, 2015. Interested U.S. parties are encouraged to share their comments and/or concerns with USDA's enquiry point (us.spsenquiry@fas.usda.gov). For potential inclusion in the U.S. official position, please send your comments by November 1, 2015.

An unofficial English translation of the above-referenced draft document can be found below.

BEGIN UNOFFICIAL TRANSLATION:

**EURASIAN ECONOMIC COMMISSION
COUNCIL**

DECISION

_____ 20

No.

**On Approval of the Rules Regulating Circulation of Feed Additives in the Customs
Territory of the Eurasian Economic Union**

For the purpose of implementing p. 14 of the Protocol on the Application of Sanitary, Veterinary and Sanitary, and Quarantine Phytosanitary Measures (Appendix No. 12 to the Treaty on the Eurasian Economic Union of May 29, 2014), the Council of the Eurasian Economic Commission **decided**:

1. To approve the attached Rules Regulating Circulation of Feed Additives in the Customs Territory of the Eurasian Economic Union.
2. This Decision shall become effective upon expiry of 6 months from the date of its official publication.

Members of the Council of the Eurasian Economic Commission:

From the Republic of Armenia	From the Republic of Belarus	From the Republic of Kazakhstan	From the Kyrgyz Republic	From the Russian Federation
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V. Gabrielyan

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definitions:

1) the Unified Registry of Registered Feed Additives of the Eurasian Economic Union (hereinafter – the “Registry of Feed Additives of the Union”) – register which includes information on all feed additives registered in the territory of the member states;

2) applicant – physical person or legal entity, or individual entrepreneur authorized by the right holder for making food additive registration and submitting registration documents to the Authorized Registration Body of member state, as well as for conducting other actions specified in the power of attorney;

3) feed additives - products or their combinations of plant, animal, microbiological, mineral and synthetic origin intended for inclusion in the formulation of animal feedstuffs and diets to ensure their full physiological value, stimulation of animal productivity, optimized bioavailability of feed nutrients, optimization of microbiological composition of feed, preservation of feed components, improvement of taste and technological properties of feedstuffs, achievement of the target characteristics of animal-derived products and desired decorative characteristics of external conformation in animals;

4) number of the registration certificate – code assigned to feed additive at the time of its state registration;

5) regulatory document – document on the quality control of feed additive including the list of tests, description of analytical techniques and appropriate criteria of feed additive acceptability;

6) right holder of the registration certificate on feed additive – legal entity possessing the right of ownership for registration certificate, process of production of feed additive, results of studies, which bears responsibility for the quality, efficacy and safety of feed additive and its production technology;

7) feed additive producer – organization conducting production, storage, marketing and sales of feed additive;

8) registration dossier – a package of documents submitted for the registration of feed additive;

9) registration of feed additive – entry of feed additive in the Registry of Feed Additives of the Union based on the results of its expert assessment and issuance of a registration certificate on the feed additive;

10) registration certificate on feed additive – document proving the fact of state registration of the feed additive;

11) state body of a member state authorized for making registration of feed additive (hereinafter – the Authorized Body of member state) – the authorized body of member state with the following scope of competence: decision making functions in the process of registration of feed additive in the customs territory of the Union or an individual member state; expert assessments of feed additive when the relevant data on feed additive are entered in the Registry of Feed Additives of the Union; and, functions related to control and/or surveillance of the circulation of feed additives;

12) expert institution – organization engaged by the Authorized Body of the member state in the process of expert assessment of the feed additive during its registration.

II. Requirements for the Production of Feed Additives

4. General requirements

10. Production of feed additives in the customs territory of the Union is organized in compliance with the acts comprising the Union law and the legislation of the member states.

11. In case of incompliance with the requirements for production of feed additives, the producers bear responsibility in accordance with the legislation of the member states.

12. Production of feed additives shall comply with the requirements of the regulation (“industrial regulation” or “technical regulation”) which is approved by the Chief Executive Officer of the producer of feed additives and include the list of active and auxiliary substances, specifying the amount of each of them; data on the operated equipment; description of the process and control methods at all stages of feed additive production.

13. The producer of feed additives should organize their production in such a way as to prevent incompliance with the requirements of the regulation and the regulatory documents.

14. The production of the following is forbidden in the Union:

- 1) feed additives not included in the Registry of Feed Additives of the Union;
- 2) falsified and counterfeited feed additives.

15. Marketing and sales of feed additives registered in accordance with these Rules are carried out by their producers without posing additional requirements to the organizations serving as agents for wholesale trade and retail sale vs. the requirements established in the present Rules.

III. Circulation of Feed Additives in the Customs Territory of the Eurasian Economic Union

5. Circulation of feed additives registered in accordance with these Rules in the Customs Territory of the Eurasian Economic Union

16. Circulation of feed additives is allowed in the customs territory of the Union, provided that they have been registered in accordance with these Rules and that the information on them has been entered in the Registry of Feed Additives of the Union.

17. These Rules establish requirements for structure, format and content of the registration dossier; structure and content of the expert report; form of the registration certificate on feed additives; procedure for making modifications to the registration dossier; rationale for registration rejection; recall, suspension or termination of the registration certificate on feed additive.

18. The member states do not allow re-registration of the feed additives registered in the Union in accordance with these Rules.

19. Settlement of disputes arising in the course of procedures related to the registration of feed additives is conducted taking into consideration recommendations of the Expert Board composed upon suggestion of the Authorized Bodies of the member states.

20. Decisions of the Authorized Body of a member state associated with the registration procedures and expert assessment of feed additive could be appealed in the court of this member state in the manner envisaged for the settlement of disputes arising from administrative or other public legal relationships in the legislation of said member state.

21. Registration in the customs territory of the Union is required for:

- 1) new feed additives;
- 2) feed additives registered earlier but produced in different forms or with a new dosage, or with a different formulation of auxiliary substances;

3) generic feed additives.

22. Registration in the customs territory of the Union does not apply to the following:

1) mixes and combinations of feed additives registered earlier;

- mixes of vitamins;

- mixes of minerals;

- mixes of vitamins and minerals;

- premixes;

- protein-vitamin-mineral concentrates (PVMC);

- protein-vitamin-mineral additives (PVMS).

2) feed additives intended for export;

3) feed additives intended for use as exhibits;

4) feed additives imported by a physical person for individual use;

5) specimens of feed additives imported for registration.

23. Registration of the following articles is not allowed in the customs territory of the Union:

1) feed additives with identical qualitative and quantitative formulation manufactured by the producer under different trade names and presented for state registration as two or more feed additives;

3) feed additives under the same trade name which have different qualitative and quantitative formulation;

24. Registration of feed additives and other registration-related procedures shall be accomplished in the manner and according to the requirements established by these Rules for the purpose of circulation of feed additives, both in the entire customs territory of the Union, and in the territories of individual member states.

25. Registration of feed additives, confirmation of registration, making modifications to the registration dossier, cancellation of registration and other procedures associated with the registration of feed additives, are carried out by the Authorized Bodies of the member states.

26. Expert assessment of feed additives is performed by expert institution(s) designated by the Authorized Body of member state in accordance with the legislation of the member state (hereinafter – the “expert institution”).

27. The Authorized Body of member state in compliance with the legislation of the member state can delegate its authority on registration of feed additives to the national expert institution.

28. Decision on feed additive registration is made by the Authorized Body of member state based on the results of expert assessment - review of the registration dossier and studies of feed additives specimens.

29. Duration of the procedure from the date of acceptance of application by the Authorized Body of member state:

1) registration of feed additive should not exceed 300 business days (flowchart of feed additive registration process is given in Annex No. 1 to these Rules);

2) confirmation of feed additive registration should not exceed 150 business days (in case where modifications are made to the registration dossier on feed additive at the stage of confirmation of feed additive registration, the procedure of registration confirmation can be extended to 200 business days; expert assessment of materials submitted by the applicant can be extended to 100 business days);

3) incorporation of modifications in the documents comprising the registration dossier on registered feed additive, with expert assessment of feed additive specimens in cases envisaged in

these Rules should not exceed 300 business days;

4) incorporation of modifications in the documents comprising the registration dossier on registered feed additive, without expert assessment of feed additive specimens in cases envisaged in these Rules should not exceed 150 business days.

30. Based on the results of registration of feed additive, a registration certificate on the feed additive is issued. The period of validity of the registration certificate issued for the first time is 5 years. After expiration of the period of validity of the registration certificate, the feed additive is subject to registration confirmation and then the registration certificate is issued for an unlimited time.

31. Costs incurred by the applicant within the registration, confirmation of registration and the incorporation of modifications to the registration dossier, cancellation of registration and other procedures linked to the registration of feed additives, expert assessment of feed additives, as well as expert reviews to verify conformance to the requirements established in these Rules initiated in connection with the implementation of said procedures, are not repaid.

32. Key principles of wholesale trade, transportation, storage and disposal of feed additives within their circulation in the customs territory of the Union are highlighted in Annex No.2 to these Rules.

IV. Rules for Implementing Procedure of Feed Additive Registration and other Procedures Associated with Registration

6. Submission of application and presentation of registration materials

33. At the time of submission of an application for food additive registration, the applicant shall, at his/her own discretion, select an Authorized Body of one of the member states of the Union; the application shall include a list of member states in the territory of which the feed additive circulation is planned (an application for the registration of feed additive can be submitted by the applicant in electronic format according to Form 1 given in Annex No.3 to these Rules).

The applicant shall, in addition to the application, submit to the Authorized Body of member state a registration dossier on the feed additive in hard copy and in electronic format, as per checklist, in the Russian language (the Applicant shall bear responsibility for the authenticity and identity of the presented registration materials).

Before an application is submitted for the registration of feed additive and other registration-related procedures, the authorized bodies and/or expert institutions of the member states are entitled, upon applicant's request, to hold scientific and pre-registration consultations in accordance with the national legislation as regards the issues pertaining to feed additive studies; registration procedure aspects, e.g. concerning the list of documents submitted for registration and the data included in the registration dossier; format and way of submission of the application and registration dossier; and, the need for feed additive specimens, reference samples of active substances, test systems and/or materials, specific reagents, and consumables required for performing expert assessment in the expert institution or according to its instruction, etc.

34. The Authorized Body of the member state which accepted the registration materials shall be a reference body for the registration process (hereinafter – the “Reference Registration Body”).

The Reference Registration Body shall in no more than 15 business days:

1) notify the authorized bodies of the member states in the territories of which the circulation of feed additives is planned on the receipt of registration dossier;

2) check completeness of the submitted registration dossier on feed additive;
3) make decision on referral of the registration materials to expert assessment or on refusal from their referral to expert assessment (specifying the reason for refusal).

35. The Reference Registration Body communicates its decision to the applicant and the authorized bodies of the member states in the territories of which the circulation of feed additive is planned via an official letter. To facilitate communication, the Reference Registration Body can notify the applicant on adopted decision in electronic format.

Date of initiation of the procedure for feed additive registration and other registration-related procedures is the date when the Reference Registration Body makes decision on referral of the full package of registration dossier on feed additive provided by the applicant to expert assessment.

Within 10 days from the date of decision on referral of the registration dossier on feed additive provided by the applicant to expert assessment, the Reference Registration Body shall:

1) notify the authorized bodies of the member states in the territories of which the circulation of feed additives is planned, on the initiation of the procedure for food additive registration;

2) send the registration dossier on feed additive (including a draft regulatory document for feed additive, instructions for use and package design) to the expert institution(s).

36. Registration dossier can be provided by the Reference Registration Body for information to experts of the authorized bodies of other member states mentioned in the application, upon requests of the authorized bodies of the member states within 1 business day from the date of receipt of such request.

37. Within 25 business days from the date of decision made by the Reference Registration Body on acceptance of the registration materials for expert assessment, the Applicant shall dispatch specimens of feed additive to expert institution(s) of member state(s) assigned by the Reference Registration Body for testing the feed additive specimens and expert assessment of the quality and safety of the feed additive. The registration procedure is suspended for this time period.

38. In cases where the feed additive specimens with the necessary reference samples of active substances and the appropriate test systems are not delivered within 25 business days, the expert institution shall, within no more than 3 business days, notify thereof the Reference Registration Body. Within no more than 5 business days from the date of receipt of the notification from the expert institution, the Reference Registration Body shall make decision on refusal from the feed additive registration procedure; the applicant and the authorized bodies of the member states mentioned in the application are informed on this decision. The registration procedure is finished.

39. Upon receipt of the feed additive specimens with the necessary reference samples of active substances and the appropriate test systems, the registration procedure is re-started from the date of their receipt; the expert institution shall, within no more than 3 business days, provide a documented confirmation to the applicant that the above materials had been received and notify thereof the Reference Registration Body.

40. Within 5 business days the expert institution makes its assessment of whether it is possible to conduct the necessary studies and, if neither tests, nor expert assessment of the specimens provided by the applicant can be performed, the expert institution will notify thereof the Reference Registration Body. The registration procedure is suspended and:

1) in cases, where the national expert institution(s) of member state cannot carry out any

test or expert assessment of the specimens provided by the applicant, the national expert institution(s) of the member state shall, upon agreement with the Reference Registration Body, send the feed additive specimens and the necessary reference samples of active substances and/or test systems for conducting quality control to any of the expert institutions of another member state where technical capabilities are available for performing the required tests and assessments;

2) in cases, where it is not possible to carry out any tests or expert assessments of the specimens provided by the applicant due to their poor quality (spoilage, off-grade, defect, etc.), the Reference Registration Body shall, within 3 business days, inform the applicant and authorized bodies of member states on a failure to perform tests of the feed additive specimens provided by the Applicant due to their poor quality. The Applicant shall, within 25 business days from the date of receipt of the relevant information, for the second time provide necessary specimens of the feed additive to the expert institution. The registration procedure is suspended for this time period. In cases where the specimens of the feed additive are not delivered to expert institution within 25 business days, the expert institution shall, within 3 business days, notify thereof the Reference Registration Body; the latter will, within 3 business days, make decision on the completion of the registration procedure and notify thereof the applicant and the authorized bodies of the member states.

7. Common principles of expert assessment of feed additives

41. Expert assessment of feed additives is carried out for receiving data on scientific evaluation of the quality and safety of feed additives and may include the following:

1) review of documents and data provided by the applicant in the registration dossier on feed additive;

2) studies of feed additive specimens or relevant test systems with respect to their conformity to the requirements of the regulatory document on the quality and verification of analytical quality control techniques in cases established by these Rules;

3) compilation of expert report on feed additive assessment.

Expert assessment of feed additives is carried out by a commission of experts of the expert institution; staff from other institutions or organizations can be included as experts in the commission. The commission of experts is composed according to the legislation of member state.

Expert involved in the expert assessment of feed additives should have higher education in animal medicine and/or medicine, and/or pharmacy, and/or biology, and/or chemistry, and possess competence confirmed in accordance with the legislation of member state (hereinafter – the “expert”).

42. In cases where expert assessment is performed:

1) experts cannot be dependent in any way on the person who assigned expert assessment(s), the Applicant, or other individuals interested in the results of expert assessment;

2) to obtain on demand the materials necessary for expert assessment(s) from the Applicant or other persons is not allowed. In cases where data and/or information in the registration package received by the expert institution for the issuance of expert report is not sufficient, the expert institution will address the Reference Registration Body with an appropriate request. The Reference Registration Body will send the request for necessary materials to the Applicant;

3) to disclose data that have become known to experts in connection with the expert assessment(s), or data comprising state, commercial or another secret protected by the Union legislation or the national legislation of member state is prohibited;

4) experts are not entitled to conduct expert assessment(s) upon informal request of the Applicant, collect, on their own discretion, materials for performing expert assessment(s), or to perform expert assessment(s) in the capacity of non-government experts;

5) expert must accomplish in full the expert assessment of the registration materials, provide a justified and objective report on the issues raised or a motivated report stating that he/she cannot perform expert assessment of the feed additive;

6) expert may, if necessary, apply to the manager of the expert institution with a proposal to involve other experts in the assessment of feed additive;

7) expert must ensure safe custody of the provided registration materials.

8) Every expert engaged in the expert commission assigned to the execution of expert assessment of feed additive shall independently and individually conduct studies, assess results obtained by himself/herself and other experts, and compile conclusions with respect to the raised issues within his/her area of expertise.

9) Experts included in the commission are informed on the responsibility for issuing report with non-justified or falsified conclusions in accordance with the legislation of member state.

43. Expert assessment of feed additive is carried out within:

1) 150 business days in case of feed additive registration;

2) 60 business days in case of confirmation of feed additive registration;

3) 60 business days in case where modifications are made to the documents contained in the registration dossier on the registered feed additive.

44. Expert assessment of feed additive includes:

1) expert review of the registration dossier on feed additive comprising the evaluation of completeness and authenticity of provided information;

2) expert assessment of the quality and safety of feed additive comprising:
- studies of feed additive specimens for conformity to the regulatory document requirements and for evaluation of reproducibility of the claimed quality control techniques;
- comparability of the obtained results of feed additive quality and safety studies with the data provided by the applicant in the registration dossier on feed additive as regards the quality and safety of the feed additive under registration.

45. The results of expert assessment are documented in expert report of the expert commission of the expert institution(s) involved in the execution of these assessments using the form presented in Annex No.4 to these Rules.

Expert report specifies the results of expert review of the registration dossier on feed additive, the results of assessment of feed additive quality and safety, and the conclusions based on these results. Expert whose opinion does not agree with the decision of the expert commission is entitled to express in writing his/her opinion which is included in the report.

Expert report and attached study protocols are forwarded by the expert institution to the Reference Registration Body that has assigned the performance of relevant expert assessment(s); the latter shall, within 3 business days, notify the Authorized Bodies of the member states indicated in the application on their receipt. The Reference Registration Body may submit the expert report with attached study protocols to the authorized bodies of the member states indicated in the application, upon their request, within 1 business day from the date of receipt of the request. In turn, the latter shall, within 3 business days, send them to the appropriate expert institutions for review.

46. The review of expert report (including study protocols) and list of questions (remarks) No.1, raised in the course of review, are completed by expert institutions within the time period

not exceeding 30 business days from the date when the Reference Registration Body sent notification of the authorized bodies of member states mentioned in the application, on the receipt of expert report and test protocols.

The list of questions (remarks) is forwarded by the authorized bodies of member states to the Reference Registration Body within 3 business days; in turn, the latter will, within 3 business days, send to the applicant all questions (remarks) received from the authorized bodies of other member states. The registration procedure is suspended from the date of sending out questions (remarks) to the applicant.

47. The applicant shall provide replies to the questions (remarks), including revised/updated/additional materials, within no more than 90 business days from the date of sending out the questions (remarks) to the applicant.

The registration procedure is re-started from the date of receipt of applicant's replies to the questions (remarks), including revised/updated/additional materials, to the Reference Registration Body.

48. The Reference Registration Body within 5 business days shall:

1) notify the authorized bodies of the member states specified in the application that the replies to questions (remarks), including revised/updated/additional materials, have been delivered to its address. The Reference Registration Body may provide the replies to questions (remarks), including revised/updated/additional materials, to the authorized bodies of the member states specified in the application upon their request within 1 business day from the date of receipt of such request;

2) send the replies to questions (remarks), including revised/updated/additional materials, received from the applicant to expert institution(s) for their review.

49. The authorized bodies of the member states shall, within 3 business days, send replies to the questions (remarks), including revised/updated/additional materials, received the Reference Registration Body to an expert institution for review.

The expert institution within 20 business days shall review the replies to the questions (remarks), including revised/updated/additional materials. If during the review process some other questions or (remarks) arise, a list of additional questions (remarks) is prepared and sent again to the authorized body of the member state.

The list of additional questions (remarks) is sent by the authorized bodies of the member state to the Reference Registration Body within 3 business days; in turn, the latter shall, within 3 business days, direct to the applicant all additional questions (remarks) received from the authorized bodies of other member states. The registration procedure is suspended from the date of sending out questions (remarks) to the applicant.

50. The applicant shall prepare replies to additional questions (remarks), including revised/updated/additional materials, within the time period not exceeding 30 business days.

The registration procedure is re-started from the date of receipt of applicant's replies to additional questions (remarks), including revised/updated/additional materials, by the Reference Registration Body.

51. The Reference Registration Body within 5 business days shall:

- notify the authorized bodies of the member states specified in the application that the replies to additional questions (remarks), including revised/updated/additional materials, have been delivered to its address. The Reference Registration Body may provide the replies to additional questions (remarks), including revised/updated/additional materials, to the authorized bodies of the member states specified in the application upon their request within 1 business day

from the date of receipt of such request;

- send the replies to additional questions (remarks), including revised/updated/additional materials, received from the applicant to expert institution(s) for their review.

52. For the purposes of preparing a list of questions (remarks) and a list of additional questions (remarks), the procedure of feed additive registration and other registration-related procedures can be suspended for not more than two times.

53. Based on the results of completed expert assessments and applicant's replies to the questions, the expert institutions shall, within 17 business days, compile an expert report and forward it to the appropriate authorized bodies of the member states. In cases where an authorized body of member state had involved multiple expert institutions, the authorized body of the member state will consolidate all expert reports received from the expert institutions into a single report.

54. Based on the expert report the authorized bodies of the member states engaged in the feed additive registration procedure or another registration-related procedure shall, within 3 business days, make decision regarding the feed additive and send this decision together with a copy of expert report to the Reference Registration Body in the form of official letter.

In cases where the applicant fails to provide replies to the questions (remarks) and additional questions (remarks), including revised/updated/additional materials, within the established timeframe, the Reference Registration Body will, within 5 business days, adopt decision on refusal from feed additive registration or another registration-related procedure and no later than in 3 business days notify the applicant and the authorized bodies of the member states specified in the application on its decision.

8. Process of making decisions on feed additives

55. Based on the expert reports and taking into consideration the opinion of the authorized bodies of the member states involved in the procedure, the Reference Registration Body shall, within 5 business days, make decision on:

- 1) registration or refusal from registration of the feed additive;
- 2) confirmation of the registration or refusal from confirmation of the feed additive registration;
- 3) incorporation of modifications to the registration dossier on feed additive or refusal from their incorporation;
- 4) suspension or recall of the registration certificate on the feed additive.

56. In cases where all authorized bodies of the member states involved in the feed additive registration procedure or another registration-related procedure have unanimous consent on the registration of feed additive, or confirmation of registration of feed additive, or incorporation of modifications the registration dossier on feed additive, the Reference Registration Body shall, within 10 business days, inform the authorized bodies of the member states on the decision made with respect to the feed additive, enter necessary data on the feed additive in the Union Registry of Feed Additives and issue to the applicant:

- 1) registration certificate on the feed additive according to the form given in Annex No. 5 to these Rules;
- 2) regulatory document (for feed additives produced in the territory of the member states);
- 3) instruction for use of the feed additive according to the form given in Annex No. 6 to these Rules.

57. In cases where the Reference Registration Body receives from the authorized body of one (or more) of the member states involved in the feed additive registration procedure or another registration-related procedure a justified refusal from the registration of feed additive, or from the confirmation of registration of feed additive, or from the incorporation of modifications to the registration dossier on feed additive, the Reference Registration Body shall, within 10 business days, inform the authorized bodies of the member states on the decision made with respect to the feed additive, issue and release to the applicant a registration certificate for the feed additive according to the uniform format; the certificate allows circulation of this feed additive in the territories of those member states which gave their consent to its registration.

58. In cases where all authorized bodies of the member states involved in the feed additive registration procedure or another registration-related procedure have unanimous consent on the refusal from registration of feed additive or refusal from the confirmation of registration of feed additive, or refusal from the incorporation of modifications to the registration dossier on feed additive, the Reference Registration Body shall, within 10 business days, inform by official letter the authorized bodies of the member states on the decision made with respect to the feed additive.

9. Procedure for the confirmation of feed additive registration

59. Date of the confirmation of feed additive registration is determined taking into consideration the date of registration carried out by the Reference Registration Body in accordance with these Rules.

60. To initiate the confirmation of feed additive registration, not earlier than 100 business days prior to expiration of the period of validity of the registration certificate issued for 5 years, the applicant (right holder of the registration certificate) shall submit the following documents in the Russian language to the authorized body of the member state which at the time of primary registration of the feed additive functioned as the Reference Registration Body:

1) application for the confirmation of feed additive registration (the application for the confirmation of feed additive registration can be submitted by the applicant in electronic format) according to Form 2 given in Annex No. 3 to these Rules.

2) report on the monitoring of safety of feed additive use over the registration period (the form of report on monitoring of safety of feed additive use – see Annex No. 7 to these Rules.).

61. In case where the right holder of registration certificate does not submit an application for the confirmation of feed additive registration within the timeline established by these Rules, the registration certificate is recognized as invalid by the Reference Registration Body. Within 3 business days the Reference Registration Body shall notify on this decision the authorized bodies of the member states in the territories of which the feed additive has circulated.

62. The confirmation of feed additive registration is carried out taking into account the results of safety assessment of the feed additive by experts.

In case where modifications to the registration dossier on feed additive are made at the stage of confirmation of feed additive registration, the procedure of registration confirmation may be extended to 200 business days and the expert review of materials submitted by applicant may be extended to 100 business days.

63. In the course of confirmation of feed additive registration, the applicant, if necessary, has the right to change:

- design of package and/or label;
- trade name;

- package size without changing material of the package.

During the procedure of confirmation of feed additive registration, this feed additive may remain in the circulation, provided that it had been manufactured during the period of validity of the registration certificate.

64. The following reasons can provide grounds for refusal from the confirmation of feed additive registration:

- 1) proof of harm from the feed additive application;
- 2) non-conformity of the qualitative and/or quantitative formulation of feed additive to its claimed formulation;

- 3) evidences showing that the data included in the registration materials attached to the application on registration confirmation, are not correct and/or not updated, and/or the conditions of confirmation of feed additive registration established in the Rules were not respected;

- 4) evidences showing that the right holder of the registration certificate did not make corrections in response to the remarks or did not reply to the questions raised during the expert assessment within the allotted timeframe.

65. In cases where the registration of feed additive is not confirmed upon expiration of the period of validity of the registration certificate issued for 5 years, the Reference Registration Body will delete data on the feed additive from the Union Registry of Feed Additives.

The registration dossier on feed additives deleted from the Union Registry of Feed Additive should be provided by the Reference Registration Body to the authorized bodies of the member states, upon requests thereof, within 10 business days from the date of receipt of the request over a period of 10 years from the date of deletion.

66. The registration is not confirmed for the feed additive which has not been in circulation for three or more years in the member states where this feed additive passed the registration procedure.

10. Procedure for making modifications to documents included in the registration dossier on registered feed additive

67. To make modifications to the documents included in the registration dossier on registered feed additive, the applicant shall submit the following documents in the Russian language to the authorized body of the member state which at the time of primary registration of the feed additive functioned as the Reference Registration Body:

- 1) application (application on making modifications to the documents included in the registration dossier on registered feed additive can be submitted by the applicant electronically) according to Form 3 given in Annex No. 3 to these Rules);

- 2) draft documents with modifications;

- 3) documents proving the need for such modifications;

- 4) feed additive specimens (if necessary).

68. Expert assessment of feed additive specimens is performed in cases relating to the following changes:

- 1) extension of the shelf life of feed additive (in this case it is necessary to provide a feed additive specimen with the shelf life which expires soon but not later than 60 days prior to the expiration date),

- 2) technology of feed additive production;

- 3) modifications of and/or additions to the methods of feed additive quality control;

- 4) formulation and quantity of auxiliary substances.

69. In cases where it is necessary to make other modifications to the registration dossier on registered feed additive, expert assessment of the feed additive is not performed.

The circulation of feed additive produced before the date of decision made by the Reference Registration Body on making modifications to the documents included in the registration dossier on the earlier registered feed additive, is allowed until the expiration date of this feed additive.

70. In the period of validity of the registration certificate, the right holder must inform the Reference Registration Body about any modifications proposed for inclusion in the registration dossier on registered feed additive and provide comprehensive data on the reasons of such modifications and their effect on the efficacy, safety and quality of the registered feed additive.

71. Potential deterioration of safety and quality of the feed additive is considered as justification for refusal from making modifications the registration dossier on the feed additive.

11. Suspension or recall of the registration certificate on feed additive

72. Decision on suspension or recall of the registration certificate on feed additive with the inclusion of relevant modifications in the Union Registry of Feed Additives is made by the authorized body of the member state which at the time of primary registration of the feed additive functioned as the Reference Registration Body.

The Reference Registration Body adopts the above decision upon reaching consensus between all authorized bodies of the member states involved in the process in the following cases:

1) where the Reference Registration Body has received information on the risk or threat to animal health and life from the use of the feed additive based on the results of regular safety monitoring of feed additives conducted by the Reference Registration Body (the form of report on the results of regular safety and efficacy monitoring of feed additives is attached (Annex No. 8 to these Rules);

2) where the right holder of the registration certificate on feed additive or its authorized agent (another legal entity) submits an application on suspension or recall of the registration certificate on feed additive (application on suspension/recall of the registration certificate on feed additive can be submitted electronically) according to Form 4 given in Annex No. 3 to these Rules;

3) a lack of confirmation of the registration of feed additive upon expiration of the period of validity of the registration certificate;

4) where the right holder failed to provide information which can lead to the need of making modifications to the documents included the registration certificate on registered feed additive within 30 business days from the date of occurrence of these modifications;

5) where the court has made a verdict on the violation of rights of the right holder for intellectual property items in the process of feed additive circulation;

6) non-presence of feed additive in the circulation for 3 or more years.

73. In the above cases, the authorized bodies of the member states undertake appropriate measures (actions) to ensure the cancellation of shipment of the feed additive and its withdrawal from the circulation in the customs territory of the Union.

74. In case of disagreements regarding the decision on suspension or recall of the registration certificate on feed additive, or the limitation of application areas, or the incorporation of modifications to the conditions of the registration certificate on feed additive, the completion of this procedure shall be based on the outcome of discussions with respect to the disagreements

at the Expert Board.

12. Settlement of disputes concerning the decision making process

75. To settle disputes concerning the decisions made with respect to the registration procedure or another procedure related to the registration of feed additives, the authorized bodies of the member states involved in the registration procedure or other registration-related procedures may address the Reference Registration Body, and the latter shall, within 10 business days, initiate review of the issues at the Expert Board meeting (Provision on the Expert Board is given in Annex No. 16 to the Rules Regulating the Circulation of Veterinary Drugs in the Customs Territory of the Eurasian Economic Union).

76. In this case, the registration procedure or other registration-related procedures are suspended from the date of delivery of the relevant information to the Reference Registration Body from the authorized bodies. Upon receipt of report of the Expert Board, the Reference Registration Body shall, within 5 business days, make one of the decisions concerning the feed additive taking into consideration the report of the Expert Board:

- possibility of registration or refusal from registration of the feed additive;
- possibility of the confirmation of registration or refusal from the confirmation of registration of the feed additive;;
- possibility of making modifications or refusal from making modifications to the registration dossier on feed additive;
- possibility of suspension or recall of the registration certificate on feed additive.

77. The Reference Registration Body shall notify the authorized bodies of the member states involved in the registration procedure or other registration-related procedures and the applicant on the adopted decision within 3 business days from the date of decision.

78. In case where the applicant disagrees with decision of the Reference Registration Body, the former may, within 10 business days from the date of receipt of the decision, apply to the Reference Registration Body for considering the issue at the Expert Board meeting. The Reference Registration Body shall, within 10 business days, initiate consideration of the issue at the Expert Board meeting.

79. Upon receipt of report from the Expert Board, the Reference Registration Body shall within 5 business days, make decision on the feed additive, taking into consideration the report of the Expert Board. The Reference Registration Body shall, within 3 business days from the date of decision, notify the authorized bodies of the member states involved in the registration procedure or other registration-related procedures on the adopted decision.

13. Revision of the list of member states of the Union in the territory of which the circulation of feed additive is planned

80. In case where the applicant is interested in revising the list of member states of the Union in the territory of which the circulation of feed additive registered in compliance with these Rules takes place (before the expiration of the shelf life of feed additive), an application is submitted to the authorized body of the member state which at the time of primary registration of the feed additive functioned as the Reference Registration Body.

81. Changes in the list of member states of the Union in the territory of which the circulation of feed additive registered in compliance with these Rules is planned include the following:

- 1) addition of other member states to those specified in the registration certificate on feed

additive;

2) substitution of one of the member states (or multiple member states) specified in the registration certificate on feed additive with another (other) member state(s) .

In this event, the Reference Registration Body shall, within 5 business days from the date of receipt of the application, send copies of the following registration documents to the authorized body (bodies) of the “added” member state(s): registration dossier; Expert Report; protocols of the expert assessment of feed additive specimens; regulatory document; instructions for use of feed additive; design of primary and secondary package, specifying the number of the registration certificate on feed additive, as well as a copy of the registration certificate issued by the Reference Registration Body for the circulation of the feed additive in the territory of individual member states.

82. The authorized body (bodies) of the “added” member state(s) shall, within the time period not exceeding 100 business days, make decision on registration of feed additive or refusal from its registration, having performed their review and, if necessary, having asked clarification questions to the applicant. The Reference Registration Body shall be informed on the adopted decision within 5 business days.

83. As soon as the registration procedure is completed with adoption of decision on the registration of the feed additive for the purpose of its circulation in the territory of the “added” member state(s), the Reference Registration Body will enter all necessary data on the registered feed additive into the Union Registry of Feed Additives and release the following documents to the applicant:

1) registration certificate on feed additive of the uniform format with the period of validity of 5 years, in exchange for the earlier issued registration certificate;

2) regulatory document (for feed additives produced in the territory of the Union member states);

3) instruction for use of the feed additive;

4) design of the primary and secondary packages specifying registration number of the feed additive indicated on the packages.

14. Requirements for the registration dossiers on feed additives and the feed additive specimens delivered for registration

84. For the state registration of feed additive, the Applicant shall submit to the authorized body of one of the member states (the Reference Registration Body) a registration dossier, containing the following:

1) application for state registration of the feed additive;

2) legal address of the producer organization;

3) name of the feed additive;

4) original name of the feed additive, if it has been registered as a trade name in accordance with the legislation of the member states;

5) formulation (specifying the quantitative content of components included in the feed additive formulation, guaranteed analytical content with specified ranges of the components; as regards microorganisms, a number of viable cells is established expressed in CFU/g; as regards enzymes, a number of activity units is specified);

6) draft instruction for use of the feed additive;

7) copy of patent (if available)

8) regulatory document for the feed additive;

9) data on production (description of the production process for the feed additive manufacture, its key stages effecting quality and safety of the feed additive);

10) copies of documents authenticated according to the established procedure and proving eligibility of the Applicant or his/her designee for the feed additive registration;

11) contract between the right holder and the producer (if necessary);

12) results of safety studies of the feed additive:

- results of toxicology studies in the laboratory animals, including findings of acute, subchronic and chronic toxicity studies, as well as studies of long-term effects (teratogenic, embryotoxic, mutagenic and carcinogenic effects) in case where the formulation of feed additive includes new components not used earlier for nutrition purposes (for feed additives intended for non-productive animals it is required to provide only data on acute toxicity studies in the laboratory animals);

- data on the feed additive tolerability in target animal species;

- data on the content of potentially hazardous substances and harmful impurities as well as intermediate products of microbiological and chemical synthesis;

- data on the safety of products derived from animals which received feed additives, their residual amounts and metabolites (with regard to new components not used earlier for nutrition purposes);

- data on the safety of feed additive for individuals who contact with it while handling feedstuffs or water containing this feed additive;

- data on the safety of feed additive for the environment as a result of exposure to the additive or released animal metabolites.

13) findings of stability studies of the feed additive (proof of the claimed storage period);

14) findings of the studies of efficacy of application (data proving efficacy for each of the claimed areas of application);

15) design of labels;

16) documents proving that the feed additive is registered outside the Union (if available);

17) document confirming payment of the commission (fee) for conducting review of the documents contained in the registration dossier on feed additive (review of the expert report) and/or expert assessment of the quality and efficacy of feed additive specimens in accordance with the rates established by the legislation of member state.

85. Documents executed in a foreign language should be submitted to the Reference Registration Body with the translation certified according to the procedure established in the legislation of the member state.

86. With respect to individual groups of feed additives, the following safety and efficacy requirements are applied to the dossier:

1) processing aids (including preservatives, anti-oxidants, emulsifiers, stabilizers, thickeners, gelatinizing agents, binders, absorbents of radioisotopes, mycotoxins and bacterial toxins, anti-caking agents, acidity regulators, denaturants):

- provision of the findings received in feed additive studies regarding the safety of its application (tolerability) in the target animal species (except silage additives), toxicology studies in the laboratory animals;

- efficacy of all processing aids is supported by the results of laboratory studies in vitro, except absorbents of radioisotopes;

2) flavor additives and dyes:

- for flavoring agents: specify a group of flavoring agents (natural products or synthesized agents);
- for natural products: it is not required to provide data on toxicological characteristics or tolerability;
- information on taste properties of the additive is based on the literature data and/or in-house studies (if available);
- for all dyes it is required to provide safety data; with regard to substances that, when used for feeding, cause coloration of animal-derived food products, it is required to provide data on tolerability of the feed additive in the target animal species; data on safety of the additive for consumers of animal-derived products and safety of the additive for environment (to be provided as literature data and/or in-house studies (if available));
- with regard to substances enhancing or restoring the feed color as well as substances effecting the coloration of ornamental fishes and birds, it is required to provide only the data on additive tolerability in the target animal species.

3) additives ensuring full biological value of feedstuffs (vitamins and their derivatives; compounds of macro- and trace elements; amino acids, their salts and analogs; urea and its derivatives; protein additives; substances normalizing functions of the animal organs and tissues):

- with regard to amino acids, their salts and analogs; compounds of macro- and trace elements; vitamins; pro-vitamins; protein agents and substances with identified chemical formulation used earlier as feed additives, it is not required to include toxicology or tolerability studies in the dossier;

- with regard to vitamins; pro-vitamins; amino acids; compounds of macro- and trace elements; urea derivatives; and, substances with identified chemical formulation proposed for the first time for use as feed additives, it is required to provide data on the tolerability studies in the target animal species and toxicology studies in the laboratory animals;

- in case where a submitted application covers all or multiple animal species, tolerability studies shall be performed in the most susceptible animal species (including the rationale for selection of the target group);

- studies for concentrations of residues in the animal-derived products shall be performed only for the substances proposed for the first time as feed additives;

- efficacy studies are not required for urea; amino acids, amino acid salts and their analogs; compounds of macro- and trace elements; vitamins, pro-vitamins; and, substances with identified chemical formulation used earlier as feed additives;

4) zootechnical additives (enzymes, prebiotics, probiotics, silage additives, and substances that have beneficial effect on the environment):

- it is required to provide the results of tolerability studies of the feed additives used in the target animal species and toxicology studies in the laboratory animals.

15. Registration certificate on feed additive

87. Registration certificate on feed additive has a unified number generated by the authorized body of member state of the Union which, according to these Rules, is the Reference Registration Body.

Number of registration certificate on feed additive is assigned according to the following template:

“KD-EAES-[NNNNNN]-[YY], where: KD – feed additive;

EAES – the Eurasian Economic Union, indicating that the registration has been performed in compliance with these Rules and that the feed additive is intended for the circulation in the territory of the Union or territories of individual member states selected by the applicant;

[NNNNNN] – a six-figure serial number assigned by the Reference Registration Body to feed additive at the time of registration;

[YY] – a two-character code of member state of the Union in accordance with the international standard ISO 3166-1, the authorized body of which was the Reference Registration Body according to these Rules;

88. Registration certificate is written in the Russian language and, if there is a relevant requirement in the legislation of member state, in the national language of the member state, the authorized body of which is the Reference Registration Body. In case where the said document is written in the Russian language and national language of one of the member states, the registration certificate on feed additive is executed by the Reference Registration Body on a double-sided letterhead each side of which corresponds to one of the languages.

16. Regulatory document

89. Regulatory document for feed additive is agreed with the authorized body of member state and contains a list of quality indicators with the description of their control methods and the requirements for testing instruments, reagents, standardized solutions, indicators, and reference specimens of active substances.

17. Instructions for use of feed additive

90. Instructions for use of feed additive are approved by the Reference Registration Body and executed in accordance with the form given in Annex No.6.

V. Identification marks of feed additives

91. Feed additives which have identification marks composing of the data placed on the primary and, if available, secondary package (except specimens of feed additives intended for registration tests) are allowed for the circulation in the customs territory of the Union in accordance with these Rules. Design of the primary and, if available, secondary package should contain registration number and be agreed with the Reference Registration Body.

92. Text information on the identification marks should be provided in the Russian language and, if necessary, in the language of the member state using easily readable font. Information not envisaged in this article is not allowed on the label.

93. Identification marks placed on the secondary (consumer) package of feed additive should contain the following:

- 1) name and/or trade name of the feed additive;
- 2) information on the intended purpose of the feed additive;
- 3) name and address of the producer;
- 4) series (lot) number of the feed additive;
- 5) date of production;
- 6) expiration date (inclusively);
- 7) storage conditions;
- 8) signature “Feed additive”;
- 9) safety precautions (if necessary).

94. Identification marks placed on the primary package of feed additive should contain the

following:

- 1) name and/or trade name of the feed additive;
- 2) series (lot) number of the feed additive;
- 3) expiration date (inclusively)

VI. State control (surveillance) in the area of circulation of feed additives

95. The member state shall conduct state control and surveillance over the circulation of feed additives in accordance with the procedure established by the legislation of the member states taking into consideration the acts comprising the law of the Union.

96. The authorized bodies of the member states cooperate with each other for exchanging experience, maintaining and optimizing the system of quality control and safety of feed additives and ensure that inspectors participate in the events (including those held by international organizations) for improving their skills.

97. Feed additives circulating in the territory of the member states, are subject to efficacy and safety monitoring for the purpose of revealing: potential negative consequences of their application; individual intolerability; poor quality, counterfeited and falsified feed additives, as well as for preventing and minimizing negative effects from the use of such feed additives, or their withdrawal from the circulation in the customs territory of the Union.

98. Based on the results of completed monitoring, the authorized body of member state shall, within no more than 3 business days from the date of confirmation of received information, send to the authorized bodies of the member states the information on:

- poor quality, counterfeited and falsified feed additives found in the territories of the member states of the Union;
- revealed negative effects from the application of feed additives, including reports (information) on a lack of their efficacy;
- suspended or recalled registration certificates on feed additives;
- renewal of the validity of registration certificates on feed additives.

The results of monitoring shall be placed on official website of the authorized body.

99. Entities involved in the circulation of feed additives must, according to the procedure established in these Rules, inform the authorized body of the member state about negative effects resulting from the use of feed additives as well as other facts and circumstances posing a threat for animal life or health from the use of feed additives, identified at all stages of the circulation of feed additives in the territory of the member states and other countries.

100. In cases where information is found on the negative effects resulting from the use of feed additives, individual intolerability, as well as other facts and circumstances from the use of feed additives, the right holder of the registration certificate on feed additive, or other legal entities authorized by the latter must take measures aimed at eliminating the negative consequences of the use of such feed additives, preventing harmful effects on animal life or health and protecting them against the use of such feed additives.

101. For non-disclosure or concealment of information envisaged in p. 100 of these Rules, the right holder of the registration certificate on the feed additive, producer of the feed additive, and officials who became aware of this information by the nature of their office, will bear responsibility in accordance with the legislation of member state.

102. In cases where the authorized body of member state, within the conducted monitoring, has received evidences on non-compliance of feed additive with the established requirements, or received information on non-conformity of the data on feed additive efficacy

and safety to the data contained in the instruction for its use, the authorized body of member state shall, according to the established procedure, consider an issue on the suspension of use of such feed additive.

VII. Unified Registry of Registered Feed Additives of the Eurasian Economic Union and Information System of the Eurasian Economic Union in the Sphere of Circulation of Feed Additives

18. Unified Registry of Registered Feed Additives of the Eurasian Economic Union

103. To ensure conditions for the circulation of safe, effective and high-quality feed additives registered in accordance with these Rules in the territories of the member states, the authorized bodies of the member states shall create and maintain a Registry of Feed Additives of the Union according to the form given in Annex No. 9 to these Rules.

104. Entry of data on a registered feed additive in the Registry of Feed Additives of the Union is done by the Reference Registration Body within the time limit not exceeding 1 business day from the date of one of the following decisions made by the Reference Registration Body: decision on the feed additive registration; decision on making modifications to the documents included in the registration dossier on the registered feed additive; decision on the confirmation of registration of the feed additive; decision on the suspension of registration certificate or the cancellation of registration of the feed additive.

19. Information System of the Eurasian Economic Union in the Sphere of Circulation of Feed Additives

105. The Information System of the Eurasian Economic Union in the Sphere of Circulation of Feed Additives (hereinafter – the “information system”) is designed to create conditions necessary for the circulation of safe, effective and high-quality feed additives in the customs territory of the Union.

The information system is a part of the integrated information system of the Union (hereinafter – the “integrated system”) and includes the common information resource - the Registry of Feed Additives of the Union.

106. Common information resources of the information system (hereinafter – the “common information resources”) are generated on the basis of information exchange between the member states of the Eurasian Economic Union and the Eurasian Economic Commission.

107. The member states designate authorized bodies or authorized organizations (hereinafter – the “expert organizations”) responsible for the submission of data necessary for creating and maintaining the common information resources to the Eurasian Economic Commission.

108. The information system facilitates the exchange of information between the member states concerning the feed additives which fail to comply with the quality and safety requirements, as well as counterfeited and falsified feed additives, found adverse reactions to feed additives and suspended, recalled, prohibited for use and non-registered feed additives.

Information exchange arising between the authorized bodies (expert organizations) and the Commission, as well as between the authorized bodies (expert organizations) of the member states takes place via the implementation of common processes within the Union, using capabilities of the integrated system.

109. Process documents regulating information exchange within the common processes

using capabilities of the integrated system, including the requirements for formats and structures of electronic documents and data used for such communication, are developed and approved by the Commission in accordance with the Requirements for the Model Structure of Process Documents regulating information exchange with the use of capabilities of the integrated system for foreign and mutual trade of the common process.

110. Access to the common information resources is provided to interested parties through the data portal of the Commission.

111. Data contained in the information resources are provided on the no-cost basis.

112. Information exchange arising between the applicant and the authorized body of member state in the process of registration of feed additives can be done in electronic format.

113. Requirements for electronic format of documents (electronic documents), procedure of sending out and receiving messages (requests) in the process of said information exchange shall be defined by the Commission.

VIII. Requirements for the Import and Export of Feed Additives in/from the Territory of the Union

114. Feed additives are imported in the customs territory of the Union provided that:

- the imported feed additive is included in the Registry Feed Additives of the Union (e.g. in the period of confirmation of registration of feed additive);
- availability of import permit issued by the authorized body of the member state according to the procedure established by the regulatory legal acts comprising the law of the member state.

115. Import of feed additives not registered in the Union according to the procedure established in the Union, is allowed subject to availability of import permit issued by the authorized body of the member state according to the procedure established by the regulatory legal acts comprising the law of the member state, for the following purposes:

- to conduct studies (expert assessment) of feed additive specimens within the registration procedure (subject to their further destruction in the territory of the member state at the expense of the owner of unused specimens upon completion of the studies);
- to use exhibition samples (subject to their further destruction in the territory of the member state at the expense of the owner of these samples or their return);

114. Import or circulation of falsified, poor quality or counterfeited feed additives in the territory of member state is not allowed.

Counterfeited, falsified and poor quality feed additives are subject to withdrawal and further destruction or return from the customs territory of the Union (when found at the checkpoint on the Union borderline).

The destruction of feed additives is carried out at the expense of their owner according to the procedure established by the member states.

Persons who import or had imported falsified and/or poor quality, and/or counterfeited feed additives in the customs territory of the Union, shall bear responsibility in compliance with the legislation of the member state in the territory of which the actual violation is proved.

115. Feed additives from the customs territory of the Union are exported according to the procedure established by the legislation of the member state from the territory of which they are exported.

IX. Final and Transitional Provisions

116. Prior to bringing the regulatory legal acts of the Union and the member states into line with these Rules, the regulatory legal acts effective in the territory of the member states shall be used insofar as it does not conflict with these Rules.

117. The circulation of feed additives registered in accordance with the requirements of the Union member states prior to the entry of these Rules into force, is allowed in the customs territory of the Union through December 31, 2019.

118. The acceptance of applications on registration of feed additives for the purpose of their circulation in the customs territory of the Union pursuant to Decision of the Commission of the Customs Union of June 18, 2010, No. 317, will be stopped ninety business days prior to the entry of these Rules into force.

119. Data on feed additives attributed to the feed additives for animals in accordance with the Provision on the Uniform Procedure of Veterinary Control at the Customs Borderline of the Customs Union and the Customs Territory of the Customs Union, approved by Decision of the Commission of the Customs Union of June 18, 2010, No. 317, and included, prior to entry of these Rules into force, by the authorized bodies of the Union member states in the Registry of registered veterinary drugs, diagnostic systems, agents for animal treatment for parasites and feed additives for animals in compliance with the Common Veterinary (Veterinary and Sanitary) Requirements, applied to commodities subject to veterinary control (surveillance) approved by Decision of the Commission of the Customs Union of June 18, 2010, No. 317, shall be included in the Registry of feed additives of the Union in compliance with these Rules.

120. Through December 31, 2019, the confirmation of registration / re-registration of feed additives; the incorporation of modifications to the documents included in the registration dossier on feed additives; the cancellation of registration of feed additives which have registration certificates issued prior to the entry of these Rules into force; and, other procedures associated with the registration of such feed additives is carried out in accordance with the legislation of the member states.

121. The authorized body of member state shall enter in the Registry of Feed Additives of the Union the following information: on the confirmation of registration / re-registration of feed additives; on the incorporation of modifications to the documents included in the registration dossier on feed additives, as well as on the cancellation of registration of feed additive, registered prior to the entry of these Rules into force.

122. Beginning January 01, 2020, the circulation of feed additives, registered in accordance with the requirements of the Union member states prior to the entry of these Rules into force, is not allowed.

ANNEX No. 1

to the Rules Regulating Circulation of Feed Additives in the
Customs Territory of the Eurasian Economic Union

Flowchart of Registration of Feed Additives

Pre-registration procedure	
Day 0	Applicant submits an application on feed additive registration together with a registration dossier on feed additive to the Reference Registration Body.
Day 0	The Reference Registration Body verifies completeness of registration dossier on feed additive and, if the registration dossier is not complete, it will send a letter to the applicant's address (with a copy to the authorized bodies of the member states of the Union) stating that it is impossible to accept the presented registration dossier on feed additive for expert assessment because of its incompleteness.
Day 0	Applicant re-submits an application on feed additive registration together with a registration dossier on feed additive plus additional, earlier missing, documents, materials or data to the Reference Registration Body.
Day 0	The Reference Registration Body verifies completeness of registration dossier on feed additive and, if the registration dossier is complete, will make decision on accepting the registration dossier on feed additive for expert assessment. In case where the applicant submits incomplete registration dossier for one more time, the Reference Registration Body will again send an appropriate letter to the applicant (with a copy to the authorized bodies of the member states of the Union).
Beginning of feed additive registration procedure	
Day 0	The Reference Registration Body adopts decision to forward the registration dossier on feed additive to expert assessment.
Day 10 (10 days)	The applicant and the authorized bodies of the member states of the Union are notified that the registration dossier on feed additive has been accepted for expert assessment. The Reference Registration Body sends the registration dossier on feed additive (including draft regulatory document on feed additive, draft instruction for its use and package design) to the expert institution. Upon request of the authorized bodies of the member states of the Union, the registration dossier may be sent by the Reference Registration Body to their address within 1 business day from the date of receipt of the request.
Day 0	Suspension of registration procedure Applicant shall, within 25 business days from the date of decision made by the Reference Registration Body on acceptance of the registration materials for expert assessment, send feed additive specimens to expert institution(s) assigned by the Reference Registration Body.

Day 13 (3 days)	Renewal of registration procedure In case where the feed additive specimens are not received by the expert institution within 25 business days, the expert institution will notify thereof the Reference Registration Body.	Day 18 (5 days)	The Reference Registration Body makes decision on refusal from registration of feed additive and notifies thereof the applicant and the authorized bodies of the member states of the Union. Registration procedure is finished.
	Renewal of registration procedure In case, where the expert institution receives the feed additive specimens, it provides a documentary confirmation of their receipt to the applicant.	Day 18 (5 days)	The expert institution estimates whether it is possible to perform studies. In case where the national expert institution(s) of member state of the Union cannot perform any of the tests or expert assessment of the feed additive specimens provided by the applicant, the expert institution will communicate this information to the Reference Registration Body.
Day 0	Suspension of registration procedure In case where the expert assessment (individual studies) cannot be performed in the facility of the expert institution assigned by the Reference Registration Body, the latter shall, within 30 business days, send the specimens to any of the expert institution(s) of another member state of the Union, where technical capabilities are available for performing necessary tests and expert assessments.		
Day 0	Suspension of registration procedure In case where tests of the feed additive specimens provided by the applicant cannot be performed due to their poor quality (spoilage, of-grade, defect, etc.) the expert institution will communicate this information to the Reference Registration Body.		
Day 0	Suspension of registration procedure The Reference Registration Body shall, within 3 business days inform the applicant and the authorized bodies of the member states of the Union that it is impossible to perform tests of the feed additive specimens provided by the applicant due to their poor quality.		
Day 0	Suspension of registration procedure The applicant shall, within 25 business days, provide again the necessary feed additive specimens to the expert institution.		
Day 21 (3 days)	Renewal of registration procedure In case where the feed additive specimens are not received within 25 business days by the expert institution, the latter will communicate this information to the Reference Registration Body.	Day 26 (5 days)	The Reference Registration Body makes decision on refusal from registration of the feed additive and notifies thereof the applicant and the authorized bodies of the member states of the Union. Registration procedure is finished.

	Renewal of registration procedure In case, where the expert institution receives the feed additive specimens, it provides a documentary confirmation of their receipt to the applicant and proceeds with expert assessment. In case of impossibility of performing tests of the re-provided feed additive specimens due to their poor quality (spoilage, of-grade, defect, etc.) the sequence of actions is repeated.		
Day 171 (150 days)	The expert institution conducts expert assessment of the feed additive. The results of studies of the feed additive specimens are documented in the protocol of studies, specifying what methods were used. The results of expert assessment are documented in expert report. The expert report together with the study protocols are sent by the expert institution to the Reference Registration Body.		
Day 174 (3 days)	The Reference Registration Body notifies the authorized bodies of the member states of the Union on receipt of the expert report on feed additive and the study protocols. Upon request of the authorized bodies of the member states of the Union, the expert report on feed additive and the study protocols can be sent by the Reference Registration Body to their address within 1 business day from the date of receipt of the request.		
Day 177 (3 days)	The authorized bodies of the member states of the Union send the expert report on feed additive and the study protocols to the expert institution for review.		
Day 207 (30 days)	The expert institution reviews the expert report on feed additive and the study protocols. If questions (remarks) are raised with respect to the presented materials, the expert institution will prepare a list of questions (remarks) and forward it to the authorized body of member state of the Union).		
Day 210 (3 days)	The authorized bodies of the member states of the Union send the list of questions (remarks) prepared by the expert institution(s) to the Reference Registration Body.		
Day 213 (3 days)	The Reference Registration Body sends to applicant the list of questions (remarks) received from the authorized bodies of the member states of the Union.		
Day 0	Suspension of registration procedure Applicant shall, within the time period of no more than 90 business days, provide replies to the questions (remarks) together with revised/updated/additional materials to the Reference Registration Body.		
Day 218 (5 days)	In case where applicant fails to provide replies to the questions (remarks) together with revised/updated/additional materials, the Reference Registration Body makes decision on refusal from feed additive registration.	Day 221 (3 days)	The Reference Registration Body notifies applicant and the authorized bodies of the member states of the Union on the termination of feed additive registration procedure, specifying the reason. Registration procedure is finished.

	<p>Renewal of registration procedure The Reference Registration Body notifies the authorized bodies of the member states of the Union on receipt of replies to the questions (remarks) together with revised/updated/additional materials from applicant. Upon request of the authorized bodies of the member states of the Union, replies to the questions (remarks) together with revised/updated/additional materials from applicant can be forwarded by the Reference Registration Body to their address within 1 business day from the date of receipt of the request. The Reference Registration Body sends replies to the questions (remarks) together with revised/updated/additional materials received from applicant to the expert institution for review.</p>	<p>Day 221 (3 days)</p>	<p>The authorized bodies of the member states of the Union send replies to the questions (remarks) together with revised/updated/additional materials received from the Reference Registration Body to the expert institution for review.</p>
<p>Day 241 (20 days)</p>	<p>The expert institution reviews replies to the questions (remarks) together with revised/updated/additional materials provided by applicant. In case where questions (remarks) arise in the process of review, a list of additional questions (remarks) is compiled and sent again to the authorized body of member state of the Union.</p>		
<p>Day 244 (3 days)</p>	<p>The authorized bodies of the member states of the Union send a list of additional questions (remarks) compiled by the expert institution(s) to the Reference Registration Body.</p>		
<p>Day 247 (3 days)</p>	<p>The Reference Registration Body sends out the lists of additional questions (remarks) received from the authorized bodies of the member states of the Union.</p>		
<p>Day 0</p>	<p>Suspension of registration procedure Applicant shall, within no more than 30 business days, submit replies to the additional questions (remarks) together with revised/updated/additional materials to the Reference Registration Body.</p>		
<p>Day 252 (5 days)</p>	<p>Renewal of registration procedure. In case where applicant fails to provide replies to additional questions (remarks) and revised/updated/additional materials, the Reference Registration Body makes decision on refusal from feed additive registration.</p>	<p>Day 255 (3 days)</p>	<p>The Reference Registration Body notifies applicant and the authorized bodies of the member states of the Union on the termination of feed additive registration procedure, specifying the reason. Registration procedure is finished.</p>

	<p>Renewal of registration procedure. The Reference Registration Body sends a notification to the authorized bodies of the member states of the Union stating that it has received replies to additional questions (remarks) together with revised/updated/additional materials from applicant. Upon request of the authorized bodies of the member states of the Union, the replies to additional questions (remarks) together with revised/updated/additional materials can be sent by the Reference Registration Body to their address within 1 business day from the date of receipt of the request. The Reference Registration Body sends replies to additional questions (remarks) together with revised/updated/additional materials received from applicant to the expert institution for review.</p>	<p>Day 255 (3 days)</p>	<p>The authorized bodies of the member states of the Union send the replies to additional questions (remarks) together with revised/updated/additional materials received from the Reference Registration Body to the expert institution for review.</p>
<p>Day 272 (17 days)</p>	<p>The expert institution performs review of replies to additional questions (remarks) together with revised/updated/additional materials and prepares an expert report based on the results of completed expert assessment and applicant's replies and sends the report to the authorized body of member state of the Union.</p>		
<p>Day 275 (3 days)</p>	<p>The authorized bodies of the member states of the Union make decision regarding the feed additive and together with a copy of the expert report send it to the Reference Registration Body.</p>		
<p>Day 280 (5 days)</p>	<p>The Reference Registration Body makes decision on registration of feed additive (provided that positive decision is made by the authorized bodies of all member states of the Union).</p>	<p>Day 290 (10 days)</p>	<p>The Reference Registration Body:</p> <ul style="list-style-type: none"> - informs the authorized bodies of the member states of the Union on decision adopted with regard to feed additive; - enters the relevant information in the Unified Registry of Registered Feed Additives of the Eurasian Economic Union; - informs applicant and issues a registration certificate as well as an agreed regulatory document and instruction for use of feed additive.

	The Reference Registration Body makes decision on refusal from registration of feed additive (provided that negative decision is made by the authorized bodies of all member states of the Union.	Day 290 (10 days)	The Reference Registration Body informs applicant and the authorized bodies of the member states of the Union on the adopted decision regarding feed additive.
Day 0	Suspension of registration procedure In case of disagreement on the issue of making decision on registration or refusal from registration of feed additive, the Reference Registration Body shall, within 3 business days, address the Eurasian Economic Commission with request to organize a meeting of the Expert Board.		
Day 0	Suspension of registration procedure Based on the results of the Expert Board meeting the Commission within 5 business days prepares its recommendations for making decision on a particular feed additive which within 3 business days will be sent by the Commission to the Reference Registration Body.		
Day 0	Suspension of registration procedure The Reference Registration Body makes decision on registration or refusal from registration of feed additive.		
Day 300 (10 days)	Renewal of registration procedure In case where decision is made on registration of feed additive, the Reference Registration Body will: - inform the authorized bodies of the member states of the Union on decision made with respect to feed additive; - enter the relevant information into the Unified Registry of Registered Feed Additives of the Eurasian Economic Union; - issue a registration certificate to the applicant as well as agreed regulatory document and instruction for use of feed additive.		
	Renewal of registration procedure In case where decision is made on refusal from registration of feed additive, the Reference Registration Body will inform applicant and the authorized bodies of the member states of the Union on the decision adopted with respect to feed additive.		

to the Rules Regulating Circulation of Feed Additives in the Customs Territory of the Eurasian Economic Union

Wholesale trade, transportation, storage and disposal of feed additives

Key principles of wholesale trade, transportation, storage and disposal of feed additives

1. Requirements for the personnel involved in storage, transportation, and sales of feed additives

All personnel involved in activity relating to storage, transportation, sales and disposal of feed additives should be properly trained and have necessary qualification before they start to perform their job duties. It is necessary to keep records on personnel training and training effectiveness should be evaluated regularly and documented.

Appropriate procedures on occupational health and personal hygiene of staff applicable to conducted operations should be established and observed. These procedures should include requirements pertaining to health, hygiene and clothes.

2. Requirements for the acceptance of incoming feed additives

Feed additives requiring special storage conditions or safety precautions should be accepted on a first priority basis. As soon as all necessary inspection measures are completed, such feed additives should be immediately moved to an appropriate storage area.

Feed additives intended for sales within the Union should be directed to the sales area after it is ascertained that all the requirements established by these Rules have been satisfied.

3. Requirements for the storage of feed additives

Feed additives and, if necessary, other products which may have impact on them should be kept separately from each other and protected against exposure to the light, temperature, humidity and other environmental factors. Feed additives, requiring special storage conditions should be stored in compliance with these conditions.

Shipping containers with feed additives should be cleaned before they are placed for storage.

Storage operations should be carried out in such a way as to ensure compliance with the required storage conditions and safety precautions.

Shipment of feed additives should be organized in such a manner as to ensure that the feed additives with an earlier date of expiration are shipped first (FEFO rule – first expired first out). Deviations from this requirement shall be documented.

Storage and handling of feed additives should include measures to prevent spillage, compromise of package integrity, contamination and mixing up. Feed additives should not be stored on the floor level.

Feed additives with expired use-by date should be removed immediately from the category of “acceptable” for delivery either physically (placed in a special storage room or area) or with the use of electronic tools, ensuring their equivalent separation.

Inventory analysis should be performed on a regular basis and found deviations should be documented and followed by investigation.

3.1. Facilities

Facilities should be designed and arranged in such a way as to ensure compliance with the required conditions for proper storage of feed additives.

Facilities should be clean and dry; necessary temperature and humidity conditions are to be maintained in the facilities. They should be protected, robust and have sufficient capacity for safe storage and handling of feed additives. To ensure accuracy and safety of all operations carried out in the storage area, the facilities must have proper lighting.

Feed additives should be kept appropriately in the dedicated and clearly marked areas where access is provided only to the authorized personnel. Any system substituting the physical separation of storage areas, e.g. a computerized system, should ensure an equivalent safety level and be validated.

Feed additives with expired use-by-date, returned, withdrawn from the category “acceptable for shipment” or suspicious for falsification, recalled or rejected, for which decision on handling is not made yet, should be separated and placed for storage to a dedicated area. Necessary precautions should apply to these areas in order to guarantee that feed additives stored in such areas will remain separated from feed additives acceptable for distribution. These storage areas should be properly marked and protected against unauthorized access. Feed additives received from third countries and not intended for sales on the common market of the Union should be separated physically during their storage.

Feed additives requiring special handling should be stored in the appropriate conditions.

Delivery and shipment areas should be protected against the weather conditions. It is required to have adequate separation of delivery, shipment and storage areas. Procedures should be developed to define the process of control over incoming and outgoing flows of feed additives. Inspection areas designed to check the incoming products should be designated and equipped appropriately.

The delivery area should allow cleaning of containers.

It is necessary to set up an appropriate security system with anti-intrusion protection in all facilities with controlled access.

Storage facilities and equipment should be clean and free from accumulated dust or garbage. It is a requirement to have procedure documenting software and to keep records on cleanup of the facilities and equipment. Equipment, implements and consumables used for cleaning (washing), as well as detergents and disinfecting agents should be selected, used and stored in such a way as to prevent them from becoming contamination sources.

Facilities should be designed and equipped appropriately to ensure protection against the penetration of insects, rodents and other animals. A pest prevention and control program should be developed.

Personnel recreation rooms, cloak rooms, shower and rest rooms should be separated adequately from the storage areas. Food products, drinks or tobacco products are not allowed in the storage facilities.

3.2. Monitoring of temperature and storage conditions

It is necessary to have in place the appropriate equipment and procedures to monitor the storage conditions of feed additives.

Storage conditions that may require monitoring include:

temperature, lighting, humidity and cleanliness in the facilities.

It is necessary to perform a survey of the baseline temperature distribution in the storage facilities, prior to their use in accordance with the conditions meeting the operation parameters. Temperature monitoring equipment should be located according to the survey results, in the points with the largest temperature fluctuations.

If the area of facilities used for storage at room temperature is not more than a few square meters, it is necessary to conduct analysis of potential risks (e.g. the presence of heating units), and the temperature monitoring equipment should be installed taking into account the results of temperature evaluation.

3.3. Equipment

Equipment impacting storage and sales of feed additives should be designed, placed and maintained according to the instructions for its use (operation). Equipment maintenance plan should be approved for the equipment playing a key role in the execution of critical operations.

Equipment used for control and monitoring of storage conditions of feed additives (measuring instruments) should be adjusted and calibrated.

Appropriate alarm systems should be used for timely recognition of deviations from the required storage conditions. Alarm communication levels should be set up properly. Alarm

systems require regular testing to ensure their proper functioning.

Equipment repair, maintenance, verification and calibration operations should be carried out in such a way as to avoid negative effects on the quality of feed additives. If necessary, a redundant set of operational equipment and instruments should be available for the use during repair, maintenance or verification.

Repair, maintenance, verification and calibration operations performed for the critical equipment should be documented appropriately and the documentation should be archived.

Such critical equipment shall include: air conditioners; cooling chambers (refrigerators) or devices; security and fire alarm systems; access control systems; ventilation system; air humidification and/or drying system; thermal hygrometers or other types of equipment used for recording temperature and humidity, as well as transportation equipment.

3.4. Computerized systems

Before a computerized system is put into operations, it is necessary to demonstrate by validation or verification that the system is capable to receive preset results in an accurate, uniform and reproducible manner.

A detailed written description should be available (including diagrams, if applicable). The said documentation should be regularly updated. The description of computerized system should include concepts, goals, safety measures, areas of application and key fundamental features, as well as instructions for use and interface with other systems.

Data entry in computerized system or their modification should be performed only by the staff responsible for this kind of operations. Computerized system must record all changes within the system, indicating the user who made these modifications.

It is necessary to provide physical or electronic means ensuring data security and prevention of accidental or unauthorized introduction of modifications. Accessibility of saved data should be checked on a regular basis. Backup copies of saved data should be created regularly. Backup copies of the data entered in computerized system should be kept for as long as established in the legislation of the Union member states, but not less than 5 years, in a separately located and safe place.

It is necessary to establish procedures defining sequence of operations in case of system malfunction or failure. Data recovery measures should be envisaged.

3.5. Qualification and validation

The organization has to identify key equipment and processes subject to qualification and/or validation to prove that their installation and operation are performed properly. The scope of work carried out within the qualification and/or validation (e.g. storage, preparation to shipment and packing) should be defined on the basis of the documented risk analysis.

Equipment and processes should be appropriately qualified and/or validated prior to putting into operations or after any significant modification is made (e.g. as a result of repair or maintenance).

The execution of validation or qualification shall be documented in reports. Such reports must summarize the obtained results and provide clarifications on the found deviations.

Deviations from the established procedures are documented, and measures for their elimination and prevention of their recurrence in the future (corrective and preventive measures) should be developed. Concepts of corrective and preventive measures should be applied wherever necessary. It is required to receive evidences proving that the equipment or processes are acceptable which should be approved by the staff members in charge.

3.6. Documentation

Appropriate documentation is an integral part of the quality system. Documentation includes the following: written procedures; instructions; contracts; records; reports; study protocols and other data recorded as hard copy or in electronic format.

Documentation should prevent errors arising from the verbal communications and ensure traceability of appropriate operations in the process of sales of feed additives.

Documentation should be accessible for the authorized personnel and systematized.

Processing of personal data of the staff members, individuals who sent claims, or any other

physical persons or legal entities is conducted in compliance with the requirements of the legislation of the Union member states, defining the procedure for personal data processing and storage, including communication of personal data to a third party.

Documentation should cover adequately all processes exercised by the distributor and be clear to the personnel. The text of documents should be straightforward, not admitting ambiguous interpretations or mistakes.

Procedures should be approved, signed and dated by a person in charge. Documentation should be approved, signed and dated by designated persons according to the established requirement. Documentation should not be written by hand and in cases, where there is a need to add hand-written notes, necessary fields should be envisaged.

Any corrections entered in the documentation should be dated and signed; corrections should be made in such a way as to allow reading original notes. If necessary, the reasons for making corrections should be specified.

Documentation should be kept during the time period established in the legislation of the Union member states but not less than for 5 years. Personal data of the personnel should be deleted or depersonalized as soon as their storage is no more required for the distribution of feed additives.

Personnel should have on-line access to the documentation required for accomplishing their job duties.

Emphasis should be made on the use of effective procedures approved according to the established practice. Document contents should be free from ambiguous interpretations; document name and goal should be defined clearly. It is necessary to revise documents on a regular basis and keep them updated.

It is required to keep records relating to the execution of any actions with respect to received or shipped products, as well as records pertaining to the provision of broker services, e.g. applications, bills, packing lists or other records in electronic or another format.

Records should include but not limited to the following data: date; name of feed additive, quantity of purchased or shipped feed additives, name and address of vendor, receiver or consignee (as applicable).

Records should be executed at the time when respective operations are performed.

4. Requirements for the dispatch (shipment) of feed additives

4.1. Processing for shipment

Feed additives of good quality are allowed for shipment.

At the time of processing for shipment, the feed additives should have the remaining shelf life agreed by the receiver and shipper.

4.2. Shipment

Shipment of feed additives should be accompanied by the documents envisaged in the legislation of member state of the Union (pro-forma invoice, consignment note, CMR, invoice, air waybill, etc.). The accompanying documents shall specify the following: date; name of feed additive; shipped quantity; presentation form; standard dose rate of feed additive for animal feed; name and address of vendor; name and address of consignee (actual address of wholesale warehouse, if different from the legal address) and the required conditions of transport and storage.

Shipment records should be kept in a way that allows defining the actual location of feed additives.

4.3. Export

Organization exporting feed additives should have legitimate reasons for conducting activities on the distribution of feed additives in accordance with the legislation of member state of the Union.

In case of export of feed additives that are not registered in the territory of the Eurasian Economic Union, the exporting organization shall take necessary measures to prevent supply of such feed additives to the Union market.

5. Requirements for the transport of feed additives

A distributor company involved in shipment of feed additives must conduct their transportation in the conditions ensuring their safe custody and integrity; protection against

exposure to the environmental factors; compliance with the required temperature conditions (storage conditions) in the process of transportation; and prevention of falsifications. For any transport mode, it is required to provide a possibility for proving that the quality and integrity of feed additives were not affected during transportation.

Transportation planning should be based on the analysis of potential risks.

5.1. Transportation

Storage conditions required for feed additives should be observed during the entire transportation period in accordance with the producer instructions on the package.

In cases where deviations occur, such as incompliance with the temperature conditions or spoilage of the feed additives in the process of transportation, information of identified deviations should be communicated to the consignor and consignee. It is necessary to develop and document a procedure establishing policies for cases where deviations occur and considering investigation of such facts.

Organization should ensure that transport means and equipment used for the transportation of feed additives conform to the purposes of their use and are fitted out properly for their protection against undesirable effects that could compromise the quality or package integrity.

Transport vehicle used for the transportation of feed additives and its equipment should be kept clean and treated with detergents and disinfecting agents as necessary in compliance with the requirements of the sanitary standards established by the legislation of the Union member states.

Decision on the need of temperature monitoring should be based on the analysis of risks associated with the transportation through the selected route. Equipment for temperature monitoring during transportation installed inside the transport vehicle or container shall undergo regular maintenance, calibration and adjustment in accordance with the legislation of the Union member states.

For the transportation of feed additives it is advisable to use as much as possible such transport vehicles and equipment which conform to the purposes of their intended use and are properly fitted out to protect the feed additives against undesirable effects that could compromise the quality or package integrity.

In case of using transport vehicles and equipment that do not conform to the purposes of their intended use and are not fitted to protect the feed additives against undesirable effects that could compromise the quality or package integrity, it is necessary to develop documented procedures ensuring the preservation of their quality.

Feed additives should be delivered to the address specified in the shipment documents and transferred directly to the receiver facilities. Feed additives should not be left in any other facilities.

Transportation by a third party shall be carried out on the basis of appropriate contract. Shipping companies should be informed on the requirements for transport conditions to be provided for feed additives. Responsibility for compliance with the conditions of transport of feed additives and for keeping the transport vehicle in a clean state is imposed on the transport vehicle owner.

In cases where transportation is accompanied by unloading and re-loading operations or includes intermediate storage at the temporary storage warehouse, emphasis should be made on the storage conditions and safety measures at the temporary storage warehouses. Storage conditions to be monitored include temperature, protection against light, humidity and cleanliness in the facilities.

Measures should be taken to reduce the duration of temporary storage of feed additives prior to the next transportation stage.

5.2. Containers, packages and identification marks

Feed additives should be transported in shipping containers which do not affect their quality and ensure reliable protection against the environmental factors, including the prevention of contamination.

The selection of shipping containers should be based on the requirements for storage conditions and transportation of feed substances; space necessary for placing the required amount;

projected fluctuations of environmental temperature; and, the estimated maximum duration of the transportation period, including temporary storage in customs warehouses.

To ensure proper handling and safety level for feed additives, the shipping containers should have identification marks containing sufficient information and requirements for their handling and storage, as well as necessary safety precautions. The information on shipping containers should allow identification of the contents and the source of origin.

5.3. Feed additives requiring special handling

In the process of transportation of feed additives requiring special handling, the distributor shall ensure conditions for safe transportation protected against unauthorized access in accordance with the requirements of the legislation of the Union member states.

Additional control systems should be provided for the shipments of said feed additives. Applied safety measures should be consistent with the requirements of the legislation of the Union member states. A procedure in case of their theft should be developed and documented. All theft cases should be documented.

For the transportation of thermolabile feed additives the requirement is to use qualified equipment (insulated packages, containers or transportation vehicles in which preset temperature conditions are maintained) to ensure that the necessary transportation conditions are available when feed additives are moved between the producer, distributor and the consignee.

In case of using transport vehicles capable to maintain the required temperature conditions, the equipment used for temperature monitoring in the process of transportation should be subject to regular maintenance, adjustment and calibration.

Data supporting compliance with the temperature conditions during storage and transportation should be provided to the consignee upon request.

Cooling elements in heat-insulated containers should be arranged in such a way as to prevent their direct contact with feed additives. The personnel should be trained and aware of the requirements contained in the procedures on preparing heat-insulated containers (taking into consideration the seasonality) and the requirements for the re-use of cooling elements.

It is necessary to develop measures aimed at preventing the re-use of inadequately chilled cooling elements. Proper physical insulation between chilled and frozen cooling elements should be provided.

The process of delivery of thermolabile feed additives and control of seasonal temperature fluctuations should be described in the documented procedure.

6. Requirements for sales

All distributor activities should be arranged in a manner, preventing the loss of identity of feed additives and ensuring compliance with the requirements specified on the package.

Distributor should take necessary measures to minimize the risk of penetration of falsified feed additives in the marketing chain.

6.1. Evaluation of vendors

Distributor shall receive feed additives only from those organizations which, in accordance with the legislation of the Union member states, have the right to conduct this business.

Distributor who purchases feed additives from another distributor should verify that the vendor of feed additives complies with all the necessary requirements ensuring the preservation of quality and safety of feed additives.

Measures on the evaluation and approval of vendors should be completed prior to purchase of feed additives. These measures should be carried out according to the established procedure and their results should be documented and verified on a regular basis.

When contracts are signed with new vendors, the organization has to perform a due diligence of the vendors to verify their competence and reliability.

Emphasis should be made on:

- 1) vendor credentials and/or reliability;
- 2) offers on the shipment of most commonly falsified feed additives;
- 3) offers on the shipment of a large lot of the feed additives that are usually available only in limited quantities;

4) price quotes differing from the market prices

6.2. Evaluation of customers (consignees)

Distributor should verify that feed additives are shipped only to those organizations which have legitimate reasons in accordance with the legislation of member state of the Union to perform actions relating to the circulation of feed additives.

Distributor shall keep track of the on-going deals and conduct investigations with respect to any deviations in the chain of marketing and sales of feed additives. In case where deviations from the specified marketing and sales procedure are found that could imply that the feed additives are used for purposes other than intended, investigations shall be conducted and, if necessary, the authorized state body shall be notified on its findings.

Distributor should take measures to ensure fulfillment of the duties relating to the circulation of feed additives established in the legislation of member state of the Union.

6.3. Claims

Claims should be registered and include the following data: date of claim receipt; name of organization or name of person, their contact data (number of telephone/fax, e-mail, addresses); names of feed additives; presentation forms; amount; cause of claim, etc. In this context, it is necessary to distinguish claims relating to the quality and/or safety and/or efficacy of feed additives and those relating to compliance with the distribution requirements and conditions.

In cases where a claim is relating to the quality and/or safety and/or efficacy of feed additives or where the presence of falsified feed additives is suspected, the producer and/or the registration certificate holder should be notified promptly.

As regards claims relating to compliance with the distribution requirements and conditions, an investigation should be initiated to find out the source and cause the claim submission.

For processing claims, a person in charge should be assigned, and other staff members of the distributor, as many as necessary, may be engaged in this process.

Based on the results of investigation and analysis of claims, the appropriate measures, as necessary, should be taken, including corrective and preventive actions, e.g. notification of the authorized bodies of the Union member states, if necessary, in accordance with the established requirements.

6.2. Returned feed additives

Operations with returned feed additives should be performed in accordance with the documented procedures based on the risk assessment, taking into account their specifics, special storage conditions as well the time period from elapsed the date of their initial shipment. The return is done in accordance with the legislation of the Union member states and contractual commitments between the parties involved in the return of products.

Feed additives shipped earlier can be returned to the category “acceptable for shipment” only in case if all the below conditions are met:

1) integrity of the secondary package of feed additives is not compromised; traces of damages are not present; shelf life is not expired; products were not withdrawn from circulation;

2) feed additives can be returned to the category “acceptable for shipment” in case where the return was accomplished within the established period of time;

3) consignee presented documents proving compliance with the special storage conditions required for transportation, storage and handling of these feed additives;

4) feed additives were inspected and evaluated by the competent person assigned to the execution of these actions;

5) distributor has evidences showing that the feed additives were shipped to a particular consignee (according to the attached copies of appropriate accompanying documents); the number of series/lot is the same as those specified in the documents and there is no reason for assuming that the feed additives are falsified).

Feed additives requiring special temperature conditions during their storage can be returned to the category “acceptable for shipment” in case where documented evidences are available demonstrating that they were stored and transported in the appropriate conditions throughout the elapsed time.

In case of identification of any deviations, it is necessary to conduct a risk assessment to find evidences demonstrating whether safe keeping and integrity of the feed additives were ensured. These evidences should include the following stages:

- 1) shipment to consignee;
- 2) inspection (identification) of products;
- 3) opening-up of the shipping package;
- 4) return of feed additives in the shipping package;
- 5) collection and return of feed additives to the distributor;
- 6) placement of the feed additives into a special storage area at the distributor facilities.

Acceptance of the returned feed additives without documentation is not allowed.

Feed additives returned to the category “acceptable for shipment” should be placed in a way ensuring effective functioning of the system “shipping first the feed additives with an earlier date of expiration”.

Feed additives that were stolen and then found cannot be returned to the category “acceptable for shipment” or shipped to consignees.

6.5. Falsified feed additives

Distributor should immediately communicate information to the authorized body of member state of the Union as well as the registration certificate holder (owner) on falsified or suspicious feed additive. These actions should be described in the established documented procedures. Received information should be documented with all initial data kept, and it is necessary to conduct investigation with respect to this information.

Falsified feed additives found in the marketing and sales chain should be immediately isolated physically and placed for storage separately from other products in a dedicated facility or area with restricted access. All operations with falsified feed additives should be documented and supported with kept records.

6.6. Recall from circulation

The effectiveness of actions relating to the recall of feed additives from circulation should be evaluated on a regular basis (at least annually).

At any time, it should be possible to initiate immediately actions on recall and withdrawal from circulation.

Distributor has to follow instructions of the information notice on recall from circulation which, if necessary, should be approved by the authorized body.

Actions relating to the recall and withdrawal from circulation should be documented at the time of their implementation pursuant to the established procedures. Documentation on the recall should be accessible to the authorized bodies.

Distribution-related records should be accessible to the person responsible for recall and withdrawal of feed additives from the circulation and contain sufficient data on the distributors of feed additives and direct consignees (address, telephone and/or fax number, available during working and non-working hours, number of series/lot, name, presentation form, and shipped quantity), including data on exported feed additives and their specimens.

The sequence of actions carried out in the recall and withdrawal from the circulation should be documented and the final report should be compiled.

7. Requirements for the disposal (destruction) of feed additives

Feed additives intended for destruction should be properly marked and stored separately in the facility or area with restricted access; in this case, operations with them should be carried out in accordance with the written procedures.

The destruction should be conducted in accordance with the requirements of the legislation of the Union member states or acceptable international requirements relating to the circulation, transportation and destruction of feed additives.

Records on the destruction of feed additives should be kept for the period of time established in the legislation of the Union member states.

8. Requirements for self-inspection

A program on conducting self-inspections should be developed to cover all aspects of

activity performed by organization.

Self-inspections can be divided into multiple independent inspections relating to individual types of activity of the organization; they should be bias-free and thorough and be carried out by designated skilled personnel of the distributor. Audits performed by independent external experts are also allowed, but they cannot replace self-inspections.

The results of self-inspections should be documented. Reports should contain all information received during the inspections. A copy of the report is to be provided to the top management of the organization and other relevant persons. In cases where deficiencies or deviations are identified, it is necessary to find out their causes, develop and document corrective and preventive actions and verify their execution.

to the Rules Regulating Circulation of Feed
Additives in the Customs Territory of the
Eurasian Economic Union

Form 1

EURASIAN ECONOMIC UNION

TO: THE AUTHORIZED
BODY FOR REGISTRATION
OF FEED ADDITIVES

(specify member state of the Union)

APPLICATION

I hereby request to register feed additive

(trade name of feed additive)

For circulation in the territory of (put a check mark): Republic of Armenia
 Republic of Belarus
 Republic of Kazakhstan
 Kyrgyz Republic
 Russian Federation

1. Applicant _____
(Name of physical person or full name of legal entity or

individual entrepreneur according to the foundation documents)

2. Location of Applicant

(address of location, phone, e-mail address, INN)

3. Representative of Applicant _____

(Name, address, phone, power of attorney – date/No.)

4. Right holder of registration certificate _____
(full name of legal entity according to the foundation documents,

legal address, phone, e-mail address, INN¹)

¹- only for legal entities registered in the territory of the Eurasian Economic Union

5. Data on feed additive:

5.1. Name _____
(international non-proprietary or chemical name)

5.2. Dosage, modes of administration and application, expiration date

5.3. Formulation _____
(list of substances included in the formulation of feed additive, specifying the amount of each of them)

6. Feed additive developed by

(name of legal entity, legal address, phone, e-mail address, INN¹)

7. Feed additive produced by

Legal address phone, e-mail address, INN¹

(name of producing company / name of international producer)

8. Place of production of feed additive _____
(name and addresses of production establishments involved in the process of production of

feed additive, specifying the stage of production, INN²)

9. Data on registration of feed additive _____

(registration abroad)

Date of application submission:

« _____ » _____ 20 _____

(signature of Applicant/Applicant's representative)

(Name, position)

Stamp

¹- only for legal entities registered in the territory of the Eurasian Economic Union

²- only for legal entities registered in the territory of the Eurasian Economic Union

EURASIAN ECONOMIC UNION

TO: THE AUTHORIZED BODY FOR
REGISTRATION OF FEED
ADDITIVES

(specify member state of the Union)

APPLICATION

I hereby request to confirm the registration of feed additive

(trade name of feed additive)

1. Applicant _____
(Name of physical person or full name of legal entity or
individual entrepreneur according to the foundation documents)

2. Location of Applicant _____
(address of location, phone, e-mail address, INN)

3. Representative of Applicant _____
(Name, address, phone, power of attorney – date/No.)

4. Right holder of registration certificate _____
(full name of legal entity according to the foundation documents,
legal address, phone, e-mail address, INN¹)

5. Data on feed additive:

5.1. Name _____
(international non-proprietary or chemical name)

5.2. Dosage, modes of administration and application, expiration date

5.3. Formulation _____
(list of substances included in the formulation of feed additive, specifying the amount of each of them)

6. Feed additive developed by _____
(name of legal entity, legal address, phone, e-mail address, INN²)

¹- only for legal entities registered in the territory of the Eurasian Economic Union

²- only for legal entities registered in the territory of the Eurasian Economic Union

7. Producer of feed additive

legal address phone, e-mail address, INN¹

(name of producing company / name of international producer)

8. Place of production of feed additive

(name and addresses of production establishments involved in the process of production of

feed additive, specifying the stage of production, INN¹)

9. Data on registration of feed additive

(number and date of registration in the Eurasian Economic Union, date of expiration of the registration term, registration abroad)

Date of application submission:

« _____ » _____ 20 _____

(signature of Applicant/Applicant's representative)

(Name, position)

Stamp

¹- only for legal entities registered in the territory of the Eurasian Economic Union

EURASIAN ECONOMIC UNION

TO: THE AUTHORIZED BODY
FOR REGISTRATION OF FEED
ADDITIVES

(specify member state of the Union)

APPLICATION
on incorporation of changes in the documents contained in registration dossier on registered feed additive

1. Applicant _____
(Name of physical person or full name of legal entity or

individual entrepreneur according to the foundation documents)

2. Right holder of registration certificate _____
(full name of legal entity according to the foundation documents)

legal address, phone, e-mail address, INN¹)

3. Number of registration certificate: _____

4. Date of registration of feed additive: _____

5. Feed additive developed by company: name and address: _____

6. Registration certificate is issued for indefinite time, with the period of validity of 5 years
(underline as appropriate)

7. Data on feed additive

7.1. Trade name of feed additive: _____

7.2. International non-proprietary name or chemical name of feed additive: _____

7.3. Dosage (bulk fill of feed additive, amount): _____

¹- only for legal entities registered in the territory of the Eurasian Economic Union

EURASIAN ECONOMIC UNION

TO: THE AUTHORIZED BODY
FOR REGISTRATION OF FEED
ADDITIVES

(specify member state of the Union)

APPLICATION

I request hereby to suspend registration certificate / recall registration certificate / limit application (or) incorporate changes in the conditions of registration certificate on feed additive (delete as appropriate)

(trade name of feed additive)
1. Applicant _____
(Name of physical person or full name of legal entity or

individual entrepreneur according to the foundation documents)
2. Location of Applicant _____
(address of location, phone, e-mail address, INN)

3. Representative of Applicant _____

(Name, address, phone, power of attorney – date/No.)

4. Right holder of registration certificate _____
(full name of legal entity according to the foundation documents)

legal address, phone, e-mail address, INN ¹⁾

5. Name of feed additive _____
(international non-proprietary or chemical name)

6. Feed additive developed by _____
(name of legal entity, legal address, phone, e-mail address, INN ¹⁾)

7. Producer of feed additive _____

legal address phone, e-mail address, INN

(name of producing company / name of international producer)

8. Place of production of feed additive _____
(name and addresses of production establishments involved in the process of production of

feed additive, specifying the stage of production, INN ¹⁾)

¹- only for legal entities registered in the territory of the Eurasian Economic Union

9. Data on registration of feed additive _____

(number and date of registration in the Eurasian Economic Union, date of expiration of the registration term, registration abroad)

Date of application submission:

« _____ » _____ 20 _____
representative)

(signature of Applicant/Applicant's

(Name, position)

Stamp

¹- only for legal entities registered in the territory of the Eurasian Economic Union

to the Rules Regulating Circulation of Feed Additives in the Customs Territory of the Eurasian Economic Union

EURASIAN ECONOMIC UNION

EXPERT REPORT

of the Expert Panel on the results of expert assessment of registration materials and quality of feed additive

_____ (*trade name*).

1. General provisions:

1.1. Number and date of the assignment given by the Authorized Registration Body:

1.2. Date of receipt of the dossier from the Authorized Registration Body to the authorized expert institution and ref. registration number:

1.3. Name of feed additive:

International non-proprietary or chemical name:

1.4. Presentation form (*dosage, modes of application, weight/volume/completeness*):

1.5. Formulation of feed additive (*list of ingredients, specifying the amount of each of them*):

1.6. Applicant (*name and address*): Developed by company (*name and address*): Producer (*name and address*): Right holder (*name and address*): place of production:

1.7. Data on experts (*Name, specialty, scientific title (if available), record of work, place of work, position*).....

1.8. I have been warned on responsibility related to true and accurate information described in the report:

experts

position	Name	signature
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position	Name	signature
----------	------	-----------

position	Name	signature
----------	------	-----------

2. Contents of registration materials submitted for expert review and quality of feed additive (key provisions of the submitted documents are highlighted):

3. List of studies carried out by experts, specifying the scope of work completed by each of the experts, and ascertained facts:

4. Expert assessment of the registration materials submitted for expert review and the quality of feed additive

5. General data of feed additive, availability of literature overview:

6. Formulation:

6.1. Active substance(s):

6.2. Auxiliary substance(s):

6.3. Type of feed additive (underline as appropriate)

- animal-derived without dairy proteins;

- animal-derived containing dairy proteins;

- animal-derived containing components of plant origin;
- animal-derived containing dairy proteins and components of plant origin;
- plant-derived;
- chemical and/or microbiological synthesis;
- chemical and/or microbiological synthesis, c containing components of plant origin.

7. Package:

8. Identification marks (label with which the feed additive will be shipped to a member state or in the territory of the Union):

9. Review of the contents of draft instructions for use (purpose of the additive, conformity to the registration dossier materials and current requirements for execution):

10. Assessment of the regulatory document (methods of control and specifications of the company, TS, company standards):

10.1. Requirements for the quality of active and auxiliary substances and package:

10.2. Methods of control of the finished form of feed additive:

10.3. Missing indicators and quality control methods:

10.4. Remarks on the methods of control:

11. Review of data in the report on stability:

12. Results of laboratory studies of specimens provided by the applicant for expert examination as to their compliance to the requirements of RD (Company's specifications) and the safety requirements:

13. Review of data on the production (description of the production process, including control of feedstock, critical production stages and intermediate products):

14. Summary on Section 5-13:

15. Study of specific activity:

16. Toxicology studies:

17. Summary on Section "Toxicology":

18. Investigation of washout periods of residues of active substances:

19. Assessment of data on the efficacy of use:

20. Expert comments to Sections 2-19:

21. Conclusions of expert assessment:

21.1.....

(conclusions based on the results of expert review of registration materials and assessment of the quality of feed additive and whether its application is possible or not possible)

21.2

.....
(general conclusions, recommendations)

Expert panel composed of:
experts

position	Name	signature
position	Name	signature
position	Name	Signature

Date of execution of conclusion

ANNEX No. 5

to the Rules Regulating Circulation of Feed Additives in the Customs Territory of the Eurasian Economic Union

EURASIAN ECONOMIC UNION

Registration Certificate on Feed Additive

Number of registration certificate: _____

Date of registration: " __ " _____ 20____

Right holder of registration certificate _____

(name and address of legal entity to which the registration certificate is issued)

Member state of the Eurasian Economic Union which made registration of feed additive _____

Names and actual addresses of production establishments involved in the process of production of feed additive, specifying the production stages: _____

Trade name of feed additive: _____

International non-proprietary name or chemical name of feed additive: _____

Presentation form: _____

Application: _____

Registration certificate is issued: unlimited time / 5-year period of validity
(delete as appropriate)

For the circulation of feed additive on the territory of

(delete as appropriate):

- Republic of Armenia
- Republic of Belarus
- Republic of Kazakhstan
- Kyrgyz Republic
- Russian Federation

(position)

(signature)

(Name)

Stamp

ANNEX No. 6

to the Rules Regulating Circulation of Feed Additives in the Customs Territory of the Eurasian Economic Union

AGREED WITH
NAME
Position

«_____» _____ 20 ____

INSTRUCTION

for use of feed additive

(Developed by company: *name, address*)

I. General data

1. Trade name of feed additive in Russian and Latin. Synonyms. Intended purpose.
2. Formulation. Content and chemical name of active and auxiliary substances of feed additive.
3. Form. Appearance. Physical and chemical properties (aggregate state, color, solubility in water and other solvents).
4. Presentation form. Appearance. Pack, storage and transportation conditions, shelf life of feed additive.

II. Biological properties

5. Mode of action of feed additive.
6. Key biological and other properties of feed additive (bioavailability, toxicity, washout from the body, immunogenicity, reactivity, nutrition value, etc.).

III. Method of use

7. Indications for use (enlist).
8. Method and conditions of feed additive use, specifying animal species, procedure, standard dose rate the feed additive for animal food, etc. .
9. Potential adverse events and complications. Measures for prevention and treatment (antidotes, deactivation, neutralization).
10. Compatibility with other feed additives and drugs.
11. Contraindications for use.
12. Time periods for allowed consumption of animal-derived product after the use of feed additive, in case of forced slaughter.

IV. Personal preventive measures

13. Observance of safety precautions, personal hygiene rules, use of personal protective equipment while handling feed additives.
14. First aid provision to affected individuals. Recommended antidotes.

V. Information on producer

15. Name(s), address(es) of the producer(s) of feed additive and address(es) og place(s) of production of feed additive.

ANNEX No. 7

to the Rules Regulating Circulation of Feed Additives in the Customs Territory of the Eurasian Economic Union

**REPORT
on safety monitoring
of feed additive use¹**

I. General provisions

1.1. Name and address of right holder of feed additive _____

1.2. Name and/or trade name of feed additive _____

1.3. Date of registration of feed additive: _____

Period of feed additive quality and efficacy monitoring: from “____” _____ 20____
to “____” _____ 20____

1.4. Date of provision of the results of feed additive quality and efficacy monitoring

“____” _____ 20____

1.5. Results of feed additive quality and efficacy monitoring are provided:

(position, name, signature)

II. Registration status

2.1. Information on the use in third countries and member states of the Eurasian Economic Union²

Country ³	Name (or) trade name of feed additive	Date of registration ⁴ of feed additive	Differences contained in the instructions for use of feed additive involved in the circulation in third countries and in the customs territory of the Eurasian Economic Union
1	2	3	4

2.2. Information on refusals from registration⁴ of feed additive as a result of non-confirmation of its quality and/or efficacy

Country ³	Trade name of feed additive	Date of refusal ⁴ from registration of feed additive	Reasons for refusal from registration ⁴ of feed additive
1	2	3	4

2.3. Information on the termination of use of feed additive (deletion from the Registry of Feed Additives of the Union) due to the reasons relating to quality and/or efficacy of a particular feed additive

Country ³	Name (or) trade name of feed additive	Date of termination of use of feed additive	Reason for termination of use of feed additive	Comments
1	2	3	4	6

2.4. Information concerning the adopted decisions on incorporation of modifications to the instruction for use of feed additive and to the regulatory document from the date of registration of feed additive:

Country ³	Date of making modifications to the instruction for use of feed additive and the regulatory document	Modifications made to the instruction for use of feed additive and the regulatory document	Reason for making modifications to the instruction for use of feed additive and the regulatory document
1	2	3	4

2.5. Information on the amount of feed additive entered into circulation in the customs territory of the Eurasian Economic Union and in the territory of third countries from the date of registration of feed additive in the Eurasian Economic Union⁵

Country ³	Consumer package with specified amount of feed additive	Amount of feed additive entered into circulation (primary packages)	Member states of the Eurasian Economic Union in the territories of which the actual sales of feed additive take place ⁶
1	2	3	4

III. Information on the harm caused to animal health (HH), a lack of efficacy in the claimed area of application (LE), non-conformity of the qualitative and/or quantitative formulation (QQF) of feed additive identified from the date of registration of the feed additive⁷

3.1. Number of all HH, LE and QQF cases reported within the reporting period

Types of identified risks (ranked by their severity)	Number or reports received from veterinary experts	Number or reports received from in-house studies	Number or reports received from the authorized bodies	Number or reports received from consumers	Number or reports described in scientific journals
1	2	3	4	5	6
HH:					
Side effects (specify type)					
Individual or group intolerability					
Other negative effects (specify type)					
LE					
QQF					
Total					

IV. Analysis of data on food additive efficacy received in the monitoring period with justification of making modifications to the instruction for use or the regulatory document

¹ The results of safety monitoring of feed additive use shall be provided by the company which has developed the feed additive or the legal entity authorized by the company for the purpose of confirming registration of the feed additive.

² With attached copies of the documents confirming registration of the feed additive.

³ Countries are enlisted in the chronological order in accordance with the date of registration.

⁴ Or another procedure envisaged officially in the legislation of member state of the Union.

⁵ Information is provided separately for each year of the monitoring period.

⁶ Information is provided on direct sales contracts.

⁷ Consideration is given to information on confirmed cases based on the studies conducted in the authorized expert institutions that had been provided prior to submission of documents for confirmation of the registration of feed substance.

to the Rules Regulating Circulation of Feed Additives in the Customs Territory of the Eurasian Economic Union

REPORT
on the results of regular monitoring of quality and efficacy of feed additive use¹

I. General provisions

1.1. Name and address of right holder of feed additive _____

1.2. Name and/or trade name of feed additive _____

1.3. Date of registration of feed additive:

Period of feed additive quality and efficacy monitoring: from “___” _____ 20___
 to “___” _____ 20___

1.4. Date of provision of the results of feed additive quality and efficacy monitoring

“___” _____ 20___

1.5. Results of feed additive quality and efficacy monitoring are provided:

(position, name, signature)

II. Registration status

2.1. Information on the use in third countries and member states of the Eurasian Economic Union²

Country ³	Name (or) trade name of feed additive	Date of registration ⁴ of feed additive	Differences contained in the instructions for use of feed additive involved in the circulation in third countries and in the customs territory of the Eurasian Economic Union
1	2	3	4

2.2. Information on refusals from registration⁴ of feed additive as a result of non-confirmation of its quality and/or efficacy

Country ³	Trade name of feed additive	Date of refusal ⁴ from registration of feed additive	Reasons for refusal from registration ⁴ of feed additive
1	2	3	4

2.3. Information on the termination of use of feed additive (deletion from the Registry of Feed Additives of the Union) due to the reasons relating to quality and/or efficacy of a particular feed

additive

Country ³	Name (or) trade name of feed additive	Date of termination of use of feed additive	Reason for termination of use of feed additive	Comments
1	2	3	4	6

2.4. Information concerning the adopted decisions on incorporation of modifications to the instruction for use of feed additive and to the regulatory document from the date of registration of feed additive:

Country ³	Date of making modifications to the instruction for use of feed additive and the regulatory document	Modifications made to the instruction for use of feed additive and the regulatory document	Reason for making modifications to the instruction for use of feed additive and the regulatory document
1	2	3	4

2.5. Information on the amount of feed additive entered into circulation in the customs territory of the Eurasian Economic Union and in the territory of third countries from the date of registration of feed additive in the Eurasian Economic Union⁵

Country ³	Consumer package with specified amount of feed additive	Amount of feed additive entered into circulation (primary packages)	Member states of the Eurasian Economic Union in the territories of which the actual sales of feed additive take place ⁶
1	2	3	4

III. Information on the harm caused to animal health (HH), a lack of efficacy in the claimed area of application (LE), non-conformity of the qualitative and/or quantitative formulation (QQF) of feed additive identified from the date of registration of the feed additive⁷

3.1. Number of all HH, LE and QQF cases reported within the reporting period

Types of identified risks (ranked by their severity)	Number or reports received from veterinary experts	Number or reports received from in-house studies	Number or reports received from the authorized bodies	Number or reports received from consumers	Number or reports described in scientific journals
1	2	3	4	5	6
HH:					
Side effects (specify type)					
Individual or group intolerability					
Other negative effects (specify type)					
LE					
QQF					
Total					

IV. Analysis of data on food additive efficacy received in the monitoring period with justification of making modifications to the instruction for use or the regulatory document

¹ The results of safety monitoring of feed additive use are taken into consideration by the authorized body of member state during control (surveillance) of the feed additive conducted by this body.

² With attached copies of the documents confirming registration of the feed additive.

³ Countries are enlisted in the chronological order in accordance with the date of registration.

⁴ Or another procedure envisaged officially in the legislation of member state of the Union.

⁵ Information is provided separately for each year of the monitoring period.

⁶ Information is provided on direct sales contracts.

⁷ Consideration is given to information on confirmed cases based on the studies conducted in the authorized expert institutions that had been provided prior to submission of documents for confirmation of the registration of feed substance.

ANNEX No. 9

to the Rules Regulating Circulation of Feed Additives in the Customs Territory of the Eurasian Economic Union

Unified Registry of Registered Feed Additives (FA) of the Eurasian Economic Union

##	Trade name of FA	Registration number (number of registration certificate of FA)	Date of registration (date of issuance of registration certificate on FA)	Period of validity of registration (period of validity of registration certificate on FA)	Member states of the Eurasian Economic Union in the territories of which the circulation of FA is allowed	Right holder of registration certificate on FA	Producer of FA		Country of origin of FA	FA developed by	Presentation form of FA	Indications (area of application) of FA	Formulation of FA
							Legal address	Actual address(es) of production place(s)					
1	2	3	4	5	6	7	8	9	10	11	14	15	16

END UNOFFICIAL TRANSLATION.