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**Date:** 10/15/2015

**GAIN Report Number:** RS1582

## Russian Federation

**Post:** Moscow

### Draft Rules of HACCP Implementation in Russia

**Report Categories:**

Agriculture in the News

Sanitary/Phytosanitary/Food Safety

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**Report Highlights:**

Draft Russian Sanitary Rules for organization and implementation of production control within the food safety system based on HACCP principles were posted on the Russian Government website for public review at <http://regulation.gov.ru/>. According to the website, the document will come into effect in December 2015. Interested U.S. parties are encouraged to share their comments and/or concerns with USDA via the point of contact specified below.

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

## **General Information**

Draft Russian Sanitary Rules for organization and implementation of production control within the food safety system based on HACCP principles were posted on the Russian Government website for public review at <http://regulation.gov.ru/>:

- [Sanitary Rules SP 1.1.-2015 “Organization and Implementation of the Production Control within the Food Safety System Based on HACCP Principles”](#).

According to the website, it is planned that the document will come into effect in December 2015.

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

Interested U.S. parties are encouraged to share their comments and/or concerns with USDA at [AgMoscow@fas.usda.gov](mailto:AgMoscow@fas.usda.gov) by October 23, 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.

BEGIN UNOFFICIAL TRANSLATION:

**State Sanitary and Epidemiological Standardization in the  
Russian Federation  
State Sanitary and Epidemiological Rules and Standards**

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**Organization and implementation of production control within the food safety system based on  
HACCP principles**

**Sanitary and Epidemiological Rules  
SP 000000—00**

**CHIEF STATE SANITARY OFFICER OF THE  
RUSSIAN FEDERATION  
RESOLUTION**

\_\_\_\_\_  
Moscow

No. \_\_

On the Approval of Sanitary and  
Epidemiological Rules SP 000000—00  
“Organization and Implementation of the  
Production Control within the Food Safety System  
Based on HACCP Principles”

In accordance with Federal Law of 30.03.1999 No. 52-FZ “On Sanitary and Epidemiological Well-being of the Population” (Collection of Legislative Acts of the Russian Federation, 1999, No. 14, Article 1650; 2002, No. 1 (P. I), Article 2; 2003, No. 2, Article 167; No. 27 (P. I), Article 2700; 2004, No. 35, Article 3607; 2005, No. 19, Article 1752; 2006, No. 1, Article 0; No. 52 (P. I), Article 5498; 2007, No. 1 (P. I), Article 21, Article 29; No. 27, Article 3213; No. 46, Article 5554; No. 49, Article 6070; 2008, No. 24, Article 2801; No. 29 (P. I), Article 3418; No. 30 (P. II), Article 3616; No. 44, Article 4984; No. 52 (P. I), Article 6223; 2009, No. 1, Article 17; 2010, No. 40, Article 4969; 2011, No. 1, Article 6; No. 30 (P. I), Article 4563, Article 4590, Article 4591, Article 4596; No. 50, Article 7359; 2012, No. 24, Article 3069; No. 26, Article 3446; 2013, No. 30 (P. I), Article 4079; No. 48, Article 6165; 2014, No. 26 (P. I), Article 3366, Article 3377; 2015, No. 1 (P. I), Article 11; No. 27, Article 3951; No. 29 (P. I), Article 4339) and Resolution Of the Government of the Russian Federation of 24.07.2000 No. 554 “On Approval of the Provision on State Sanitary and Epidemiological “Standardization” (Collection of Legislative Acts of the Russian Federation, 2000, No. 31, Article 3295; 2004, No. 8, Article 663; 2004, No. 47, Article 4666; 2005, No. 39, Article 3953), I hereby resolve:

1. To approve Sanitary and Epidemiological Rules SP 000000—00 “Organization and Implementation of the Production Control within the Food Safety System Based on HACCP Principles” (Attachment).

2. This Resolution shall become effective from the date of its official publication.

A.Yu. Popova

APPROVED BY  
Resolution of the Chief State Sanitary Officer of the  
Russian Federation  
dated \_\_\_\_\_ No. \_\_\_\_

**Organization and implementation of production control within the food safety system based on HACCP principles**

**Sanitary and Epidemiological Rules  
SP 000000—00**

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**I. General provisions and scope of application**

1.1. These Sanitary and Epidemiological Rules (hereinafter – the “Sanitary Rules”) shall guide the procedure for organization and implementation of the production control over the processes of production (manufacture) of food products associated with the safety requirements for such products based on HACCP principles (in the English language HACCP – Hazard Analysis and Critical Control Points).

1.2. Control of compliance with the sanitary rules is conducted in accordance with the legislation of the Russian Federation by the bodies authorized for conducting federal state sanitary and epidemiological surveillance<sup>1</sup>.

1.3. The Requirements of the Sanitary Rules are compulsory for the fulfillment by legal entities, individual entrepreneurs and citizens whose activity is associated with the production (manufacture) of food products throughout the territory of the Russian Federation.

1.4. The Sanitary and Epidemiological Rules SP 000000—00 “Organization and Implementation of the Production Control within the Food Safety System Based on HACCP Principles” use terms and definitions given below (Annex 1).

**II. Organization of production control within the food safety system  
based on HACCP principles**

2.1. Production control over the processes of production (manufacture) of food products associated with the safety requirements for such products based on HACCP principles (hereinafter – the “production control”) shall be conducted by legal entities and individual entrepreneurs in line with their activities.

2.2. The objective of the production control within the food safety system based on HACCP principles is to ensure safety for consumers of the produced (manufactured) food products through the adequate development, introduction and maintenance of procedures based on HACCP principles and by conducting control of their effectiveness.

2.3. The object of production control is composed of organizational structure, documents, production processes and resources within the food safety system based on HACCP principles.

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<sup>1</sup> Resolution of the Government of the Russian Federation dated 5.06.2013 No. 476 “On the Issues concerning the State Control (Surveillance) and the Annulment of Certain Acts of Legislation of the Russian Federation” (Collection of Legislative Acts of the Russian Federation, 2013, No. 24, Article 2999).

2.4. Production control within the food safety system based on HACCP principles includes the following:

2.4.1. availability of officially issued regulatory legal, regulatory technical and technical documents in line with carried out activities;

2.4.2. availability of up-to-date documents of the HACCP system;

2.4.3. verification of developed, implemented and effectively functioning procedures for:

a) selecting production (manufacture) processes necessary to ensure the safety of food products;

b) selecting sequence and route of technological operations in the production (manufacture) of food products to avoid contamination of (food) raw materials and food products;

c) identifying stages of the production operations and food products at the stages of their production (manufacture) in production control programs;

d) conducting control of alimentary (food) stock, processing tools, packaging materials, devices used in the process of production (manufacture) of food products, and food products with the use of aids which guarantee the required reliability and completeness of control;

e) conducting control of the process equipment to verify whether it functions in a way ensuring that the production (manufacture) of food products satisfies the compulsory requirements for individual types of food products;

f) assuring that the data on controlled stages of the process operations and the results of control of food products are documented;

g) complying with the conditions of storage and carriage (transportation) of food products;

h) maintaining the production facilities, process equipment and implements used in the production (manufacture) of food products in the condition preventing contamination of the food products;

i) selecting methods and achieving personnel compliance with the personal hygiene rules to ensure the safety of food products;

j) selecting methods, establishing periodicity and carrying out cleaning, washing, disinfection, disinsection and deratization of production facilities, processing equipment and implements used in the production (manufacture) of food products, which assure the safety of food products ;

k) maintaining and keeping documentation, in paper and/or electronic format, which proves compliance of produced food products with the compulsory requirements ;

l) traceability of food products.

2.4.4. making arrangements for medical check-ups and professional training in hygiene, and certification of officials and employees of the organizations involved in such activities as production, storage, transport and sales of food products;

2.4.5. timely information communication to the public, local self-government authorities, and the bodies authorized for the execution of federal state sanitary and epidemiological control about emergency situations, production shutdown cases, and violations of technological processes posing a threat to the sanitary and epidemiological well-being of the population.

2.5. Spectrum, scope and periodicity of laboratory studies and tests are determined taking into consideration each of the accountable hazards, controlled steps in the process, types and quantity of the critical control points. Laboratory studies and tests shall be performed independently by a legal entity, individual entrepreneur in its in-house accredited laboratory or with the involvement of an independent laboratory accredited according to the established procedure.

2.6. Program (plan) on production control within the food safety system based on HACCP principles, as a set of documents, shall be developed independently by a legal entity, individual entrepreneur. Necessary modifications and additions to the documents of the production control program

(plan) are made when types of activity or production technologies are changed or other significant modifications are made to operations of a legal entity, individual entrepreneur.

2.7. Responsibility for the timeliness of organization, completeness and reliability of the implemented production control within the food safety system based on HACCP principles, shall be borne by legal entities, individual entrepreneurs.

2.8. Legal entities and individual entrepreneurs shall provide information on the results of production control upon requests of the bodies authorized for conducting federal state sanitary and epidemiological surveillance.

### **III. Procedure for conducting production control within the scope of food safety system based on HACCP principles**

3.1. For ensuring that released products are safe for consumer, the producer should develop processes of production (manufacture) of food products in accordance with HACCP principles (Annex 2).

3.2. Manufacturer should apply the food safety system based on HACCP principles to all processes of the production (manufacture) of food products.

3.3. Top management of the organization should define and document policy in the area of safety of released products and assure its implementation on all levels.

3.4. Top management of the organization should select and appoint a HACCP team which will bear responsibility for the development and implementation of HACCP system at the facility and for the execution of production control within the food safety system based on HACCP principles.

3.5. The HACCP team shall identify hazards (biological, physical, chemical) associated with the production (manufacture) of food products, from receiving raw materials to final consumption, assess the risk of occurrence of the hazards and specify measures necessary for their control. The results of hazard assessment can be presented in the form of table (Annex 3).

3.6. The HACCP team shall develop a prerequisite program, HACCP plan and other procedures of the food safety system (Annex 4).

3.7. The programs and procedures developed at the facility should be implemented and maintained.

3.8. Production control shall be conducted continuously and built on the implementation of programs and procedures within the food safety system based on HACCP principles specified in Annex 4, along with keeping the appropriate records (plans, programs, HACCP sheets, etc.).

In case where a deviation is found, a plan of corrective actions is developed which specifies the deadlines and persons responsible for its implementation.

3.9. The results of summary analysis of efficiency and effectiveness relating to the continual improvement of the food safety system based on HACCP principles, are documented as of a calendar year end in the form of summary table (Annex 4), dated and signed by top management of the organization.

3.10. The analysis of efficiency and effectiveness and continual improvement of the food safety system based on HACCP principles can be performed using criteria presented in Annex 5.

### **IV. Obligations of legal entities and individual entrepreneurs in the implementation of production control within the food safety system based on HACCP principles**

4.1. When violations of the sanitary rules are found at the facility covered by the production control within food safety system based on HACCP principles, a legal entity or individual entrepreneur should take appropriate actions to eliminate the detected violations and prevent their recurrence, including the following:

- to suspend or shut down its activities or operations of individual workshops, sections, buildings, structures, equipment, transport, the execution of particular types of work and the provision of services;
- to discontinue the use of stock and materials not meeting the established requirements or not ensuring the manufacture of safe (non-hazardous) products for human; recall such products from sales which do not comply with the compulsory requirements and pose a threat to human; and to undertake actions on the application (use) of such products for the purposes excluding an infliction of harm to human, or its destruction;
- to inform the body authorized to implement state sanitary and epidemiological surveillance, on the measures applied to eliminate violations of the sanitary rules;
- to take other steps envisaged in the legislation of the Russian Federation.

4.2. If the food safety system based on HACCP principles is recognized ineffective, a legal entity or individual entrepreneur should take actions to:

- determine the causes and conditions underlying a lack of effectiveness in system operation;
- eliminate the detected causes and conditions;
- update (validate, verify) the food safety system based on HACCP principles in order to renew its effective functioning.



### Terms and definitions

The Sanitary Epidemiological Rules SP 000000—00 “Organization and Implementation of the Production Control within the Food Safety System Based on HACCP Principles” use the following key definitions:

**conformity** – full compliance with the requirements;

**non-conformity** – failure to comply with the requirements;

**minor non-conformity** – incomplete compliance with the requirements, not impacting the safety of product;

**major non-conformity** – failure to comply with the requirements causing a high risk of impact on the safety of product;

**critical non-conformity** – absolute failure to comply with the requirements resulting in the release of unsafe product;

**document** – the information provided on the appropriate carrier (it could be paper, magnetic, electronic or optic carrier, CD, photo or reference specimen, or their combination);

**disposal of food products** – the use of food products not complying with the requirements of the technical regulations of the Customs Union for the purposes other than those for which the food products are intended or in which they are usually used; or the transformation of food products, not complying with the requirements of the technical regulations of the Customs Union, into the condition unacceptable for any use or application and precluding their negative effects on the human, animals and environment;

**HACCP Plan** – a package of documents on the food safety system which is based upon the principles of HACCP and which is developed for a particular establishment;

**verification** – confirmation, through the provision of objective evidences, that specified requirements have been fulfilled [ISO 9000, definition 3.8.4];

**validation** – documented actions that provide a high degree of assurance that methodology, process, equipment, material, operation or system conform to the preset requirements and that their use will consistently lead to the results meeting predetermined acceptance criteria;

**corrective action** – action to eliminate the cause of a detected nonconformity or other undesirable situation [ISO 9000, definition 3.6.5].

NOTE 1. There can be more than one cause for a non-conformity [ISO 9000, definition 3.6.5].

NOTE 2. Corrective action includes analysis of causes. It is taken to prevent recurrence of non-conformity.

**monitoring** – conducting a planned sequence of observations or measurements to assess whether the control measures (see 3.7) assure accomplishment of the expected effect;

**correction** – action to eliminate a detected nonconformity [ISO 9000, definition 3.6.6].

NOTE 1. In this case, a correction means handling of potentially hazardous products and thus can be made in conjunction with another corrective action.

NOTE 2. A correction can be, for example, rework, further processing and/or elimination of the negative effects of non-conformity (for example, rejection for the purpose of alternative use or application of special identification marks);

**critical control point** – a step in assuring the food safety at which control action is essential for preventing or eliminating a food safety hazard or reducing it to acceptable level;

**critical limit** – a criterion which separates acceptability from unacceptability.

NOTE 1. Critical limits are established to determine whether a critical control point remains under control (within the acceptable range of values). When a critical limit is exceeded or violated, products are deemed to be potentially unsafe as a result of such exposure.

## **Principles of HACCP system development**

HACCP system should be developed taking into consideration the following seven principles:

**Principle 1** – to identify potential risk or risks (hazards) associated with the production of food products, from receiving stock materials (breeding or growing) to final consumption, including all stages of the life cycle of products (treatment, processing, storage and sales) with the aim of determining the conditions for occurrence of potential risk(s) and establishing necessary measures for their control;

**Principle 2** – to determine critical control points in the production process in order to eliminate (minimize) the risk or the likelihood of its occurrence; in this context, consideration can be given to the food production operations covering supply of stock materials, selection of ingredients, processing, storage, transportation, warehousing and sales;

**Principle 3** – in the HACCP system documents or processing instructions it is necessary to establish critical limits; these limits should be observed to confirm that a critical control point is under control;

**Principle 4** – to develop a monitoring system to assess whether critical control points are under control due to the implementation of the planned measures or observations;

**Principle 5** – to develop corrective actions and apply them when the negative results of monitoring are obtained;

**Principle 6** – to develop verification procedures to be implemented on a regular basis in order to assure that the HACCP system is functioning effectively;

**Principle 7** – to document all system procedures, forms and methods of recording data pertinent to the HACCP system.

**Table for evaluating hazards  
(draft form)**

Process stage	Hazard	Likelihood	Severity of consequences	Accountability	Hazard control

Risk for each of the potential hazards is assessed using the following methodology:

1. Taking into consideration all available information and using expertise of the HACCP team, a likelihood of hazard occurrence is evaluated by the method of expert review, proceeding from four potential options of the evaluation results:

1 – the likelihood is almost equal to zero (cases of the occurrence of a hazard are absent in the facility operations; however, evidences of the hazard occurrence are known at other vegetable processing establishments; or published data on the hazards are not available);

2 – the likelihood is insignificant (a single case of the occurrence of a hazard in the facility operations);

3 – the likelihood is significant (periodical occurrence of a hazard in the facility operations);

4 – the likelihood is high (regular occurrence of a hazard in the facility operations).

2. The severity of the consequences of exposure to the hazard occurrence is evaluated via expert review, proceeding from four potential options of the evaluation results:

1 – mild (has almost no consequences; only a minor ailment is observed; loss of labor capacity in adult human is absent);

2 – moderate severity (the seriousness of consequences can be diagnosed as a disease; medicinal therapy may be needed for several days);

3 – severe (inflicts serious health damage; loss of labor capacity for a long period of time);

4 – critical (leads to the lethal outcome or disability).

3. A borderline of acceptable risk is built on the qualitative diagram with the coordinates “likelihood of the occurrence of hazard – severity of consequences” as illustrated in Fig. 1.

If the point is located on or above the borderline, the hazard is taken into consideration and if lower – is not taken into consideration.



Signatures on the diagram

Тяжесть последствий	Severity of consequences
Вероятность реализации опасного фактора	Likelihood of the occurrence of hazard
Область недопустимого риска	Area of the unacceptable risk

Область допустимого риска	Area of the acceptable risk
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Hazard control can be accomplished through the implementation of prerequisite programs or CPP control procedures.

**Fundamental requirements and procedures of the food safety system  
based on HACCP principles**

No.	Requirements	Conformity (A)	Insignificant non- conformity (B)	Significant non- conformity (C)	Critical non- conformity (D)	Max	Actual	Comments
1	2	3	4	5	6	7	8	9
1	Prerequisite program					180		
1.1	The following prerequisite programs should be implemented and maintained							
1.1.1	Cleaning and sanitation procedure							
1.1.2	Preventive disinsection and deratization procedure							
1.1.3	Scheduled preventive maintenance (SPM) procedure							
1.1.4	Procedure on personal hygiene of the personnel							
1.1.5	Procedure on personnel medical check-ups and hygiene training							
1.1.6	Procedure on making arrangements for the route of processes, specifying personnel traffic flows and zoning of the facilities used for the production and storage of food products							
1.1.7	Procedure on incoming inspection of stock, package, materials							
1.1.8	Waste management procedure							

No.	Requirements	Conformity (A)	Insignificant non- conformity (B)	Significant non- conformity (C)	Critical non- conformity (D)	Max	Actual	Comments
1.1.9	Procedure on the assessment of labor conditions							

1	2	3	4	5	6	7	8	9
2	Description of each type of manufactured products is provided, including their composition and characteristics, package, storage terms and conditions, recommended areas of application (if available)					20		
3	Process flowcharts are provided for each type of released products (from acceptance of raw materials to release into circulation)					20		
4	Top management has appointed a HACCP team. Order on assembling a HACCP team is presented					20		
5	Hazard analysis					20*K		
5.1	Hazards (biological, physical, chemical) in the process of production (manufacture) of food products are identified and documented							
6	Identification of critical control points (CCP)					20*K		
6.1	Critical control points are identified and documented							
7	Establishing of CCP critical limits					20*K		
7.1	CCP critical limits are established and documented							
8	CCP monitoring					100		
8.1	Monitoring procedure for each CCP is developed, documented and maintained							
	CCPs at the process stages are marked							
8.1.1	Persons responsible for each CCP monitoring are assigned							
8.1.2	Monitoring periodicity for each CCP is established							
8.1.3	Monitoring method (instrumental, visual, etc.) is determined							
9	Corrective actions and control of non-compliant products					240		
9.1	Procedure for corrective actions is developed, documented and maintained for cases where the monitoring results demonstrate that the CCP critical limits are exceeded							
9.1.1	Persons responsible for the implementation of corrective actions are assigned							
9.1.2	Records on the taken corrective actions are provided in cases where the monitoring results demonstrate that the CCP critical limits are exceeded							
9.2	Procedure for control of non-compliant products, manufactured when the CCP critical limits were exceeded, is developed, documented and maintained							
9.2.1	Persons responsible for control of non-compliant products, manufactured when the CCP critical limits were exceeded, are assigned							
9.2.2	Records on the completed correction and/or disposal of non-compliant products are provided							
9.3.	Procedure for the recall of products non-conforming to the compulsory requirements is developed, documented and maintained							
9.3.1.	Persons responsible for making arrangements and conducting the recall of products non-conforming to the compulsory requirements are assigned							
9.3.2	List of interested parties who should be notified on the initiation of recall procedure is composed							
9.3.3	Procedure for the identification of non-compliant products (including their identification marks) is delineated							
9.3.4	List of measures within the recall procedure (transportation, storage, disposal, etc.)							
9.3.5	Forms of documentation of the procedure for recall of non-compliant products are established							
10	Internal audits					100		
10.1	Procedure for holding internal audits is developed, documented and maintained							
10.1.1	Periodicity of internal audits (at least once a year) is established							
10.1.2	Persons responsible for holding internal audits are assigned							
10.1.3	Records on the completed internal audits are provided							
10.1.4	Records on the taken corrective actions are provided for case(s) where in the course of internal audit the case(s) of non-conformity were detected							
11	HACCP documentation					40		
11.1	List of HACCP procedures, programs is provided							
11.2	HACCP worksheets are provided							



1	2	3	4	5	6	7	8	9
12	HACCP plan verification					20*K		
12.1	Objective evidences confirming the efficiency of HACCP plan procedures (protocols of product tests, protocols of laboratory studies of the environmental conditions, results of external and internal audits, etc.) are provided							
13	Traceability					80		
13.1	Procedure for traceability is developed and maintained which enables to identify lots of food products and their association with batches of raw materials and package							
13.2	Forms of records pertaining to the process of production and distribution of products are established							
13.3	Documents confirming the origin of stock, materials and other ingredients used in production of food products are provided							
13.4	Documents confirming the shipment of finished food products to the customer(s) are provided							
TOTAL:						1600		

Max – maximum possible score in case of full compliance with the established requirements;

Actual – actually gained score based on the results of evaluation of the effectiveness of system functioning.

K – adjusting factor equal to 10.

**Recommended criteria for the evaluation of effectiveness of functioning of the food safety system based on HACCP principles**

A	Full compliance with the requirements	Score: 20
B	Insignificant non-conformity	Score: 15
C	Significant non-conformity	Score: 0
D	Critical non-conformity	Score: 25

The adjusting factor is used for the following procedures:

1. Hazard analysis;
2. Determining critical control points (CCP);
3. Establishing CCP critical limits;
4. HACCP plan verification.

The evaluation of effectiveness (EE) of functioning of the food safety system based on HACCP principles is defined as a ratio of the sum of actually gained score to the maximum possible score expressed in percent:

$$EE = (\text{Actual}/\text{Max}) \times 100 \%$$

Ranking of the establishments based on the results of evaluation of effectiveness (EE) of functioning of the food safety system based on HACCP principles:

Below 25 % – a lack of operating food safety system capable to ensuring the released food is safe for consumer;

25—69 % – individual elements of the food safety system based on HACCP principles are implemented which are not capable to ensure sustainable release of food products safe for consumer; the system needs considerable improvements.

70—84 % – most of the elements of the food safety system are implemented; the system is capable to ensure sustainable release of food products safe for consumer but needs improvements relating to individual procedures.

85—100 % – the food safety system is implemented and is capable to ensure sustainable release of food products safe for consumer; the system needs minor improvements relating to individual procedures.

END UNOFFICIAL TRANSLATION.