

THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY
USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT
POLICY

Required Report - public distribution

Date: 7/18/2011

GAIN Report Number: RS1132

Russian Federation

Agricultural Biotechnology Annual

Annual 2011

Approved By:

Levin Flake

Prepared By:

Yelena Vassilieva

Report Highlights:

The Russian government has taken some initial steps to developing a legislative framework for the cultivation of biotech crops. In October 2010, Russia adopted a Federal Law which allows the Government to develop registration procedures for this cultivation, although the development of this procedure still has not been completed. Russia continues registering biotech crops and products for food and for feed use, although all of these are required to be re-registered by January 1, 2012 to comply with Customs Union requirements.

Section I. Executive Summary:

Recently, the Russian government has demonstrated some initiative aimed at the development of biotechnology in Russia within the framework policy of Russia's modernization and innovation. In October 2010, a Federal Law was adopted which allows the Government to begin to develop a registration procedure for the cultivation of biotech crops. In April 2011, Prime Minister Vladimir Putin conducted a meeting where he confirmed that Russia is lagging far behind the rest of the world in the sphere of biotechnology, and called for its development in Russia, including development of resources for biotechnology. Putin authorized the Ministry of Economic Development to develop a draft government resolution that will regulate the release of biotech crops into the environment. At the beginning of June 2011, the Ministry of Economic Development prepared a draft government resolution on the state registration of genetically modified organisms for release into environment which was discussed by an Inter-Agency Commission, although this discussion was then postponed until the end of summer 2011.

Although biotech events for feed and food, as well as products continue to be registered in Russia, the Customs Union between Russia, Kazakhstan, and Belarus has created additional difficulties in these procedures. Russia now requires all food products, including genetically modified products, be re-registered by January 1, 2012, in order to comply with Custom Union regulations. There is currently a large backlog of re-registration applications, and this is also delaying the approval of new applications for registration. In addition, the Customs Union is in the process of adopting unified technical regulations on different groups of products, including technical regulations on safety of food products and technical regulation on feeds. These technical regulations are supposed to come to force on January 2012, although it is unclear if this deadline will be met.

Section II. Plant Biotechnology Trade and Production:

Although Some Signs of Progress, De-Facto Ban on Biotech Crop Cultivation Continues

Russia does not have an official ban on the cultivation of genetically engineered seeds. However, Russia also does not currently have any mechanism for the approval of biotech seeds for release into the environment and without such mechanism cultivation of biotech seeds is not allowed by the Russian Federal Law on Genetic Engineering. This past year, however, there has been some movement in establishing a framework for approval and the Russian Government has undertaken the following steps:

- The Federal Law No 262-FZ of October 4, 2010 amended the Federal Law on the State Regulation in the Field of Genetic Engineering, and added that "Genetically modified organisms developed for release into environment, and products derived from such organisms or containing such organisms are subject to state registration in accordance with the procedure approved by the government of the Russian Federation". For more information see GAIN RS1155 _ Russia Fails to Commit to Time-lines for GMO Legislation _ Moscow _ Russian Federation – 9/29/2010). However, the government has not yet developed the state registration procedure. Industry analysts suspect that the Federal Law No. 262 was adopted in order to demonstrate Russia's adherence to the principles of WTO on the eve of regular accession negotiations;
- In April 2011, Russian Prime Minister Vladimir Putin included development of biotechnology in

Russia (including biotechnology for agriculture) as one of the priority projects of the development of “high technologies and innovations” (so called priority Technological Platforms). He also authorized the government, namely the Ministry of Economic Development, to prepare a special coordination program on the promotion of biotechnology in Russia;

- In June 2011, the Ministry of Economic Development prepared a draft Government Resolution on the release of biotech crops to the environment. The draft amends the current legislature in order to allow the release of genetically modified crops into the environment after the mandatory state registration of these crops. The draft authorized the Federal Veterinary and Phytosanitary Surveillance Service (VPSS) at the Ministry of Agriculture to conduct registration of biotech crops for release into the environment and outlines the major application requirements for registration of biotech crops.

The draft resolution was discussed in June 2011 by an Inter-Agency Commission, but it concluded without an agreement and further discussion was postponed until the end of summer 2011.

Currently, Russian scientists do not conduct any serious research or field trials on biotech agricultural crops. While field trials are not prohibited, they need a special permission from the Variety Testing Commission at the Ministry of Agriculture which companies report is no longer granted. The Commission is responsible for tests of any varieties, even for small-scale field trials for research purposes. In the past the strongest agricultural biotechnology research center was in Krasnodar kray. However, several years ago Krasnodar kray authorities declared the province GMO-free, and the willingness of the scientists in this center to continue field tests with biotech crops ceased. Some foreign companies participated in the field tests of biotech crops in the beginning of 2000, but ceased their investments until the procedure of approval is clarified. If this is done, biotech companies are likely to quickly submit their crops for cultivation tests and examination. The drought in 2009 and 2010 in Russia especially increased interest in drought-resistant genetically-engineered crops in Russia.

Status of Product Approval for Imports and Food and Feed Use

As of July 2011, there are 18 genetically engineered products (crops) that can be legally imported to Russia for food use. These are 10 corn lines, 4 soybean lines, 1 sugar beet line, 1 rice line, and 2 potato lines. Of these 18 crops, 13 are also registered for feed use, including 9 corn lines and 4 soybean lines. The list of registered crops is in the Table 1. Monsanto, Bayer and Syngenta were the only three companies to have their biotech crops registered in Russia. One registered sugar beet variety belongs to Monsanto and KWS. In March 2011, BASF submitted its soybean variety for food registration.

Since July 2010, two new biotech crops were registered in Russia:

- Corn 3272 with α -amylase enzyme to break starch during ethanol production (Syngenta) was registered in October 2010 for feed use for 5 years. Previously it had been registered for food use for unlimited period;
- Corn MIR 162, resistant to Lepidoptera pest (Syngenta) was approved for food use in June 2011, but certificate has not been issued yet by July 2011.

Since 2006 food registration is given for an unlimited period, however, the certificate of registration can be recalled if concerns arise. Feed registrations are granted for five years.

Table 1. Russia: Approved and Registered Biotech Crops, 1999-2011

	Crop/event/trait	Applicant	Year and period of Registration	
			For Food Use	For Feed Use
1	Bt corn MON 810, resistant to European corn borer	Monsanto	2000 – 2003, 2004 – 2009 Mar. 2009 – for unlimited period	2003 – 2008 Sep. 2008 – Aug. 2013
2	Roundup Ready® corn NK 603, tolerant to glyphosate	Monsanto	2002 – 2007; 2008 – for unlimited period	2003 – 2008 Sep. 2008 – Aug. 2013
3	Bt corn MON 863, resistant to corn root worm (<i>Diabrotica</i> spp.)	Monsanto	2003 – 2008 Aug. 2008 – for unlimited period	2003 – 2008 Sept. 2008 – Aug. 2013
4	Corn Bt 11, tolerant to gluphosinate, corn borer resistant	Syngenta	2003 – 2008 Sep. 2008 – for unlimited period	Dec. 2006 – Dec. 2011, Renewal submitted in June 2011
5	LL Corn T25, tolerant to gluphosinate	Bayer Crop Sciences	2001 – 2006, 2007 – for unlimited period	Dec. 2006 – Dec. 2011
6	Roundup Ready ® corn GA 21, tolerant to glyphosate*	Syngenta	2007 – for unlimited period	Nov. 2007 – Nov. 2012
7	Corn MIR 604, resistant to corn root worm (<i>Diabrotica</i> spp.)	Syngenta	2007 – for unlimited period	May 2008 – May 2013
8	Corn 3272 with α -amylase enzyme to break starch during ethanol production	Syngenta	April 2010 – for unlimited period	Oct. 2010 – Oct. 2015
9	Corn MON 88017 (CCR), tolerant to glyphosate and resistant to corn root worm (<i>Diabrotica</i> spp.)	Monsanto	May 2007 – for unlimited period	Sep. 2008 – Aug. 2013
10	Corn MIR162, resistant to Lepidoptera pest	Syngenta	Approved in June 2011 (certificate issue pending)	
11	Roundup Ready® soybeans 40-3-2, tolerant to glyphosate	Monsanto	1999 – 2002, 2002 – 2007, Dec. 2007 - for unlimited period	2003 – 2008, Sep. 2008 – Aug. 2013
12	Liberty Link® Soybeans A2704-12, tolerant to gluphosinate	Bayer Crop Sciences	2002 – 2007 2008 – for unlimited period	Nov. 2007 – Nov. 2012
13	Liberty Link® Soybeans A5547-127, tolerant to	Bayer Crop Sciences	2002 – 2007 2008 – for	Nov. 2007 – Nov. 2012

	gluphosinate		unlimited period	
14	Soybean MON 89788 (RRS2Y), tolerant to glyphosate + yield gain	Monsanto	Jan. 2010 – for unlimited period	May 2010 – May 2015
15	Rice LL62, tolerant to gluphosinate	Bayer Crop Sciences	2003 – 2008 Jan. 2009 – for unlimited period	
16	Roundup Ready ® Sugar beet H7-1, tolerant to glyphosate	Monsanto/KWS	May 2006 – for unlimited period	
17	Bt potato “Elizaveta” (resistant to Colorado potato beetle)	Center “Bio-engineering”, Russia	Dec. 2005 – for unlimited period*	
18	Bt potato “Lugovskoy” (resistant to Colorado potato beetle)	Center “Bio-engineering”, Russia	Jul. 2006 – for unlimited period	

* In 2006 registration was changed from “up to five years” to an unlimited period.

Three crops are waiting for approval, including Monsanto’s corn for food and for feed use, Monsanto’s soybeans for food use, and BASF’s soybeans for food use (Table 2).

Table 2. Russia: Biotech Crops Awaiting Approval

	Crop/event/trait	Applicant	Date of Submission for Approval	
			For Food Use	For Feed Use
1	Corn MON 89034, resistant to Lepidoptera pest	Monsanto	Under review, submitted for registration in March 2010	Under review, submitted in June 2011
2	Bt soybeans, MON 87701, resistant to Lepidoptera pests	Monsanto	Under review, submitted for registration in July 2010	
3	Soybeans BPS-CV-127-9, imidazolinone	BASF	Under review, submitted in March 2011	

Besides registration of crops/events/traits, Russia requires that each food product, ingredient, or feed containing a biotech event is registered separately. The registration can be given only after the event is already registered.

The Customs Union between Russia, Kazakhstan, and Belarus has created additional difficulties in the registration procedures. Russia now requires all food products accompanied by sanitary-epidemiological conclusions and certificates, including genetically modified products, be re-registered by January 1, 2012, in order to comply with Custom Union regulations (for more information see GAIN report RS1123 _ Permits for biotech food shall be re-registered by January 2012_ Moscow _ Russian Federation _ 5/18/2011). Since hundreds of permits are still waiting for re-registration at the Russian Federal Service for the Protection of Consumer Rights and Well-Being of Population (Rospotrebnadzor) and the line of applicants for re-registration is very long, Dr. Onishchenko, the Head of

Rospotrebnadzor, issued a letter that the previous registrations may remain in force after January 2012 if the application had already been submitted to Rospotrebnadzor and is waiting for the re-registration.

The Customs Union is in the process of adopting unified technical regulations on different groups of products, including technical regulation of safety of food products and technical regulation on feeds. These technical regulations are said to come to force on January 2012, although it is unclear if this deadline will be met. Thus, the future Customs Union requirements for registration, labeling and marketing of biotech products and ingredients are not yet clear. So far, the requirements for biotech feeds in the Customs Union's draft technical regulation for feeds do not differ from the current Russian requirements for feeds.

Trade

Russia imports corn and soybeans and soybean products such as meal, some of which are from GMOs. Imports of these products do not have to be declared as GMO if the presence of GMO does not exceed levels determined by the Russian legislature: not more than 0.9 percent of registered or non-registered GMO in food products or ingredients, not more than 0.9 percent of registered GMO in feed ingredients, and not more than 0.5 percent of non-registered GMO in feed ingredients (for more information see section Plant Biotechnology Policy of the present report). Otherwise, imports are allowed only if they are declared GMO and include already registered events.

Russia continues to increase its poultry and swine production, and this production is increasingly concentrated in large poultry and pig farms, which use primarily compound feeds in feeding rations. Despite increased domestic production of protein and high energy feeds, production still does not meet demand and Russia continues to import soybeans, corn, and products processed from these crops. The table below shows yearly imports from June through May in the period 2009 – 2011. The overall decrease in imports in 2009/2010 is caused by the financial crisis of 2009. In 2010/2011 imports of corn, soybeans and their products began rebounding to the pre-crisis levels (Table 3). In 2010/2011 the value of imported products that come from crops which are often biotech already exceeded the level of 2008/2009 and reached \$960 million. However, the share of U.S. products remains small – at only \$41 million.

Although the anti-GMO attitude of Russian consumers seems to be diminishing, it still influences feed processors and livestock producers' decisions concerning imports of corn and soybeans and their products. Some regions in the south of European Russia, including major meat production areas such as Belgorod oblast and Krasnodar kray, have declared themselves GMO-free-zones. Here, the local governments have instructed producers and processors to only buy non-GMO feeds. In order to meet the demand in feeds in these oblasts, Russia's major soybean crushing company, Sodruzhestvo, maintains separate facilities for GM and non-GM soybeans in Kaliningrad. As for food and food ingredients, importers of these commodities report that food processors and traders still prefer certified non-biotech products in order to meet consumers' preferences.

Certified non-GMO imports of soybeans and corn, however, do not always reflect reality. The leaders in soybean supply to Russia are Paraguay and Brazil (57 percent and 31 percent of Russia's imports in 2010/2011 respectively), and the leaders in soybean meal supply to Russia are Argentina (52 percent of Russian's imports), followed by Netherlands and Germany. In many of these countries the

overwhelming majority of soybeans are GM, and the separation of non-GMO and GM soybeans at the stage of handling and processing is not always accurate.

Russia does not allow imports of GM crops from countries where these GM events are not registered for production. In 2010, Rospotrebnadzor banned shipments of GMO soybeans of Ukrainian origin, although the shippers declared that the cargo contained GMO varieties already registered for use in Russia. These imports remained blocked, though, because Rospotrebnadzor stated that since Ukrainian law does not allow cultivation of GM crops, these crops were grown illegally and thus could not be imported.

Table 3. Russia: Imports of products that may contain biotech ingredients, June May, 2009 – 2011

	2008/09	2009/10	2010/11
Metric Tons			
Corn (HS number 1005)	246,570	43,548	101,071
- from the U.S.	2,790	2,308	3,402
Corn Groats and Meal (HS number 1103 13)	27,849	25,056	22,120
- from the U.S.	0	0	2
Corn Starch (HS number 1108 12)	17,065	7,803	10,035
- from the U.S.	1	0	73
Soybeans (HS number 1201)	680,712	1,027,999	1,025,652
- from the U.S.	25,909	95,968	26,788
Soybean flour (HS number 1208 10)	5,678	2,089	1,651
- from the U.S.	-	-	-
Soybean Meal (HS number 2304)	586,950	399,219	455,142
- from the U.S.	18,422	52,160	46,023
Soybean Isolates (from HS number 3504)			
Total group HS number 3504	42,594	46,333	49,620
- from the U.S.	977	209	559
1,000 U.S. Dollars			
Corn (HS number 1005)	136,521	51,112	96,017
- from the U.S.	2,102	1,550	2,428
Corn Groats and Meal (HS number 1103 13)	10,642	7,285	8,134
- from the U.S.	0	0	6
Corn Starch (HS number 1108 12)	7,428	2,899	6,068
- from the U.S.	6	0	90
Soybeans (HS number 1201)	341,515	480,150	521,271
- from the U.S.	10,208	42,497	15,836
Soybean flour (HS number 1208 10)	3,665	1,499	1,380
- from the U.S.	-	-	-
Soybean Meal (HS number 2304)	323,844	198,337	213,405
- from the U.S.	9,246	23,186	20,938
Soybean Isolates (from HS number 3504)			
Total group HS number 3504	80,085	108,116	114,410

- from the U.S.	3,065	811	1,726
Total	903,699	849,398	960,685
- from the U.S.	24,627	68,044	41,024

Source: Global Trade Atlas

Section III. Plant Biotechnology Policy:

Russian Biotechnology Legislation

As of July 2011, Russian legislation in the sphere of agricultural biotechnology still does not contain a comprehensive harmonized code of laws and regulations. Federal laws, government resolutions and orders by the Head of Rospotrebnadzor listed below regulate Russian biotech policy at present. These include laws on product registration and consumer information about biotech ingredients in food products. In theory, Russian biotech legislation must be harmonized within the Customs Union by the adoption of several unified technical regulations by January 2012. The most important legislation for biotech trade and registration are drafted technical regulations on safety of food and on safety of feeds. These technical regulations are still under discussion, and whether they will be adopted by the beginning of CY 2012, as required, is unclear.

Recently, Prime Minister Vladimir Putin conducted a meeting where he called for the development of biotechnology in Russia and directed Government agencies to take necessary steps to make this a reality. The text of V. Putin's introductory speech at the meeting (in English) on April 1, 2011, is on the site: <http://www.premier.gov.ru/eng/events/news/14720/>. An excerpt on biotechnology is below:

“I would like the Economic Development Ministry and other federal agencies to take into account the needs of the technology platform projects underway when drafting state programs and industry development strategies.

A number of the first such projects we plan to implement will directly involve biotechnology: the technology platforms Medicine of the Future, and Bio-industry and Bio-resources. This choice has been prompted by current trends and the growing role of biotechnology in medicine and other industries, in energy and agriculture. I think it was Igor Tamm – the Russian nuclear physicist – who said that the 20th century was the age of nuclear energy, while the next century was going to be the age of biotechnology. The academics present here may correct me if I am mistaken. But the world is obviously moving in this direction. China is actively promoting such projects, and so are India, Brazil, and Japan. European nations are making large investments in biopharmaceuticals and bio-energy.

The global bio-industry was estimated to be worth more than \$2 trillion in 2010. According to the Organization for Economic Cooperation and Development, in 2030, biotechnology will be used to produce up to 35% of chemicals, up to 80% of pharmaceuticals, and 50% of agricultural products.

Russia today accounts for a mere 0.2% of the global biotechnology market, with a heavy emphasis on pharmaceutical projects. In other areas, the results are even more modest.

It is our job to change this situation – to create an atmosphere in Russia that will encourage the development of a powerful bio-industry. We have all the potential for it, such as a strong research and educational base with projects and patents meeting international standards.

We need to take stock of the whole sector and draft policies to stimulate the demand for Russian

biotechnology products, remove excessive administrative barriers that are a hindrance to businesses. We have regularly discussed this in recent years. We have done more than just talk. I hope these measures will be effective.

We must help coordinate the R&D stages of these projects to consolidate the resources of state academies, federal and departmental targeted programs, and federal, regional and corporate research centers.

I believe we should accelerate the development of a special coordination program for the promotion of biotechnology in Russia. I expect the Economic Development Ministry to submit a draft to the government no later than mid-May.”

At the beginning of June 2011, the Ministry of Economic Development prepared a draft government resolution on the state registration of genetically modified organisms for release into the environment (the title of the draft was “On Amendments to Some Acts of the Government of the Russian Federation on the Issues of the State Registration of Genetically Modified Organisms”). The draft resolution was discussed in June 2011 by an Inter-Agency Commission headed by Academician Konstantin Skryabin and with participation of different opponents to agricultural biotechnology, including the President of the Russian National Association for Genetic Safety. The result of the discussion was to postpone the discussion on the draft resolution until the end of summer 2011.

The draft Government Resolution envisages that VPSS at the Ministry of Agriculture will be responsible for registration of biotech crops, plants, animals, and agricultural microorganisms for release into environment. Thus the Ministry of Agriculture of which VPSS is a part might receive the complete authority over agricultural biotechnology (cultivation and feeds). However, the Draft Resolution does not envisage any additional funding for the Ministry of Agriculture and VPSS for these expanded activities.

Below is a summary of acting Russian laws and regulations that influence agricultural biotechnology:

- 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 (see Federal Law No 262-FZ of October 4, 2010 below). This is a foundational federal law on genetic engineering in Russia, but the law does not determine instruments for implementation;
- 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 Consumers Rights with amendments. The amendment of October 25, 2007 sets the threshold for mandatory labeling of food ingredients made from biotech material to 0.9 percent. Prior to this amendment, trace amounts of biotech food ingredients required labeling
- Resolution of the Government of the Russian Federation No. 422 of July 14, 2006 that transferred testing and registration of biotech feeds from the Ministry of Agriculture of the Russian Federation to the Federal Service for Veterinary and Phytosanitary Surveillance (VPSS)
- 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 GMO organisms

- 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 GMO food
- The Federal Law No. 7-FZ of January 10, 2002, On Environmental Protection, as amended by January 1, 2011. Article 50.1 Environmental Protection from Negative Biological Impact of Federal Law No. 7-FZ of January 10, 2002. The Article says: “it is prohibited to produce, grow and use plants, animals and other organisms not typical for natural ecological systems, or created artificially, without developing effective measures to prevent their uncontrolled reproduction, obtaining a positive state ecological expert’s conclusion, and permission from the federal bodies of executive power that conduct the state management of environment, and other federal bodies of executive power in accordance with their competence and legislature of the Russian Federation”.
- Russian federal laws on technical regulation and documents of the Customs Union on adoption of the unified technical regulations of the Customs Union. The Russian legislature on technical regulation has been changing several times since the federal law On Technical Regulation was adopted in 2002 (No 184-FZ of December 27, 2002). Thus, in course of these changes the ready-for-approval drafts of the two biotech-related technical regulations (On Requirements for Bio-safety and the Safety of Biotech Plants, and On Requirements for Safety of Foodstuffs Produced from Raw Materials Derived from Biotech Plants and Animals) were abandoned. Beginning 2010 the law potentially allows business to choose either Russian technical regulations or technical rules and standards based on “approved” foreign standards and norms (Federal Law No 385-FZ of December 30, 2009, On Amendments to the FL on Technical Regulation). The amendment also gave the Russian Government authority to introduce on a temporary basis, the technical regulations of the Custom Union, and norms and rules of the EU, where Russian technical regulations have not been adopted yet. However, when Customs Union came to force in July 2010, development and adoption of all not-yet adopted Russian technical regulations was suspended, and experts began developing new technical regulations for the whole Customs Union. The Customs Union technical regulations that will mostly influence agricultural biotechnology are the technical regulation on food safety and the technical regulation of feed safety. Both are at the stage of discussions with uncertain prospects.
- Resolution No. 42 of June 25, 2007 approved SanPiN 2.3.2.2227-07, Additions and Changes No. 5 to the Sanitary-Epidemiological Rules (SanPiN 2.3.2.1078-01 of 2002, Hygiene Requirements to Safety and Nutrition Value of Food Products). SanPiN 2.3.2.2227-07 establishes a threshold level for biotech ingredients in food products, requiring labeling for those with components over 0.9 percent biotech. The resolution acknowledges that any smaller biotech presence is adventitious.
- Federal Law No 262-FZ of October 4, 2010, On Amendments to the Federal Law “On the State Regulation in the Field of Genetic Engineering” makes some amendments in the language of the foundational Federal Law on Genetic Engineering, and authorized the Government to develop and adopt procedures for the release of the genetically modified organisms into environment. The text of the Federal Law No. 262-FZ is on the site: http://ntc.duma.gov.ru/duma_na/asozd/asozd_text.php?nm=262-Φ3&dt=2010. This federal law is a step forward towards the beginning of cultivation of biotech plants in Russia. However, the Federal Law does not stipulate how soon the Government shall adopt these procedures.

Biotech Labeling Requirements

For food, all products which contain a certain threshold of GMO contents, must be labeled as containing GMO. In accordance with the current Russian legislation, which will be in force in Russia before the final creation of the unified economic environment in the Customs Union, all organizations that import, produce, or trade food products to/in Russia must inform consumers about the presence of biotech components when each individual biotech event exceeds 0.9 percent. Labeling requirements increase the cost of products containing biotech. However, it remains rare to find a GMO label, though non-GMO label can commonly be seen on dairy, eggs and poultry products. Feed products are not required to be labeled as containing GMO.

Government Ministries and Their Roles

The role of Russian government ministries in registration of biotech crops and products for food use and for feed use has not changed in the past year. However, since the unified economic environment within the Customs Union is planned to start working on January 1, 2012, all certificates and permits on the use of biotech food and biotech ingredients must be re-registered by January 1, 2012 for circulation on the territory of the Customs Union.

Registration for Food Use

The Russian Federal Service for Consumer Rights Protection and Human Well-Being (Rospotrebnadzor) at the Ministry of Health and Social development registers biotech crops and ingredients for food use. The registration process has not changed from last year:

- The applicant submits the application and dossier to Rospotrebnadzor;
- Rospotrebnadzor assigns a safety assessment to the Institute of Nutrition of the Academy of Medical Sciences;
- The applicant concludes an agreement for the food safety assessment with this Institute; and
- On the basis of the Institute's assessment, Rospotrebnadzor issues a certificate of registration and registers the product.

It takes approximately 12 months to conduct laboratory tests required for the safety assessment and an additional two to three months to organize and prepare documents for the new biotech crops.

As mentioned, even after registering biotech events, each food product containing that biotech product must also be registered separately. The registration process for food products, however, takes considerably less time than biotech event registration. To register, it is necessary to provide a copy of the event registration certificate in the application documents when registering food products or ingredients. Only those companies with registered crops in Russia for food use (one of three companies mentioned above) can provide a copy of the crop registration certificate.

Since 2006, Rospotrebnadzor has registered food-use crops for an unlimited time period. Information on biotech 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/>. 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, it is best to search for the name of the crop and the words “genetically modified.”

The institutes that conduct biotech crop and food product research are: The Russian Academy of Medical Sciences - Institute of Nutrition and Food Safety Assessment (medical and biological studies), the Russia Academy of Sciences for Bioengineering of (genetic studies), and the Moscow State University of Applied Biotechnology (technological assessment).

For trade, Rospotrebnadzor’s Order No. 80 specifies the methods that should be used to test for biotech presence in food. For imported food products 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, 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 the import permit is recalled, and a claim for fraud may be placed on that company. Usually Rospotrebnadzor pays special attention to products containing soybean or corn ingredients.

Registration for Feed Use

Plant-origin feed imports require a veterinary certificate and a letter stating that the feed is biotech free (the maximum adventitious presence may be 5 percent). If the feed contains biotech ingredients, the shipment must include a copy of the certificate indicating that the biotech components in the feed are registered with the Federal Service for Veterinary and Phytosanitary Surveillance (VPSS). The imports must also have a phytosanitary quarantine certificate, although it is unrelated to biotechnology. Any biotech components in feed must be appropriately registered. The responsibilities of VPSS in the feed registration were confirmed by the Order of the Russian Ministry of Agriculture No. 466 of October 6, 2009 that approved the registration regulations. The Regulation states that the registration is issued for 5 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 Regulation does not allow the registration of several types of GM feeds under one name, or to register the same GM feed several times under one or under several different names. The applicant must submit the following documents:

1. application for the state registration of GM feed;
2. materials that contain information on the following
 - information on the origin of GM feed,
 - evaluation of the potential danger of use of GM feed (compared with the initial basic feed), and recommendation of the applicant on the risk reduction,
 - information on the supposed use of the GM feed, and on the registration and the use of this feed abroad,
 - information about the technology of growing the modified variety of the plant that is used for production of GM feed,
 - data on the technology of production of GM feed,
 - draft of the instruction on the use of GM feed
3. if the feed contains viable seeds (which could grow if planted), and is meant for biomass or fodder, the certificate from the Russian State Register of Selection Achievements must be

attached.

All documents shall be in Russian or shall have the certified translation into Russian. Copies of document shall be certified by a notary. VPSS will make a decision on the registration of a GMO-feed based on the Conclusion of the Experts Council on the safety of the GMO-feed.

To register formula feeds, VPSS issues feed-registration certificates to a specific applicant for an individual shipment during a certain period of time. VPSS only issues certificates for feeds produced using registered biotech crops. The certificates cannot be transferred to different importers. This registration is conducted by VPSS, but the list of registered feeds is not available on the site.

The testing of crops for feed use and the testing of biotech formula feeds is conducted by the Federal State Organization “All-Russian Center of Quality and Standardization of Animal Pharmaceuticals and Feeds – VGNIKI, subordinated to VPSS.

For trade, the maximum adventitious presence of non-registered biotech components in feeds allowed is 0.5 percent. Feed may be classified as biotech-free if the presence of each non-registered biotech line in feeds 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 feeds 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 VPSS regardless examines the products for the presence of biotech components.

Registration and Certification in the Customs Union

The creation of the Customs Union between Russia, Belarus, and Kazakhstan will result in a revamping of Russia’s technical regulations and Russia requires all biotech events for food and food products to be re-registered by January 1, 2012, in order to comply with the Custom Union regulations (for more information see GAIN report RS1123 _ Permits for biotech food shall be re-registered by January 2012_ Moscow _ Russian Federation _ 5/18/2011).

On May 28, 2010 the Customs Union Commission adopted Custom Union’s Standard Sanitary and Epidemiological and Hygienic Requirements to Food Product Safety and Nutritional. These requirements (Decision of the Commission #299 of May 28, 2010) are posted on the web-site of the Customs Union: http://www.tsouz.ru/KTS/KTS17/Pages/P2_299.aspx. These requirements include GMO presence and labeling requirements very similar to Russian requirements stipulated in SanPiN 2.3.2.1078-01 (with all amendments referring to GMO). However, the mechanism for implementing these new requirements in the Customs Union has not been developed. Russia’s Rospotrebnadzor is conducting permanent consultations on how to implement these requirements at the borders and in the Customs Union.

Fees for Registration of Biotech Events:

Rospotrebnadzor's charges for all examinations and related services, including comprehensive studies required to register biotech events for food. Fees are capped at approximately \$135,000 for the approval of new events for an unlimited period. The option to register for an unlimited period began in 2006. The fee varies, depending on the range of examinations and studies, but averages around \$100,000. The fee for re-examination and re-approval of events that were registered before 2006 is approximately \$10,000. Registration of food products that contain a previously registered biotech event is 20,000 rubles (approximately \$714).

For feed use, VPSS usually registers events only after it has been approved for food use. However, the registration fee is higher and the process is more cumbersome. The registration fee is not fixed, and VPSS's charges for examination and a 5 year event registration for feed use varies from \$120,000 to \$130,000. The charge is the same for registration for the first time and for re-registration every five years. Companies that import formula feeds with registered biotech components also need to register these feeds as biotech feeds. The registration is given to the company that imports this feed and VPSS requires that each feed that contains a registered GM event also be registered.

Section IV. Plant Biotechnology Marketing Issues:

Labeling requirements increase the price of food containing biotech ingredients. The price of examining products for the presence (or absence) of biotech components is high because the approved methods of testing are extensive. It is rare to find a GMO label, though non-GMO label can commonly be seen on dairy, eggs and poultry products.

Section V. Plant Biotechnology Capacity Building and Outreach:

In 2010-2011 activities of anti-biotech groups decreased, however, with current legislation on cultivation being created it may lead to a resurgence of anti-biotech lobbying. Pro-biotech groups have not received new funds in spite of a declared support of innovations and advanced technologies by the Russian Government. The mass media is still mostly anti-biotech, but the issue has lost its importance and is discussed very little in the mainstream media.

Section VI. Animal Biotechnology:

This is only at the stage of some limited laboratory research, but information is very limited.