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Report Highlights:

The report provides an update on the Russian veterinary situation in 2019 and the first half of 2020. The following aspects are covered in the report: 1) an update on the veterinary legislation and regulations, including the implementation of the antimicrobial resistance policy and good manufacturing practices (GMP) requirements for producers of veterinary drugs; 2) an update on the Russian epizootic situation in 2019 and 2020; and 3) an update on veterinary issues related to Russian plans to increase agricultural exports.

RUSSIAN FEDERATION VETERINARY SITUATION UPDATE – 2019-2020

1. LEGISLATION AND REGULATIONS

1.1. The Law on Veterinary

On December 27, 2019, President Putin signed **Federal Law #447-FZ “On Amending Certain Legislative Acts of the Russian Federation on Improving the Implementation of Federal State Veterinary Supervision”**.¹ The Law provides for the implementation of a single Federal State veterinary supervision, moving Russia from a federalist model to a more centralized one. As a result, regional veterinary no longer have oversight of inspections. According to the Law, federal state veterinary supervision is now to be carried out by authorized federal executive bodies in accordance with their competence in the manner established by the Government of the Russian Federation, through the Federal Service for Veterinary and Phytosanitary Surveillance/Rosselhoznadzor (VPSS).

The Law stipulates that VPSS may delegate to the regional executive bodies the authority to carry out federal veterinary supervision (exclusively in their region) with regards to citizens engaged in breeding, rearing and transporting animals and in some other agricultural activities. In addition, the Law provides the chief state veterinary inspector and certain other high-ranked federal veterinary officials with the right to request from the regional authorities seizure of animals and (or) livestock products during the elimination of foci of especially dangerous animal diseases. The VPSS head noted that the new Law “should correct the negative consequences of the administrative reform of 2004, which led to the fragmentation of the system of state veterinary supervision”.

According to VPSS, previously, both regional and federal inspectors could inspect a company subject to veterinary surveillance, leading to duplication and creating an excessive burden on business. In addition, each region could develop its own regulations for veterinary supervision, which could be viewed as excessive or unfounded. VPSS further alleges that some important facts about the spread of contagious diseases were concealed under this dual surveillance, and suspect livestock products were not taken out of circulation in a timely manner.

“Federal agencies are meant to operate within a transparent and well-established regulatory framework in the case of a federal veterinary inspector under the federal veterinary law”, VPSS notes. Therefore, common standards for monitoring and decision-making have “finally” been defined under this Law. “But we must understand that the new law does not deprive the regional branch services of all powers. Regional services reserve all the previous functions, except for the right of inspections, which are assigned to the federal authorities - inspectors of territorial offices of the VPSS,” - said the Head of the Veterinary Office of Internal Supervision of the VPSS.

In addition, if the company has a production laboratory, the federal inspector will be able to study the research protocols. According to VPSS, the agency has been given the authority to inspect more than 230,000 regional enterprises, along with more than 250,000 objects of federal supervision. VPSS reports having enough resources to conduct such a large number of inspections. Most of the work will be carried out using the electronic veterinary certification system, “Mercury”, that is intended to ensure product traceability.

¹<https://rg.ru/2019/12/30/vet-dok.html>,
<https://rg.ru/2019/12/29/veterinarnyi-nadzor-zakrepili-na-federalnom-urovne.html>

“Our goal is to facilitate the work of the state service, so that it is engaged in the treatment of animals, prevention of their diseases, epizootic measures, while the regional veterinary services often wanted to just get money for the issuance of veterinary documents, replacing the work of the veterinary service,” Sergey Dankvert, the Head of the VPSS said in an interview. “We are going to build a normal system. We consider the adoption of the Law a great victory”, he noted.

According to the head of VPSS, “the next stage of strengthening the entire chain of veterinary oversight and improving biological safety is the adoption of amendments to the law on veterinary medicine, which will ensure the labeling and accounting of domestic and agricultural animals”.

1.2. Implementation of the State Antimicrobial Resistance (AMR) Policy

AMR has been identified among the Russian government’s priorities in the “Fundamentals of state policy in the field of chemical and biological safety up to 2025 and beyond”, adopted by the Decree of the President of the Russian Federation on March 11, 2019 N 97.² Despite a strong desire to prevent the excessive use of drugs in products in Russia, the regulatory framework and methods for monitoring their use have not yet been adjusted.

VPSS, as part of its new authority to control regional veterinary surveillance, developed and sent to the Ministry of Agriculture in early January 2020 a draft amendment to the law "On Veterinary Medicine", which implies a ban on the use of antimicrobials as growth stimulants, as well as preventive measures. In addition, the document defines the rules for the prescription of antibiotics and proposed to introduce an entire article regulating the manufacture of feed with added drugs.

In accordance with Decision No. 28 of the EEC Collegium adopted in February 2018 “On the Residues of Veterinary Medicines”, more than 70 types of antibiotics in livestock are currently approved for use in Russia. The Technical Regulation (TR) of the CU 021/2011 “On Food Safety” regulates the use of six groups of veterinary medicines in animal products: chloramphenicol, tetracycline, streptomycin and penicillin - for milk and grisin and bacitracin – for meat, poultry, eggs, fish and other products.

Meanwhile, according to Decision No. 28 of the EEC Collegium, which entered into force in the summer of 2018, producers and suppliers are entrusted with controlling the antibiotic residues in raw materials and products of animal origin during production along with control by supervisory authorities. According to the EEC clarification, the Decision does not obligate producers to carry out production control for the presence of all listed veterinary medicines.

At the same time, producers are given the opportunity to implement a risk-based approach. This means that the processor who purchases raw materials, such as meat, receive information from the supplier about the antibiotics used and, if necessary, can check them for antibiotics residues. Moreover, the document gives entrepreneurs the right to use any research methods that significantly simplify their work. Laboratory control methods described in the document are considered by many processors very expensive thus representing a major problem.

In 2019, the Law on the Circulation of Medicines introduced a new requirement on the mandatory indication of the method for detecting antibiotic residues in products in the registration dossier. There are certain requirements for the residual amount of antibiotic content in meat and milk. For example, some of them establish necessary residue removal time for dairy cattle to ensure that milk is not contaminated. The need to

² <http://docs.cntd.ru/document/553849979>

indicate the methodology in the registration dossier eliminates the gap when the antibiotic is already available for sale, and there is no methodology for its detection in the products, Sergey Dankvert stated in an interview to the official GOR daily “Rossiiskaya Gazeta”.

Control of drug residues in the finished product is still a problem. Soyuzmoloko [the Russian Union Of Dairy Producers] maintains the position that it is unacceptable that antibiotics, which should be controlled at the farm level, are monitored in finished dairy products, especially when the products are made from raw materials for which a valid veterinary certificate has been issued, guaranteeing its safety. Today, according to Soyuzmoloko, only four groups of antibiotics are regulated, but there are at least more than 50 groups of new drugs for which zero tolerances are established. This creates a very serious burden on the business. “The Ministry of Agriculture proposes to resolve the issue by amending the technical regulations, but we are sure that there is no need to impose responsibility on the processor and strengthen the responsibility of the veterinarian who issues the certificate,” the head of Soyuzmoloko Artyom Belov emphasized.

VPSS, meanwhile, insists on expanding the list of mandatory antibiotics for control. “I would like to wish the Eurasian Commission, firstly, to increase the list of antibiotics, for which residues should be controlled in livestock products intended for human consumption. Secondly, to create a unified electronic traceability system within the Eurasian community”, Sergey Dankvert said.

1.2.1 The Federation Council Debate on AMR³.

According to FAO report of November 19, 2019, the Federation Council (upper chamber of the Russian Parliament) held a special discussion on AMR as a step to improving the state food safety policy. The round table was co-organized by the World Health Organization (WHO), Food and Agriculture Organization of the United Nations (FAO) and the World Organization for Animal Health (OIE).

It was alleged that the long period of “virtually uncontrolled” use of antimicrobials in health care, veterinary medicine and agriculture has led to the spread of forms of microorganisms, including infectious agents with genetic characteristics that cause resistance to antimicrobials, including antibiotics, anti-tuberculosis, antiviral, anti-parasitic and anti-fungal drugs, as well as disinfectants.

Russia participates in international efforts to fight AMR and is a co-author of various regulatory documents in this area, in particular, the UN High-Level Meeting on Antimicrobial Resistance in 2016, which adopted a Political Declaration defining the multidisciplinary and intersectoral approach to addressing AMR at the national, regional and global levels. Russia joined the Global Center for Research and Development in AMR (Global AMR R&D Hub) established in May 2018.

On 25 September 2017, the GOR signed a decree “On the strategy for preventing the spread of antimicrobial resistance in the Russian Federation for the period to 2030” establishing a number of activities to prevent the spread of antimicrobial resistance.

With regards to tracking antimicrobial-resistant threats, the Reference Center of the Russian Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing (Rospotrebnadzor) plays an important role in monitoring the antimicrobial residues in raw materials and food products, as well as antibiotic resistance of bacteria. The Reference Center cooperates with FAO and provides advisory and methodological assistance to territorial bodies and organizations of Rospotrebnadzor organizations and institutions of the EAEU and members of the Commonwealth of Independent States (CIS).

1.2.2 The Law on Organic Products as It Relates to Animal Health

³ <http://www.fao.org/russian-federation/news/detail-events/en/c/1251884/>

On January 1, 2020, the Law on Organic Products entered into force in Russia⁴. Organic producers will be listed in the state register, and their products will be marked with a special sign. Also, the country will have its own system of certification of organic products. Accreditation of certification companies is carried out by the Federal Service for Accreditation (RusAccreditation). At the end of 2019, three organizations received certification. A special list of requirements has been defined for organic livestock products. They relate to animal welfare conditions and the prohibition of the use of antibiotics, including for prophylactic purposes,” said Sergei Korshunov, the chairman of the board of the Union of Organic Agriculture. Please refer to 2019 Gain report [Russia to Adopt New Law on Organics](#) for more information on Russia’s Organic Law.

1.3. Vaccine registration

Since November 29, 2019 new rules have been in place under which manufacturers and importers may release medicines into circulation.⁵ If the drugs entered the market before this date, they are subject to storage, transportation, sale, transfer, use before the expiration date. At the moment, the procedure for drugs to enter into public circulation is determined not by technical regulation (as before), but by the Federal Law 61 “On Circulation of Medicines” and the GOR Resolution N 1510⁶. The Ministry of Agriculture and the Federation Council initiated amendments to Law 61 in order to introduce a permit for release of vaccines for veterinary use into circulation. In March 2020, the amendments were submitted to the State Duma of the Russian Federation. According to the amendments, in order to import veterinary medicines into Russia, all manufacturing sites that are involved in the production process must have Russian Good Manufacturing Practices (GMP) certification, i.e. from vaccine production to packaging. The approximate approval date of this regulation is late 2020.

1.3.1. The Resolution of the Government of the Russian Federation 1510 of 26.2019 “On the order on putting in public circulation of medicines for medical treatment”.

In accordance with an Article 52.1 of the Federal Law "On the Circulation of Medicines", the Government of the Russian Federation approved:

1. Rules for the submission of documents and information on medicinal products for medical use introduced into civil circulation;
2. Rules for issuing a test report on the compliance of the first three series or batches of a medicinal product for medical use (with the exception of an immune-biological medicinal product), first produced in the Russian Federation or first imported into the Russian Federation, with the quality indicators provided for in the regulatory documentation;
3. Rules for issuing permits for the introduction into civil circulation of a batch or batch of an immunobiological medicinal product, issuing an opinion on the compliance of a batch or batch of immunobiological medicinal product with the requirements established during its state registration;
4. Rules for making a decision to terminate the civil circulation of a series or batch of a medicinal product for medical use.

⁴ <http://rosorganic.ru/files/Zakon%20RF%20organica.pdf>

⁵ <http://www.consultant.ru/cons/cgi/online.cgi?req=doc&cacheid=7A1D2629FAC56FEBB2DD44C53AD713EF&mode=backrefs&div=LAW&opt=1&SORTTYPE=0&BASENODE=1-1&ts=2591158230817615915&base=LAW&n=339179&rnd=44B74F35EB30CB02AA47DD276CA57302#2h7hcrj079k>

⁶ http://www.consultant.ru/document/cons_doc_LAW_338709/

Earlier, on November 13, 2019, the State Duma held a round table on the topic “Circulation of Veterinary Medicines”. The Duma also discussed plans to change legislation for introduction and labeling of veterinary drugs, as well as regulations for remote sales of medicines. However, this issue was removed from the agenda of legislative discussions in the first quarter of 2020.

1.3.2. Draft procedure for introduction into public circulation of medicines for veterinary purposes⁷

The Government of the Russian Federation canceled, by its Resolution No. 489 of April 24, 2019, the mandatory certification of veterinary vaccines⁸. The abolition of mandatory certification of veterinary vaccines was expressly provided for by the provisions of the federal law “On Technical Regulation”. The GOR has introduced, instead, a requirement for veterinary drug manufacturers to obtain GMP certification from VPSS through its institute (VGNKI) at their facilities (domestic and foreign).

According to Resolution 489, vaccines and anatoxins (drugs that stimulate the production of antibodies to toxins) are excluded from the list of products subject to mandatory certification, before being put into civil circulation. For other drugs - serums, drugs obtained by genetic engineering, as well as for bacteriophages and allergens used in veterinary medicine - the need for declaration is void. "But if a declaration has been established for medicines on a voluntary basis, certification is mandatory for vaccines. Thus, “for vaccines, changes are the most critical,” Tatiana Balagula, head of the Internal Veterinary Supervision Department of VPSS said. Initially the law concerned only medicines for human use, but during its consideration, amendments were made, as a result of which all medicines, including veterinary drugs, were subject to the law. As a result, many veterinary drug manufacturers are facing difficulties with the implementation of the new law. Current estimates are that 65 percent of veterinary drugs used in Russia are imported and this number has been gradually increasing for the last several years.

Since 2011, rules on mutual recognition of registration of medicines have been in force in the EAEU. Russia recognizes the registration of drugs in Kazakhstan, Armenia, Belarus, and Kyrgyzstan, and these countries recognize the registration in Russia. However, other EAEU states register drugs manufactured in third countries, such as Egypt and India, that are being called into question for mutual recognition or it has been reported that some companies may be registering their product in one EAEU member state in order to bypass registration in another country. State registration of vaccines for veterinary use is still mandatory, but their certification is voluntary. Most drugs currently available in the market already have valid certificates and new emerging vaccines are marketed without certificates. According to Anna Babushkina, it may be necessary to introduce additional restrictive measures to control the quality of vaccines coming to Russia from the EAEU.

Many large and medium-sized enterprises prefer to employ their own veterinary doctors who themselves can vaccinate animals. “As a result, there is a long-term relationship between the companies of the livestock sector and Russian manufacturers of vaccines, of which there are about ten”, the General Director of Agrikonsalt Group of Companies, Andrei Golohvastov, explains. Veterinary specialists of livestock companies purchase a wide range of products from the same suppliers, so the abolition of certification, at least initially, will not play a big role, assures the expert.

Domestic vaccine manufacturers are eager to gain market share, which mirrors the import substitution goals of the government, broadly speaking.

1.3.3. GMP standards in Russia and supplier audits

⁷ <http://www.consultant.ru/cons/cgi/online.cgi?req=doc;base=PRJ;n=183298>

⁸ http://www.consultant.ru/document/cons_doc_LAW_323497/

The Russian Federation did not support the World Health Organization's initiative on the GMP system in 1969. Instead, it decided to develop its own procedure to standardize the turnover of medicines⁹. The development of the Russian GMP (based on an EU model) began in 1998 with a plan to apply GMP international standards to the Russian pharmaceutical industry. In 2004, GOST (State Standard) 52.249-2004 "Drug production and quality control rules" was approved in this area, followed by GOST P 52249-2009. This document applies to all categories of medicines (including veterinary preparations) and defines the general requirements for their production and quality assessment. In addition, it sets specific requirements for the manufacture of active pharmaceutical substances and certain types of medicines.

In 2014, Federal Law 61 "On the Turnover of Medicines" was adopted, stipulating that all national enterprises involved in the production of medicines had to meet the Russian GMP requirements and introducing mandatory verification of GMP compliance. Although the rules and regulations set out in the standard must be strictly observed by all pharmaceutical companies, not all companies have managed to implement them, according to industry experts.¹⁰

In 2016, The Council of the Eurasian Economic Commission adopted Decision N 77 "On the approval of the Rules of Good Manufacturing Practice of the Eurasian Economic Union", which became effective on May 6, 2017¹¹. According to the document, a production permit (license) is mandatory for the manufacturer of medicines of Member States regardless of whether these products are sold in the territories of Member States or beyond. Compliance with the Regulations is mandatory to obtain permits (licenses) for the production of medicines, and it is based on inspections of drug manufacturers. The requirements of these Regulations to the production of veterinary medicines are the same as for human pharmaceuticals.

On November 27, 2019, the EAEU approved the Working Group on Pharmaceutical Inspections and Provisions for compliance with the rules of appropriate pharmaceutical practices in the treatment of medicines within the EAEU. The main tasks of the working group are collection and analysis of information on problematic issues arising from the implementation of the EAEU requirements for the production of medicines and pharmaceutical inspections, as well as the presentation of data on planned and occurring changes in the rules of the EU GMP, WHO, FDA and PIC/S. In addition, the working group on pharmaceutical inspections organizes and sends to the Eurasian Economic Commission proposals and drafts of changes in the existing solutions and recommendations on pharmaceutical inspections. In order to enhance mutual trust among the inspectors of EAEU member states, the working group will provide organization of joint training, joint pharmaceutical inspections with representatives of pharmaceutical inspectors of Member States, as well as exchange of information and experience. However, to the date, the Working Group has not produced any documents and its activities have been suspended because of the coronavirus pandemic.

The main document regulating the GMP issues in Russia is GOR Decree of March 12, 2015 N 1314¹² "On determining the compliance of drug manufacturers with the requirements of the rules of good manufacturing practice", with additional provisions stipulated by the "Rules of the organization and inspection of drug manufacturers to meet the requirements of the rules of good manufacturing practice, as well as issuing the conclusion on compliance of the manufacturer of medicines to these requirements".

The Russian GMP regulations apply to both medical and veterinary drugs, with the Ministry of Trade overseeing medical and the Ministry of Agriculture overseeing veterinary drugs.

⁹ <https://www.gluvelab.com/standart-gmp-poyavlenie-v-mire-i-v-rossii-nadlegashhey-proizvodstvennoy-praktiki/#3>

¹⁰ <https://gilsinp.ru/?news=utverzhdeno-polozhenie-o-rabochej-gruppe-po-voprosam-provedeniya-farminspektsij-v-eaes>

¹¹ <http://docs.cntd.ru/document/456026099>

¹² http://www.consultant.ru/document/cons_doc_LAW_190256/

The top Russian authority responsible for checking the compliance of medicinal drugs against the GMP standard is the State Institute of Drugs and Good Practices (FBU GILS and NP), subordinated to the Russian Ministry of Industry and Trade. The Ministry of Industry and Trade (MIT) has no authority to conduct inspections of veterinary drug manufacturers. The authority of VPSS to conduct inspections of manufacturers of veterinary drugs is spelled out in the following documents:

- The Russian Government Decree of 30.06.2004 N 327¹³ (ed. from March 30, 2020). "On the Approval of the Regulations on the Federal Service for Veterinary and Phytosanitary Surveillance." According to the decree, VPSS organizes and/or inspects the subjects of treatment of medicines for veterinary use to meet the requirements of the rules of good manufacturing practices.
- The Ministry of Agriculture Order of 01.03.2017 N 82¹⁴ "On the approval of the Administrative Regulations of the VPSS on the provision of a public service to issue a conclusion on the compliance of the manufacturer of medicines for veterinary application with the requirements of the rules of good manufacturing practice" (Registered in the Russian Ministry of Justice 24.05.2017 N 46807). The order appoints VGNKI as the authorized institution for GMP audits.

The Order of the VPSS Head N 97 of 29.02.2016 authorizes the All-Russia State Scientific Control Institute (FGBU "VGNKI") to audit foreign manufacturers of veterinary drugs for GMP compliance. VGNKI has a special Division of Inspections of foreign manufacturers of drugs for veterinary use¹⁵. All expenses related to the audits are covered by the applicant and may be calculated based on a methodology stipulated by VPSS Order N 835 of 25.11.2016¹⁶.

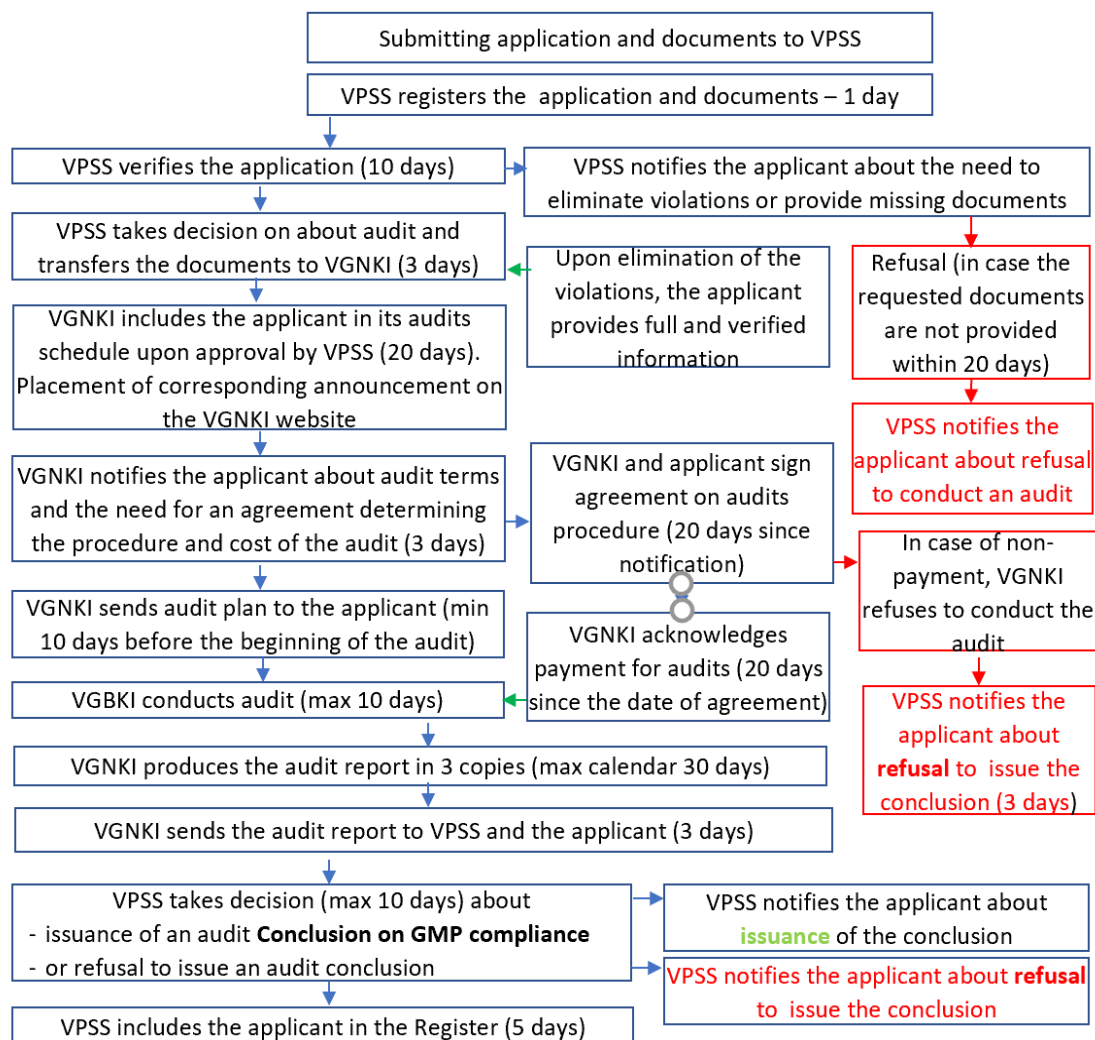
¹³ <http://base.garant.ru/12136097/#ixzz6OKRXzWJP>

¹⁴ <https://legalacts.ru/doc/prikaz-minselkhoza-rossii-ot-01032017-n-82-ob-utverzhenii/>

¹⁵ <http://www.vgnki.ru/otdel-inspekcii-proizvodstva-na-sootvetstvie-trebovaniyam-nadlezhashhej-proizvodstvennoj-praktiki.html>

¹⁶ <http://www.vgnki.ru/otdel-inspekcii-proizvodstva-na-sootvetstvie-trebovaniyam-nadlezhashhej-proizvodstvennoj-praktiki.html>

Fig.1 Procedure for obtaining conclusions on GMP compliance of foreign veterinary drug producers



Source: VGNKI

Audits are conducted according to an approved plan which is periodically updated and placed on VGNKI website.

In 2019, VGNKI conducted 31 planned and 41 unplanned audits of Russian manufacturers of medicines for veterinary use. About 80% of the audited facilities failed to meet the requirements of GMP (good manufacturing practice). Among 35 foreign producers audited in 2019, about 63 per cent did not meet the Russian GMP inspectors' criteria.

Russian manufacturers of medicines for veterinary use must comply with RU GMP rules, as well, but there is a different procedure used to obtain it: via the manufacturing license, which is issued by the same authorities. A veterinary manufacturing license is granted for an indefinite period, but typically each site is audited every three years. As noted above, if the authorities detect any findings (including "critical" findings) the manufacturing license usually is not withdrawn, instead the company would be subject to a penalty for violation of GMP rules and there would be no disruption in production. The authorities typically then provide time for the company to address these findings, equivalent to a Corrective Action Preventive Action process (CAPA), which is common

around the world. However, a similar CAPA has yet to be established for foreign companies. Thus, since foreign firms do not have a Russian manufacturing license, they would also not have an analogous period to take corrective actions after an audit. As a result, if a site were rejected after inspection, a foreign firm would need to re-start the process of obtaining GMP certification.

In January-March 2020, VGNKI experts conducted five planned and 13 unplanned GMP audits in Russia and six audits of foreign veterinary drug manufacturers. Due to the coronavirus pandemic, the remaining planned audits of 24 companies in 12 countries, including the United States, will take place in the second half of the year. Foreign manufacturers are also concerned that delays in inspections due to COVID-19 could negatively impact their ability to obtain the GMP certificate. By contrast, inspectors for human pharmaceuticals are reportedly conducting inspections virtually during COVID-19.

Among the most common non-compliances, VGNKI points out at the following ones:

1. Validation of processes carried out under aseptic conditions does not include modeling of the process using a nutrient medium (filling with nutrient media). The requirements for validating MFT aseptic processes are not met: 1) not all interventions that may occur during a routine production, as well as "the worst case scenario", are modeled during MFT; 2) the frequency of MFT and participation of operators is not observed.
2. During production of sterile medicinal products, the frequency of particle monitoring in clean areas is not observed. No microbiological monitoring in all the prescribed ways is carried out during aseptic processes.
3. Validation of processes is not performed on three consecutive series (cycles), during which the parameters should be observed within the specified limits.
4. Lack of cleaning validation of labware and production equipment in contact with the product.
5. The time and temperature of thermo labile medicinal products for veterinary use outside the established storage conditions are not determined.
6. The storage conditions (temperature, humidity) for raw materials, packaging materials and finished products set by the manufacturer are not met or are not properly monitored.
7. Storage of control samples of each batch of raw materials, packaging materials and finished products is not organized. The number of control samples is insufficient two complete analytical tests of the product series.
8. Control samples do not provide a representative sample of a series of raw materials.
9. Archived samples do not represent a series of ready-made medicines in the form in which they are sold in the Russian Federation.
10. Control methods used in quality control laboratories do not meet the requirements of the registration dossier for the declared medicinal products for veterinary use.
11. Series of drugs in each existing dosage and in each existing type of primary packaging for further stability studies are not provided. The program for subsequent stability studies does not include unpackaged products that are stored for a long time before being transferred to packaging.
12. Lack of control of outsourced activities.

1.4. Amendments to the Technical Regulations of the Customs Union “On Food Safety”

The EAEU published on January 13, 2020, Decision of the EEC Council No. 115 of 08.08.2019 “On Amending the Technical Regulations of the Customs Union “On Food Safety” (TR CU 021/2011)¹⁷.

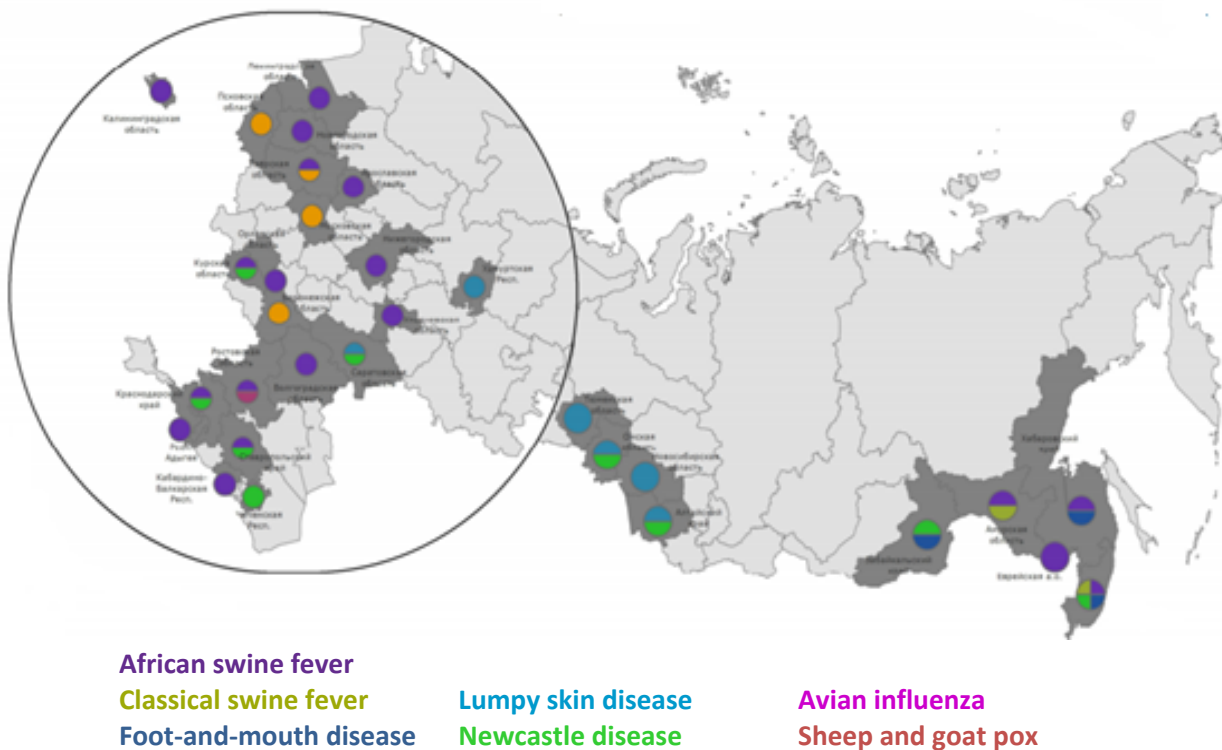
The document clarifies the requirements for unprocessed food raw materials of animal origin intended for the production of food products; prohibits the circulation of poultry meat, rabbits and horsemeat treated with ionizing radiation, and the circulation of any raw material treated with dyes, flavors or ultraviolet rays; clarifies the requirements for unprocessed food raw materials from productive animals that were exposed to veterinary drugs; eliminates the requirement for the antibiotic "grisin"; adds the new items to the list of plants and their processed products containing psychotropic, narcotic, potent or toxic substances. The document becomes effective July 11, 2020.

2. EPIZOOTIC SITUATION IN RUSSIA

2.1. Epizootic situation in 2019

In December 2019, VPSS notified the OIE about a total of 141 outbreaks of African Swine Fever (ASF), seven outbreaks of classical swine fever, 29 outbreaks of lumpy skin disease, 13 outbreaks of sheep and goat pox and 17 outbreaks of Foot and Mouth Disease (FMD), 18 outbreaks of Newcastle disease and 2 outbreaks of highly pathogenic avian influenza¹⁸.

Fig.2. Epizootic Situation in the Russian Federation in 2019



Source: VPSS

¹⁷ <http://base.garant.ru/73399079/>

¹⁸ <http://www.fsvps.ru/fsvps/news/33688.html>

Table 1. Number of outbreaks of animal diseases in Russia Federation in 2019, by region

No	Disease	Total outbreaks	Region of the Russian Federation
1	African Swine Fever	141	Kaliningradskaya region Khabarovskiy territory Leningradskaya region Krasnidarskiy territory Kabardino-Balkarskaya republic Rostovskaya region Republia Adygeia Novgorodskaya region Volgogradskaya region Nizhegorodskaya region Primorskiy territory Tverskaya region Ulyanoskaya region Amurskaya region Kurskaya region Yevreiskaya autonomous region Saratovskaya region Stavropolskiy territory Orlovskaya reion
2	Classical Swine Fever	7	Primorskiy territory Saratovskaya region Amurskaya region
3	Food and Mouth Disease	17	Primorskiy territory Khabarovskiy territory Zabaikalskiy territory Udmurtskaya republic
4	Lumpy skin disease	29	Udmurtskaya republic Saratovskaya region Novosibirskaya region Omskaya region Tyumenskaya region Altai territory Omsk region
5	Sheep and goat pox	13	Moscow region Tver region Voronezh region Pskov region
6	Newcastle disease	18	Krasnodar region Chechen republic Stavropol territory Saratov region Altai territory Zabaiskasky territory Omskaya region

			Kurskaya region Primorsky Territory
7	Highly Pathogenic Avian Influenza	2	Rostov region

Source: VPSS

In 2019 Russia registered 144 foci of African Swine Fever - 65 in wild boars and 79 in domestic pigs in 20 regions – which is serious increase compared to the number of outbreaks in 2018 (55 and 54 correspondingly).

There was a particularly serious spread of ASF in the Russian Far East (RFE) in the second half of 2019, according to the Permanent Anti-Epizootic Commission of the Government of the Russian Federation. In the first half of 2019, only one new ASF outbreak was recorded in domestic pigs in the Rostov Region. According to VPSS, eight ASF outbreaks in wild boars were registered in Primorsky Territory; four in the Jewish Autonomous Region, the last of which was on November 26, 2019. On July 31, 2019, ASF was detected at the border district of Primorsky territory, close to an automobile crossing with China. The source of infection could have been not only migrating wild boars, but also food products from China. In August, the virus spread to several areas of the RFE. VPSS reported 15 active outbreaks in the RFE by the beginning of November 2019: eight in the Jewish Autonomous Region (including seven in backyard farms) and seven in Primorsky territory (four in backyard farms).

Outbreaks of ASF were also recorded in several regions of the Central Federal District during the year. These outbreaks including the detection of finished products infected with the ASF virus. The virus genome was detected in sausage products from the company Itera JSC, in the Kaluga Region. The infected products had already been sent to 39 regions of the country. This company reportedly used “gray” schemes for purchasing raw materials, which some suspect could have been at the root cause of the infection. In addition, the press service of the Novgorod government reported the detection of ASF in the Volotov and Soletsky districts of the Novgorod oblast on December 7, 2019.¹⁹ The infection was detected in two boars in the local hunting area. Restrictive measures were to last until February 7, 2020, but the regional emergency commission decided to lift the quarantine ahead of schedule, due to the lack of infection, the statement said.²⁰

Another hot topic of discussion of the Permanent Anti-Epizootic Commission was the lack of actions of local authorities to reduce the number of wild boars. According to VPSS, Russia has not been effective in reducing the number of wild boars in several regions. It was also noted that VPSS conducted large-scale ASF monitoring among wild boars in 2019. As of November 25, 2019, 24,652 samples had been taken of which 79 tested positive for ASF. The number of wild boars was reduced to the established maximum indicators in a number of Belgorod, Kursk, Voronezh, Tambov and Lipetsk regions.

2.2. Epizootic situation as of end of April 2020²¹

In January-May 200, Russia registered the following animal diseases

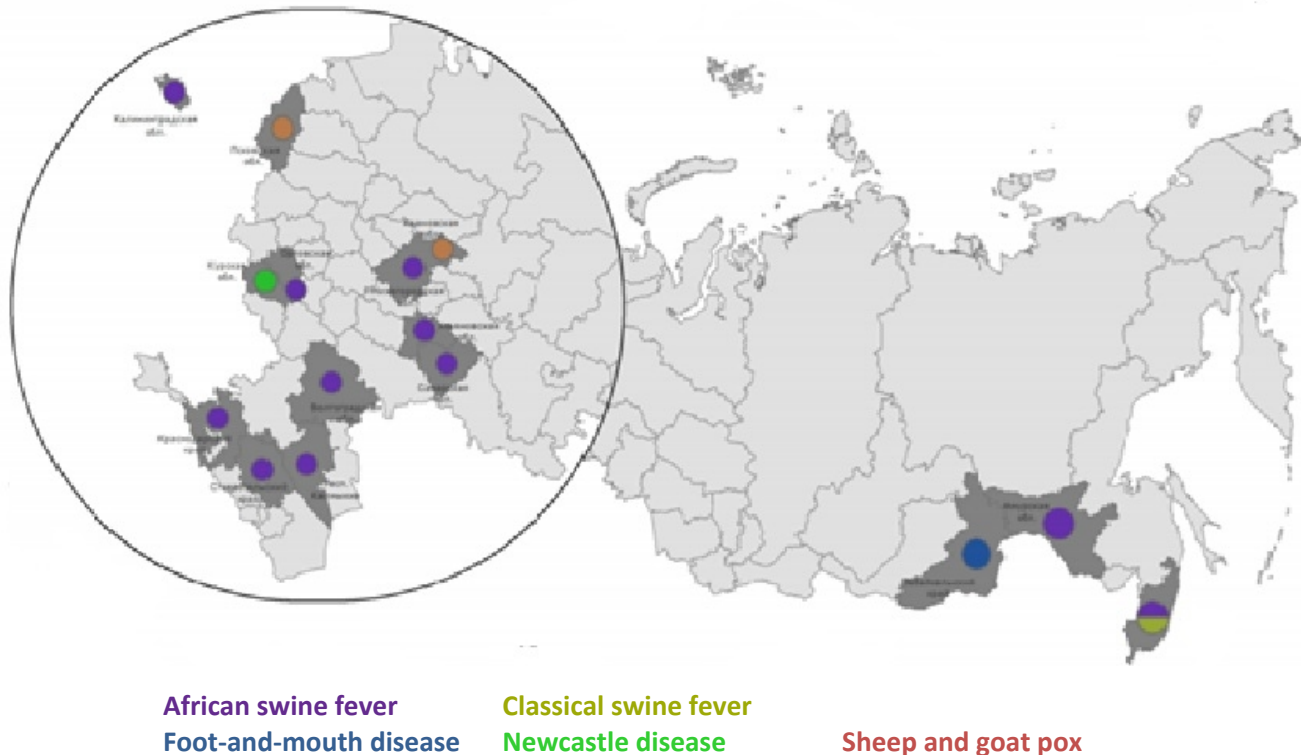
- African Swine Fever: 32 new cases (26 in wild boars and 6 in domestic pigs) in 12 regions. In eleven locations the disease has not been eradicated since 2019.
- Newcastle disease: three cases in Kursk region
- Sheep and goat pox: two cases – in Pskovskaya and Ivanovskaya regions.
- Classical swine fever (CSF): four cases in wild boars in Primorsky Territory.
- Foot and mouth disease (FMD): one case in cattle in Zabaikalsky Territory

¹⁹http://soyanews.info/news/karantin_po_ach_s_dosrochno_otmenili_v_dvukh_rayonakh_novgorodskoy_oblasti.html

²⁰<https://yaroslavl.meatinfo.ru/news/virus-afrikanskoy-chumi-sviney-viyavlen-u-403786>

²¹<http://www.fsvps.ru/fsvps/iac/af/maps.html>

Fig. 2. Epizootic Situation in the Russian Federation in Jan-May 2020



Source: VPSS

2.2.1. Spread of African swine fever (ASF) in 2020

The situation with ASF in Russia from the beginning of 2020 remains tense. A significant number of outbreaks were observed in different regions of the country. There were a total of 25 findings of ASF, including 21 among wild boars and four among domestic pigs in 10 regions of the Russian Federation.

Several cases of ASF have been registered in Stavropolskiy Territory since the beginning of the year.²² In early January, in the village of Pokoynoye in the Budennyovskiy district, ASF was detected in one of the private households (several pigs died from the virus). There were 406 head of swine in this territory, which were destroyed. Owners of the destroyed animals received compensation from the regional reserve fund. The preliminary amount of compensation was estimated at RUR 2.2 million (USD 34,900). On January 14, the territorial veterinary department recorded a mass death of pigs on a farm near the village of Ptichye, Izobilnenskiy urban district. It turned out that the farm owner was burying the dead animals in the nearest forest.

In early February, in the Trunovskiy district of the Stavropol Territory (at a dump near the village of Bezopasnoye), the region's veterinary department discovered carcasses of pigs infected with ASF. The virus was detected in a private farm in the same area in October 2019. More than 5.5 thousand pigs were destroyed there. Three administrative cases have been filed against the owner of the swine farm for violations of quarantine rules in the Izobilnenskiy district of the Kray in mid-January 2020 for trying to cover up the outbreak

²²http://soyanews.info/news/na_stavropole_obnaruzhen_tretiy_za_mesyats_ochag_chumy_sviney.html

of the ASF, reports the Regional Information Policy Office²³. Cases were filed for concealment of information about sudden death or simultaneous mass diseases of animals, as well as violation of veterinary and sanitary rules for the collection, disposal and destruction of biological waste. The owner buried the corpses of the dead animals in a nearby forest strip without any permission to do so.

In the Samara region²⁴, according to the local VPSS Directorate, several cases of ASF were detected in the territory of the Koshkinsky district in January and February 2020. More than 200 domestic pigs were destroyed in 11 settlements there. Another outbreak of ASF was registered in the Krasnoyarsk district, where five wild boars were killed.²⁵

As of the end of April 2020, 39 outbreaks remained not eradicated (including 18 from 2019).

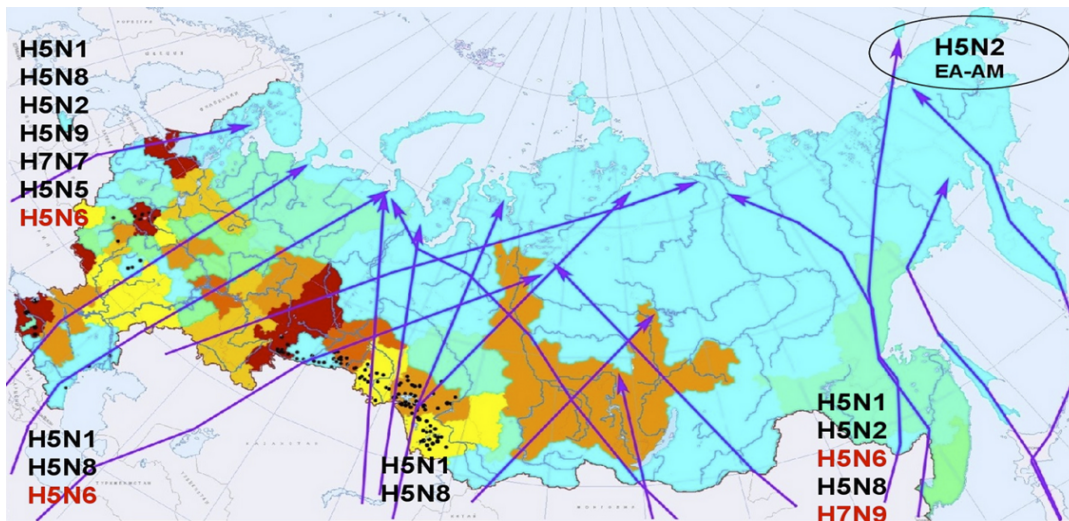
2.2.3. Situation with Avian Influenza

According to the Federal Center for Animal Health (ARRIAH), the highly pathogenic avian influenza (HPAI) situation in Russia in 2019 was stable, with no outbreaks and few findings during monitoring of wild birds. ARRIAH experts believe that the HPAI wave which hit Russia in 2016-2018 (H5N8 and H5N2) covered much less territory than the one of 2005-2008 (H5N1), but caused much more serious losses of poultry flocks, especially in the industrial sector. In total, in 2016-2019 15 poultry farms depopulated 6 million birds, while in 2005-2008 Russia lost only 2.8 million.

Two major outbreaks of HPAI in Rostov region at Evrodon turkey complex, which affected both commercial birds and breeders, led to a complete stamping out of the flocks, closure of the company and its bankruptcy.

Despite the normalization of the HPAI situation in the second part of the year, the VPSS points out at serious risks for more outbreaks due to the proximity of HPAI outbreaks in Eastern Europe (Hungary, Ukraine, Romania, Poland) and China.

Figure. Potential risks of AI outbreaks in Russia caused by migrating birds in 2020, by strain.



Source: ARRIAH

²³ http://soyaneews.info/news/na_stavropole_vozbudili_administrativnye_dela_iz-za_popytki_skryt_vspyshku_achs.html

²⁴ <https://samara.meatinfo.ru/news/na-severe-samarskoy-oblasti-obyavlena-chrezvichaynaya-404370>

²⁵ http://soyaneews.info/news/v_samarskoy_oblasti_obnaruzhili_novyj_ochag_afrikanskoy_chumy_sviney.html

In 2019, the Russian poultry industry suffered a higher occurrence of low pathogenic avian influenza. The H9N2 strain was detected in Nagaibaksky and Magnitogorsky poultry farms in Chelyabinsk region and Perm Krai in 2019 and 2020. ARRIAH warns that in 2020 the threat of H5N6 and H7N0 HPAI is still extremely high, especially considering the expansion of new outbreaks in Eastern Europe and continuous outbreaks in Asia.

2.3. Official status and regionalization for particularly dangerous animal diseases

According to the national project (program) "International Cooperation and Export",²⁶ for 2018-2024, Russia expected to receive official recognition by the OIE of Russia as a country/zone/compartiment free from foot and mouth disease, spongiform encephalopathy of cattle, plague of small ruminants and contagious cattle pleuropneumonia by June 15, 2020. As of the date of this report, the OIE website does not reflect the update for FMD but it does list Russia as free from plague of small ruminants.

On May 20, 2019 Russia restored its OIE status as a country with a zone free from FMD without vaccination, the Head of VPSS said, summing up the work of the service in 2019²⁷. As a result, several regions of Russia, where there are no hotbeds of this disease and no vaccination against it, have been able to expand the exports of livestock products. VPSS has also sent dossiers to the OIE in May 2019 to obtain the status of a country free of the contagious pleuropneumonia of cattle and the plague of small ruminants. Russia received a negative conclusion on its BSE dossier sent to the OIE and started implementing corrective actions.

Hong Kong, Brazil and Vietnam recognized the regionalization of Russia in ASF and FMD.

Saudi Arabia, the United Arab Emirates, Qatar, Kuwait Bahrain, Azerbaijan, Iraq, Iran and Hong Kong recognized the regionalization of Russia for HPAI in 2019.

The Committee on Animal Health of Japan on January 31, 2020, decided to recognize HPAI regionalization in two regions of Russia (Bryansk and Tula).²⁸ As a next step, Japan will send to VPSS its draft veterinary requirements for the supply of poultry meat from Russia to Japan for their further verification of adherence.

3. EXPORTS

The Ministry of Agriculture has published a report on the opening of new markets to increase the volume of agricultural exports. According to the report, in 2019 beef was supplied to 14 countries, pork to 16, poultry to 29, ready meat products to 21, small ruminants' meat to two countries and dairy products to 29 countries. In addition, in 2019 Russia obtained the right to supply poultry, pork and beef as well as by-products to Hong Kong; poultry, pork and beef to Venezuela; pork to Cuba; poultry to the Philippines; beef to Brazil; live small ruminants and lamb to Iran; fish meal, straw and heat-processed by-products to Japan; dairy and egg products to Tunisia; genetic materials and live chickens to the UAE; poultry meat to Singapore; rabbits to Korea; dairy products and live horses to Turkey; pork to Vietnam and beef to Morocco. (Please see Section 3.3 for details.) VPSS believes that it is important not only to open new markets, but also to maintain the share of exports in the existing ones.

3.1 Certificates of health for exported agricultural products

The Ministry of Agriculture is developing proposals to authorize VPSS to issue health certificates for exported agricultural products that would comply with form CAC/GL 38-2001 recommended by Codex Alimentarius²⁹. So

²⁶ <http://mineco.e-mordovia.ru/upload/medialibrary/f59/f5988f5671068e3c3f445e7ff589ea3f.pdf>

²⁷ <http://www.fsvps.ru/fsvps/news/33552.html>

²⁸ <http://www.fsvps.ru/fsvps/news/34047.html>

²⁹ <https://www.dairynews.ru/news/rosselkhoznadzor-mozhet-poluchit-polnomochiya-po-v.html>

far, VPSS officially has no such authority, although veterinary and quarantine certificates issued by it basically are similar to health certification.

3.2 Accompanying documents for exporting goods

VPSS has developed several proposals to simplify the procedures related to the issuance of veterinary documents accompanying exported goods controlled by veterinary supervision. This refers to the cancellation of export veterinary certificates for breeding material, meat and meat products, raw materials of animal origin and poultry eggs, if the importing country does not require this.

3.3. New veterinary agreements with other countries and export audits

In 2019, Russia obtained the right to export various types of livestock products to 17 countries, according to a VPSS report.³⁰

In 2019, a total of 21 veterinary delegations visited Russia: the EU (4), Japan, Georgia, Republic of Korea, Venezuela, Moldova, Mongolia (2), Azerbaijan, Kyrgyzstan, Armenia, Thailand (2), China, Uzbekistan (2), New Zealand and Vietnam. Representatives of competent authorities visited 65 Russia enterprises including potential exporters of livestock products, 17 of which became eligible to exports to new destinations.

In October 2019, the Department of Animal Health (DAH) of Vietnam and VPSS agreed on a simplified procedure for the consideration of DAH dossiers to evaluate Russian enterprises. In November 2019, VPSS confirmed it could comply with the DAH the conditions for the supply of Russian pork and pork offal to the Vietnamese market and signed the corresponding veterinary certificate. Initially, three beef processing plants, 11 poultry meat and three pork producers were certified for supplies to Vietnam in 2019. On December 20, 2020, the DAH approved for export three more Russian enterprises (one pork plant and two poultry plants).

In 2019, the Veterinary service of Hong Kong approved three Russian beef, 17 poultry and 15 pork processing plants to export to Hong Kong.

Also, in October 2019, Russia and the Kingdom of Saudi Arabia (KSA) signed a Memorandum on the mutual expansion of exports of agricultural products and food. According to this document, bilateral trade will increase deliveries of live animals and livestock products (poultry, beef, lamb, eggs) from Russia as well imports of Saudi products into Russia. At the same time, the KSA authorities lifted the ban on imports of eggs and chickens from Russia introduced earlier for highly pathogenic avian influenza (HPAI).

VPSS and the Veterinary Quarantine Department of the Ministry of Agriculture and Fisheries of Oman agreed in January 2020 on a veterinary certificate for exports of milk and dairy products obtained from cattle and small cattle to Oman.³¹

Japan completed a risk assessment of Russian poultry products and recognized the Bryansk and Tula regions free of highly pathogenic avian influenza on January 31, 2020.³² The Krasnobor agricultural holding, one of the leaders of the Russian turkey meat market, became the first Russian turkey producer to receive certificates in August 2019 for the supply of smoked turkey meat and sausages to Japan.

In December 2019, VPSS discussed with the Republic of Congo cooperation in agriculture. The Ministry of Agriculture of Congo showed interest in organizing the industrial production of poultry meat, creating a

³⁰ <http://www.fsvps.ru/fsvps/news/33552.html>

³¹ <https://sfera.fm/news/v-strane/rossiya-nachnet-postavlyat-moloko-v-oman>

³² <http://www.fsvps.ru/fsvps/news/34047.html>.

laboratory base for monitoring safety and quality of products of animal origin. VPSS asked their Congolese colleagues to agree on bilateral veterinary certificates for exports to the Republic of beef, pork, poultry meat, meat offal, ready meat and dairy products, eggs and egg products and submitted finalized draft of the relevant documents for signing by their competent Supervisory Service.

The veterinary service of Cuba certified 16 Russian enterprises in October 2019 for exports of beef, poultry, processed meats, milk and dairy products after the approval of veterinary certificates.

VPSS informed the Ministry of Agriculture of Indonesia in November 2019, that it was awaiting approval of certificates for the export of Russian products, namely: poultry, finished meat products, table eggs and processed egg and other food products. VPSS is still awaiting feedback on its completed questionnaire and application form for exports, presented to Indonesian veterinary service.

In December 2019, VPSS discussed with representatives of the South Korean Ministry of Agriculture the terms of access for the Russian poultry exporters to the Korean market considering that the whole territory of Russia has been free from HPAO since August 20, 2019.

The Head of VPSS and the Minister of Agriculture of Moldova discussed in January 2020 issues related to bilateral supplies of plant and livestock products. VPSS notified the Minister of Russia's interest in seriously expanding the list of enterprises approved to export to Moldova and announced its readiness to receive Moldovan veterinary inspectors to audit Russian companies.³³

As a result of the inspection conducted by Mongolian veterinarians in November 2019, the list of the Russian pork companies eligible for exports to the Mongolian market was been expanded to ten.³⁴

In July 2019, representatives of VPSS and of the Ministries of Trade and Agriculture of Turkey discussed issues related to the mutual supply of poultry. The parties agreed on further cooperation in the field of livestock products trade.

VPSS and the Ministry of Agriculture of India discussed on December 11 agricultural trade issues, including Russia's intention to supply poultry meat to India and the signing of relevant veterinary certificates. The Indian side expressed interest in expanding the list of enterprises authorized to export poultry products to their country.

According to the results of the inspection of Russian enterprises for the production of animal products conducted by specialists of the veterinary service of Georgia, three Russian companies producing beef, pork, poultry, located in the Bryansk and Belgorod regions, received the right to supply their products to Georgia.³⁵ Since Georgian legislation allows imports of processed (cooked) meat products from Russia without additional inspections by the Georgian veterinary service, several Russian meat processors that passed VPSS audits for compliance with Georgian requirements were included in the list of eligible exporters to Georgia.

3.3.1. "Opening" of the Chinese market for poultry and negotiations on pork

For many years, China did not allow Russian meat products to enter its market. In November 2018, the countries agreed on reciprocal supplies of poultry meat, while pork is still banned. Following several problems at Chinese customs with the first shipments of poultry products from Russia, VPSS and the Main Customs Directorate (GTU) of the PRC discussed in Beijing on July 9, 2019 the procedure for exports of Russian poultry products to China, including the procedures for issuing veterinary certificates and changes to the lists of eligible Russian facilities.

³³ <http://www.fsvps.ru/fsvps/news/33790.html>

³⁴ <http://www.fsvps.ru/fsvps/news/33762.html>

³⁵ <https://www.tks.ru/news/nearby/2019/11/25/0004/print>

As a result, after a fifteen-year break, China approved a list of Russian enterprises allowed to supply poultry to their market resulting in exports of 60,000 tons of poultry meat and poultry products from Russia in 2019. That list was expanded in early 2020, from 44 to 55 facilities.

According to VPSS, China has expressed readiness to import pork from Russian regions free of ASF provided its safety can be verified. The Russian side, in turn, offered to organize another visit of Chinese specialists to visit several pork processing enterprises and familiarize themselves with the existing measures of control. In addition, according to the press service of the Ministry of Agriculture, it is necessary to resolve the issue of recognition by China of the principles of regionalization of Russia for various animal diseases, including ASF.

The presence of ASF continues to affect the ability of Russian companies to export to China and other markets³⁶

3.3.2. Deliveries of livestock products allowed through China's railway crossing points

After negotiations between VPSS and the General Customs Office of the People's Republic of China on February 18, 2020, exports of Russian animal products by rail are not authorized.³⁷ Deliveries can be made through China's railway crossing points (Alashankou, Horgos, Baktu, Manchuria, Erlyan-Hoto, Suifenhe) with veterinary control at the final destinations, the cities of Chongqing and Chengdu.

3.3.3. Exports of beef to China

On January 17, the GTU of the PRC approved a bilateral Protocol with VPSS regarding inspection, quarantine and veterinary and sanitary requirements for beef exported from the Russian Federation to the China, as well as the corresponding certificate.³⁸ The signing of the protocol was preceded by a lengthy procedure for assessing the Russian beef surveillance system, as well as agreeing on the text of the protocol. Russian meat processing plants are ready to supply both premium beef for European-style Chinese restaurants and meat from a more affordable segment, according to the National Meat Association of Russia.³⁹ The PRC certified two Russian enterprises for the supply of beef - Zarechnoye and the Bryansk Meat Company (part of Miratorg). The Zarechnoye company started seeking partners in China to supply its products, the Head of the company said, adding that Russian beef will be in demand, as it is of premium category, while suppliers from South America export more mass and inexpensive products. Russian meat will also be able to compete in the Chinese market with American and Australian suppliers, Andrey Nitsenko, CEO of Prime Food, the official distributor of Zarechnoye company, said.

4. OTHER VETERINARY AND PHYTOSANITARY ISSUES

The Ministry of Agriculture plans to expand the list of contagious diseases, including highly dangerous animal infectious diseases that can be quarantined.⁴⁰ A draft order developed by the Ministry stresses the need to “harmonize the veterinary legislation of the Russian Federation with the legislation of the Eurasian Economic Union” and to ensure the epizootic well being of the Russian territory. The following infectious diseases are

³⁶ <https://www.agroinvestor.ru/markets/article/33172-kogda-svinina-poedet-v-kitay-potentsial-eksporta-v-knr-otsenivaetsya-v-350-tysyach-tonn/>

³⁷ <http://www.fsvps.ru/fsvps/news/34318.html>

³⁸ <http://www.fsvps.ru/fsvps/news/33807.html>

³⁹ <https://ria.ru/20200123/1563738033.html>

⁴⁰ http://soyanews.info/news/minselkhoz_rasshirit_spisok_podkarantinnykh_zaraznykh_bolezney_zhivotnykh.html

planned to be included on the list: anaplasmosis, goat arthritis/encephalitis, contagious pleuropneumonia of cattle, contagious pustular dermatitis (ecthyma), pullurosis-typhus of birds, trichomoniasis and camel plague. Public comments period on the draft started on January 28, 2020.

Members of the Agrarian Committee of the State Duma of the Federal Assembly of the Russian Federation met the OIE Deputy General Director Jean-Philippe Dop, Advisor to the OIE General Director Romano Marabelli and the Head of the OIE Regional Representative Office in Moscow Budimir Plavsic. The parties discussed issues related to compliance with OIE standards, ensuring the epizootic wellbeing of the country and safety of livestock products. OIE representatives stressed the need for early adoption of amendments to the Russian legislation in the field of veterinary medicine regarding the introduction of a unified system of animal identification. It was noted that this is a key point in the system of traceability of food products, which allows proper planning preventive measures for infectious diseases and successfully eliminating them in case of their occurrence and spread. In addition, the presence of animal identification and traceability systems is a prerequisite for the OIE to obtain a country's official international status of controlled risk for bovine spongiform encephalopathy (BSE). OIE experts also noted the need to implement a unified monitoring system for the use of veterinary drugs as one of the most important elements for ensuring food safety.

Attachments:

No Attachments.