# ALRUD

# Legal Regulatory Guide Russia

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## Introduction

#### Dear Readers,

In today's fast-paced business landscape, it is crucial to stay abreast of the latest regulatory changes. We are pleased to present our Legal Regulatory Guide for the second half of 2024, an essential resource for companies in Russia navigating through the regulatory landscape at the international level. It covers the most significant and comprehensive regulatory insights for Russia and the Eurasian Economic Union (EAEU) for our clients.

This edition of the guide includes descriptions of several key themes in the fields of technology, media, and telecommunications (TMT), life science and pharmaceuticals, consumer goods, agriculture and general regulations. More specifically:

- Regulations are constantly amended to address the rapid development of the TMT sector, including the ongoing deepening of cryptocurrency regulation. Understanding the regulatory framework governing these sectors is necessary for both companies looking to innovate and expand their digital footprint and companies using the outcomes of digital transformation in their daily business activities (please refer to TMT section for more details).
- This Guide also addresses regulatory updates in the life sciences and pharmaceutical sectors including medicines, medical devices, dietary supplements and veterinary medicines. This guide will help businesses understand how to conduct pharmaceutical business in Russia without interruption as the regulatory requirements change (please refer to <u>Life Science</u> and <u>Pharmaceuticals section</u> for more details).

- Additionally, for many companies, it is important
  to remain alert to the regulations of consumer
  goods relevant to their particular business. The
  rules for trading potentially harmful goods for
  human health are gradually tightening and
  moving towards support for environmental
  initiatives and environmental protection as well
  as the protection of consumers in terms of how
  purity is defined for organic products (please
  refer to Consumers goods section for more
  details).
- Meanwhile, Russian legislators are focused on ensuring the country's food security, including agriculture, while maintaining their pace in protecting the domestic market from certain imported goods (please refer to <u>Agriculture and</u> <u>General Regulations section</u> for more details).

We sincerely hope that this guide will allow the reader to better understand the changes in the Russian regulatory landscape and will serve as an indispensable key to expanding business opportunities amidst the rapidly changing regulatory trends.



Maxim Alexeev
Senior Partner
Head of Private Clients
and Tax practices, Business
Regulation (Regulatory)

E: MAlekseyev@alrud.com



Boris Pribylov
Senior Associate
Corporate/M&A, Business
Regulation (Regulatory)
E: BPribylov@alrud.com



## **TMT**

## Changes in telecommunications licensing in Russia: the future of VoIP services

On 26 December, 2024 the Government of the Russian Federation made changes to the list of telecommunications services subject to licensing<sup>1</sup>. From September 01, 2025 data communication services for voice transmission are excluded from the list of telecommunications services. In Russia, the holders of such telecommunications licenses are generally providers of Voice over Internet Protocol (or VoIP) services or IP telephony services. According to the Government's official statements, the amendments were made to the list of telecommunications licenses to limit telephone fraud, including Caller ID spoofing attacks.

Once Decree No. 1898, which introduces the amendments is in force (i.e., from September 01, 2025), telecommunications services providers have 1 year to apply to the licensing authority (The Federal Service for Supervision of Communications, Information Technology and Mass Media, or Roskomnadzor) to change the title of their telecommunications services licenses from "data communication services for the purpose of voice transmission" to "local telephone communication services, except for local telephone communication services using payphones and means of collective

access" or "data communication services, except for data communication services for the purpose of voice transmission". If the holder of the license for data communication services for voice transmission fails to submit such an application to Roskomnadzor in time, the said license will be terminated. Roskomnadzor changes the license title without an assessment of the license holder's compliance with the licensing terms for the type of replacement license chosen by the applicant or the payment of the fees to the state. Roskomnadzor will consider the application within five business days.

According to the regulator's position<sup>2</sup>, the use of IP telephony is not prohibited, and such services will continue to be provided. The provision of such services will be regulated as telephone communication services, and the respective license is required. Meanwhile, the Russian authorities also noted that calls between the users via messengers (such WhatsApp, Viber, Telegram etc.) without access to a fixed or mobile telephone network (i.e., exclusively via the Internet) are not covered by such regulatory changes.

<sup>1</sup> The changes were introduced by the Decree of the Government of the Russian Federation No. 1898, of 26 December, 2024, "On the Introduction of Amendments to Certain Acts of the Government of the Russian Federation" (Decree No. 1898).

<sup>2</sup> The Ministry of Digital Development, Communications and Mass Media of the Russian Federation; the statement is available via the Ministry's official telegram channel (in Russian only).



On a separate note, on January 09, 2025 the Government of the Russian Federation officially published the concept of a state system for countering unlawful acts committed through information and telecommunication technologies<sup>3</sup>. Inter alia, it declares that the introduction of new types of services (IP-telephony, virtual automatic telephone exchanges) on the telecommunications market should be preceded by normative regulation thereof to reduce the risks of anonymisation of the actual consumer. Thus, we can expect some other regulatory changes and

increased governmental control with respect to IP telephony / VoIP services in the future.

At present, we consider it reasonable for the telecommunications providers rendering IP telephony / VoIP services to consider whether it is necessary to apply to Roskomnadzor in light of the legislative amendments described and whether any gap-filling compliance measures need to be implemented to meet Russia's regulations for telephone services.

### New Russian telephone services regulations in 2025

At the end of 2024, the Government of the Russian Federation issued an updated version of the telephone services regulations by adopting the Decree of the Government of the Russian Federation dated 30 December No 1994, "On Approval of the Rules for the Provision of Telephone Communication Services and the List of Organisations Entitled to Confirm Information on Subscribers - Natural Persons" (the "Telephone" Services Rules 2025"). It regulates relations between a subscriber or user of telephone communication services and a provider of local, intrazone, long-distance and international telephone communication services in the public communications network, as well as when providing mobile radio communication services, mobile radio-telephony services, or mobile satellite radio communication services in the public communications network.

Decree No. 1994 replaces the previous version of the telephone services regulations provided by Decree No. 59 dated 24 January, 2024 (the "Telephone Services Rules 2024").

The 2025 Telephone Services Rules are in fact very similar to the 2024 Telephone Services Rules. Nevertheless, the updated version obliges telecommunication services providers, prior to the commencement of telecommunication services, to verify information about a subscriber and the total number of subscriber numbers issued. The verification procedure is stipulated in the 2025 Telephone Services Rules.

In this regard, the updated regulations contain the list of organizations entitled to verify individual

subscribers (natural persons) of telephone services in Russia. This includes companies that qualify as backbones of the Russian economy related to the telecommunications industry, systemically important credit institutions, multifunctional centres for the provision of state and municipal services, and mobile service providers meeting specific strict requirements under the 2025 Telephone Services Rules.

Additionally, the 2025 Telephone Services Rules include the following innovations in the regulation of telephone services:

- A) A telecommunications services provider now bears statutory obligation for notification in relations with subscribers when it has grounds to suspend or terminate a contract with such a subscriber;
- B) A subscriber may obtain information about its phone numbers and telephone services contracts with providers via the Gosuslugi portal<sup>4</sup>;
- C) A telecommunications services provider is obliged to record (electronically) and store information on subscribers' actions for 5 years (the previous term was 3 years);
- D) The fee for a tariff plan change is not to be charged from the subscriber if more than one month has passed from the date of the tariff plan change.

The 2025 Telephone Services Rules are expected to be valid until 31 December, 2030.

<sup>3</sup> Order of the Government of the Russian Federation No. 4154-r, of 30 December 2024.

# The regulatory framework for cryptocurrency mining in Russia

Starting from November 01, 2024 stricter regulatory restrictions came into force for cryptocurrency mining in the Russian Federation. Amendments were made to a number of legislative acts, including the Russian law on the electric power industry, by adopting Federal Law No. 221, dated 08 August 2024, and Federal Law No. 349-FZ, dated 25 October 2024.

Under the new regulations, such mining is the performance of mathematical calculations through technical and appliance means for making records in an information system including the use of distributed register technology, with the purpose of issuing digital currency (i.e., cryptocurrency under Russian law) and (or) receiving remuneration in digital currency for the confirmation of records in the information system by the party performing such an activity. Cryptocurrency mining activities in Russia may be conducted by legal entities and individual entrepreneurs subject to registration in a special register maintained by the Federal Tax Service of Russia (the Register and the FTS of Russia respectively)5. The violation of Russian antimoney laundering laws or any specific regulatory requirements for cryptocurrency mining may be legal grounds for exclusion from the Register<sup>6</sup>.

Natural persons may conduct cryptocurrency mining without registration with FTS of Russia if they do not exceed the energy consumption limits stipulated by Decree of the Russian Federation No. 1469 dated 01 November, 2024. The Government of the Russian Federation, in agreement with the Bank of Russia, has the right to establish other requirements for cryptocurrency mining in Russia.

Similar requirements have been established for the operators of mining infrastructure, i.e., facilities used to accommodate the technical and appliance facilities used for cryptocurrency mining, including engineering and technical support (power supply), and (or) the technical and software-hardware means specified (for instance, the operators may be data processing centers or hosting providers).

Such operators will also be included in the FTS of Russia's Register, and they are not allowed to provide services to cryptocurrency miners not listed in the Register. The regulations specific to the operators of mining infrastructure are stipulated in Decree of the Government of the Russian Federation No. 1463, dated 31 October, 2024, "On the Approval of Requirements for the Activities of a Mining Infrastructure Operator", including requirements particular to personnel and certain processes.

The new regulations also introduce the notion of a mining pool, which is the combined capacities of several technical and appliance means belonging to different owners (mining pool participants) and used to mine digital currency (cryptocurrency), as a result of which the digital currency (cryptocurrency) issued (received) is distributed among the participants of the mining pool. The operators of mining pools are not obliged to be included to the Register unless they conduct the mining themselves. Nevertheless, there are certain restrictions on natural persons and legal entities operating mining pools. If such natural persons have committed certain economic crimes, crimes against the state, or money laundering crimes, or a decision to freeze (block) monetary funds or other property has been made in respect of them, they cannot operate mining pools. Legal entities are also not allowed to operate mining pools if they themselves or their founders (participants), beneficial owners, or sole executive body do not meet the requirements for business reputation. The same restrictions are generally applicable to cryptocurrency miners themselves and operators of mining infrastructure.

On a separate note, the Government of the Russian Federation now has the power to ban cryptocurrency mining (including participation in a mining pool) in certain regions of the Russian Federation or in certain territories thereof, as well as to specify the procedure and conditions for imposing such a ban. Currently, cryptocurrency

<sup>5</sup> The registration procedure is regulated by Decree of the Government of the Russian Federation oNo. 1464, of 31 October 2024, "On Approval of the Rules for Maintaining the Register of Persons Engaged in Digital Currency Mining and the Rules for Maintaining the Register of Mining Infrastructure Operators".

<sup>6</sup> Other legal grounds are provided in Decree of the Government of the Russian Federation No. 1462, of 31 October, "On Establishing Other Cases of Exclusion of an Entity Engaged in Digital Currency Mining (Including a Member of a Mining Pool) from the Register of Persons Engaged in Digital Currency Mining".

mining is banned in a list of Russian regions for a period defined for each group of such regions based on Decree of the Government of the Russian Federation No. 1869, dated 23 December, 2024, "On the establishment of a ban on the mining of digital currency (including participation in a mining pool) in certain regions of the Russian Federation and in certain territories of regions of the Russian Federation".

As such, a number of new requirements and regulations have come into force for the crypto mining industry in Russia. For all companies and entrepreneurs already active in the market (or planning to enter the market in Russia) we consider it reasonable to pay attention to these new regulations and ensure compliance to those applicable.

### The introduction of a utilization fee for foreign telecommunication equipment in Russia has been postponed

According to recent public statements from the Russian Minister of Digital Development, Communications and Mass Media and information in reputable mass media outlets, the Government of the Russian Federation has postponed the introduction of a fee for the use of foreign telecommunication equipment in Russia.

Previously<sup>7</sup>, this mechanism was expected to be a part of the strategy for the development of the telecommunications sector in Russia up to 2035 and should have served as one of the methods to finance support for the production and introduction of domestic telecommunications equipment. To expand support for the production and introduction of domestic telecom equipment, a proposal had been made to co-finance domestic developers' expenses for the development of such equipment, as well as to provide soft loans to domestic equipment manufacturers to stockpile components for the subsequent production of equipment.

Market participants feared that the introduction of such a measure would lead to a significant increase in equipment costs and a reduction in the quality of telecommunications services, therefore, the reaction of the business community to the initiative and the general unreadiness of the telecommunications equipment market may have inspired the Government's decision to postpone the introduction of the fee.

We continue to follow this matter and will keep you updated.



# Life Science and Pharmaceuticals

# A number of exemptions to the restrictive measures against Russia have been extended

### IMPORT AND SALE OF MEDICINES IN FOREIGN PACKAGING

Medicines in foreign packaging can be imported and sold in the Russian Federation without a special permit **until December 31, 2025**, in the event of a shortage of medicines or the risk of such an occurrence due to the restrictive economic measures placed on the Russian Federation. This assumes that the medicines comply with the requirements established during their registration, with the exception of the requirements for primary packaging, secondary (consumer) packaging, and if the secondary (consumer) packaging of the medicines has a self-adhesive label containing information about the medicine in Russian.

Legal acts: Resolution of the Government of the Russian Federation No. 593 of 05.04.2022 and Resolution of the Government of the Russian Federation No. 1964 of 28.12.2024.

## SIMPLIFIED PROCEDURE FOR STATE REGISTRATION OF MEDICINES AND MEDICAL DEVICES

Resolution of the Government of the Russian Federation No. 1851 of 21.12.2024 extended the simplified procedures for state registration of certain medicines and the most popular medical devices **until the end of 2027**.

The list of medicines and medical devices is determined by a special interdepartmental commission which includes representatives of the Ministry of Health, Roszdravnadzor, the Ministry of Industry and Trade, the Ministry of Finance, the Federal Antimonopoly Service, and the Federal Customs Service of the Russian Federation.

# Legal developments in the regulation of dietary supplements

### MANDATORY DIGITAL LABELING FOR A CERTAIN DIETARY SUPPLEMENTS

As Resolution of the Government of the Russian Federation No. 1680 of November 30, 2024, from March 01, 2025 mandatory labeling will apply to dietary supplements with certain HS codes.

Market participants will be required to apply means of identification to consumer packaging and submit information to the Chestny ZNAK System on the application of the means of identification, and the introduction into circulation, circulation, and withdrawal from circulation of the goods in accordance with Rules for labeling dietary supplements approved under Resolution of the Government of the Russian Federation No. 886 of May 31, 2023.

## EXPERIMENT TO MONITOR DIETARY SUPPLEMENT MANUFACTURERS THROUGH A LABELING SYSTEM

In accordance with Resolution of the Government of the Russian Federation No. 1607 of November 22, 2024, an experiment to monitor dietary supplement manufacturers through a labeling system will be launched for the period from March 01, 2025 to June 30, 2025. The experiment is being conducted for market participants on a voluntary basis.

During the monitoring, authorized bodies will evaluate the reliability of information about the manufacturing that companies and individual entrepreneurs enter into the Chestny ZNAK System.

#### BAN ON RETAIL SALE OF DIETARY SUPPLEMENTS BASED ON INFORMATION FROM THE CHESTNY ZNAK SYSTEM

In accordance with the Resolution of Government of the Russian Federation No. 1944 of 21 November 2023, **from November 01, 2024** in the following cases, it is forbidden to sell dietary

supplements at retail according to the following information from the Chestny ZNAK System:

- i. information on labeling is missing;
- ii. the product has been withdrawn from circulation;
- iii. the product has been banned or suspended for sale by decision of state monitoring (supervision) bodies,
- iv. there is no information on the introduction of the product into circulation;
- v. the product verification code does not correspond to the characteristics of the means of identification, including the structure and format established by the Rules for the Labeling of Dietary Supplements with Means of Identification, approved by Decree of the Government of the Russian Federation No. 886 of May 31, 2023.

# AGGREGATORS MAY BE REQUIRED TO CHECK THE ACCURACY OF INFORMATION ABOUT DIETARY SUPPLEMENTS

In December 2024, **bill** No. 794537-8 was introduced to the State Duma of the Russian Federation obliging aggregator owners to check the accuracy of information about the quality, composition, and manufacturer of dietary supplements. If inaccurate information is detected, the aggregator must suspend the sale of such products until the violations are eliminated. The bill is currently **under consideration**.

### UNIFIED EAEU RULES FOR LABELING DIETARY SUPPLEMENTS

The EEC Council established unified rules for labeling dietary supplements by Decision of the Council of the Eurasian Economic Commission No. 99 of September 24, 2024. EAEU member states

will be able to determine the date of introduction and stages of labeling in their country, and notify the commission no later than six months in advance.

### Mandatory digital labeling of veterinary medicines

In accordance with Resolution of the Government of the Russian Federation No. 675 of 27.05.2024, from October 01, 2024 mandatory digital labeling of veterinary medicines has been introduced.

Market participants must apply means of identification to consumer packaging and submit information to the Chestny ZNAK System on the

application of the means of identification, and the introduction into circulation, circulation, and withdrawal from circulation of veterinary medicines as per the Rules for Labeling Veterinary Medicines approved under Resolution of the Government of the Russian Federation No. 675 of 27.05.2024.

# Legal developments in the registration process for medical devices and medicines

### RECOMMENDATIONS FOR EAEU REGISTRATION OF MEDICAL DEVICES

The EEC Board approved new Methodological Recommendations on the content and structure of documents for the registration dossier of a medical device and the examination of its safety, quality, and effectiveness to register it under Recommendation No. 27 of 23.12.2024 instead of ECC Board Recommendations No. 14 of 21.05.2019 and No. 29 of 08.10.2019.

## NEW NATIONAL RULES FOR STATE REGISTRATION OF MEDICAL DEVICES

As per Resolution of the Government of the Russian Federation No. 1684 of 30.11.2024, the new national Rules for the state registration of medical devices have been approved and will **enter into force on March 01, 2025** to replace the rules approved under Resolution of the Government of the Russian Federation No. 1416 of December 27, 2012.

### NEW PROCEDURE FOR EAEU REGISTRATION OF MEDICINES

A) The Council of the Eurasian Economic Commission adopted a draft amendment to the Rules for the Registration of Medicines in the EAEU, introducing a procedure, at the initiative of the authorized body of a member state, for recognizing the registration of medicines in other member states to ensure a sufficient range of medicines in those member states that expect low sales volumes.

The new procedure can be applied by decision of the authorized body in the absence of registration of analogues of such medicine on the market of the state. Registration will be carried out on the basis of the examination conducted in the reference state.

B) New rules for the registration of medicines, the packaging of which includes various additional devices, such as means of administration, measuring cups and spoons, or means for proper preparation and storage of the medicines.

Depending on the type of product included in the packaging, the manufacturer is obliged to provide documents confirming the quality and proper performance of the product in dosing and using the medicine in the registration dossier. Separate registration of such products as medical devices is not mandatory.

The new rules also provide for a separate registration certificate for each new dosage method for the medicine.

THE LIST OF GROUNDS FOR MAKING CHANGES TO THE REGISTRATION DOSSIERS OF MEDICINES ACCORDING TO THE NATIONAL RULES HAS BEEN EXPANDED

As per Order of the Ministry of Health of the Russian Federation No. 291H of 10.06.2024.

the following grounds for making changes to the registration dossiers of medicines without an examination of the quality, effectiveness, and safety: "on changes in medicine safety data based on information from an expert institution posted on the official website of the Ministry of Health of the Russian Federation" has been introduced.

### Limiting marketing bonuses for pharmacies

Bill No. 755616-8 has been introduced to the State Duma to protect medicine manufacturers from the aggressive marketing policies of pharmacy chains and distributors. The bill is currently under consideration.

The bill establishes that the total maximum amount of additional remuneration of a distributor/pharmacy (for the purchase of a certain volume of medicines, or for the provision of services for the provision, distribution, and access to information about the medicines, logistics services, and services in preparation for sale and other similar services) must be calculated in the manner determined

by the Government of the Russian Federation, and it is **prohibited to charge the pharmaceutical manufacturer** any other remuneration in excess of the amount specified. If adopted, it may significantly change the current commercial practices between pharmaceutical manufacturers and pharmacy chains/distributors.



## Consumers goods

### New tobacco product regulations in Russia

The fight against smoking is one of the main priorities in Russia's social policy, and Russian legislation regarding tobacco and nicotine-containing products has been steadily tightening during the second half of 2024, as seen in the following.

The new Federal Law adopted on November 30, 2024, No. 438-FZ "On amendments to certain legislative acts of the Russian Federation" forbids the sale to minors of potentially dangerous gas-containing household products including lighters and cans for refilling them. The list of such products will be established by the Government. A seller is empowered to demand from a buyer a document confirming their legal age and is obliged to refuse the sale if there are doubts about the age or no document is presented. This Federal Law will come into effect as of March 01, 2025.

Draft law No. 782111-89 intends to increase the level of liability, *inter alia*, for:

 failure to comply with restrictions and (or) violation of prohibitions in the retail sale of nicotine-containing and tobacco products;

- ii. violation of the prohibition on wholesale or retail sale of nasvay, nicotine-containing food products or nicotine-containing products intended for chewing, sucking or sniffing, or sucking tobacco (snus);
- iii. sale to a minor of tobacco products, nicotinecontaining products, the raw materials for their production, hookahs, devices for the consumption of nicotine-containing products, or the raw materials for their production.

The Federal Law No. 515-FZ of December 28, 2024<sup>10</sup> establishes criminal liability for the repeated sale to minors of tobacco products, nicotine-containing products, the raw materials for their production, hookahs, devices for consumption of nicotine-containing products, or the raw materials for their production.

Draft law No. 787164-8<sup>11</sup> proposes to give the constituent entities of Russia the right to establish time restrictions and other additional restrictions on the conditions and places of retail sale of nicotine-containing products and devices for their consumption, including the right to completely ban the retail sale of such products and devices.

- 8 Link to the text of the Law: https://www.consultant.ru/document/cons\_doc\_LAW\_491952/.
- 9 Link to the text of the Draft Law: https://sozd.duma.gov.ru/bill/782111-8 (as of December 22, 2024).
- 10 Link to the text of the Draft Law: http://publication.pravo.gov.ru/Document/View/0001202412280017 (as of December 22, 2024).
- 11 Link to the text of the Draft Law: https://sozd.duma.gov.ru/bill/787164-8#bh\_histras (as of December 22, 2024).

The Ministry of Finance of Russia, in its Order No. 87n<sup>12</sup> of June 11, 2024, approved eight risk indicators to be identified during federal state monitoring of the production and turnover of tobacco and nicotine-containing products and the raw materials for their manufacture.

Thus, tobacco regulations are becoming stricter, which should be considered by all those involved in the turnover of tobacco and nicotine-containing products in the Russian market, from manufacturers to retail distributors.

#### New measures on tightening alcohol control

Control over the turnover of alcoholic beverages is becoming stricter as well, as the state is taking measures to limit the availability and attractiveness of alcoholic beverages to the public. Furthermore, the Government of the Russian Federation approved an action plan for its Concept for reducing alcohol consumption in the Russian Federation up to 2030 and beyond in its Decree No. 3610-p<sup>13</sup> of December 07, 2024. The Concept implies, inter alia, raising excise taxes and minimum retail prices, restricting of advertising, prohibiting discounts for the retail sale of alcohol to consumers for personal needs, restricting display in the checkout areas of retail facilities, and strengthening responsibility for the illegal retail sale of non-food alcohol-containing products by individuals and private entrepreneurs.

Nevertheless, the regulators strive to provide a comfortable business environment for bona fide market participants and make it easier to obtain a license. As such, the new Federal Law No. 316-FZ<sup>14</sup> of August 08, 2024 has been adopted. Thus, in order to obtain licenses for the production and turnover of ethyl alcohol or alcoholic and alcohol-

containing products, it will be necessary to send only 4 documents to Rosalkogoltabakkontrol: (i) an application; (ii) information on the testing laboratory; (iii) confirmation of paid-up authorized capital; and (iv) a calculation of the capacity of the main production equipment. The documents will be accepted only through the Unified Portal of State Services or the Unified State Automated Information System for the accounting of the production and turnover of ethyl alcohol or alcoholic and alcohol-containing products.

The term for issuing a license will be no more than 20 business days from the date the documents are registered. In some cases, it may be extended for no more than 10 business days.

Thus, as part of measures to reduce alcohol consumption in Russia, additional restrictions on its sale and advertising are being introduced. Nevertheless, the Government is interested in maintaining an atmosphere of compliance in the alcoholic market and creating convenient infrastructure for obtaining the necessary permits.

### Adoption of limitations on tonic drinks

Recently, increasing attention has been paid to regulating the sale of tonic drinks. The state is taking measures to limit their consumption, especially among minors. Here are the recent developments in this sphere:

A) From March 01, 2025 a nationwide ban on the sale of non-alcoholic energy drinks to minors will come into effect<sup>15</sup>.

B) A group of members of parliament has suggested Draft law No. 791244-8<sup>16</sup> for consideration, according to which a company will be subject to an administrative fine of up to RUB 500,000 for the retail sale of a non-alcoholic tonic drink (including an energy drink) to a minor. These amendments are intended to come into effect on March 01, 2025. So far, such sales are punished only in a number of regions (for example, in Moscow region and St. Petersburg). However, the regional fines are much lower than those suggested.

- 12 Link to the text of the Law: https://www.consultant.ru/document/cons doc LAW 480485/.
- 13 Link to the text of the Decree: http://publication.pravo.gov.ru/document/0001202412130056.
- 14 Link to the text of the Law: http://publication.pravo.gov.ru/document/0001202408080123?ysclid=m6gph41d8t223078902.
- 15 Federal Law No. 304-FZ as of August 08, 2024 (link to the text of the law: http://publication.pravo.gov.ru/document/0001202408080108).
- 16 Link to the text of the Draft law: https://sozd.duma.gov.ru/bill/791244-8.

C) Draft decree of the Government of the Russian Federation No. 01/01/11-24/00152141<sup>17</sup> of November 02, 2024 suggests that the biometric personal data which individuals have entered into the unified system via an application should be used, when selling non-alcoholic tonic drinks, including energy drinks. This will allow the seller to verify the age of a buyer who has been identified or authenticated using the unified biometric system and the public services portal of the Russian Federation without presenting a passport or other ID.

D) Draft decree of the Ministry of Industry and Trade of Russia No. 01/02/01-25/00153811<sup>18</sup> suggests approving of a list of documents which the seller of non-alcoholic tonic drinks (including energy drinks) is entitled to request from a purchaser in order to confirm their age.

The state imposes restrictions and sanctions for violations of these requirements to prevent negative consequences from the consumption of tonic drinks by minors. We encourage all participants in this market to follow the development of the above restrictions and adapt in a timely manner.

### Amendments regarding labelling of organic products

We are seeing an increase in the public interest in organic products. In the current legislation, organic products are defined as environmentally friendly agricultural products, raw materials, and foodstuffs, the production of which meets, inter alia, the following requirements:

- A) separation of organic production from nonorganic production;
- B) prohibition of the use of agrochemicals, pesticides, antibiotics, growth and fattening stimulants, and hormonal drugs;
- c) prohibition of embryo transplantation, cloning, and genetic engineering;
- D) prohibition of the hydroponic method of growing plants;
- E) prohibition on the use of ionizing radiation;
- F) prohibition of the use of packaging and consumer and transport containers that may lead to the contamination of organic products and the environment, including the use of polyvinyl chloride in packaging or consumer and transport containers.

Due to the growing interest in organic products, the government is taking measures to regulate their production, labelling, and sale. Thus, Draft law No. 782666-8<sup>19</sup> of November 29, 2024 proposes to clarify the requirements for the labelling of organic products. According to the amendments, from September 01, 2025, organic products are to be labeled with the following inscriptions: "organic", "biodynamic", "biological", "ecological", "environmentally friendly", "green" or similar or their abbreviations, or the designations "eco" or "bio". If the products do not meet the requirements for the production of organic products, such labeling cannot be used. Nevertheless, if the technical regulations allow the use of the designation "bio", the restrictions should not apply to labelling.

The Draft law stipulates that, for trademarks, service marks, and brand names containing the aforementioned distinguishing eco-phrases, such intellectual property shall be brought in line with the legislation on organic products by 01 September 2035.

Thus, the amendments to the legislation on organic products are subject to ongoing considerations which should be taken into account by manufacturers, importers, and distributors. These shifts reveal the trend toward tighter organic production requirements and an increase in the state's defense of consumer rights to environmentally compliant products.

<sup>17</sup> Link to the text of the Draft decree: https://regulation.gov.ru/Regulation/Npa/PublicView?npaID=152141.

<sup>18</sup> Link to the text of the Draft decree: https://regulation.gov.ru/Regulation/Npa/PublicView?npaID=153811.

<sup>19</sup> Link to the text of the draft law: https://sozd.duma.gov.ru/bill/782666-8.



# Agriculture And General Regulations

# New rules on importing seeds for scientific and related purposes

In recent years, the Russian government has devoted special attention to various tools for monitoring imported products to ensure the country's food security. Particular attention is paid to the import of seeds into the Russian Federation.

On September 01, 2024, the Rules for the Importation of Agricultural Plant Seeds into the Russian Federation for Expert Examination and Research Work, as well as for Educational Purposes, approved by the Resolution of the Government of the Russian Federation No. 80 of January 24, 2023 ("Rules") came into force.

These Rules apply to relations regarding the importation of seeds carried out by scientific organizations and educational organizations for (i) expert examinations, (ii) research work, (iii) use for educational purposes, as well as other organizations for (iv) expert examination (i.e., for obtaining permission from Gossortkomissiya to use commercial seeds in Russia granted by) (Scientific Seeds).

To import Scientific Seeds, one must obtain a confirmation of the intended purpose

("**Confirmation**") issued by the Ministry of Agriculture of the Russian Federation ("**MinAgro**").

Applications for obtaining confirmations are submitted online (via the Gosuslugi platform). In practice, the applicant should fill in an electronic form and attach a scanned copy of the signed supply contract.

MinAgro will make a decision in five business days. The grounds for refusal to issue a confirmation are (i) non-compliance of the application with the requirements set out in the Rules or (ii) providing MinAgro with unreliable information in the application. However, in practice there is some discretion in the decision-making process given the policy to reduce imports of foreign seeds to prioritize domestic ones.

A confirmation is valid for 1 year and applies to the contracted volumes and types of seeds.

Confirmations are checked by Russian Customs, so it is important to complete all the formalities before the goods cross the border. It is also recommended to allow for some extra time in



case of any delays in the process of obtaining the confirmation.

NB! Imports from EAEU member-states do not require a confirmation.

NB! Import of Scientific Seeds of "unfriendly" origin requires a similar confirmation governed by other rules, which are described in next paragraph of this Guide.

### Import quotas for seeds of "unfriendly" origin

The Russian Government is implementing a policy aimed at restricting the import volumes of seeds of "unfriendly" origin.

Resolution of the Government of the Russian Federation No. 1983, dated December 30, 2024 (**Resolution**) establishes new quantitative restrictions on imports of certain types of seeds for agricultural plants originating in "unfriendly" states which apply until the end of 2025.

NB! From November 26, 2024<sup>20</sup>, seeds are deemed to be of "unfriendly" origin if, as of February 15, 2024, the originator of such seeds is a person from an "unfriendly" state.

Type of agricultural plant seeds	Total quota (thousands of tons) <sup>21</sup>
Seed potato	12
Malting seed barley	0.5
Waxy seed corn	0.6
Hybrid rapeseed for sowing	2
Hybrid, high oleic sunflower seed for sowing	0.5
Hybrid sugar beet seed	2.7

Zero quotas were introduced for ordinary corn, soybeans, and some other agricultural plants.

On January 23, 2025, the Ministry of Agriculture of the Russian Federation (**MinAgro**) published the list of companies which passed the competitive selection and received quotas.

It is noteworthy that, this year, MinAgro followed a new methodology when deciding who will obtain quotas:

 the number of applications submitted by the related companies should not give them an advantage in the competitive selection process. Rather, it means that MinAgro calculated the volumes of such related applicants based on a special formula so that a single applicant and a group of companies receive approximately the same volumes:

 the applicant, in all cases, should be a person historically engaged in seed import to Russia.
 As such, MinAgro requested that the Russian Federal Customs Service provide statistics on imports of seeds for the period between December 01, 2021 and November 30, 2024 (inclusive).

<sup>20</sup> Based on Resolution of the Government of the Russian Federation No. 1470, of 01 November 2024, "On Amendments to Resolution of the Government of the Russian Federation No. 72, of 27 January 2024". Similar provisions were duplicated in the Resolution.

<sup>21</sup> Each figure in the table applies to the whole market and means, for instance, that 12,000 tons of potato seeds should be distributed between the applicants participating in the competitive selection process.

Furthermore, the Resolution set forth an innovation regarding imports of "unfriendly" seeds of certain agricultural plants (e.g., sunflower, rapeseed, corn, etc.) used for scientific purposes<sup>22</sup>. In 2024, the volumes of imported scientific seeds were not restricted subject to the receipt of a confirmation of their intended use from MinAgro. In 2025, one

can import such seeds only subject to quantitative restrictions<sup>23</sup>. The differences between these and quotas are that the limits are set not per crop in general, but per sample, and there is no competitive selection process. That said, scientific seeds are now available to more companies.

# Developments in the rules for state and municipal monitoring and supervision

In December 2024, Federal Law No. 248-FZ "On State Control (Supervision) and Municipal Control in the Russian Federation" of July 31, 2020 ("Law") was updated, with significant changes in the frequency, procedures, and timing of monitoring (supervisory) and preventive measures. The key changes to pay attention to are as follows:

#### A. UNSCHEDULED INSPECTIONS

At the end of 2024, a long moratorium on unscheduled inspections of local businesses expired. Inspired by that temporarily experiment, it was decided that the permanent rules for such inspections should be aligned with the recent practices and that monitoring in certain sensitive cases should be enhanced.

Unscheduled inspections are now possible when:
(i) risk indicators, or deviations from them, are identified; (ii) there is information about harm to the life and health of citizens or an immediate threat thereto; in cases of national defense and state security; in the event of potential natural or man-made emergencies, epidemics, or epizootics; (iii) conducting business without notifying the authorities of the start of such activities, operating a license-bound activity without a license, or trading goods without providing information to the Chestny ZNAK state track & trace system; (iv) a monitored entity evades a mandatory preventive visit.

#### B. MANDATORY PREVENTIVE VISITS

The amendments to the Law provide for preventive visits, which are mandatory for the person

monitored. However, entrepreneurs may refuse to undergo such visits by providing prior notice (so-called voluntary preventive visits).

One of the key differences between voluntary and mandatory preventive visits is that, during a mandatory one, an inspector can issue orders to rectify any violations of mandatory requirements revealed. Mandatory preventive visits may be carried out when there are legitimate grounds to do so.

#### C. DIGITALIZATION OF INSPECTIONS

The Law establishes the option of using the mobile app Inspector (tested in 2024) for certain remote inspections, like inspection visits, on-site audits, and raid inspections.

The app can track the geo-position of the person monitored, store photos, video and audio made during an inspection, and provide access to the full history of monitoring activities.

#### D. PUBLIC COMPLIANCE RATINGS

The Law introduced a basis for making a public assessment of the level of compliance with the requirements following the monitoring. The public ratings will be used as a non-monetary incentive.

It is implied that the rules and criteria for ranking entrepreneurs will be elaborated separately with respect to different spheres of activity and types of monitoring.

<sup>22</sup> It concerns the purposes of use, similar to those listed on page [New rules of import of seeds for scientific and related purposes] of the Guide.

#### E. SETTLEMENT AGREEMENTS

Monitored persons which have violated therequirements may apply for settlement agreements with the supervisory authorities (Agreement).

Under such an Agreement (a) the person monitored undertakes to rectify violations based on the remediation program provided and (b) the authority will suspend the respective orders (prescriptions). Subject to introduction of respective amendments to the law, it might also be possible to become exempt from administrative liability upon the conclusion of such an agreement.

Should a monitored person breach the agreement, the authority is entitled to renew the order to rectify the violations.

An agreement may be concluded if rectification of the violation requires substantial time and money, capital investments, the allocation of budgetary funds to state-funded institutions, or to prevent mass layoffs, or a reduction of output of goods and services of strategic importance or socio-economic significance. It is understood that the detailed grounds and procedure for concluding such agreements are yet to be determined.

### Ban on PET packaging

In 2024, work on one of the regulations implementing the concept of a closed-loop economy was finalized.

The Russian Government established a list of products the manufacture and use of which are prohibited because of the complexity or impossibility of recycling the of packaging thereof<sup>25</sup>.

The list includes the following packaging:

- i. polyethylene terephthalate (PET) bottles for the food industry of all colors except colorless, blue, green, brown, and white. The package designation is "PET" or "PETE" either "01" or "1";
- ii. PET packaging with a polyvinyl chloride label, except for a shrink label. The package

#### F. OTHER DEVELOPMENTS

- On-sight inspections may be launched in the event of, inter alia, (i) full or partial non-payment of wages for more than one month involving over 10% of the average headcount or more than 10 employees, (ii) leaks from databases containing personal data to the Internet.
- The term for the consideration of a pre-trial complaint has been reduced from 20 to 15 business days.
- An entity monitored may refuse to admit an inspector, not provide them with the documents, or refuse other monitoring (supervisory) activities if the documents have been drawn up incorrectly;
- 13 new risk indicators which can be grounds for conducting unscheduled inspections of business entities involved in the distribution of consumer goods traced via the Chestny ZNAK state track & trace system have been implemented<sup>24</sup>. The changes concern, inter alia, tobacco, nicotine-containing and nicotine-free products and devices, dairy products, packaged water, perfumes, and food supplements.

designation is "PVC" or "V" either "03" or "3" in combination with "PET" or "PETE" or "01" or "1";

iii. multilayer PET bottles. They are indicated as "Other" or "O" either "07" or "7".

The amendments concerned could drastically affect the business of both Russian and foreign manufacturers and importers of products. The ban applies to products imported from EAEU member states and any other countries.

Those affected should find a replacement for PET packaging by September 01, 2025 when the law comes into force. The carve-out from the requirement will apply to products manufactured before September 01, 2025.

<sup>24</sup> Decree of Rospotrebnadzor No. 627, of 02 September 2024, "On Amendments to the List of Risk Indicators of Violation of Mandatory Requirements in the Implementation of Federal State Monitoring (Supervision) in the Field of Consumer Protection, Approved by Order of Rospotrebnadzor No. 635, of 14 September 2023".

Note: please be aware that all information provided in this letter is based on an analysis of publicly available information as well as our understanding and interpretation of legislation and law enforcement practices. Neither ALRUD Law Firm nor the authors of this letter bear any liability for the consequences of any decisions made in reliance upon this information.

125196, Russia, Moscow, 7 Lesnaya street, 12th floor E-mail: info@alrud.com | www.alrud.com | Tel. +7 495 234-9692

