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**Report Highlights:**

Despite the continuation of anti-biotech rhetoric and legislation, Russia continues to import many biotech products. Registering biotech crops for import is a lengthy but transparent process. While Russia imports many biotech feed- and food-use crops, it is still illegal to grow biotech crops on Russian soil. The most significant change over the past year was an amendment that defined the adventitious presence of biotech components in food products. Producers must now label biotech components only if they account for more than 0.9 percent of the product.

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## Executive Summary

During the fall of 2007, the impending Duma and Presidential elections heavily influenced Russia's attitude towards agricultural biotechnology. Potential Duma candidates and regional authorities used anti-biotech rhetoric to win votes as a means of displaying their concern for the health of Russia's population. Even though Russia's elections are over, their legacy still influences the development of regional biotech policies. "GMO-free" labeling requirements for food products in Moscow, Russia's largest food market, and declarations of "GMO-free" zones in some provinces are continuations of earlier anti-biotech campaigns. Significant improvements in these policies are not likely in the first half of the 2008/2009 crop market year. Nevertheless, Russia is expected to continue to import biotech products, including large quantities of soybean meal. Russia is also expected to continue to register biotech products for importation as food and feed<sup>1</sup>.

The Russian government did not develop a consistent federal biotechnology policy in 2007/2008. For example, it is still illegal to grow biotech crops in Russia despite a bilateral agreement with the United States (November 2006) to establish a workable system for cultivation. Proposed amendments to the Federal Law for Environmental Protection could have solved this problem, but the government has indefinitely postponed their consideration. In addition, October 2007 amendments to the federal law "On the Protection of Consumer Rights" introduced new labeling requirements for food products. While there were previous requirements to label the presence of biotech ingredients, the new amendment defined the adventitious presence of biotech components in food products as 0.9 percent. This official threshold prevents local authorities from pursuing companies for not labeling biotech ingredients when they compose less than 0.9 percent of the product.

The Federal Service for the Protection of Consumer Rights and Human Well-being of the Ministry of Health (Rospotrebnadzor) registers biotech food-use crops, while the Federal Service for Veterinary and Phytosanitary Surveillance of the Ministry of Agriculture (VPSS) registers biotech feed-use crops. It takes approximately twelve months to register a new crop for either food- or feed-use and cost approximately \$150,000 to \$160,000. While the requirements for registering biotech products are transparent, they may hinder trade. Importers must now provide notarized certification of documents and samples. Preparing these dossiers may take more time and increase the real cost of certifying crops, thereby decreasing companies' willingness to submit their varieties for certification.

The fervent anti-biotech campaign in Russia has dampened consumer demand for biotech food products. However, Russian farmers are demanding more domestic and imported feeds, suggesting that demand for biotech feed products is also growing. Official information on the use of and demand for biotech foods and feeds are not available, but rising imports of soybeans and soybean meal support estimates of growth in feed demand.

There are no specific bans on importing biotech products. However, U.S. exporters of biotech products encounter similar difficulties faced by other U.S. exporters. For example, Russia banned all U.S. rice in 2006. Trade resumed after the U.S. agreed to certify that the exported rice does not contain traces of LL601. In another case, VPSS imposed phytosanitary restrictions on a 2007 shipment of biotech corn and only approved the shipment after the United States raised the issue during negotiations on Russia's accession to the WTO.

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<sup>1</sup> Feeds include the products of plants, animals, and microbiological origin as well as their components that are used to feed animals. These feeds contain simulated nutrients that do not negatively impact the animals' health.

## Biotechnology Trade and Production

As of July 2008, there are 16 biotech crops registered for import into Russia and for use in the food and feed industry. These include three soybean varieties, nine corn varieties, one rice variety, one sugar beet variety, and two potato varieties. Of these 16 varieties, 11 are registered for feed use, including all three soybean varieties and eight corn varieties. Two new biotech crops, Corn 3272 (Syngenta) and the soybean MON 89788 (Monsanto), were submitted for registration in 2007/2008. They are waiting for approval.

### Status of Product Approval

Only three companies register their biotech crops in Russia: Monsanto, Bayer Crop Science, and Syngenta. Table 1 shows the list of approved and registered biotech crops in Russia.

**Table 1. Russia: Approved and Registered Biotech Crops, 1999-2008**

Crop	Applicant	Year and Period of Registration	
		For Food Use	For Feed Use
Bt corn MON 810, resistant to European corn borer	Monsanto	2000 - 2003, 2004 - 2009*	2003 - 2008*
Roundup Ready® corn NK 603, tolerant to glyphosate	Monsanto	2002 - 2007; 2008 - for unlimited period	2003 - 2008*
Bt corn MON 863, resistant to corn root worm ( <i>Diabrotica spp.</i> )	Monsanto	2003 - 2008*	2003 - 2008*
Corn Bt 11, tolerant to gluphosinate, insect resistant	Syngenta	2003 - 2008*	Dec. 2006 - 2011
LL Corn T25, tolerant to gluphosinate	Bayer Crop Sciences	2001 - 2006, 2007 - for unlimited period	Dec. 2006 - 2011
Roundup Ready ® corn GA 21, tolerant to glyphosate**	Monsanto	2000 - 2003, extended for 2004 - 2009	2003 - 2008
Roundup Ready ® corn GA 21, tolerant to glyphosate**	Syngenta	2007 - for unlimited period	2007 - 2012
Corn MIR 604, resistant to corn root worm ( <i>Diabrotica spp.</i> )	Syngenta	2007 - for unlimited period	2008 - 2013

Corn MON 88017, stacked product: tolerant to glyphosate and resistant to corn root worm ( <i>Diabrotica spp.</i> )	Monsanto	May 2007 – for unlimited period	2007*
Roundup Ready® soybeans 40-3-2, tolerant to glyphosate	Monsanto	1999 – 2002, 2002 – 2007, December 2007 - for unlimited period	2003 – 2008, 2008 – 2013
Liberty Link® Soybeans A2704-12, tolerant to gluphosinate	Bayer Crop Sciences	2002 – 2007 2008 – for unlimited period	2007 – 2012
Liberty Link® Soybeans A5547-127, tolerant to gluphosinate	Bayer Crop Sciences	2002 – 2007 2008 – for unlimited period	2007 – 2012
Rice LL62, tolerant to gluphosinate	Bayer Crop Sciences	2003 – 2008***	
Roundup Ready ® Sugar beet H7-1, tolerant to glyphosate	Monsanto/	2006 – for unlimited period	
Bt potato “Elizaveta” (resistant to Colorado potato beetle)	Center “Bio-engineering”, Russia	2005 – for unlimited period****	
Bt potato “Lugovskoy” (resistant to Colorado potato beetle)	Center “Bio-engineering”, Russia	July 2006 – for unlimited period	

\*Application for re-registration has been submitted.

\*\* Monsanto sold RR corn GA 21 to Syngenta, and Syngenta received registration for this crop for importation and food use in 2007. In Russia, Monsanto’s registration of this corn for food use will be valid until 2009 and for feed use until 2008.

\*\*\* Cannot submit final documents for re-registration because company has problems with VPSS on imports of samples.

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

### Approval for Imports and Food Use

The Federal Service for the Protection of Consumer Rights and Human Well-being of the Ministry of Health (Rospotrebnadzor) registers biotech food-use crops. In 2007/2008, Rospotrebnadzor continued to approve new and previously registered biotech crops. In May 2007, it became possible to obtain approval for biotech crops for food use without an expiration date, provided there is no evidence of harmful effects on humans. Consequently, companies had to re-register seven crops in 2007/2008. Only three companies register their biotech crops in Russia: Monsanto, Bayer Crop Science, and Syngenta.

Table 1 lists registered biotech food-use products.

### Approval for Imports and Feed Use

The Federal Service for Veterinary and Phytosanitary Surveillance of the Ministry of Agriculture (VPSS) registers biotech feed-use crops. In 2006, responsibility for the registration of biotech feed-use crops was moved to the Federal Service for Veterinary and Phytosanitary Surveillance of the Ministry of Agriculture (VPSS) and registrations resumed by December 2006. In 2007, VPSS developed and adopted new registration procedures<sup>2</sup> reportedly similar to an earlier protocol used in 2004. Registration for feed use still expires after five years.

Table 1 lists registered biotech feed-use products.

### Biotech Crops Awaiting Approval, Expected Applications, and Closure of Products

Table 2 lists expected applications and biotech crops awaiting approval. The list includes crops submitted for re-registration and crops submitted for the first time.

The registration for some biotech crops for food use will expire in 2008 and 2009. Monsanto and Syngenta have submitted or will submit re-registration forms during 2008. In 2007 re-registration for biotech crops food use was less time-consuming (approximately 4-6 months) and expensive than the original registration (approximately 12 months). In the future, registration may become more difficult, as Russia expands its examinations to include multi-generational tests for both new and previously registered crops.

Some international biotech producers have stopped exporting selected varieties to Russia. Often, the limited revenue from biotech crops does not justify the costs of the examination and registration process. For example, Monsanto/Syngenta discontinued its Roundup Ready® Sugar Beet 77 project in Russia after its registration expired in 2006. In 2008, Monsanto decided not to renew some registrations that expired in 2007, including Bt potato Russet Burbank NL and Bt Potato Superior NL. Both crops were approved for food and feed use. In 2002, Monsanto received five-year biosafety<sup>3</sup> approvals from the Interagency Commission. In 2004, however, the Interagency Commission ceased to exist and no other entity was granted the authority to issue biosafety approvals. While Monsanto had once believed it would be able to grow these crops on Russian soil, it is unlikely that Russia will allow farmers to grow biotech crops in the near future. Therefore, Monsanto decided that registering these crops simply for importation was unjustifiably time-consuming and expensive, and subsequently dropped the projects. Similarly, Bayer Crop Science closed a project in 2003 for LL Corn T 25 because there was no procedure for biosafety registration.

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<sup>2</sup> Please see GAIN RS7078 *Biotechnology / Registration Procedure for GMO Feeds*

<sup>3</sup> The term "biosafety" is analogous to environmental safety in the U.S.

**Table 2. Russia: Biotech Crops Awaiting Approval and Anticipated Applications**

Crop	Applicant	Date of Submission for Approval	
		Food and Food-processing	Feeds
Bt corn MON 810, resistant to European corn borer	Monsanto	Submitted for re-registration in July 2008	Submitted for re-registration in July 2008
Corn MON 88017, stacked product: tolerant to glyphosate and resistant to corn root worm ( <i>Diabrotica</i> spp.)	Monsanto		Submitted for registration in 2007. Registration is expected in August 2008
Rice LL62	Bayer Crop Science	Company intends to re-register the crop in 2008, but it cannot get a permit from VPSS to import samples	
Corn 3272 with $\alpha$ -amylase enzyme to break starch during ethanol production	Syngenta	Submitted for registration in 2007	Will be submitted shortly
Bt corn MON 810, resistant to European corn borer	Monsanto	Submitted for re-registration in July 2008	Submitted for re-registration in July 2008
RR corn NK 603	Monsanto		Registration will expire on November 14, 2008. Submitted for re-registration in July 2008
Bt corn MON 863	Monsanto	Re-registration is expected in August 2008	Submitted for re-registration in July 2008
Corn MON 88017, stacked product: tolerant to glyphosate and resistant to corn root worm ( <i>Diabrotica</i> spp.)	Monsanto		Under registration. Registration is expected in August 2008
Soybean MON 89788, tolerant to glyphosate, 2 <sup>nd</sup> generation	Monsanto	Submitted for registration in July 2008	Submitted for registration in July 2008

In addition to the time and expense of examinations, other factors impede registration. Anti-biotech rhetoric has created an unfavorable environment for most biotech products in Russia. In addition, some Russian authorities block biotech imports for unrelated restrictions. For example, VPSS delayed the re-registration of Monsanto's RR Corn NK 603 for food use by placing a phytosanitary ban on U.S. corn imports. VPSS refused to grant import quarantine permits for U.S. biotech corn for research and examination in laboratories, even though no field tests were involved. VPSS cited existing quarantine restrictions on the import of U.S. seed corn. The U.S. ultimately resolved the issue during negotiations with Russia over its WTO accession. Bayer Crop Science is still unable to get permits from VPSS to import samples of glyphosate-tolerant Rice LL62 for the laboratory tests required for re-registration. VPSS also restricts importation of highly processed soybean products, such as protein

concentrates and textured proteins. Whether the products are biotech or not, VPSS requires U.S. exporters to provide quarantine certificates and import quarantine permits. These demands are inconsistent with international standards.

### **Biosafety Approval**

In 2004, the Interagency Commission ceased to exist and no other entity has been granted the authority to issue biosafety approvals. Therefore, biotech crops may not be grown in Russia. They may only be imported if they, or products containing them, are registered in Russia for uses other than planting.

### **Production and Development**

Current legal interpretations remove any prospect for growing biotech crops in Russia. According to the Federal Law for Environmental Protection, "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 ..." (Article 50, Protection of the Environment from Negative Biological Impact of the Federal Law). Theoretically, Article 50 should apply to all artificially created plants, animals, and organisms. In practice, however, authorities only use this article to restrict biotech crops. The government has not amended this law and will not likely do so in the foreseeable future.

VPSS and some officials in the Ministry of Agriculture are reportedly trying to strengthen Russia's prohibitions on biotech cultivation. They are trying to insert anti-biotech requirements into agriculture-related laws, including the draft Law on Seeds. Government officials have drafted federal prohibitions on cultivating biotech crops and using biotech crops in food for the army and baby food.

Various agencies and local administrations are trying to declare all of Russia a "GMO-free zone," and Moscow Mayor Yuriy Luzhkov avidly supports the Moscow city government taking this direction. Mayor Luzhkov and some governors of other Russian territories hope to place a moratorium on biotech products throughout Russia. Many politicians embraced the idea of a moratorium in the run-up to Duma elections in November 2007. Anti-biotech rhetoric has further increased as Russia moves closer to joining the WTO. Some politicians claim that if Russia joins the WTO, Russia will have a "heavy transgenic reliance on the Western food holding companies." This correlation in rhetoric implies that Russian officials propose anti-biotech legislation out of protectionism rather than true concern for the well-being of Russia's population.

### **Trade**

Even though Russia imports biotech food and feed, it does not record specific trade data on these imports. Most biotech imports, however, have corn or soybean components. Information on corn and soybean imports, therefore, may indirectly provide data on biotech imports. From July 2007 through March 2008, Russia imported 70,830 MT of corn. Corn imports dropped 48 percent from the same period of the preceding year. Imports decreased primarily because domestic corn production increased and because Ukraine, Russia's main corn supplier, had a small corn crop in MY 2007. Ukraine supplied 44 percent of Russia's total corn imports, down from 70 percent a year ago. Corn imports from the United States increased in July 2007 through March 2008 to 16,521 MT, up from 1,155 MT a year ago. In this year, the United States became the second largest supplier of corn to Russia. Hungary

exported to Russia 6,863 MT of corn, France - 5,105 MT, Canada - 4,047 MT, Serbia - 3,513 MT, Romania - 1,289 MT, and Argentina - 973 MT.

Development of livestock production<sup>4</sup> in Russia increased demand for protein feeds, and Russia's imports of soybeans and soybean meal subsequently skyrocketed. Russia imported 215,259 MT of soybeans from July 2007 through March 2008, compared with only 2,333 MT in the same period of the preceding year. These included 163,187 MT from Brazil, 27,231 MT from Paraguay, 23,978 MT from Ukraine, 615 MT from Moldova, and 232 MT from Austria. There is no information on U.S. soybean exports to Russia in this period. Importers claim that they import only non-biotech soybeans, including those from Brazil. This is highly unlikely since over 80 percent of soybeans on the world market are biotech.

From July 2006 to March 2007, Russia imported 3,140 MT of soybean flour (HS No. 1208 10). During the same period of the following year, imports rose to 3,168 MT. Kazakhstan exported 1,667 MT, more than half of the total. Belgium exported 445 MT, China exported 324 MT, Serbia exported 310 MT, India exported 216 MT, Hungary exported 20 MT, and an unknown country exported 186 MT. From July 2007 to March 2008, Russia imported 657,040 MT of soybean meal (HS No. 2304). This is a 14 percent increase from the same period of the preceding year.

Eleven different countries exported soybean meal to Russia. Argentina was the leading provider, supplying 431,667 MT and 66 percent of imports. Brazil was the second largest exporter, shipping 132,860 MT, a 50 percent increase from the previous period. From July 2007 through March 2008, Russia imported 27,729 MT from the Netherlands, up from 7,530 MT in the same period of the preceding year, making the Netherlands the third largest supplier of soybean meal to Russia. Dutch soybean meal usually contains U.S. soybeans that have been processed in the Netherlands or other EU countries. The United States exported 26,805 MT of soybean meal to Russia, up from 24,415 MT in July 2006 through March 2007. Although importers claim that they prefer non-biotech soybean meal, restored registration of biotech feeds stimulated imports of soybean meal from countries where significant portions of soybeans, if not all beans, are biotech.

Russia requires registration for all imported products containing biotech crops. Importers must also register feeds according to the registered crops they contain. While all imported foods and feeds require registration and certification, the procedures are different for biotech foods and feeds.

There are no specific bans on importing biotech products into Russia. The 2006 restriction on rice, however, was indirectly related to biotechnology. In September 2006, VPSS placed an overall phytosanitary ban on rice imports from the U.S., including all types and points of origin. VPSS banned rice after the unapproved LLRICE 601 variety reportedly entered the commercial rice supply. After consultations with the U.S. during negotiations for Russia's WTO accession, VPSS resumed issuing import quarantine permits for U.S. rice as of January 25, 2008. It further permitted entry of U.S. rice into the Russian Federation as of February 25, 2008. All shipments must be accompanied by a phytosanitary certificate, a copy of a signed letter from USDA GIPSA, and documentation indicating that one of six approved U.S. laboratories tested the rice and found it free of Liberty Link rice (LLRice).<sup>5</sup>

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<sup>4</sup> GAIN RS7020 *Progress of the National Priority Projects in Agriculture*; GAIN RS5086 *Agriculture as a "National Priority Project"*

<sup>5</sup> GAIN RS8029 *Product Brief / Russia Lifts Ban on U.S. Rice Imports*

## Food Aid

Russia will not likely receive food aid in the foreseeable future. Russia is increasing its grain and oilseed production, the economy is growing, and incomes are rising. Officially, all imports, including food aid, are allowed only if a biotech product is registered with Rospotrebnadzor at the Ministry of Health and Social Development (for food and food-processing imports) or with VPSS at the Ministry of Agriculture (for feed imports).

## Biotechnology Policy

In the last year, Russia passed a federal law clarifying the adventitious presence of biotech ingredients in food products. Nevertheless, there is still no comprehensive biotech policy or harmonized code of laws to regulate biotech issues.<sup>6</sup> Below is a short summary of the laws that regulate biotech policy. These include laws on product registration and consumer information about biotech ingredients in food products.

- Federal Law No. 86-FZ of July 5, 1996, On State Regulation in the Sphere of Genetic Engineering Activities. Amended by Federal Law No. 96-FZ of July 12, 2000, On Making Changes and Amendments to the Federal Law On State Regulation in the Sphere of Genetic Engineering Activities.
- Federal Law No. 29-FZ of January 2, 2000, On the Quality and Safety of Food Products. Amended on December 30, 2001, January 10, 2003, June 30, 2003, August 22, 2004, May 9, 2005, December 5, 2005, December 31, 2005, and March 31, 2006.
- Federal Law No. 2300-1 of February 7, 1992, On the Protection of Consumers Rights. Amended on June 2, 1993, January 9, 1996, December 30, 2001, August 22, 2004, November 2, 2004, December 21, 2004, and October 25, 2007. **NEW:** The amendment of October 25, 2007, stipulated in Federal Law No. 234-FZ, On Amendments to the Federal Law of the Russian Federation on Protection of Consumer Rights and to the Second Part of the Civil Code of the Russian Federation, raises 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. Russia's new law is consistent with European Union regulations.
- Resolution of the Government of the Russian Federation No. 422 of July 14, 2006, On Amendments to Resolution No. 26 of the Russian Federation Government Dated January 18, 2002. This resolution 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). This resolution also decreases the number of documents required for registration. It further releases VPSS from any obligation to share the establishment of the Expert Council for Biological Safety with the Interagency Commission on Genetic Engineering, as outlined in Resolution No. 26.<sup>7</sup> The Expert Council for Biological Safety has not yet been re-established.
- Resolution of the Government of the Russian Federation No. 120 of February 16, 2001, On State Registration of Genetically Modified Organisms and Registration Regulation.

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<sup>6</sup> See GAIN RS7052 *Biotechnology / Annual Report 2007* for a complete list of basic laws and federal regulations that concern agricultural biotechnology and the use of biotech products in foods and feeds.

<sup>7</sup> More on the Resolution No. 422 see GAIN RS7052 *Biotechnology / Annual Report 2007*

- Resolution of the Government of the Russian Federation No. 988 of December 21, 2000, On State Registration of New Food Products, Materials, and Goods. Amended by Resolutions No. 324 of April 27, 2001, No. 11 of January 14, 2002, and No. 90 of February 11, 2003, as well as by Regulations of State Registration of New Food Products, Materials, and Goods.
- Article 50.1 Environmental Protection from Negative Biological Impact of Federal Law No. 7-FZ of January 10, 2002, On Environmental Protection. This article prohibits approving biotech plants for cultivation. As the Federal Law for Environmental Protection stipulates, “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...”
- Federal Law of the Russian Federation No. 65-FZ of May 1, 2007, On Amendments to the Federal Law “On Technical Regulation,” made several amendments that could influence the adoption of biotech-related technical regulations:
  - There are 17 “priority” technical regulations to be adopted before January 1, 2010. The list, however, does not include any technical regulations specifically for biotech products. Consequently, the process of adopting two already drafted technical regulations, On Requirements for Biosafety and Safety of Biotech Plants as well as On Requirements for Safety of Foodstuff Produced from Raw Materials Derived from Biotech Plants and Animals, may be indefinitely suspended.
  - In paragraph 8 of Article 7, “International standards and/or national standards may be used fully or partially as a basis for development of technical regulations...” now reads as “International standards shall be used fully or partially as a basis for the development of drafts of technical regulations, excepting cases in which the use of international standards is acknowledged to be impossible due to climatic and geographic peculiarities of the Russian Federation, technical and/or technological peculiarities, or other grounds, or if the Russian Federation, in accordance with the established procedures, opposed the adoption of international standards or its separate provisions. National standards may be used fully or partially as a basis for the development of drafts of technical regulations in the case of these exceptions.” The amendment prioritizes Russia-specific standards over international science-based approaches for developing technical regulations. The climatic, geographic, technical, and technological peculiarities of Russian standards are often ill-defined and arbitrary. This premise will seriously affect areas in which international science is significantly ahead of Russia’s.
  - Article 46, Transitional Provisions, now contains the following sub-paragraph 1: “Until the day when the respective technical regulation comes into force, the Government of the Russian Federation and the federal bodies of executive power ... within their responsibilities have the right to introduce ... changes to the regulatory acts of the Russian Federation, which will be used until the respective technical regulation comes into force”. This amendment gives the federal authorities - including Ministries, Services, and Agencies – the right to declare and amend norms and standards.
- Order of the Ministry of Education and Science of the Russian Federation No. 154 of May 27, 2005, On the Interagency Commission on Genetic Engineering Activity. The Commission has had several organizational meetings, but it did not meet during the last half of the year. The Commission has minimal decision-making power, and it has done

nothing to develop national biotech policy. Moreover, government reorganization began in May 2008, and the roles that different agencies play in developing national biotech policy may still change.

- Resolution No. 42 of June 25, 2007<sup>8</sup> 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. These shall not be considered biotech products, and they shall not require special consumer information. The Ministry of Justice of the Russian Federation registered Resolution No. 42 on July 16, 2007 under Registration No. 9852. The resolution thus established an accepted federal level,<sup>9</sup> and SanPiN 2.3.2.2227-07 came into force on September 1, 2007<sup>10</sup>.

Federal Law FZ-25, On Amendments and Changes to the Federal Law On Technical regulation, clarified the status of orders developed by the Chief Medical Officer and other ministries and agencies. These orders became mandatory after being registered at the Ministry of Justice of the Russian Federation. Rospotrebnadzor's unregistered instructions regulate only the activities of employees within that agency. However, these instructions also influence producers and traders, because Rospotrebnadzor inspectors follow these instructions when surveying production sites, shops, warehouses, and other facilities.

In addition to amending SanPiN 2.3.2.1078-01, the Chief Medical Officer instructed his line officers to strengthen control over the presence of biotech ingredients in food products. He issued Order No. 80, On Surveillance of Turnover of Food Products Containing GMO, on November 30, 2007. He also issued several orders concerning the methods of testing biotech ingredients along with documents and samples required for registering biotech crops for food use.

Order No. 80 mandates that all organizations that import, produce, or trade food products must inform consumers about the presence of biotech components in food products, provided the share of biotech in these components is more than 0.9 percent. Rospotrebnadzor registered this order with the Ministry of Justice of the Russian Federation on February 6, 2008 under registration number 11117. Rospotrebnadzor's regional departments and railway transportation divisions must consider surveillance of biotech food products a major priority. Order No. 80 specifies the methods that should be used to test for biotech presence in food. It also clarifies the process of biologically evaluating the safety of biotech products derived from plants. This order, as well as Sanitary – Epidemiological Rules and Norms (SanPiN 2340-08), sets new requirements for documents and samples submitted for registering new products. These include biotech crops for food use. These new procedures require more time and effort from traders to register and re-register biotech crops and products. SanPiN 2340-08 was registered at the Ministry of Justice on March 11, 2008 under Registration No. 12311.

There are no federal legislative requirements regarding the adventitious presence of biotech ingredients in feeds. Recently, however, VPSS issued internal instructions on the adventitious

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<sup>8</sup> Russia's Chief Medical Officer (Chief Sanitary Inspector of the Russian Federation) issued Resolution No. 42 as the Head of Rospotrebnadzor.

<sup>9</sup> The Ministry of Justice approved the Resolution No. 42 after adopting Federal Law No. 65-FZ, Amendments to the Federal Law on Technical Regulations, on May 1, 2007.

<sup>10</sup> For more information see GAIN RS7053 *Biotechnology / Russia Establishes 0.9% Threshold for Biotech Labeling*

presence of biotech components in feeds to the heads of VPSS's regional departments and veterinary departments. VPSS defines feed as biotech-free if 0.5 percent or less of each component contains non-registered biotech products and if 0.9 percent or less of each component contains registered biotech products. In this case, "registered" refers to products registered in Russia and "non-registered" refers to products not registered in Russia.

### **Status of Technical Regulations Concerning Biotechnology**

Two technical regulations have been prepared and submitted to different ministries for approval. On Requirements for Biosafety and Safety of Biotech Plants regulates biotech plants, and On Requirements for Safety of Foodstuff Produced from Raw Materials Derived from Biotech Plants and Animals regulates biotech food. Neither has yet been adopted. Agencies have issued amendments to existing federal laws, and these have temporarily resolved some issues. Agencies issue these instructions under Federal Law No. 65-FZ of May 1, 2007, On Amendments to the Federal Law "On technical regulations." Nevertheless, postponing the adoption of the technical regulation on biotech plants deprives Russia of a consistent policy on the commercialization of plants. It also hinders the development of Russia's feed industry.

### **Present Regulatory Framework for Agricultural Biotechnology**

During the May 2008 government reorganization, work of the Interagency Commission on Genetic Engineering was halted. Thus, the government has lost its mechanism for setting regulatory policy related to agricultural biotechnology

During Russia-U.S. negotiations on Russia's accession to the WTO, the parties agreed to several biotechnology initiatives, including the development of a Bilateral Consultative Mechanism on Agricultural Biotechnology for exchanging information on U.S. and Russian developments in this area. The first meeting of this mechanism is scheduled for the end of July 2008. This meeting is expected to disseminate information on the trends of Russian policy on agricultural biotechnology as well as on Russia's progress in developing framework structures to coordinate this policy.

### **Government Ministries and Their Roles**

#### **Registration for Food Use**

Rospotrebnadzor registers biotech crops and ingredients for food use. The registration process is as follows:

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

To conduct safety assessments, the Institute of Nutrition subcontracts with other research institutes for medical, genetic, and technological tests.

It takes 12 months to conduct laboratory tests and an additional two to three months to organize and prepare documents. This is a longer testing period than in Western Europe. To alleviate consumer concerns, the Ministry of Health and Social Development decided to

conduct medical and biological tests for major biotech crops over several generations. These tests are for scientific purposes, however, and will not affect registration procedures or increase the testing period.

Overall, registering biotech imports for food use is a transparent process. For example, examination costs are publicly available. New registration costs approximately \$150,000 to \$160,000, and re-registration costs approximately one quarter of that. This cost may increase, however, as the Chief Medical Officer issues new orders that set stricter requirements for the dossier. For example, exporters must now notarize documents in the country of origin for submitted crops.

Table 1 shows the list of biotech crops registered for food use. Since 2006 Rospotrebnadzor has registered food use crops for an unlimited period. Rospotrebnadzor's website lists the food products that can have these registered crops as an ingredient or source material. The address of the site is the following:

<http://fp.crc.ru/gosregfr/?oper=s&type=min&pdk=on&pril=on&text=%E3%E5%ED%E5%F2%E8%F7%E5%F1%EA%E8+%EC%EE%E4%E8%F4%E8%F6>. 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

Plant-origin feed imports require a veterinary certificate and a letter stating that the feed is biotech free. 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 VPSS. The imports must also have a phytosanitary quarantine certificate, but it is unrelated to biotechnology. Any biotech components in the feed must be appropriately registered.

The registration process is as follows:

1. The applicant submits the application and dossier to VPSS;
2. VPSS assigns a safety assessment to its Research Institute of Veterinary Control (All-Russian Center of Quality and Standardization of Veterinary Pharmaceuticals and Feeds);
3. The applicant concludes an agreement for the food safety assessment with this Institute; and
4. On the basis of the Institute's assessment, VPSS issues a certificate of registration and registers the product.

Table 1 shows the list of biotech crops registered for feed use. At present, VPSS does not have a separate list of biotech feeds and feed ingredients registered for export to Russia.

To register formula feeds rather than crops, VPSS issues feed-registration certificates to a specific applicant for an individual shipment during a certain period of time. The Ministry of Agriculture only issues certificates for feeds produced using registered biotech crops. The certificates cannot be transferred to different importers. Soybean meal and other feed imports are increasing.

### Role of the Biosafety Commission

No information exists on the re-establishment of the Biosafety Commission.

## Policy on Coexistence of Biotech and Non-Biotech Crops

There are no commercial biotech crops. For scientific purposes only, research institutes conduct limited field trials in isolated and strictly controlled areas. Researchers are studying coexistence at the laboratory level. One argument against commercial biotech cultivation in Russia is that it would be impossible or too expensive to separate biotech and non-biotech crops.

## Food Labeling

On October 25, 2007 Russian President Vladimir Putin signed Federal Law No. 234-FZ, On Amendments to the Federal Law of the Russian Federation On Protection of Consumer Rights and to the Second Part of the Civil Code of the Russian Federation. Russia's new law is consistent with European Union regulations, and it raises the threshold for mandatory labeling of food ingredients made from biotech material to 0.9 percent. Prior to the amendment, trace amounts of biotech food ingredients required labeling.

The amended paragraph of Article 10 Item 2 reads as follows<sup>11</sup>:

Article 10. Information about Goods (Tasks, Services)

...

2. Information about Goods (Tasks, Services) shall contain the following:

...

data on the basic consumer properties of goods (tasks, services). Foodstuffs shall contain information about their composition, including the names of food additives used in the process of making foodstuffs, biologically active additives, information on the presence in foodstuffs of components produced with the use of organisms modified by genetic engineering **in cases when the presence of these organisms in the component is more than nine tenth of a percent**, food value, purpose, conditions of use, storage of foodstuffs, ways of cooking ready-made dishes, weight (volume), date and place of manufacture, packing (parceling) of foodstuffs, and data on contraindications for their consumption in the case of certain diseases...

Prior to Federal Law No. 234-FZ, Chief Medical Officer Gennadiy Onishchenko issued Resolution No. 42 on June 25, 2007 to clarify the adventitious presence of biotech components in food products. This resolution, SanPiN 2.3.2.2227-07 Additions and Amendments No. 5 to the Sanitary-Epidemiological Rules SanPiN 2.3.2.1078-01 Hygiene Requirements to Safety and Nutrition Value of Food Products, established a 0.9 percent threshold for biotech components in food products for labeling. SanPiN 2.3.2.2227-07 came into effect on September 1, 2007.

The 0.9 percent threshold is a helpful clarification for some. Food companies that pay high prices for non-biotech ingredients are unable to guarantee the absolute absence of biotech traces in their products. Now they can label their products as biotech free, even if they contain those trace amounts. Even so, most Russian consumers are price conscious and will probably pay little attention to biotech labels. Despite the risk of incurring penalties from Rospotrebnadzor inspectors, most small and medium size food producers will probably ignore the labeling requirement.

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<sup>11</sup> The amendment is in bold letters. An unofficial translation of the previous reading of Article 10 of the federal law On Protection of Consumers' Rights is given in GAIN Report RS6015 *Trade Policy Monitoring/Consumer Information about Goods*.

Some local governments have additional requirements for labeling biotech ingredients in food products. The Moscow city government has enormously influenced consumers' attitudes towards biotech food with its voluntary "GMO-free" labeling.<sup>12</sup> Beginning July 1, 2007, food producers could voluntarily test their products for biotech ingredients through the Moscow city government. Products without biotech ingredients are marked with a special label, "Does not contain GMO!" Moscow also has the ability to force major food processors to label their biotech products. Consequently, the costs of product testing and non-biotech ingredients have increased food prices. Since Moscow accounts for over 20 percent of food consumed in Russia, such actions have influenced the national food market.

In some oblasts and regions of the Russian Federation, local authorities invent and advertise special labels for products that do not have biotech components. Sometimes they create labels for "ecologically pure" products. For example, Nizhniy Novgorod Oblast encourages using an emblem of a green leaf and a drop of water for products produced without the use of "non-natural" components. If Russia adopts the new SanPiN for organic products,<sup>13</sup> some products may have "organic" rather than "GMO-free" labeling.

### Feed Labeling

There are no formal requirements for labeling feeds. However, VPSS issued instructions for the adventitious presence of registered and non-registered biotech components in feeds. The instruction defines feed as biotech-free if 0.5 percent or less of each component contains non-registered biotech products and if 0.9 percent or less of each component contains registered<sup>14</sup> biotech products.

### Status of Ratification of the Biosafety Protocol

Russia has neither signed nor ratified the Biosafety Protocol. The Russian Customs Service does not require any documentation certifying conformity of shipped samples to the Biosafety Protocol.

### Marketing Issues

There has been little change in Russian attitudes towards biotech food. Most consumers are highly price sensitive and still prefer less expensive food.

As incomes rise, however, consumers are increasingly concerned with safety. This is especially true in large cities. Specialists complain that the media have presented a one-sided, anti-biotech approach to food safety and hygiene. The negative rhetoric is strongest in Moscow. Even though Moscow contains less than 10 percent of Russia's population, the following factors place Moscow in a position to influence national trends:

- In 2006, Moscow accounted for about 40 percent of Russia's wholesale turnover of foodstuffs;
- Moscow accounted for about 24 percent of Russia's retail food trade; and

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<sup>12</sup> For more information, see GAIN RS-7023 *"GMO-Free" Labeling of Food Products in Moscow*.

<sup>13</sup> GAIN RS-8045 *New SanPiN for Organic Products*

<sup>14</sup> "Registered" refers to biotech products registered by VPSS for use in the Russian Federation and "non-registered" refers to products not registered by VPSS for use in the Russian federation.

- One-fifth of the food consumed in Moscow goes through the Moscow city government's Food Procurement Authority.

In 2007, the Moscow city government allocated approximately \$2 million to create biotech-testing laboratories. The city government further recommended that major retail chains and supermarkets buy only those products that have the "Does not contain GMO!" label. Some large supermarkets have followed the recommendation, informing their suppliers that they will only purchase such labeled food products. Testing for biotech components is expensive, and the associated costs will be passed to the consumer, as food prices will likely rise. The resolution, while purportedly "voluntary," effectively forces producers, traders, wholesalers, retailers, and food processors to avoid using biotech products. Experts believe this voluntary labeling system will further reduce Moscow's biotech product market.

In addition to this labeling campaign, the Moscow city government has enacted other anti-biotech legislation. For example, it prohibits the purchase of biotech food using city funds and bans the use of biotech products in baby food. With its procurement and certification programs for all major activities of the Moscow food sector, the Moscow city government exerts significant influence on food production and trade nationwide.

Despite the anti-biotech legislation and rhetoric, it is still difficult to find products in Moscow or in the rest of Russia that display biotech information.

### **Capacity Building and Outreach**

Pro-biotechnology groups in Russia are underfunded. Anti-biotech groups, such as Greenpeace Russia and other NGOs, are significantly better funded. Russia's media are happy to accept payment to print articles, and thus anti-biotech groups pay to publish anti-biotech propaganda disguised as factual reporting. There are rarely science-based articles to counter the propaganda.

### **Other Relevant Reports**

RS8051 Biotechnology / Adventitious Presence of Biotech Components in Feeds  
<http://www.fas.usda.gov/gainfiles/200807/146295105.pdf>

RS8045 Organic Products / New SanPiN for Organic Products  
<http://www.fas.usda.gov/gainfiles/200806/146294938.pdf>

RS7078 Biotechnology / Registration Procedure for GMO Feeds  
<http://www.fas.usda.gov/gainfiles/200711/146292888.pdf>

RS7077 Biotechnology / Federal Law Sets Biotech Labeling Threshold at 0.9 Percent  
<http://www.fas.usda.gov/gainfiles/200711/146292887.pdf>

RS7053 Biotechnology / Russia Establishes 0.9 % Threshold for Biotech Labeling  
<http://www.fas.usda.gov/gainfiles/200707/146291830.pdf>

RS7052 Biotechnology / Annual Report  
<http://www.fas.usda.gov/gainfiles/200707/146291797.pdf>

RS7028 Biotechnology / Russian Sanitary Inspectors Strengthen Control over Biotech Food  
<http://www.fas.usda.gov/gainfiles/200703/146280576.pdf>

RS7023 Biotechnology / "GMO-Free" Labeling of Food Products in Moscow  
<http://www.fas.usda.gov/gainfiles/200703/146280370.pdf>