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## **Russian Federation**

### **Agricultural Biotechnology Annual**

#### **Agricultural Biotechnology Annual 2017**

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**Report Highlights:**

On June 29, 2017, the Government of the Russian Federation issued Resolution No. 770 “On Amending the Resolution of the Government of the Russian Federation No. 839 of September 23, 2013”. The Resolution conforms to Federal Law No 358 of July 3, 2016, which bans cultivation and breeding of genetically engineered (GE) plants and animals within the territory of the Russian Federation. With respect to registration of GE products, the requirements for registration of feed are often more rigorous than the registration for food. Currently there are no methodological guidelines for registration of stacked events, making it impossible for those events to be registered.

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### Executive Summary:

On June 29, 2017, the Government of the Russian Federation issued Resolution No. 770 “On Amending the Resolution of the Government of the Russian Federation No. 839 of September 23, 2013”.

Resolution No. 770 amends Russia’s framework of rules for the registration of genetically engineered (GE) organisms and products derived or containing such organisms. The Resolution conforms to Federal Law No 358 of July 3, 2016, which bans cultivation and breeding of GE plants and animals within the territory of the Russian Federation. For more information please refer to (Post GAIN report [Russia Bans Cultivation and Breeding of GE Crops and Animals 7-12-2016.pdf](#)) and [Agricultural Biotechnology Annual 4-3-2017.pdf](#)

There is no ban on imports of GE crops, food and feed. However, the Government of Russia (GOR) requires that GE lines present in food, feed and crops must be registered in Russia. The registration of food and feed that contain these registered GE lines is also required. The procedures for registration of food and feed are each separate and administered by two different GOR entities. Intended registration of GE crops for cultivation and the actual registration of GE crops for feed use have been under the authority of the Federal Service for Veterinary and Phytosanitary Surveillance (VPSS). The changes made by Federal Law (FL) No. 358 stopped development of a mechanism for registration of GE crops for cultivation. Moreover, Federal Law No. 358 resulted in a de-facto suspension of registration of new GE lines for feed use. The requirements for registration of feed are often more rigorous than the registration for food. VPSS currently has no methodological guidelines for registration of stacked events, making it impossible for those events to be registered.

Currently sixteen corn lines, nine 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 nine soybean lines are registered for feed use (please see table, below). Feed use registrations were only granted for five years, and the registration periods for four soybean lines and at least five corn lines are set to expire either before the end of 2017 or in the first half of CY 2018. These lines were submitted for re-registration, but given the de-facto suspension of registration for feed use until a regulatory mechanism for registration is developed, the registration renewal process and timeline are unclear.

There is no information on research in the field of GE animals and cloning in Russia. Federal Law

No.358prohibits 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.)**

## **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 and approval from Interagency GMO Commission, which are typically not granted.

Given the seeming disinterest in cultivating or using GE crops and animals in Russia coupled with the current economic situation in Russia and the tight federal budget, and the lack of an implementation mechanism to register GE lines for feed, financing of research for development of Russian GE crops in the near term is unlikely.

##### 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 but was pre-empted on July 3, 2016, when 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. Government Resolution No. 770 of June 29, 2017 amends Russia’s framework of rules for the registration of GE organisms and products derived or containing such organisms. The Resolution conforms to Federal Law No 358 of July 3, 2016, which bans cultivation and breeding of GE plants and animals within the territory of the Russian Federation. For more details please refer to [FAS GAIN Report](#).

The Federal Service for Surveillance of Consumer Rights Protection and Human Welfare (Rosпотребнадзор) had developed regulatory documents for registration of GE organisms for food by July 1<sup>st</sup>, 2017 and the mechanism is working for registration of GE organisms for food. Overall the registration procedure for GE food has not changed and registration once granted is given an unlimited term while registrations for feed use are granted for any period from one up to ten years. The regulatory documents approved by the EAEU take precedence over the regulatory documents issued for

registration of GE organisms for food on the national level. However, the regulatory documents for registration of GE organisms for feeds, feed additives and veterinary drugs were not developed by July 1, 2017 by the Federal Service for Veterinary and Phytosanitary Surveillance (Rosselkhoznadzor or VPSS, English abbreviation). Moreover, the EAEU does not have any regulatory documents that refer to registration of GE organisms for feed use. Therefore, any applications submitted after July 1, 2017, for GE line registration for feed use have been rejected by VPSS based on the lack of methodological guidance (MUK) for registration. Reportedly, MUK currently is being developed by the Ministry of Agriculture, however, industry sources inform FAS that the work on it is lagging behind and most likely will be delayed until later in 2018. As a result, the status and future of registration of GE organisms for feed is not clear.

According to the seed developer Monsanto, all registered GE events starting from 1999 were moved to the list for “GMO” products. The reason for this move is unclear. As a result, Monsanto currently does not have any GE event registered. According to GOR #839, Monsanto will have to initiate a new registration process for each GE event prior to registering any GE products containing these GE line.

a) EXPORTS:

Russia’s soybean production has been steadily increasing while imports have gone down. As a result, exports have been down slightly, to 300 TMT in CY17. All soybeans are considered 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. With respect to corn, in calendar year 2016, Russia exported 5.3 MMT that is an increase of 47 percent versus corn exports in in CY 2015. In the first nine months of CY 2017 (January – September), Russia exported 3.7 MMT of corn, compared to 3 .4 MMT in the same period in 2016. Despite of slight increase in exports of corn in the first nine months nine months of 2017, unfavorable weather conditions in summer and autumn resulted in lower yields in the main corn producing federal districts accounting for 90 percent of the total corn crop in Russia. As a result, a smaller corn crop will likely translate into lower export numbers. 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 and some territories in the south, Russia expects to increase exports of soybeans in the future.

Table 1. Russia: Exports of corn, soybeans and soybean meal, CY 2012-2016 and Jan-Sept 2017 compared with Jan-Sept 2016

	2012	2013	2014	2015	2016	Jan-Sept 2016	Jan.-Sept. 2017
Metric Tons							
Corn (HS Number 1005)	2,185,232	2,599,288	3,418,920	3,698,768	5,334	3,397	3,651
Soybeans (HS Number 1201)	118,476	83,553	78,732	382,490	422,000	318,603	300,000
Soybean meal (HS number 2304)	11,246	210,306	548,037	458,247	450,814	370,304	227,699
1,000 U.S. Dollars							

Corn (HS Number 1005)	570,093	590,073	688,082	600,939	861,798	544,208	605,841
Soybeans (HS Number 1201)	34,878	26,202	23,761	119,177	133,156	101,597	96,944
Soybean meal (HS number 2304)	7,687	126,540	315,915	226,321	201,713	162,116	108,980

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.

## b) IMPORTS

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. With no finalized regulatory documents for biosafety or for the registration of GE feeds, feed additives and veterinary pharmaceuticals, there is a de facto suspension on new registrations of feeds and feed additives containing GE organisms or products derived from GE organisms. The ongoing uncertainty of the situation will continue to have a serious impact on the trade of these products, specifically 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 REGULATIONS and paragraph LOW LEVEL PRESENCE (LLP) POLICY in PART B of this report).

On June 30, 2017, President Putin signed decree No. 293 extending Russia's ban on the import of agricultural products from the countries that applied economic sanctions against Russia from the United States, Canada, the European Union, Australia, Norway, Ukraine, Albania, Montenegro, Iceland, and Lichtenstein including the United States, until the end of 2018. The Government issued decree No. 790 of July 4, 2017, implementing the decree of the President without any changes to the lists of covered countries or products. ([RS1741 Russia Extended Food Import Ban through End 2018](#)).

Imports of corn, soybeans, or products thereof, are not covered by this ban. However, 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 fall 2016, imports of soybeans nearly came to a halt. (More in paragraph STACKED or PYRAMID EVENT APPROVALS in PART B of this report).

Table 2. Russia: Imports of products that may contain GE ingredients, CY 2012-2016 and Jan-Sept. 2017 compared with Jan-Sept. 2016, metric tons (MT)

	2012	2013	2014	2015	2016	Jan-Sept. 2016	Jan.-Sept. 2017
<b>Metric Tons</b>							
Corn (1005)	41,150	55,271	52,728	43,844	41,124	29,456	41,272
- from the U.S.	6,455	6,210	3,986	3,435	370	370	0
Corn Groats and Meal (1103 13)	17,822	14,343	5,350	232	82	54	83
- from the U.S.	0	0	0	0	0	0	0
Corn Starch (1108 12)	18,095	15,941	18,032	13,253	14,258	8,977	8,953
- from the U.S.	78	6	0	0	1	0	0
Soybeans (1201)	693,677	1,145,155	2,028,163	2,179,719	2,283	1,689	1,600
- from the U.S.	55,964	208,274	390,008	526,171	216,018	216,018	0
Soybean flour (1208 10)	1,340	873	344	277	194	134	140
- from the U.S.	0	0	0	2		0	0
Soybean Meal (2304)	497,773	630,557	532,933	532,684	229,139	208,272	44,759
- from the U.S.	17,388	7,257	24,171	7,898	2,833	2,833	0
Soybean Isolates (from 3504)							
Total group 3504	52,219	54,559	58,711	46,245	43,485	29,095	31,757
- from the U.S.	300	190	485	120	126	108	117
<b>1,000 U.S. Dollars</b>							
Corn (1005)	97,890	161,299	221,429	146,367	141,308	98,244	138,090
- from the U.S.	5,781	6,294	4,071	3,202	343	343	0
Corn Groats and Meal (1103 13)	7,415	6,464	2,115	188	64	42	67
- from the U.S.	0	0	0	0	18	0	0
Corn Starch (1108 12)	11,351	12,107	11,495	7,243	6,628	4,513	4,701
- from the U.S.	99	36	1	4	6	2	3
Soybeans (1201)	440,916	675,783	1,150,758	941,790	977,488	709,783	688,482
- from the U.S.	31,830	121,985	215,294	219,849	81,541	81,541	0
Soybean flour (1208 10)	1,130	968	383	252	164	115	118
- from the U.S.	0	0	0	2	0	0	0
Soybean Meal (2304)	280,055	403,840	334,379	257,610	97,665	86,984	20,369
- from the U.S.	11,900	4,801	15,673	4,418	1,029	1,030	0
Soybean Isolates (from 3504)	0	0	0	0		0	0
Total group 3504	136,244	149,459	165,381	128,136	103,989	71,594	81,688
- from the U.S.	1,252	1,203	4,618	676	764	608	739

Source: Global Trade Atlas

c) 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.

d) 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**

The following government ministries and agencies are responsible for regulation of GE plants (food, feed, seed, and environmental safety issues):

Federal Service for Surveillance of Consumer Rights Protection and Human Welfare

(Rospotrebnadzor) (website: <http://rospotrebnadzor.ru/about/> - in Russian). 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;
- 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: [www.mcx.ru](http://www.mcx.ru) – in Russian)

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 2017 (which conforms to Federal Law No 358 of July 3, 2016, which bans cultivation and breeding of GE plants and animals within the territory of the Russian Federation); 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.

The regulatory documents for registration of GE organisms for food were developed on time by Rospotrebnadzor and are already used in registration of GE organisms for food, while the regulatory documents for GE organisms for feeds, feed additives and veterinary pharmaceuticals were not developed by the Ministry of Agriculture by July 1, 2017. Currently The Ministry of Agriculture is developing methodological guidance (MUK) for registration of GE lines for feed and feed additives, however, according to sources this work is lagging behind and it is unlikely that MUK will be approved by July 2018. .

**The Federal Service for Veterinary and Phytosanitary Surveillance (VPSS)** is subordinated to the Ministry of Agriculture of the Russian Federation (website: <http://www.fsvps.ru/> [in Russian](#)). 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;
- 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 2017 (together with the Ministry of Agriculture, VPSS is currently in the process of developing regulations for the use and monitoring of GE crops, including for cultivation, and GE animals; and
- Together with the Federal Service for Surveillance of Consumer Rights Protection and Human Welfare, monitors the influence of GE crops, animals and products on people and the environment.

According to GOR#839, VPSS and Rospotrebnadzor are required to forward the information on state registration to Consolidated Register, maintained by the Ministry of Health.

The Consolidated Register is maintained by the Ministry of Health of the Russian Federation in electronic form in compliance with the requirements established by legislation of the Russian Federation on information, information technologies and protection of information.

The relevant information is entered into the Consolidated Register by the registration authorities in compliance with the order established by the Ministry of Health of the Russian Federation in concurrence with the Ministry of Mass Communications, the Ministry of Education and Science, the Ministry of Agriculture, and the Federal Service for Surveillance of Consumer Rights Protection and Human Welfare. The Consolidated Register includes a Register of modified organisms and a Register of products. The information in the consolidated Register is open and publicly available for individual and legal entities and posted on the official site of the Ministry of Health. (<https://gmo.rosminzdrav.ru/>).

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

**The Ministry of Economic Development of the Russian Federation** (website: [www.economy.gov.ru](http://www.economy.gov.ru) – [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 [Program on Development of Biotechnology in Russia through 2020](#));

**The Russian Academy of Sciences (RAN)** (website: [www.ras.ru](http://www.ras.ru) – 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. This law 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. These academies finally united by the end of 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.

**The Federal Agency of Scientific Organizations (FANO)** (website: [www.fano.gov.ru](http://www.fano.gov.ru) – 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 [Agricultural Biotechnology Annual 7-9-2015.pdf](#).

**The Eurasian Economic Union (EAEU)** (website: [www.eaeunion.org](http://www.eaeunion.org)) unites Kazakhstan, Russia, Belarus, Armenia and Kyrgyzstan. The EAEU develops and adopts common customs and technical regulations for all member countries.

## **LEGISLATION AND REGULATIONS**

At present agricultural biotech policy is being regulated by the Decisions of the Eurasian Economic Union (EAEU) – 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.

### **Decisions of the Eurasian Economic Union (EAEU)**

Since July 2010, the EAEU has 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 a “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:

- RS 1036 Customs Union [Update](#) No.299 dated May 28, 2010 On Applying Sanitary Measures in

Eurasian Economic Union

- [RS1233 Customs Union Technical Regulation on Food Safety;](#)
- [RS1250 Customs Union Technical Regulation on Safety of Grain;](#)
- [RSATO1211 Customs Union Technical Regulations on Food Products Labeling;](#)
- [RS1326 Customs Union Technical Regulation on Fat and Oil Products;](#)
- [RS1334 Customs Union Technical Regulation on Juice.](#)

Note: “GMO” Registration for food is carried out in compliance of the Customs Union Regulation which prevails any regulations approved on the national level, for example GOR #839. However, “GMO” Registration for feed is implemented in compliance with GOR #839.

The technical regulations (TR) of the EAEU are mandatory for all members of the Eurasian Economic Union. 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:

- **CU Technical Regulation No 021/2011 on Safety of Food Products** (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 non-cellular, 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 is not excused in cases where the mass of the compound ingredient is not more than two 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 proof<sup>1</sup>. Organizations or individual entrepreneurs releasing such food products for circulation in the unified customs area of the EAEU shall keep the documents with proof of

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<sup>1</sup> Producers should be able to provide documentation certifying the absence or presence of food product ingredients containing or not containing GE events.

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 or 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, mycotoxins, 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 GE 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).
- **CU Technical Regulation No. 024/2011 on Fat and Oil Products** (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>2</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>3</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>4</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";
- **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

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<sup>2</sup> At the time of signing the FL 358 of July 3, 2016, the exchange rate was 64 rubles per \$1.

<sup>3</sup> [http://www.gazeta.ru/science/news/2016/06/24/n\\_8804021.shtml](http://www.gazeta.ru/science/news/2016/06/24/n_8804021.shtml) (in Russian)

(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 100,000 to 500,000 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](#) (in Russian) for individual entrepreneurs are from 20,000 to 50,000 rubles<sup>5</sup> (from \$364 to \$909), and for legal entities are from 100,000 to 300,000 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**

- 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 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 FAS/Moscow reported on Resolution No. 839 in the GAIN Report: Resolution on GMO Registration for Environmental Release\_Moscow\_Russian\_Federation\_9-
-

25-2013.pdf.; 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.
- On June 29, 2017, the Government of the Russian Federation issued Resolution No. 770 “On Amending the Resolution of the Government of the Russian Federation No. 839 of September 23, 2013”. Resolution No. 770 amends Russia’s framework of rules for the registration of GE organisms and products derived or containing such organisms. The Resolution conforms to Federal Law No 358 of July 3, 2016, which bans cultivation and breeding of GE plants and animals within the territory of the Russian Federation. For more details please refer to FAS GAIN Report.

In November 2017, the Government of Russia issued two official documents related to biotech feed registrations. The title of the first one is: “On Suspension of Several Provision of the Rules for 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, including Above Mentioned Products Shipped (Imported) into the Territory of the Russian Federation; and the Approval the Rules for State Registration of Feeds, Derived from Genetically-Engineered-Modified Organisms or Containing Such Organisms.”

The second draft is: “On Amendments to GOR Resolution # 839 dated September 23, 2013.”

This essentially is an addendum to Resolution #839 (Rules of State registration RS1366 Government Resolution on GMO Registration for Environmental Release). Russian importer Sodrugestvo initiated both proposed Drafts and they apply to the submission of Sodrugestvo only in order to finalize registration of the stacked soybean meal line MON87701xMON89788 for feed use. The developers (Monsanto and Bayer) appealed to the government to amend the initial drafts, proposed by Sodrugestvo, with an extension period to the expiration date of the currently approved/registered biotech feed lines, which have expiration dates between July 1, 2017 and July 1, 2018. At this point it is unclear whether the change will be incorporated into the final document.

The developer (Monsanto) has submitted papers to Rospotrebnadzor for food registration of the MON 87708 (Dicamba) Soybean, and it is undergoing registration according to the Regulation #839 rules for food use. The approval for registration is expected shortly. However, its further registration for feed use can’t be implemented before methodological guidance is approved by the Ministry of Agriculture. Reportedly, members of the “GMO” interagency commission which includes representatives from the Ministry of Agriculture, VPSS, businesses and Sodrugestvo disagree on the draft of methodological guidance that will likely cause a delay in its final approval. Presumably, the GOR will use this time from November 2017 to July 2018 to develop implementing regulations/methodology to be able to register biotech feed. If so, it will be added as an implementing documentation to Resolution 839.

### **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 the 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 Genetically-Engineered-Modifies Organisms was repealed as of September 3, 2017, as Order of the Ministry of Agriculture No. 366 dated July 26, 2017 came into force, The document can be viewed here <http://www.garant.ru/products/ipo/prime/doc/71651236/> (in Russian)

## **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. Decisions of EAEU prevail over Government of Russia regulation for GE crops/lines registration for food use. The registration for food use is implemented in compliance with Decision of Eurasian Economic Union No.299 dated July 26, 2010, while registration for feed use has to comply with GOR # 839. Rospotrebnadzor has developed Methodological guidance (MUK) that conforms to requirements of Government Resolution # 839. This guidance is published on the website [http://rospotrebnadzor.ru/documents/details.php?ELEMENT\\_ID=7871](http://rospotrebnadzor.ru/documents/details.php?ELEMENT_ID=7871).....

The registration process for food remains the same as was stated in the Annual Biotechnology GAIN reports for 2011 through 2014 ([Agricultural Biotechnology Annual 7-9-2015.pdf](#)):

- The applicant submits an application and dossier to Rospotrebnadzor;
- Rospotrebnadzor assigns a safety assessment study to the Federal Research Center of Nutrition, Biotechnology and Food Safety or former Federal State Budget Enterprise “Science and Research Institute of Nutrition” (ION), 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 Center; and
- Based on the Institute’s assessment, Rospotrebnadzor issues a certificate of registration and registers the product. Rospotrebnadzor grants registration for food use for unlimited period as stated in EAEU Decision. Information about registration of biotech crops and ingredients for food use should be forwarded to the [Consolidated Register](#) maintained by the Ministry of Health.

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: <http://fp.crc.ru/gosregfr/> (in 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

Registration for feed use has been effectively suspended since the adoption of FL 358 in July 2016, largely due to the reorganization of the research institute that was previously subordinated to VPSS.

However, according to the amendments to GOR # 839 that came into force starting July 1, 2017, the procedure for registration of GE crops for feed use has changed. The responsibilities of VPSS in feed registration were confirmed by Order No. 366 of the Russian Ministry of Agriculture on July 26, 2017 “On Approving Administrative Regulation of Federal Veterinary and Phytosanitary Service for Providing Services on State Registration of Genetically-Engineered-Modified Organisms, Used for Production of Pharmaceuticals for Veterinary Use, as well as Feeds and Feed Additives for Animals, Received from Genetically-Engineered-Modified Organisms or Containing such Organisms.

<http://www.garant.ru/products/ipo/prime/doc/71651236/>

Order 366 states that the registration is issued for the period from one up to 10 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.
- The Russian Federal Center of Quality and Standardization of Veterinary Pharmaceuticals and Feed (VGNKI) subordinate to VPSS is authorized to conduct safety assessment and studies for GE crop/line registration for feed use.

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: <http://www.fsvps.ru/fsvps/regLicensing> (in Russian). The List of Registered GE feed, before July 15, 2015, is provided [here](#) (in Russian). The List of Registered GE feed after July 15, 2015, is available at the site: <https://galen.vetrif.ru/#/registry/gmo/registry?page=1>.

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.

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.

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 \$76,300) 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 (\$338).

For registration of biotech events for feed use, VPSS usually registers an event only after it has been approved for food-use. On average, the charge for examination and a five year event registration for feed use is 4.5 million rubles (approximately \$76,300). The charge for re-registration of the event every five years is 3.8 million rubles (approximately \$64,400). 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.

ii. **RECENT ACTIVITIES OF RUSSIAN AUTHORITIES IN REGARDS TO GE CROPS**

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 to Russian GE policy declared by GOR #839 and its amendments. While Rospotrebnadzor has developed regulatory mechanisms for registration and monitoring of GE plants, products for food use, VPSS has not developed the system within the current framework for feed registration, since it does not have a clear understanding of the goal and authorities in the registration process.

b) APPROVALS:

Table 2. Russia: Approved and Registered Biotech Crops, 1999-2017 (As of October 2017 – updated)

	<b>Crop/line/event/trait</b>	<b>Applicant</b>	<b>Year and period of Registration</b>
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			<b>For Food Use</b>	<b>For Feed Use</b>
1	Bt corn MON 810, resistant to European corn borer <i>Ostrinia nubilalis</i>	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	Was registered 2003-2013
4	Corn Bt 11, tolerant to gluphosinate and resistant to corn borer <i>Ostrinia nubilalis</i>	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 03.10.2017 – 03.10.22
6	Roundup Ready ® corn GA 21, tolerant to glyphosate*	Syngenta	2007 – for unlimited period	Nov. 2007 – Nov. 2012; Nov. 2012 – Nov. 2017 Re-registration suspended
7	Corn MIR 604, resistant to corn root worm ( <i>Diabrotica spp.</i> )	Syngenta	Jul. 2007 – for unlimited period	May 2008 – May 2013; May 2013 – May 2018
8	Corn 3272 with $\alpha$ -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 2012 – March 2017 Jan. 2017 - Jan. 2022
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 Re-registration suspended
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 Re-registration suspended
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 Re-registration suspended
20	Soybeans SYHT0H2, herbicide HPPD* + glufosinate	Syngenta (Producers Syngenta /Bayer)	Jan. 2016 – for unlimited period	Apr. 2013 – Apr. 2019

21	Rice LL62, tolerant to glufosinate ammonium	Bayer Crop Sciences	2003 – 2008 Jan. 2009 – for unlimited period	X
22	Roundup Ready ® Sugar beet H7-1, tolerant to glyphosate	Monsanto/ KWS	May 2006 – for unlimited period	X
23	Bt potato “Elizaveta” (resistant to Colorado potato beetle)	Center “Bio-engineering”, Russia	Dec. 2005 – for unlimited period**	X
24	Bt potato “Lugovskoy” (resistant to Colorado potato beetle)	Center “Bio-engineering”	Jul. 2006 – for unlimited period**	X
25	Soybeans MON 87708 (Dicamba)	Monsanto	Submitted January 2017	Submission upon receipt Registration for food
26	Corn MZHG0JG Tolerant to glyphosate and glufosinate ammonium	Syngenta	Submitted Nov 2015 expected Dec 2017	Submission upon receipt food registration
27	Corn MZIR098 Resistance to Diabrotica and tolerance to glufosinate ammonium	Syngenta	Submitted Jan.2017	Re-registration suspended
28	Corn 1507 resistance to certain Lepidoptera pests and tolerance to glufosinate	Pioneer Hi-Bred International & Dow AgroSciences	March 23, 2017 (unlimited)	Not submitted
29	Corn DAS 40278-9 tolerant to herbicide 2,4 D	Dow AgroSciences	Submitted Feb.2017	Not submitted
*				
HPPD – herbicides that inhibit the enzyme hydroxy-phenyl-pyruvate-dioxygenase				
**Bt potato “Elizaveta” and “Lugovskoy” are registered for food use only for Russia, because these two potato varieties were not registered for the EAEU				

The above information is provided based on information received from certain applicants willing to share their registration information. However, Post believes 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

Government Resolution #839 as amended, implemented starting from July 1, 2017, does not contain any reference to rules or procedures for stacked event registration. So far, Rospotrebnadzor has developed some recommendations on the registration (for food) of stacked events (breeding stacks), which are similar to the rules adopted by the European Union. However, these recommendations have not been

adopted by VPSS. Since 2016 VPSS intensified thorough testing of feed produced from imported soybeans, and regularly started finding traces of stacked events not registered in Russia. The situation resulted in de facto suspension of imports of soybeans and soybean meal to Russia as the importer could not be reasonably assured the imported product would not contain an unregistered event. Reportedly, in the fall of 2016, major poultry producers in the Russian North and Northwest, (which usually purchased soybean meal from the company Sodrugestvo, a major importer and crusher) appealed to the Ministry of Agriculture and VPSS that their businesses would be jeopardized without this meal. MinAg/VPSS considered this “emergency” situation and agreed to allow Sodrugestvo (only) to sell soybean meal crushed from imported soybeans that could contain unapproved stacked events to these poultry companies (and only to these companies). This “exception” was originally granted from October 2016 to February 2017, and then was extended through December 2017. Ironically, Sodrugestvo received an approved registration of a stacked event for food use, which theoretically permits the importation of stacked soybeans (with the approved event), but only for food. Currently, Sodrugestvo imports the following GE soybeans from South America: 1) Genetically modified soybeans with the line MON87701 x MON89788, resistant to lepidopteran pests and resistant to glyphosate; Sodrugestvo registered this stacked line in 2016 with Rospotrebnadzor (food) and they've started safety feeding trials with Rosselkhoznadzor to get a feeding registration on soybean meal. The registration of stacked lines was possible since Monsanto had registered individual lines earlier. After registration of the GE soybeans, Sodrugestvo received registration for soybean meal with this line; 2) Soybeans genetically modified with the line 40-3-2, glyphosate resistant.

Industry sources report that the methodological guidance draft for GE crops/lines for feed use currently being developed by the GOR, has no reference to a mechanism for stacked line registration. At this point it is unclear what a mechanism for stacked line registration would look like and when it could be approved

#### d) FIELD TESTING

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.

#### 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: [Draft TBT Measure on Food Labeling Notified to WTO 5-25-2016.pdf](#). However, this draft was amended and the latest [Draft](#) (in Russian) is still pending EAEU approval.

Feed labeling: 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, Ministry of Agriculture authorizes 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.<sup>6</sup> 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 underwent 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 percent of registered GE lines and not more than 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 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.

l) 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.<sup>7</sup> 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

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[http://gossort.com/gk\\_documents.html#1481282222420-7dd10f37-7d05](http://gossort.com/gk_documents.html#1481282222420-7dd10f37-7d05)<sup>6</sup>

<sup>7</sup> <http://www.fedlab.ru/minzdrav/proekt-federalnogo-zakona-o-vnesenii-izmeneniya-v-chast-vtoruyu-nalogovogo-kodeksa-rossiyskoy-federa/> (in Russian)

development of mechanism for GE cultivation) for development of a registration mechanism. However, FL 358 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/FORUMS:

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. FAS/Moscow is not aware of the positions on biotech related issues by the GOR at these forums.

n) RELATED ISSUES: Not applicable

**PART C: Marketing:**

a) PUBLIC/PRIVATE OPINIONS:

There are no active pro-GE (agricultural biotechnology) organizations, with the exception of a few select farmers' organizations and unions that are interested in increasing Russia's grain and oilseeds production. In general, the feed trade does not reflect any strong pro- or anti-biotech bias.

The "anti-GMO" preference of Russian consumers can still influence imports of corn and soybeans and their products, especially soybeans and soybean products. 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 ruble, decreased imports, tight budget, and a decrease of purchasing power of Russian consumers) has 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.

Russian Greenpeace and the Alliance of the Commonwealth of Independent States "For Biosafety" (<http://biosafety.ru>) are active in anti-GE campaigns and influence consumer choices. 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.

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 the 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. 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 bio-additives 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/FORUMS: Not applicable.
- f. RELATED ISSUES: Not applicable.

**PART F: Marketing**

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