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# **Russian Federation**

# **Agricultural Biotechnology Annual**

# **Agricultural Biotechnology Annual 2016**

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## **Report Highlights:**

On July 3, 2016, Russia adopted FL 358-FZ, which prohibits the cultivation of genetically engineered (GE) plants and the breeding of genetically engineered animals on the territory of the Russian Federation. In addition, FL 358-FZ provides for stronger state monitoring and control of the processing and the importation of GE organisms and products derived from such organisms, and sets penalties for violations of this federal law.

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# **Section I. Executive Summary:**

Over the last several years, there have been numerous heated public discussions and various federal legislative drafts considered regarding the use of plant and animal biotechnology. Finally, on July 3, 2016, Russia adopted the Federal Law 358-FZ (FL 358); "On amendments to certain legislative acts of the Russian Federation concerning improvement of the state regulation in the sphere of genetic-engineering activities," which prohibits the cultivation of genetically engineered (GE) plants and the breeding of GE animals on the territory of the Russian Federation. In addition, FL 358-FZ provides for stronger state monitoring and control of the processing and the importation of GE organisms and products derived from such organisms, and sets penalties for violations of this federal law (Post GAIN report Russia Bans Cultivation and Breeding of GE Crops and Animals 7-12-2016.pdf)

Since FL 358 was passed, the agencies responsible for the regulation of GE products initiated updating their regulations. FL 358 requires that all regulatory updates be completed by July 1, 2017, including amendments to the current regulatory documents on GE registration for food and for feed, when the prescribed penalties come into force. The date of July 1, 2017, was set as the deadline under Russian Government Resolution 839 for the development of a mechanism for the registration of GE crops for cultivation (Post Gain Report "GMO" Registration for Cultivation Postponed 6-27-2014.pdf). Intended registration of GE crops for cultivation and the actual registration of GE crops for feed use has been under the authority of the Federal Service for Veterinary and Phytosanitary Surveillance (VPSS). The changes made by FL 358 stopped development of a mechanism for registration of GE crops for cultivation. Moreover, FL 358 resulted in a de-facto suspension of registration of new GE lines for feed use.

Currently twelve corn lines, eight soybean lines, one rice line, and one sugar beet line are registered for food use in Russia and in the Eurasian Economic Union (EAEU). Two potato lines are registered for food use only in Russia. Eleven corn lines and eight soybean lines are registered for feed use. The registration for feed use is only granted for five years, and the registration period for the two corn lines expires in December 2016. These lines were submitted for re-registration, but given the de-facto suspension of registration for feed use, the registration renewal is unclear.

The anti-GE campaign has also stimulated legislative authorities to draft amendments on labeling requirements for GE food products. These requirements are regulated by the EAEU's Technical Regulation (TR) on food labeling and may be adopted only on the consent of the member-states of the

Eurasian Economic Union. (Post GAIN report <u>Draft Measure on Food Labeling Notified to WTO\_25-2016.pdf</u>). To date, no new measures have been adopted.

Journalists in Russia often report of consumer concerns with GE products. Some food companies voluntarily label their products as "Does not contain GMO," and prefer purchasing non-GE raw materials. Companies must engage testing on their own to confirm the absence of GE materials and there is no government authority supervision. These products are usually more expensive than comparable products that may contain GE components. Given the decreasing incomes of Russian consumers during the period 2014 to 2016, price is the dominant concern now for both food processors and consumers.

There is no information on the research in the field of GE animals and cloning. FL 358-FZ prohibits breeding of GE animals on the territory of the Russian Federation.

(Note: All Russian legislative and regulatory documents use the term "GMO" (genetically modified organisms) or "GMM" (genetically modified microorganisms) instead of genetically engineered (GE) organisms/microorganisms. Therefore, throughout this report, when referring to language in those documents, we will default to the terms as used in the document.)

# Section II: Plant and Animal Biotechnology

## CHAPTER 1: PLANT BIOTECHNOLOGY

#### **PART A: Production and Trade**

#### a) PRODUCT DEVELOPMENT:

There is no information on the development of GE crops in Russia. Before the ban on cultivation of GE crops, Russian scientists conducted some laboratory research on GE crops, but the research had not yet reached the stage of field trials. Although field trials are not technically prohibited, they need special permission from the Variety Testing Commission at the Ministry of Agriculture, which is never granted.

Given the current economic situation in Russia and the tight federal budget, financing of research for development of Russian GE crops in the next couple of years is unlikely. In 2015, Russia's Federal law on the 2015 budget approved cuts to the subprogram "Technical and technological modernization, innovative development" of almost 1 billion rubles (\$18 million) to 2.15 billion rubles (\$39 million) <sup>1</sup>. This subprogram covers all innovation projects, including agricultural biotechnology. The cuts in overall federal budget spending in 2016 affected further spending on science and innovation, although there is no information on actual federal spending. Moreover, there is no information on the participation of Russian private businesses in financing research in agricultural biotechnology. In mid-2015, the Russian Innovation Center, "Skolkovo" was authorized to conduct research in the field of agricultural biotechnology. However, to date there is no information on when the center will begin its work on agricultural biotechnology, what resources will be utilized, and what concrete fields of research will be covered. <sup>2</sup> In fact, the Skolkovo center is still in the process of development.

<sup>&</sup>lt;sup>1</sup> FAS/Moscow GAIN report: Agricultural budget 2015 6-24-2015.pdf

<sup>&</sup>lt;sup>2</sup> FAS/Moscow GAIN report: Russian Agricultural Policy and Situation Bi-Weekly Update 8 6-2-2015.pdf. Amendment to the Federal Law On the Innovation Center Skolkovo added agricultural biotechnology to the list of activities of this Center.

## b) COMMERCIAL PRODUCTION:

Russia does not cultivate any GE crops, including GE seeds.

A de-facto ban on cultivation of GE crops in Russia existed previously because the legislative mechanism for approval of GE crops for cultivation did not exist. At the end of 2013, the Russian Government adopted Resolution 839, "on development of a mechanism for the registration of GE crops for cultivation by July 1, 2014." Subsequently, the implementation of this Resolution was postponed to July 1, 2017. On July 3, 2016, the Federation Assembly, Russian's major legislative body, adopted FL 358 that prohibits cultivation of genetically engineered plants and breeding of genetically engineered animals on the territory of the Russian Federation. This made the July 1, 2017 deadline for implementation of Resolution 839 moot.

## Illegal cultivation:

On August 28, 2015, Dr. Nikolay Vlasov, the Deputy Head of the Russian Service for Veterinary and Phytosanitary Surveillance (VPSS) at the Ministry of Agriculture, notified Russian exporters that they may have problems with GE rapeseed that, according to some information, has been illegally cultivated in Russia. Vlasov called for the use of VPSS's laboratories to check for the presence of GE rapeseed in shipments for export. He also noted that unfortunately VPSS does not have the right to control the circulation of planting seeds and that there is no legislation in Russia for the control of cultivation of GE crops in Russia<sup>3</sup>. Later, the Ministry of Agriculture authorized the Variety Testing Commission to conduct testing for the presence of GE in planting seeds submitted for registration in the Russian Federation (for more information see paragraph MONITORING AND TESTING in PART B of this report).

#### c) EXPORTS:

In 2015 and 2016, Russia increased its production of soybeans and corn, and also increased exports of these crops. In calendar year (CY) 2014, Russia exported 3.42 million metric tons (MMT) of corn and in CY 2015, 3.7 MMT. In the first eight months of CY 2016 (January – August), Russia exported 2.99 MMT of corn, compared with only 2.09 MMT in the same period in 2015. While there is no cultivation of GE crops in Russia, there are also no approved methods and/or laboratories for certification of GE-free production of corn and soybeans. Therefore, producers and exporters cannot register their crops as GE-free, and exporters are not paid premiums for GE-free crops. Along with the growth of soybean production in the Far East, Russia has also increased exports of soybeans from 78 thousand metric tons (TMT) in CY 2014 to 382 TMT in CY 2015. From January to August 2016, exports of soybeans reached nearly 318 TMT, compared to 244 TMT during the same period in 2015. All soybeans are considered as non-GE, but lack any certification to this effect. If meal is from crushed, imported beans Russia's soybean meal exports may contain GE lines.

Table 1. Russia: Exports of corn, soybeans and soybean meal, CY 2011-2015 and Jan-Aug 2016 compared with Jan-Aug 2015

The amendments primarily concern property rights and facilities for Skolkovo. Reference to agricultural biotechnology is contained in only one added sentence, which does not specify the exact fields of agricultural biotechnology to be developed. 

http://www.fsvps.ru/fsvps/news/14889.html

	2011	2012	2013	2014	2015	Jan- Aug 2015	Jan Aug. 2016
Metric Tons							
Corn (HS Number 1005)	709,45 3	2,185,23 2	2,599,28 8	3,418,92 0	3,698,76 8	2,093,57 5	2,992,10 2
Soybeans (HS Number 1201)	4547	118476	83553	78,732	382,490	243,603	317,608
Soybean meal (HS number 2304)	33,783	11,246	210,306	548,037	458,247	324,969	342,142
1,000 U.S. Dollars							
Corn (HS Number 1005)	156,35 3	570,093	590,073	688,082	600,939	351,388	477,817
Soybeans (HS Number 1201)	1,156	34,878	26,202	23,761	119,177	76,733	101,436
Soybean meal (HS number 2304)	17,753	7,687	126,540	315,915	226,321	163,094	148,067

Source: Global Trade Atlas

NOTE: Since Russia does not cultivate GE crops, it is assumed that exports of corn and soybeans in the table above are all non-GE, although these products are not certified as non-GE. Soybean meal that is produced in whole or in part from imported soybeans may be GE soybean meal.

#### d) IMPORTS

There currently is no ban on the registration of GE crops/lines/traits for imports for food and feed. However, Russia does not permit the importation of GE planting seeds. Therefore, U.S. exports of GE planting seeds to Russia are not allowed, and registration of GE lines in imports for processing into food and feed has become more and more difficult. This is partially due to increased regulatory scrutiny. However, it is also due to a restructuring of the registration process, and entities responsible for the process, which has not yet been completed. These factors have an adverse effect on U.S. trade with Russia in bulk crops, such as soybeans, corn, and other crops that may contain GE, as well as processed products made with GE components.

Russia allows the importation of GE crops, and processed products containing GE ingredients if these crops/products have been tested and registered in Russia for food and/or feed use (See paragraph APPROVALS in PART B of the report).

Russian Customs data does not separate GE products from non-GE products. However, most corn and soybeans imported into Russia, as well as products produced from imported corn and soybeans, may contain GE crops and GE ingredients in amounts that do not exceed Russian and the EAEU GE presence requirements (For more information see section LEGISLATION AND REGULATIOS and paragraph LOW LEVEL PRESENCE (LLP) POLICY in PART B of this report).

Russia is increasing its poultry and swine production at large, integrated poultry and swine farms that use compound feed in feeding rations. The demand for protein and energy ingredients, such as corn and soybeans/soybean meal, is increasing. Russia is trying to increase domestic production of these crops. In 2015, Russia's corn crop reached a record level of 12 MMT and in 2016 corn crop production is forecast to exceed 14 MMT. Russian farmers also continue to increase area sown to soybeans, and production of beans in 2016 is forecast at three MMT, approximately 60-70 percent of currently requirements for the Russian feed industry. However, half of this production is in the Russian Far East,

while poultry and livestock industries are principally in the European part of Russia. Transportation between these two regions is a significant cost and logistical impediment. Despite increased domestic production of protein and high energy feed, such as soybeans and corn, Russia continues to import soybeans, corn, and products processed from these crops (Table 3).

Some regional authorities and companies in the south of European Russia, including Belgorod oblast (Russia's major meat producer), have declared themselves GE-free-zones and buy only non-GE feed. Such feed is more and more difficult to find in the market. These regions have increased their own production of soybeans, but these beans are usually more expensive than imported soybeans. The anti-GE campaigns in 2008-2011, and in 2014-2015 affected decisions of some processors, which preferred certified non-GE products in order to meet consumers' preferences. Sodruzhestvo, Russia's major soybean crushing company that crush primarily imported beans, maintains separate facilities for GE and non-GE soybeans in Kaliningrad. However, in the current economic environment, price is the major factor in purchasing decisions (see more in PART C of this report).

On June 29, 2016 Russian President Vladimir Putin signed Decree No. 305, extending the counter sanctions ban on certain imported foods from the United States, Canada, the European Union, Australia, Norway, Ukraine, Albania, Montenegro, Iceland, and Lichtenstein until the end of 2017 (Moscow ATO GAIN report Russia Extends Import Food Ban through End 2017 7-1-2016.pdf). However, imports of corn, soybeans, or products thereof, are covered by this ban. Since February 15, 2016, Russia temporarily banned imports of corn (HS code 1005), planting seeds of sweet corn (HS code 071290 110 0) and soybeans (HS code 1201) from the U.S. based on reported findings of regulated weeds in these imported crops. In the summer of 2016, VPSS also had positive findings of non-registered stacked GE lines in soybeans from South America. In fall 2016, imports of soybeans nearly came to a halt. (More in paragraph STACKED or PIRAMID EVENT APPROVALS in PART B of this report).

Table 2. Russia: Imports of products that may contain GE ingredients, CY 2011-2015 and Jan-Aug 2016

compared with Jan-Aug 2015, metric tons (MT)

	2011	2012	2013	2014	2015	Jan-Aug 2015	Jan Aug. 2016
Metric Tons							
Corn (1005)	113,04 1	41,150	55,271	52,728	43,844	29,170	26,901
- from the U.S.	4,467	6,455	6,210	3,986	3,435	2,213	370
Corn Groats and Meal (1103 13)	18,017	17,822	14,343	5,350	232	184	53
- from the U.S.	2	0	0	0	0	0	0
Corn Starch (1108 12)	11,456	18,095	15,941	18,032	13,253	9,077	7,708
- from the U.S.	221	78	6	0	0	0	0
Soybeans (1201)	909,55 0	693,67 7	1,145,15 5	2,028,16	2,179,71	1,377,23 4	1,533,26 1
- from the U.S.	26,788	55,964	208,274	390,008	526,171	256,135	216,018
Soybean flour (1208 10)	1,342	1,340	873	344	277	152	94
- from the U.S.	0	0	0	0	2	2	0
Soybean Meal (2304)	523,96 1	497,77	630,557	532,933	532,684	345,582	206,243

- from the U.S.	28,600	17,388	7,257	24,171	7,898	7,898	2,833
Soybean Isolates (from 3504)							
Total group 3504	51,924	52,219	54,559	58,711	46,245	28,717	24,593
- from the U.S.	359	300	190	485	120	89	101
1,000 U.S. Dollars							
Corn (1005)	107,85 7	97,890	161,299	221,429	146,367	97,440	91,664
- from the U.S.	3,484	5,781	6,294	4,071	3,202	2,065	343
Corn Groats and Meal (1103 13)	7,720	7,415	6,464	2,115	188	150	41
- from the U.S.	6	0	0	0	0	0	0
Corn Starch (1108 12)	7,743	11,351	12,107	11,495	7,243	4,886	3,978
- from the U.S.	270	99	36	1	4	4	3
Soybeans (1201)	505,62	440,91 6	675,783	1,150,75 8	941,790	607,638	642,038
- from the U.S.	15,836	31,830	121,985	215,294	219,849	115,796	81,541
Soybean flour (1208 10)	1,319	1,130	968	383	252	143	81
- from the U.S.	0	0	0	0	2	2	0
Soybean Meal (2304)	250,49 8	280,05 5	403,840	334,379	257,610	172,367	85,777
- from the U.S.	13,884	11,900	4,801	15,673	4,418	4,418	1,030
Soybean Isolates (from 3504)	0	0	0	0	0	0	0
Total group 3504	128,02 2	136,24 4	149,459	165,381	128,136	80,662	60,650
- from the U.S.	1,159	1,252	1,203	4,618	676	460	553

Source: Global Trade Atlas

#### e) FOOD AID:

Russia provides in kind food aid of grain, flour, vegetable oil, and grain and oilseeds products to some countries. Presumably, since Russia does not cultivate GE crops, their food aid does not contain any GE products. Russia is not a recipient of food aid.

#### f) TRADE BARRIERS:

Russia bans the cultivation of GE crops, and this impedes U.S. exports of planting seeds of crops, such as soybeans, rapeseed, sugar beets and corn. Russia's demand for efficient, drought-resistant varieties and hybrids of planting seeds of these crops is very high, but there is no open market for these seeds.

## **PART B: Policy**

## a) REGULATORY FRAMEWORK:

# i. RESPONSIBLE GOVERNMENT MINISTRIES

NOTE: Federal Law 358, of July 3, 2016, that bans the cultivation and breeding of GE crops and animals did not specify the authorities that will monitor the influence of GE crops and products derived with the use of such crops on human beings, animal and environment. It stipulates that this monitoring shall be conducted by the federal executive bodies pursuant to the procedure established by the Government of the Russian Federation. Until the Government establishes the new procedures, Post assumes that responsibilities of the Government Ministries in the sphere of GE remain the same as they were prior to July 2016.

Federal Service for Surveillance in the Sphere of Human Rights Protection and Human Well-Being (Rospotrebnadzor) (website: <a href="http://rospotrebnadzor.ru/about/- in Russian">http://rospotrebnadzor.ru/about/- in Russian</a>). Rospotrebnadzor has the following functions:

- Conducts state registration of new GE lines for food use and new food products containing GE organisms, including those that are imported into Russia for the first time;
- Conducts surveys and control of turnover of GE food products in accordance with Russian and EAEU legislation;
- Keeps the state register of GE food products allowed for sale, production and importation into the territory of the Russian Federation;
- Develops legislation on GE food products; and
- Monitors the influence of GE crops and products on people and the environment.

Since the unified economic space within the Customs Union, now the Eurasian Economic Union (EAEU), started on January 1, 2012, valid certificates and permits on the use of biotech food and biotech food ingredients are those that were issued for circulation within the territory of the EAEU.

The Ministry of Agriculture of the Russian Federation (website: <a href="www.mcx.ru-in Russian">www.mcx.ru-in Russian</a>) participates in the development of agricultural biotechnology policy together with Ministry of Economic Development and the Ministry of Science and Education of the Russian Federation. Its functions include the following:

- Overall policy development for the use of GE crops and organisms in agriculture. In accordance with Government Resolution 839 of September 2013, amended in June 2014 (see below), by July 1, 2017, the Ministry of Agriculture should develop regulations for the use of GE crops in agriculture; and
- Overall legal regulation of veterinary and phytosanitary conditions of agricultural production and the use of agricultural products, including legal regulation aimed at mitigation of any negative effects of GE crops and organisms on agricultural animals, plants, the environment, agricultural raw products, and processed food products.

**Federal Service for Veterinary and Phytosanitary Surveillance (VPSS)** is subordinated to the Ministry of Agriculture of the Russian Federation (website: <a href="http://fsvps.ru-in Russian">http://fsvps.ru-in Russian</a>). VPSS has the following functions:

- Conducts state registration of new GE lines for feed use and new feed containing GE organisms, including those that are imported into Russia for the first time;
- Issues certificates of registration for GE feed;
- -Maintains the state registration of feed derived from GE crops;
- Surveys the safety of feed and feed additives derived from GE crops at all stages of production and turnover:
- In accordance with Government Resolution 839 of September 2013, amended in June 2014 (see

below), by July 1, 2017, together with the Ministry of Agriculture, VPSS should develop regulations for the use and monitoring of GE crops, including for cultivation, and GE animals; and - Together with the Federal Service for Surveillance in the Sphere of Human Health, monitors the influence of GE crops, animals and products on people and the environment.

# The Ministry of Industry and Trade of the Russian Federation (website:

<u>http://www.minpromtorg.gov.ru – in Russian)</u> participates in the development of national standards and technical regulations which set requirements for biological safety of regulated items. This Ministry participates in the development of technical regulations of the Eurasian Economic Commission (formerly - Customs Union);

The Ministry of Economic Development of the Russian Federation (website: <a href="www.economy.gov.ru">www.economy.gov.ru</a> — in Russian) since 2012 monitors the implementation of the Comprehensive Program on Development of Biotechnology in the Russian Federation through 2020 (more on the Program see FAS/Moscow GAIN report <a href="Program on Development of Biotechnology in Russia through 2020">Program on Development of Biotechnology in Russia through 2020</a>);

The Russian Academy of Sciences (RAN) (website: <a href="www.ras.ru">www.ras.ru</a> – in Russian). On September 27, 2013, the Russian President signed the Federal Law "On the Russian Academy of Sciences, Reorganization of the State Academies of Sciences and on Amendments to Some Legal Acts" (Federal Law No. 253-FZ) with immediate effect. Federal law 253-FZ envisaged that the formerly independent Russian Academy of Sciences, Russian Academy of Medical Sciences and Russian Academy of Agricultural Sciences would merge into the Russian Academy of Sciences. The expected transfer period for uniting these academies will be finalized within three years, or by fall 2016. The main function of the new Academy is to coordinate fundamental science and research and expertise on science-related programs and projects, including in the field of agricultural biotechnology. So far there is no information on the unified strategy of RAN in development of programs and projects in the field of agricultural biotechnology. The applied research in the field of agricultural biotechnology is still conducted by research institutes, which were under the authority of the three formerly independent academies. Now these institutes are subordinated to the Federal Agency of Science Organizations (see below) and are undergoing the process of reorganization.<sup>4</sup>

The Federal Agency of Scientific Organizations (FANO) (website: <a href="www.fano.gov.ru">www.fano.gov.ru</a> – in Russian) was organized in 2013 after the merger in 2013 of three former independent Russian Science Academies (Russian Academy of Sciences, Russian Academy of Medical Sciences and Russian Academy of Agricultural Sciences) into the Russian Academy of Sciences. The FANO owns and operates the property of all these three Academies, including the property of their institutes. FANO also is assigned to finance research in these institutes, including institutes, which before the reorganization conducted research in the field of agricultural biotechnology: Institute of Agricultural Biotechnology, Center for Quality and Standardization of Veterinary Drugs and Feed, Institute of Nutrition, Center of Bioengineering. For more information on the functions of these institutes before the reorganization, see FAS/Moscow GAIN report <a href="Agricultural Biotechnology Annual 7-9-2015.pdf">Agricultural Biotechnology Annual 7-9-2015.pdf</a>. Since these institutes are still in the process of reorganization under FANO, Post does not have valid information on the current activities of these institutes in the field of agricultural biotechnology.

<sup>&</sup>lt;sup>4</sup> More information on the reorganization of the three Russian Science Academies is in FAS Moscow GAIN reports <u>Agricultural Policy and Situation Bi-Weekly Update 10-18-2013.pdf</u> and <u>Russian Agricultural Policy and Situation Bi-Weekly Update 11-1-2013.pdf</u>.

The Eurasian Economic Union (EAEU) (website: <a href="www.eaeunion.org">www.eaeunion.org</a>) replaced the Customs Union of Kazakhstan, Russia and Belarus (CU), and now unites Kazakhstan, Russia, Belarus, Armenia and Kyrgyzstan. The EAEU develops and adopts the common customs and technical regulations for all member countries of the Eurasian Economic Union. For Armenia and Kyrgyzstan, which joined the EAEU in 2015, there is a transitional period for adapting to the technical regulations of the EAEU.

#### ii. LEGISLATION AND REGULATIONS

Decisions of the Eurasian Economic Union (EUAU) (former Customs Union) – so called "technical regulations" of the CU, Russian federal laws, government resolutions and orders of the heads of the Russian regulation ministries, agencies and services regulate Russian agricultural biotech policy at present.

# **Decisions of the Eurasian Economic Union (EUAU) (former Customs Union)**

Since July 2010, the EAEU adopted several technical regulations that have influenced agricultural and food biotechnology. These technical regulations came into force on July 1, 2013, and all regulations require marking the presence of "GMOs" on labels, and informing consumers in cases when food products are processed from or with the use of "GMO," even if there is no DNA or proteins of "GMO" components in the marketed food products. For the unofficial translations of the CU technical regulations that cover food safety and labeling issues and that came into force on July 1, 2013, please see GAIN reports:

- RS1233 Customs Union Technical Regulation on Food Safety;
- RS1250 Customs Union Technical Regulation on Safety of Grain;
- RSATO1211Customs Union Technical Regulations on Food Products Labeling;
- RS1326 Customs Union Technical Regulation on Fat and Oil Products;
- RS1334 Customs Union Technical Regulation on Juice.

The technical regulations (TR) of the EAEU are mandatory for all members of the Eurasian Economic Union but there are transitional periods for the new members, such as Armenia and Kyrgyzstan. Information on the CU TRs was provided in the previous Annual Agricultural Biotechnology Reports in 2014 and 2015. The summary of the CU technical regulations are below:

- <u>CU Technical Regulation No 021/2011 on Safety of Food Products</u> (adopted in December 2011, came into force on July 1, 2013): The definition of "GMO" in this technical regulation of "genetically modified (genetically engineered, transgenic) organisms" is "an organism or several organisms, any noncellular, unicellular or multicellular formations capable of reproduction or transfer of genetic material differing from natural organisms obtained with the use of genetic engineering methods and (or) containing genetically engineered material including genes, their fragments or gene combinations." This Technical Regulation states the following:
  - Food products can be processed only from "GMO/GMM" registered in the EAEU (Paragraph 9 of Chapter 2);
  - If the producer did not use "GMOs" during processing of food products, the presence of 0.9 percent and less of "GMOs" is considered an adventitious, unavoidable presence, and the product is not "GMO" (Paragraph 9, Chapter 2);
  - The use of "GMO" in baby food and in food for pregnant and nursing women is not allowed (Paragraph 1 of Article 8).

- CU Technical Regulation No 022/2011 on Food Labeling: requires that food products with "GMO" shall be labeled, and determines the format of this labeling. The presence of 0.9 percent and less of "GMO" shall not be labeled, and the product is not considered as a genetically modified ("GM") product. Labeling of food products as "non-GMO" is voluntary and the absence of "GMO" shall be proved and documented through private tests conducted by private labs. There is no official monitoring of these tests. Labels for packaged food products are required to contain information on the presence of food product ingredients obtained with the use of genetically modified organisms. Listing of "GMO" ingredients are not excused in cases where the mass of the compound ingredient is not more than 2 percent of the mass of the product (Paragraph 4.10). The information about the specific characteristics of food products, including absence of components obtained from "GMO" (or) with the use of "GMO," shall be confirmed by proofs. Organizations or individual entrepreneurs releasing such food products for circulation in the unified customs area of the EAEU shall keep the documents with proofs of presence of specific characteristics of food products. The Technical Regulation on Food Labeling also has a special paragraph (4.11.) "Requirements for Specification of Information on Presence of Ingredients Obtained with the Use of Genetically Modified Organisms in Food Products in Food Products Labeling" (for more information see previous Agricultural Biotechnology annual reports).
- CU Technical Regulation No 015/2001 on the Safety of Grain (adopted in December 2011, came to force on July 1, 2013): The Technical Regulation determines requirements for information on grain/oilseeds during transportation either in bulk of in consumer packs (for feed purposes). Article Four (Safety Requirements, paragraph 16) stipulates that grain transported unpackaged should be accompanied by shipping documents that ensure its traceability and provide information on "GMOs" if the presence of "GMOs" is higher than 0.9 percent ... For GE grain the following information should be provided: "Genetically modified grain" or "grain obtained from the use of genetically modified organisms" or "grain contains components of genetically modified organisms," indicating the unique identifier of the transformation event. In addition, in the sanitary requirements for grain/oilseeds (MRLs of toxic elements, micotoxins, pesticides, radionuclide and pests) the technical regulation stipulates that grain/oilseeds (both for food and for feed use) may contain only registered "GMO" lines (registered in accordance with the legislation of the states, members of the EAEU), and the presence of non-registered GM grain lines shall not exceed 0.9 percent "Grain may contain only those "GMO" lines that are registered in accordance with the legislation of the member states of the EAEU. Grain that contains a "GMO" presence of not more than 0.9 percent of non-registered "GMO" lines is allowed." The same standards (GOSTs) as in Technical Regulation 021/2011 shall be applied (GOST R 52173-2003 and GOST R 52174-2003).
- <u>CU Technical Regulation No. 024/2011 on Fat and Oil Products</u> (adopted December 2011, came into force on July 1, 2013): This technical regulation requires labeling of oil and fat products released into circulation for human consumption, and labels shall include information on the presence of "GMOs."
- CU Technical Regulation No 023/2011 "On Fruit and Vegetable Juices and Their Products" (came into force on July 1, 2013): The EAEU Technical Regulation on Juices and their products bans the use of "GMOs" in baby food (fruit and vegetable juice products for babies) and requires state registration of any product that was processed using methods of genetic modification.

#### Federal Laws of the Russian Federation

- Federal Law No. 358 of July 3, 2016 (FL 358 in Russian) "On amendments to certain legislative acts of the Russian Federation concerning the improvement of state regulation in the sphere of genetic-engineering activities." FL 358 bans the cultivation of GE crops, formalizing the previous de-facto ban resulting from the lack of a regulatory framework (see previous Biotechnology Annuals) to a specific, legal ban. FL 358 amends Federal Law No. 86 of July 5, 1996, Federal Law No. 149 of December 17, 1997, Russian Federal Code of Administrative offences, and Federal Law No. 7 of January 10, 2002. (For more information on FL 358 see FAS/Moscow GAIN report Russia Bans Cultivation and Breeding of GE Crops and Animals 7-12-2016.pdf). These amendments specifically prohibit the cultivation of GE plants and the breeding of GE animals on the territory of the Russian Federation, except for the cultivation and breeding of plants and animals required for scientific expertise or research. The penalties for violating officials will be from 10,000 rubles to 50,000 rubles. The penalties for violations by judicial persons will be from 100,000 rubles to 500,000 rubles.<sup>5</sup> Federal Law 358 will come into force on the date of its official publication (July 4, 2016), except the article pertaining to penalties in cases of violations, which will come into force on July 1, 2017. This law makes an exception for "the cultivation and breeding of plants and animals required for scientific expertise or research." Based on monitoring of the effect of "GMO," or products derived from/or containing "GMO," on humans and the environment, the Government shall have the right to ban imports into Russia of genetically modified organisms intended for environmental release and (or) products derived from or containing such organisms."<sup>6</sup>
- Federal Law No. 86-FZ of June 5, 1996, On the State Regulation in the Sphere of Genetic Engineering Activities" with amendments made in 2000 and in 2010. This is a foundational federal law on genetic engineering in Russia, but the law does not provide instruments for implementation. There were several amendments to this federal law, including the last one, made by FL 358 of July 3, 2016, which emphasized the role of state control over the release of genetically-engineered organisms into the environment, state monitoring of the effects of such release on the environment and also on the health of human beings. The amendments add the responsibility of control and monitoring, as well as registration, of genetically engineered organisms and products, including imported goods, to the state. The amendments broaden the meaning of "safety control in the sphere of genetic engineering," and emphasize that, based on the results of monitoring the effects of GE organisms and products on the environment and on human health; the authorized bodies of the executive power can ban imports of genetically-engineered organisms and/or products derived from GE organisms into Russia.<sup>7</sup>
- **Federal Law No 52-FZ of March 30, 1999**, On the Sanitary-Epidemiological Well-being of the Population;
- **Federal Law No. 29-FZ of January 2, 2000**, On the Quality and Safety of Food Products with amendments made in 2001 2008;

<sup>&</sup>lt;sup>5</sup> At the time of signing the FL 358 of July 3, 2016, the exchange rate was 64 rubles per \$1.

<sup>6</sup> http://www.gazeta.ru/science/news/2016/06/24/n\_8804021.shtml (in Russian)

<sup>&</sup>lt;sup>7</sup> The text of this FL No. 86 with amendments (in Russian) is provided at: http://base.consultant.ru/cons/cgi/online...10756232845596969

- **Federal Law No. 2300-1 of February 7, 1992**, On the Protection of Consumer Rights with amendments. The amendment of October 25, 2007 sets the threshold for mandatory labeling of food ingredients made from biotech material at 0.9 percent. Prior to this amendment, trace amounts of biotech food ingredients required labeling;
- The Federal Law No. 7-FZ of January 10, 2002, "On Protection of the Environment" with amendments made in 2011 and in 2016. Amendment made by FL 358 of July 2016, to Article 50.1 adds the following text: "it is prohibited to grow or breed plants and animals whose genetics have been modified by using genetic-engineering methods and which contain genetic-engineering materials that cannot be introduced as a result of natural (spontaneous) processes, with exception of growing and breeding such plants and animals in the course of expert examination and research activities."
- Federal Law of December 17, 1997, No. 149-FZ "On Seed Industry" as amended by FL 358 of July 3, 2016, bans imports of GE planting seeds into Russia, with the exception of sowing (planting) such seeds for research activities." "It is prohibited to import into the Russian Federation territory, or to use for sowing (planting), the seeds of plants which have modified genetics through the application of gene-engineering methods and which contain gene-engineering material that cannot be introduced as a result of natural (spontaneous) processes, with the exception of sowing (planting) such seeds in the course of expert examination and research activities."
- Russian Federation Code of Administrative Violations, as amended by FL 358, under Article 6.3. Article 6.3 "Violation of the legislation of the Russian Federation in the Area of Genetic Engineering Activity." A violation of the legislation of the Russian Federation in the Area of Genetic Engineering Activity consisting of the use of genetically modified organisms and/or products, derived with the use of such organisms or containing such organisms, that have not been registered with the state in cases where state registration is required by said legislation, or where the period of validity of the certificate on state registration has expired, or in the case where genetically modified organisms are not used in conformity with the purpose(s) for which they were registered, or where there is failure to comply with genetically modified organisms stipulated special use conditions are not complied with, e.g. in the manufacture of specific type of products, will involve imposition of a penalty on officials in the amount ranging from Ten Thousand to Fifty Thousand Rubles; on legal entities – from One Hundred Thousand to Five Hundred Thousand Rubles." The previous amendments to the Code of Administrative Violations (made in December 2014) set fines for violations of mandatory requirements for labeling food products derived from genetically engineered organisms (referred to as "GMO" in the Russian documents) or containing such organisms. The fines for individual entrepreneurs are from 20 thousand to 50 thousand rubles (from \$364 to \$909), and for legal entities are from 100 thousand to 300 thousand rubles (from \$1,818 to \$5,455). The law also provides Rospotrebnadzor with the authority to draw up protocols on administrative violations in such cases and submit these cases to the consideration of the court.

#### **Resolutions of the Russian Government**

<sup>&</sup>lt;sup>8</sup> As of end of June 2015 the exchange rate of Russian ruble is 55 rubles per \$1.

- Resolution of the Government of the Russian Federation No. 988 of December 21, 2000, On State Registration of New Food Products, Materials, and Goods with amendments. The resolution authorizes registration of GE foods;
- Resolution of the Government of the Russian Federation No. 120 of February 16, 2001, On State Registration of Genetically Modified Organisms and Registration Regulation. This Resolution enforced the state registration of GE organisms;
- Resolution of the Government of the Russian Federation No 26 of January 18, 2002, On the State Registration of "GMO" Feed;
- Resolution of the Government of the Russian Federation No. 422 of July 14, 2006 which
  transferred testing and registration of biotech feed from the Ministry of Agriculture of the
  Russian Federation to the Federal Service for Veterinary and Phytosanitary Surveillance (VPSS)
  at the Ministry of Agriculture of the Russian Federation;
- Resolution of the Russian Government No. 717 of July 14, 2012, "On the State Program for Development of Agriculture and Regulation of Agricultural and Food Markets in 2013-2020."
   The program outlines the main directions of development of agricultural science, including biotechnology, although agricultural biotechnology is not a priority;
- Resolution of the Russian Government No. 839 of September 23, 2013, "On the State
  Registration of Genetically-Engineered-Modified Organisms Intended for Release into the
  Environment as well as Products Derived from the Use of Such Organisms or Containing Such
  Organisms." The Resolution approved the rules of registration of genetically engineered
  organisms and orders Ministries and federal bodies to update or develop procedures for the
  beginning of registration; and
- Resolution of the Russian Government No. 548 of June 16, 2014, "On the Amendments to the Resolution No. 839 of September 23, 2013" postpones the implementation of Resolution 839 from July 1, 2014 to July 1, 2017.

#### Normative acts of government bodies

- Resolution of the Chief Sanitary Doctor of the Russian Federation (No 14 of November 8, 2011), On the Procedures of Sanitary-Epidemiological Expertise of Food Products from Genetically Modified Sources;
- Methodological directives on norms and methods for testing, identification and analyses of
  genetically modified foods, organisms and microorganisms. State standards for food products.
  These methods and standards may be developed by different organizations, but are usually
  approved by Federal Agency on Technical Regulation and Metrology of the Ministry of Industry
  and Trade of the Russian Federation; and
- Order of the Ministry of Agriculture No. 466 of October 6, 2009 on approval of regulations for VPSS on the State Registration of Feed Derived from Genetic-Engineered-Modifies Organisms.

In accordance with GOR Resolution 839 of September 23, 2013, government bodies connected with agricultural biotechnology should develop a coordinated set of regulatory documents for registration and monitoring of GE food, feed, and crops, including for cultivation. However, when the implementation of this resolution was postponed until July 1, 2017, development of such regulatory documents slowed down. With adoption in July 2016 of the FL 358, the development of such documents was, for all

practical purposes, halted. So far there is no information on adoption of any such documents. Moreover, constraints of the federal budget and reorganization of some research institutes may curb development and adoption of such documents in 2016 and 2017.

#### iii. GE CROPS/LINES REGISTRATION FOR FOOD AND FEED USE

#### Registration for Food Use (procedure)

Rospotrebnadzor registers biotech crops and ingredients for food use for Russia and for the Eurasian Economic Union. The registration process remains the same as was stated in the Annual Biotechnology GAIN reports for 2011 through 2014 (<u>Agricultural Biotechnology Annual\_7-9-2015.pdf</u>):

- The applicant submits an application and dossier to Rospotrebnadzor;
- Rospotrebnadzor assigns a safety assessment study to the Institute of Nutrition (Federal State Budget Enterprise "Science and Research Institute of Nutrition"), which may coordinate with other Russian science institutes and laboratories in the field of biotechnology and microbiology;
- The applicant concludes an agreement for the food safety assessment with this Institute; and
- Based on the Institute's assessment, Rospotrebnadzor issues a certificate of registration and registers the product.

Laboratory tests required for the safety assessment take approximately twelve months to conduct and an additional two to three months are needed to organize and prepare documents for the new GE crops. Registering food products and ingredients requires less time. However, registration is only granted if the biotech product contains biotech events that have already been registered. Since 2006, Rospotrebnadzor has registered food-use crops for an unlimited time-period. Information on GE crops registered for food-use for food products or an ingredient containing registered biotech ingredients is available on Rospotrebnadzor's website: <a href="http://fp.crc.ru/gosregfr/">http://fp.crc.ru/gosregfr/</a> (Russian). The list of registered products contains all new food products, not only biotech products or products with biotech ingredients. There are several hundred different products and names. To find permitted food products for a specific crop, search for the name of the crop and the words "genetically modified."

#### Registration for Feed Use

The registration for feed use has been effectively suspended since the adoption of FL 358, largely due to the reorganization of the research institute that was previously subordinated to VPSS. However, the procedure of registration of GE crops for feed use remains the same.

Plant-origin feed imports no longer require a veterinary certificate but still require a letter stating that the feed is biotech free. Feed may be classified as biotech-free if presence of each non-registered biotech line in feed does not exceed 0.5 percent and if the presence of each registered biotech line in the feed does not exceed 0.9 percent. In this case, "registered" refers to products registered in Russia and "non-registered" refers to products not registered in Russia. The presence of genetic alterations in feed components is calculated separately and not comprehensively. For example, if two registered components in feed contain 0.6 percent of genetic alterations in each, then the feed is considered to be non-biotech, although together the sum is 1.2 percent. The pre-export identification of feed as "non-GMO" is not required. It is up to the producer/exporter to declare the feed as "non-GMO," but regardless, VPSS examines the products for the presence of GE components.

<sup>&</sup>lt;sup>9</sup> VPSS regularly examines feed for the presence of GE components. Thus, at the end of June 2015, the Russian Federal Center of Quality and Standardization of Veterinary Pharmaceuticals and Feed (VGNKI) subordinate to VPSS conducted testing of 43 samples of feed originated from Ukraine (40 samples)/ Netherlands (2 samples) and Russia (1 sample) for

If the feed contains GE ingredients, and is not declared as biotech free, the shipment must include a copy of the certificate indicating that the biotech components in the feed are registered with VPSS. The imports must also have a phytosanitary certificate, although this requirement is unrelated to biotechnology. Any biotech components in feed must be appropriately registered. Presence of each non-registered biotech line shall not exceed 0.5 percent. The EAEU's Technical Regulation on Feed has not been adopted yet, but the draft has the same 0.5 percent maximum for non-registered biotech lines, as in current Russian regulations. However, the adopted Technical Regulation on Safety of Grain stipulates that feed (grain/oilseed) is considered "non-GMO" if the presence of each non-registered biotech lines does not exceed 0.9 percent. The Technical Regulation on Safety of Grain came into to force on July 1, 2013.

The responsibilities of VPSS in feed registration were confirmed by Order No. 466 of the Russian Ministry of Agriculture of October 6, 2009. Order 466 states that the registration is issued for five years. The regulation covers "products of plant, animal and microbiological origin, and their components, used for feeding animals, and which contain animal health non-harmful digestible nutrients." The Order does not allow the registration of several types of GM feed under one name, or the registration of the same GM feed several times under one name or under several different names. The applicant must submit the following documents:

- application for the state registration of GE feed;
- information on the origin of GE feed, evaluation of the potential danger of use of GE feed (compared with the initial basic feed), and recommendation of the applicant on risk reduction, information on the supposed use of the GE feed, and on the registration and use of this feed abroad; information about the technology of growing the modified variety of the plant that is used for production of GE feed, data on the technology of production of GE feed, draft of the instruction on the use of GE feed; and if the modified plant variety, which is used for feed is viable and is meant for biomass or fodder

growing, the certificate from the Russian State Register of Selection Achievements must be attached.

All documents shall be in Russian, or shall have a certified translation into Russian. Copies of documents shall be certified by a notary. VPSS will make a decision on the registration of a GE feed based on the Conclusion of the Experts Council on the safety (non-safety) of the GE feed. The procedures and necessary documents for registration of feed containing "GMOs" is provided on VPSS's website: <a href="http://www.fsvps.ru/fsvps/regLicensing">http://www.fsvps.ru/fsvps/regLicensing</a> (in Russian). The List of Registered GE feed, before July 15, 2015, is provided <a href="here">here</a> (in Russian). The List of Registered GE feed after July 15, 2015, is available at the site: <a href="https://galen.vetrf.ru/#/registry/gmo/registry?page=1">https://galen.vetrf.ru/#/registry/gmo/registry?page=1</a>.

To register formula feed, VPSS issues feed-registration certificates to a specific applicant for an individual shipment during a certain period of time. VPSS only issues certificates for feed produced using registered GE crops. The certificates cannot be transferred to different importers. This registration is conducted by VPSS.

"GMO" content. "GMO" content in excess of maximum (more than 0.9%) of GM soy line 40-3-2 was revealed in all samples. Therefore, all producers involved in the research violated requirements of the Russian Federation related to the "GMO" registration and labeling. VGNKI sent the results of tests to VPSS for the latter to take appropriate action <a href="http://fsvps.ru/fsvps/news/14082.html">http://fsvps.ru/fsvps/news/14082.html</a>. However, there is no information on what actions VPSS have taken. Moreover, industry analysts consider that it is physically impossible to control GE in all feed, and that was one of the strong arguments of the livestock and poultry industries lobbying against the draft federal law that required a ban on imports and circulation of GE food and feed in the Russian Federation.

## Fees for registration of biotech events (all fees are set in rubles)

Rospotrebnadzor's charges for all examinations and related services, including comprehensive studies required to register biotech events for food use. The fee varies, depending on the range of examinations and studies, but averages around 4.5 million rubles (approximately \$81,800) for the approval of new events for an unlimited period. The option to register for an unlimited period began in 2006. Registration of food products that contain a previously registered biotech event is 20,000 rubles (\$364).

For registration of biotech events for feed use, VPSS usually registers events only after it has been approved for food-use, although in some cases registration for feed use may precede registration for food. On average, the charge for examination and a five year event registration for feed use is 4.5 million rubles (approximately \$81,800). The charge for re-registration of the event every five years is 3.8 million rubles (approximately \$69,100). Companies that import formula feed with registered biotech components also need to register these feed as biotech feed. The registration is given to the company that imports this feed and VPSS requires that each feed containing a registered GM event must also be registered.

## iv. RECENT ACTIVITIES OF RUSSIAN AUTHORITIES IN REGARDS TO GE CROPS

Since the adoption of FL 358, enacting a prohibition of the cultivation of GE plants and breeding of GE animals in the territory of the Russian Federation, activities of Russian authorities have been concentrated on the following:

- VPSS stimulates its subordinate institutes and laboratories to increase capacity for testing of GE components in feed, feed components, and raw material for feed production.
- In summer 2016, VPSS reported increased findings of non-registered, or not properly, registered feed and feed ingredients.
- Ministries and institutes, including institutes subordinate to the Ministry of Science and Education, Ministry of Health, Rospotrebnadzor and VPSS, that are involved in the development of regulatory mechanisms for registration and monitoring of GE plants, products and ingredients continue working on regulations considering new approaches in Russian GE policy declared by FL 358. The amendments are supposed to be ready by July 2017. Post is aware of the preparation of several draft amendments to registration procedures of GE products for food and feed use. None of these amendments have yet been adopted. Moreover, usually the texts of these amendments or the status of discussion of these amendments are not available for the public.
- Authorized Ministries and agencies continue to work on the amendments to the regulatory documents for registration and circulation of GE crops and microorganism in the Russian Federation, primarily with consideration to the strengthening of controls over such registration and controls over the presence of GE lines in food and feed products. The previously adopted mechanism for the registration of GE lines for food and for feed and for registration of products containing such organisms still remain in force.
- However, work on new regulations hampers registration within the current framework, especially for feed registration, since VPSS does not have a clear understanding of the goal and authorities in the registration process. Moreover, the development of new mechanisms has been further complicated by the continuing reorganization of the Russian scientific and research institutes and bodies following the merger of three Russian Scientific Academies (the Academy)

of Science, the Academy of Agricultural Science, and the Academy of Medical Science). (See section RESPONSIBLE GOVERNMENT MINISTRIES of this report).

## b) APPROVALS:

Table 2. Russia: Approved and Registered Biotech Crops, 1999-2016

	Crop/line/event/trait	Applicant	Year and period of Registration	
			For Food Use	For Feed Use
1	Bt corn MON 810, resistant to European corn borer <i>Ostrinia</i> nubilalis	Monsanto	2000 – 2003, 2003 – 2008 Mar. 2009 – for unlimited period	2003 – 2008 Sep. 2008 – Aug. 2013 Aug. 2013 – Sep. 2018
2	Roundup Ready® corn NK 603, tolerant to glyphosate	Monsanto	2002 – 2007; Feb. 2008 – for unlimited period	2003 – 2008 Sep. 2008 – Aug. 2013 Aug. 2013 – Sep. 2018
3	Bt corn MON 863, resistant to corn root worm ( <i>Diabrotica spp.</i> )	Monsanto	2003 – 2008 Aug. 2008 – for unlimited period	10
4	Corn Bt 11, tolerant to gluphosinate and resistant to corn borer Ostrinia nubilalis	Syngenta	2003 – 2008 Sep. 2008 – for unlimited period	Dec. 2006 – Dec. 2011, Dec. 2011 – Dec. 2016 Oct. 2016 submitted for re- registration
5	LL Corn T25, tolerant to gluphosinate	Bayer Crop Sciences	2001 – 2006, Feb. 2007 – for unlimited period	Dec. 2006 – Dec. 2011; Dec. 2011 – Dec. 2016 Oct. 2016 submitted for re- registration
6	Roundup Ready ® corn GA 21, tolerant to glyphosate*	Syngenta	2007 – for unlimited period	Nov. 2007 – Nov. 2012; Nov. 2012 – Nov. 2017
7	Corn MIR 604, resistant to corn root worm (Diabrotica spp.)	Syngenta	Jul. 2007 – for unlimited period	May 2008 – May 2013; May 2013 – May 2018

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<sup>&</sup>lt;sup>10</sup> Registration for feed ended in August 2013, and Monsanto did not renew the registration for feed because discontinued production of these seeds. The registration for food remains because these seeds may still be under circulation in some countries, and traces of this corn may be found in commercial shipments.

8	Corn 3272 with α-amylase enzyme to break starch during ethanol production	Syngenta	April 2010 – for unlimited period	Oct. 2010 – Oct. 2015 March 2016 – March 2021
9	Corn MON 88017 (CCR), tolerant to glyphosate and resistant to corn root worm ( <i>Diabrotica spp.</i> )	Monsanto	May 2007 – for unlimited period	Sep. 2008 – Aug. 2013; Sep. 2013 – Sep. 2018
10	Corn MON 89034, resistant to Lepidoptera pest	Monsanto	December 2014 – for unlimited period	Mar. 2013 – Mar. 2018
11	Corn MIR162, resistant to Broad Lepidoptera spp.	Syngenta	Apr. 2011 - for unlimited period	March 1212 – March 2017
12	Corn 5307, resistant to corn root worm ( <i>Diabrotica II</i> , <i>Coleoptera</i> )	Syngenta	Apr. 2014 – for unlimited period	Apr. 2014 – Apr. 2019
13	Roundup Ready® soybeans 40-3-2, tolerant to glyphosate	Monsanto	1999 – 2002, 2002 – 2007, Dec. 2007 - for unlimited period	2003 – 2008, May 2008 – May 2013 May 2013 – May 2018
14	Bt soybeans, MON 87701, resistant to Lepidoptera pests	Monsanto	May 2013 – for unlimited period	Jul. 2013 – Jul. 2018
15	Soybean MON 89788 (RRS2Y), tolerant to glyphosate + yield gain	Monsanto	Jan. 2010 – for unlimited period	May 2010 – May 2015 Oct. 2015 – Oct. 2020
16	Liberty Link® Soybeans A2704-12, tolerant to gluphosinate	Bayer Crop Sciences	2002 – 2007 Feb. 2008 – for unlimited period	Nov. 2007 – Nov. 2012 Nov. 2012 – Nov. 2017
17	Liberty Link® Soybeans A5547- 127, tolerant to gluphosinate ammonium	Bayer Crop Sciences	2002 – 2007 Feb. 2008 – for unlimited period	Nov. 2007 – Nov. 2012 Nov. 2012 – Nov. 2017
18	Soybeans FG72, tolerant to isoxaflutole and glyphosate	Bayer	Dec. 2015 – for unlimited period	Apr. 2014 – Apr. 2020
19	Soybeans BPS-CV-127-9, imidazolinone	BASF	Dec. 2012 – for unlimited period	Sep. 2012 – Sep. 2017
20	Soybeans SYHT0H2, herbiside	Syngenta	Jan. 2016 – for	Apr. 2013 – Apr.

	HPPD* + glufosinate	(Producers Syngenta /Bayer)	unlimited period	2019
21	Rice LL62, tolerant to gluphosinate ammonium	Bayer Crop Sciences	2003 – 2008 Jan. 2009 – for unlimited period	
22	Roundup Ready ® Sugar beet H7-1, tolerant to glyphosate	Monsanto/ KWS	May 2006 – for unlimited period	
23	Bt potato "Elizaveta" (resistant to Colorado potato beetle)	Center "Bio- engineering", Russia	Dec. 2005 – for unlimited period**	
24	Bt potato "Lugovskoy" (resistant to Colorado potato beetle)	Center "Bio- engineering"	Jul. 2006 – for unlimited period**	

<sup>\*</sup>HPPD – herbicides that inhibit the enzyme hydroxy-phenyl-pyruvate-dioxygenase

The above information is provided based on information received from certain applicants willing to share their registration information. However, Post believe other registration activities have been initiated (but not yet approved), but information related to these possible registration requests is not available.

#### c) STACKED or PYRAMID EVENT APPROVALS

Russia does not yet have a mechanism for the approval of stacked events. During the spring and summer of 2016, VPSS intensified thorough testing of feed produced from imported soybeans, and regularly started finding traces of stacked events not registered in Russia. This led to the suspension of soybean imports from Paraguay, Brazil, and Argentina, where stacked soybeans are widely produced. Resolution of this issue is possible only if Russia develops a system for the registration of stacked lines. So far Rospotrebnadzor has developed some recommendations on the registration (for food) of stacked events, but these recommendations have not been adopted for registration (for feed) by VPSS.

#### d) FIELD TESTING

Not applicable. Since cultivation is banned, Russian researchers do not conduct wide scale field tests of GE crops, although the FL 358 does not ban imports of planting seeds of GE crops for laboratory tests and experiments.

#### e) INNOVATIVE BIOTECHNOLOGIES:

There is no information on the development of innovative plant biotechnologies. According to available information, Russian research in biotechnology is limited to biological means of plant protection, growth stimulators, and microbiological fertilizer.

<sup>\*\*</sup>Bt potato "Elizaveta" and "Lugovskoy" are registered for food use only for Russia, because these two potato varieties were not registered for the EAEU

#### f) COEXISTANCE:

Not applicable since there is no mechanism and legislation for cultivation of GE crops.

## g) LABELING

Labeling and information for consumers on the presence of GE ingredients in food products is regulated by the technical regulations of the EAEU on safety and labeling of food products. These regulations require that in any of the EAEU member states, products must be labeled if the presence of GE lines is over 0.9 percent. According to amendments to the Russian Code of Administrative Violations made in December 2014 (see section Federal Laws of the current report), penalties for violations in labeling of GE food have strengthened. In Russia, fees for violating this labeling requirements range from 20,000 rubles to 50,000 rubles for individual entrepreneurs, and from 100,000 rubles to 300,000 rubles for legal entities. The EAEU technical regulation for feed has not yet been adopted. Feed sold in Russia does not require labeling. However registration of GE lines for use in feed is required if the presence of registered lines is over 0.9 percent and the presence of non-registered lines is over 0.5 percent

#### Food labeling:

In accordance with the Technical Regulations of the EAEU that came into force on July 1, 2013, all organizations that import, produce, or trade food products to/in member countries of the Eurasian Economic Union must inform consumers about the presence of biotech components in food products if each individual biotech event does not exceed 0.9 percent. In 2015, Armenia and Kyrgyzstan became members of the Eurasian Economic Union. These two members must also follow the EAEU technical regulations/ including technical regulations on labeling food products, after a transitional period. The methods that should be used to test for biotech presence in food are also specified in the Attachments to the EAEU Technical Regulations on Food Safety and Food Labeling, and are the same that were used in Russia by Rospotrebnadzor before the EAEU Technical Regulations on Food labeling and Food Safety came into force.

For food products imported into Russia, Rospotrebnadzor has the right to conduct sample tests to detect the presence of biotech components. In order to verify the biotech-free claim, the producer or exporter may conduct its own tests at independent laboratories (it may be an IP system or PCR test), but the results of these tests are not accepted by Rospotrebnadzor. These pre-export tests are voluntary for producers and exporters. If a producer/exporter claims that its products are not genetically altered, Rospotrebnadzor still has the right to examine these products. Furthermore, if the presence of genetic alteration in the products is more than 0.9 percent, a claim for fraud may be lodged against that company. Usually Rospotrebnadzor pays special attention to products containing soybean or corn ingredients. For more information on the EAEU's food labeling requirements please see section Decisions of the Customs Union, above.

In 2016, the EAEU notified the WTO of the draft amendments to the TR on Food Labeling ("GMO" sign on food label shall be of the same size and next to the Unified mark of products circulating in markets of EAEU member states). FAS/Moscow reported on this draft in the GAIN report: <a href="Moscow reported">Draft TBT</a> Measure on Food Labeling Notified to WTO 5-25-2016.pdf. However, this draft has not been adopted yet by the EAEU.

Organic Products: starting January 1, 2017, food producers will be able to obtain a voluntary certification for "organic." The State Standard on the production of organic products (GOST 56508-2015) has been in force since January 1, 2016, but the procedure for voluntary organic certification was adopted only recently by GOST 57022-2016 and the actual certification shall begin on January 1, 2017.

<u>Feed labeling</u>: Information on the composition of feed, including the presence of biotech components is provided on the shipping documents, but so far Russia has not required labeling of presence of "GMOs" in feed on consumer packs of feed. The EAEU Technical Regulation on Feed is still under discussion, and has not been adopted. Requirements for information on "GMO" in shipping documents for grain and oilseeds, and their products, are in the EAEU's Technical Regulation on Safety of Grain. For more information please see section Decisions of the Customs Union, above.

#### h) MONITORING AND TESTING:

In Russia, Rospotrebnadzor monitors/tests GE food products and VPSS monitors/tests grains, oilseeds for animal consumption, feed additives, and ingredients (for more information see paragraph above on the role of different ministries and agencies.) Given the current concerns in Russia that illegal cultivation may occur in Russia, the Ministry of Agriculture strengthened controls over planting seeds. The Ministry of Agriculture issued Order 335 of October 6, 2016, authorizing its subordinate State Commission for Testing and Protection of Selection Achievements (Gossortcommission), to conduct expertize on the presence of GE constructions in planting seeds submitted for registration in the Russian Federation. 11 The expertise shall be conducted by PCR methods in varieties of the following agricultural crops: corn, soybeans, sugar beets, rapeseed, potato, tomato, and cotton. The applicant shall provide additional seed samples (for testing for the presence of GE in new varieties) in the following quantities: 100-gram samples for each variety/hybrid of corn, soybeans, rapeseed, sugar beets, and cotton; five-gram samples for each variety/hybrid of tomatoes, and ten bulbs of potato varieties. The samples shall be provided by December 10<sup>th</sup> each year. If the samples are note provided on time, the application for inclusion of the variety in the State Register of Selection Achievements is considered invalid. The Commission plans to complete the testing of all samples for GE presence by January 25, 2017. Industry analysts report that the Commission itself does not have any equipment for such tests, and that the tests will be conducted by the former Institute of Agricultural Biotechnology, which is now in the process of reorganization (see part on regulatory institutions). Thus, this GE testing requirement for planting seeds may hinder the process of registration of new varieties of planting seeds in Russia, which, without adding this, takes no less than two years.

#### i) LOW LEVEL PRESENCE (LLP) POLICY:

Russian scientists have participated in international workshops on LLP policy, but Russia has not officially acceded to the LLP international initiatives.

In accordance with Russian and EAEU legislation, imported food products are considered non-GE if the presence of GEs does not exceed levels determined by Russian and EAEU legislation: not more than 0.9 percent of registered or non-registered GE lines in food products or ingredients, and not more than 0.9

<sup>&</sup>lt;sup>11</sup> http://gossort.com/docs/prikaz/Prikaz 335.pdf - in Russian.

percent of registered GE lines and not more that 0.5 percent of non-registered GE lines in feed or feed ingredients. However, in 2016 the attention of Russia's feed surveillance authorities to the presence of non-registered lines in feed and the absence of information on the registered lines increased. In several cases, VPSS, the watchdog for control of GE in feed, temporarily suspended imports of feed on the basis of finding non-registered GE ingredients. However, these threshold levels do not mean that Russia has adopted or follows any coordinated LLP policy. (For more information please see the section of this report on CU Technical Regulations.)

j) ADDITIONAL REGULATORY REQUIREMENTS: Not Applicable.

#### k) INTELLECTUAL PROPERTY RIGHTS (IPR):

Not applicable so far since there is no official information on the presence of GE crops in the fields of Russian farmers. However, this may become a serious issue if the illegal presence of GE crops is detected in Russian fields.

## 1) CARTAGENA PROTOCOL RATIFICATION:

Russian scientists understand the necessity to monitor biotechnology at the international level, including through measures envisaged by the Cartagena protocol. However, Russia has not ratified this protocol, and is not a party to the Protocol. In January 2015, the Russian Ministry of Health suggested a draft FL to join the Cartagena protocol. The draft envisaged a FL coming into force on July 1, 2017, if signed. This is the same date as deadline established in the postponed GOR Resolution No. 839 (on development of mechanism for GE cultivation) for development of a registration mechanism. However, FL 358-FZ of July 3, 2016, banned cultivation of GE crops in Russia, and forced the biotechnology scientific community to re-consider many draft regulatory documents in the field of biotechnology. Thus, as of November 2016, the FL to accede to the Cartagena protocol has not been adopted.

#### m) INTERNATIONAL TREATIES/FORA:

Russia participates in the APEC High Level Policy Dialogue on Agricultural Biotechnology, in the meetings of the CODEX Alimentarius (Codex), and in the meetings of the International Plant Protection Convention (IPPC). Russia participated in the Global LLP Initiative in Rosario, Brazil, in September 2012 and also in some LLP events in 2013.

n) RELATED ISSUES: Not applicable

## **PART C: Marketing:**

#### a) PUBLIC/PRIVATE OPINIONS:

The "anti-GMO" preference of Russian consumers can still influence imports of corn and soybean and their products, especially soybeans and soybean products. In general, the feed trade does not reflect any strong pro- or anti-biotech bias.

<sup>&</sup>lt;sup>12</sup> <a href="http://www.fedlab.ru/minzdrav/proekt-federalnogo-zakona-o-vnesenii-izmeneniya-v-chast-vtoruyu-nalogovogo-kodeksa-rossiyskoy-federa/">http://www.fedlab.ru/minzdrav/proekt-federalnogo-zakona-o-vnesenii-izmeneniya-v-chast-vtoruyu-nalogovogo-kodeksa-rossiyskoy-federa/</a>

There are no active pro-GE organizations, with the exception of a few select farmers' organizations and unions that are interested in increasing Russia's grain and oilseeds production. On the other hand, Russian Greenpeace and the Alliance of the CIS Countries "For Biosafety" (http://biosafety.ru) are very active in anti-GE campaigns. Even after the postponement of the registration of GE crops for cultivation for three years, from July 2014 to July 2017, Russian anti-GE groups continued campaigning against GE crops. Public opinion in general reflects a negative attitude toward plant biotechnology. However, this negative opinion is seldom reflected in purchasing priorities of the Russian population, which are based on the price of products. The present economic situation in Russia (volatile rubles, decreased imports, high inflation, tight budget, decrease of purchasing power of Russian consumers) have resulted in cuts of financing of biotechnology research and development of GE-lines of Russian origin. Moreover, the current economic environment has increased consumer demands for cheaper products, meaning that consumers don't necessarily show a preference for non-GE products at the cash register.

The Russian Government often uses the phrase "environmentally clean" to describe domestic agricultural production, cementing the idea with the Russian public that domestic production is cleaner than some imported products.

#### b) MARKET ACCEPTANCE/STUDIES:

Post is not aware of any recent market acceptance studies. Journalists in Russia often report of consumer concerns with GE products. However, since the recent passage of the new legislation, such press reports have decreased.

It is worth noting that labeling requirements increase the price of food containing GE ingredients. The price of examining products for the presence (or absence) of biotech components is high because the approved methods of testing are expensive. It is rare to find a "GMO" label in Russia, though non-GE labels still can be seen on dairy, eggs and poultry products. In 2012, the Moscow city government stopped requiring non-GE labeling and many food processors in Moscow discontinued these special tests to determine the absence of GE ingredients. However, some products are still sold with the special "Does not contain GMO" label. This is a voluntary, promotional label because Russia does not have standards for "organic" foods. Some food processors still prefer purchasing non-GE products, especially soybeans and soybean products. However, price is the main concern now for both food processors and consumers.

#### CHAPTER 2: ANIMAL BIOTECHNOLOGY:

#### **PART D: Production and Trade**

a. PRODUCT DEVELOPMENT: Research on GE animals was conducted in Russia under the guidance of Professor Lev Ernst, Academician of the Russian Academy of Sciences and the Russian Academy of Agricultural Sciences (he died in April 2012). His research focused on the cloning and genetic modification of animals' immune response to infectious diseases. However, during the last three years there has been no information on the continuation of this research.

- b. COMMERCIAL PRODUCTION: Increased cattle production is one of the priorities of the Russian Government and the GOR supports low interest rate loans to livestock producers, including loans for importing pedigree breeding animals, semen and embryos. This support does not include any research on GE animals or clones.
- c. EXPORTS: Russia does not export any GE animals or livestock clones.
- d. IMPORTS: There is no information on any official restrictions on imports of GE animals or livestock clones. And there are no known facts of any imports of such products, even for research.
- e. TRADE BARRIERS: Not Applicable.

# **PART E: Policy**

- a. REGULATORY FRAMEWORK: Russia's Program BIO 2020, the road map for the development of biotechnology in Russia is still valid. Although agricultural biotechnology is not a priority of Program BIO 2020, it is defined as a section of biotechnology dealing with issues of theory, methodology and implementation of its achievements in plant and animal production. Moreover, in the State Program for Development of Russian agriculture in 2013 the development of biotechnology in animal and feed production envisages development of bioadditives for improvement of quality of feed amino-acids, feed protein, ferments, and vitamin probiotics. However, the State Program includes no mention of GE animals or cloning.
- b. INOVATIVE BIOTECHNOLOGIES: No animal related initiatives.
- c. LABELING AND TRACEABILITY: Not applicable.
- d. INTELLECTUAL PROPERTY RIGHTS: Not applicable.
- e. INTERNATIONAL TREATIES/FORA: Not applicable.
- f. RELATED ISSUES: Not applicable.

## **PART F: Marketing**

- a. PUBLIC/PRIVATE OPINIONS: Not applicable.
- b. MARKET ACCEPTANCE/STUDIES: Not applicable.