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Voluntary    Public

**Date:** 4/16/2015

**GAIN Report Number:** RS1518

## Russian Federation

**Post:** Moscow

### **Draft EAEU Regulation on Development of Sanitary Requirements**

**Report Categories:**

Sanitary/Phytosanitary/Food Safety

FAIRS Subject Report

Trade Policy Monitoring

**Approved By:**

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Staff

**Report Highlights:**

The Eurasian Economic Commission (EEC), the regulatory body of the Armenia-Belarus-Kazakhstan-Russia Eurasian Economic Union (EAEU), published a new draft regulation on the development of EAEU sanitary requirements and procedures. The EEC's period for commenting on this draft starts on April 8, 2015, and closes on June 5, 2015. Interested U.S. parties are encouraged to share their comments and/or concerns with USDA's enquiry point ([us.spsenquiry@fas.usda.gov](mailto:us.spsenquiry@fas.usda.gov)). For potential inclusion in the U.S. official position, please send comments by May 26, 2015.

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

## General Information

The Eurasian Economic Commission (EEC), which is the regulatory body of the [Eurasian Economic Union](#) (EAEU)<sup>1</sup>, published the following draft document on its website:

- [On Approval of Procedure for Development, Approval, Modification and Application of the Unified Sanitary-Epidemiological and Hygienic Requirements and Procedures](#)

In particular, the draft regulation describes the process for the development of new EAEU sanitary requirements and procedures, and, among other things, calls for a public comment period of no less than 60 days.

An unofficial English translation of the above-referenced draft document can be found below. The EEC's period for commenting on this draft starts on April 8, 2015, and closes on June 5, 2015.

Interested U.S. parties are encouraged to share their comments and/or concerns with USDA's enquiry point ([us.spsenquirypoint@fas.usda.gov](mailto:us.spsenquirypoint@fas.usda.gov)). For potential inclusion in the U.S. official position, please send comments by May 26, 2015.

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

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<sup>1</sup> In addition to Russia, Kazakhstan, and Belarus, Armenia became a member of the Eurasian Economic Union as of January 2, 2015.

BEGIN UNOFFICIAL TRANSLATION:

**EURASIAN ECONOMIC COMMISSION  
COUNCIL**

**DECISION**

«        »                      20\_\_                      No.

**On Approval of Procedure for Development, Approval, Modification and Application of the  
Unified Sanitary-Epidemiological and Hygienic Requirements and Procedures**

In order to implement paragraph 3 of Article 57 of the Treaty on the Eurasian Economic Union of May 29, 2014, and in accordance with paragraph 53 of Annex No. 1 to the Rules of Procedure of the Eurasian Economic Commission approved by Decision of the Supreme Eurasian Economic Council No. 98 of December 23, 2014, the Council of the Eurasian Economic Council **decided:**

1. To approve the attached Procedure for Development, Approval, Modification and Application of the Unified Sanitary-Epidemiological and Hygienic Requirements and Procedures.

2. The present Decision shall enter into force after 30 calendar days from the date of its official publication.

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

<b>Republic of Armenia</b>	<b>Republic of Belarus</b>	<b>Republic of Kazakhstan</b>	<b>Russian Federation</b>
<b>V. Gabrielyan</b>	<b>V. Matyushevsky</b>	<b>B. Sagintayev</b>	<b>I. Shuvalov</b>

APPROVED

By Decision of the Council of the Eurasian  
Economic Commission  
of \_\_\_\_\_20\_\_\_\_. г. No. \_\_\_\_\_

**PROCEDURE  
for Development, Approval, Modification and Application  
of the Unified Sanitary-Epidemiological  
and Hygienic Requirements and Procedures**

The Procedure for Development, Approval, Modification and Application of the Unified Sanitary-Epidemiological and Hygienic Requirements and Procedures (hereinafter - the Procedure) has been developed in accordance with paragraph 3 of Article 57 of the Treaty on the Eurasian Economic Union of May 29, 2014, and paragraph 150 of the Rules of Procedure of the Eurasian Economic Commission approved by decision of the Supreme Eurasian Economic Council No. 98 of December 23, 2014, (hereinafter – EEC Rules of Procedure) and establishes requirements for development, approval, modification and application of the unified sanitary-epidemiological and hygienic requirements (hereinafter - Unified Sanitary Requirements) and procedures.

1. The Unified Sanitary Requirements and procedures shall be developed, approved, modified and applied to products (goods) subject to state sanitary-epidemiological supervision (control) and are aimed at preventing the harmful effects of environmental factors on humans and providing favorable conditions for human life and activities.

2. The Unified Sanitary Requirements shall be established:

- on the basis of scientific research, including risk assessment of harmful effects of environmental factors on human body;
- based on the analysis of international experience in order to harmonize the Unified Sanitary Requirements with international standards, guidelines and (or) recommendations.

3. The Unified Sanitary Requirements shall be included in the document – the Unified Sanitary-Epidemiological and Hygienic Requirements to Products (Goods) that are Subject to Sanitary and Epidemiological Supervision (Control).

4. The Unified Sanitary- Epidemiological and Hygienic Requirements to Products (Goods) that are Subject to Sanitary and Epidemiological Supervision (Control) and procedures shall be approved by an act of the Eurasian Economic Commission (hereinafter - EEC).

5. The Unified Sanitary Requirements and procedures shall apply:

- during the production and circulation of products (goods) that are subject to sanitary and epidemiological supervision (control);
- for the organization and implementation of industrial control over products (goods) that are subject to sanitary and epidemiological supervision (control);
- during the implementation of state sanitary and epidemiological supervision (control) in accordance with the legislation of the Member-States and the EEC acts for products (goods) that are subject to sanitary and epidemiological supervision (control);
- to ensure the sanitary and epidemiological well-being of the population;
- to carry out sanitary-epidemiological (preventive) measures;
- for the development and introduction of temporary sanitary measures;

- for the state registration of individual products;
- for public health monitoring;
- to carry out sanitary-epidemiological assessment (sanitary-epidemiological assessment, inspections, studies, tests and toxicological, hygienic and other assessments) of products (goods) that are subject to sanitary and epidemiological supervision (control);
- for the assessment of public health risks under exposure to chemical, physical and biological factors.

6. The Unified Sanitary Requirements and (or) the procedures included in the proposed technical regulations of the Eurasian Economic Union in accordance with the Regulation on the Development, Adoption, Modification and Cancellation of Technical Regulations of the Customs Union.

7. Development and modification of the Unified Sanitary Requirements and procedures shall be implemented by the EEC on the basis of proposals from the Member-States of the Eurasian Economic Union (hereinafter – Member-States).

8. Modification of the adopted technical regulations of the Eurasian Economic Union in terms of changes in the safety requirements included in the Unified Sanitary- Epidemiological and Hygienic Requirements to Products (Goods) that are Subject to Sanitary and Epidemiological Supervision (Control) and procedures shall be performed in accordance with this Procedure.

9. In order to develop, approve and modify the Unified Sanitary Requirements and procedures the Member-States shall submit the following to the EEC:

- a request (letter), containing a proposal and a rationale for the adoption of the Unified Sanitary Requirements and procedures, or amendments thereto;
- a scientific justification for the adoption of the proposed Unified Sanitary Requirements, including an analysis of international experience;
- methods of research (tests) and measurements in the absence and (or) inability to use the existing ones;
- information about the methods of research (tests) and / or measurements, approved by the Member-States in the manner prescribed by the national legislation or proposed methods (tests) and / or measurements in the absence and (or) inability to use the existing ones.

In case of sending proposals to modify the Unified Sanitary Requirements for products that are covered by an adopted technical regulation of the Eurasian Economic Union and (or) procedures, the Member-States shall additionally provide to the EEC a proposal on amendments to the relevant technical regulations of the Eurasian Economic Union.

10. The EEC shall within 10 working days of receipt of the request send the following to the Member-States:

- a confirmation of acceptance of materials envisaged by para. 9 of this Procedure, for consideration, and inclusion of this issue in the agenda of the next meeting of the Subcommittee on Sanitary Measures under the Consultative Committee for Technical Regulation, Application of Sanitary, Phytosanitary and Veterinary-Sanitary Measures (hereinafter - the Subcommittee);
- in case of absence of the materials envisaged by para. 9 of this Procedure, it shall return the submitted materials with a substantiation of the refusal to accept them.

11. The EEC shall within 30 working days of receipt of the request on the basis of the submitted materials prepare draft(s) EEC decisions - to amend the Unified Sanitary Requirements and the technical regulation (hereinafter - the drafts).

The draft(s) EEC decision and related materials shall be submitted for the next meeting of the Subcommittee.

12. Upon review of the draft(s) EEC decision and related materials the Subcommittee shall take

a decision on the publication of the EEC draft decision for public discussion.

13. In the case of a decision by the Subcommittee on publishing the draft(s) EEC decision for public discussion the EEC shall ensure its placement on the official EEC website in the Internet for comments (proposals) and notification that the draft(s) EEC decision is being developed accordance with Annex No. 1.

A period of no less than 60 calendar days from the date of official publication of the draft(s) decision on the official EEC website in the Internet shall be set for providing comments (proposals) to the draft(s) decision.

The comments, proposals (feedback) received on the draft(s) decision from the stakeholders of the Member-States and third countries shall be registered in accordance with the Rules of internal processing of documents in the Eurasian Economic Commission.

The EEC shall review all proposals (comments) received during the public discussion, as well as conduct the necessary consultations.

Within 30 working days after the expiration of the public discussion period, the EEC shall compile a consolidated list of comments (proposals) according to the form established in Annex No.2 and publish it on the official EEC website.

For each comment and suggestion included in the consolidated list, the EEC shall specify whether it was accepted or provide a rationale for its rejection.

14. According to the results of public discussion, if necessary, the EEC shall within 10 working days finalize the draft(s) EEC decision with the assistance of the competent authorities of the Member-States.

The draft EEC decision to amend the relevant technical regulation of the Eurasian Economic Union shall be sent to the Member-States for internal clearance.

15. The draft(s) EEC decision shall be submitted for consideration at the next meeting of the Consultative Committee on Technical Regulation, Sanitary, Phytosanitary, and Veterinary Measures (hereinafter - the Consultative Committee).

16. The draft(s) EEC decision approved at the meeting of the Consultative Committee shall be submitted to the EEC Council in accordance with the EEC Rules of Procedure.

17. In case the EEC Collegium takes a decision to amend the Unified Sanitary Requirements for products which are covered by a technical regulation adopted in the Eurasian Economic Union and (or) procedures, the EEC Collegium shall simultaneously approve a draft decision of the EEC Council to amend the relevant technical regulation of the Eurasian Economic Union and submits it consideration to the EEC Council.

18. The EEC Council shall take a decision to amend the relevant technical regulation of the Eurasian Economic Union.

19. In case of written complaints that EEC decisions establishing Unified Sanitary Requirements do not comply with the international standards, an expert assessment shall be carried out in accordance with the Regulation on a unified procedure for assessment of regulations in the field of sanitary, veterinary and phytosanitary measures, approved by Collegium of the Eurasian Economic Commission No. 212 of November 6, 2012, in order to harmonize sanitary measures applicable in the customs territory of the Eurasian Economic Union.

Annex No. 1  
to the Procedure for Development, Approval,  
Modification and Application of the Unified  
Sanitary-Epidemiological and Hygienic  
Requirements and Procedures

**NOTIFICATION**

**on development of a draft EEC decision**

1.	Name of draft decision:
2.	Regulated object: _____
3.	Purpose of development:
4.	Justification of development:
5.	Postal address, phone numbers, fax number, e-mail addresses for submitting comments and proposals (feedback) on a draft decision:
6.	Tentative date of closing the public discussion period (deadline for submitting comments and proposals (feedback) on the draft decision:
7.	Date of drawing of notification:

Annex No. 2  
to the Procedure for Development, Approval,  
Modification and Application of the Unified  
Sanitary-Epidemiological and Hygienic  
Requirements and Procedures

Consolidated list  
of comments (proposals) on a draft decision of the Eurasian Economic Commission

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(name of the draft decision of the Eurasian Economic Commission)

	Structural element of a draft decision	Name of the entity who submitted comments (proposals) on a draft decision (letter number and date if available)	Contents of the comment (proposal)	Decision as a result of consideration
1	2	3	4	5
No.				

END UNOFFICIAL TRANSLATION.