# ALRUD

# Legal Regulatory Guide Russia



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#### Introduction

#### Dear Readers,

In an ever-evolving regulatory landscape, staying informed is paramount for businesses operating in international markets. We are pleased to present our latest Legal Regulatory Guide, a continuation of our longstanding tradition of providing comprehensive regulatory insights tailored to the needs of our clients. This guide is the result of the collaborative efforts of our diverse regulatory team, which comprises experts with extensive knowledge across various legal domains. Our aim is to equip international companies with the critical updates necessary to navigate the complexities of operating in Russia.

This edition of the guide delves into several key themes that are particularly pertinent to businesses engaged in the Russian market. First, we explore the rapidly changing landscape of Technology, Media, and Telecommunications (TMT) regulations. As digital transformation accelerates, understanding the regulatory framework governing these sectors is essential for companies looking to innovate and expand their digital footprint.

Additionally, we provide updates on the life sciences and pharmaceutical sectors, where regulatory compliance is not only a legal obligation but also a vital component of public health and safety. Our insights will help businesses remain compliant with evolving laws and standards, ensuring that they can effectively bring their products to market while safeguarding consumer welfare.

Consumer goods regulations are another critical area of focus in this guide. With increasing scrutiny on product safety and marketing practices, it is imperative for companies to stay abreast of the latest regulatory developments to mitigate risks and enhance consumer trust.

Finally, we address the important topic of waste management regulations, which are becoming increasingly significant in light of global sustainability goals. Our analysis will provide companies with the necessary guidance to navigate compliance requirements and adopt best practices in environmental stewardship.

We trust that this guide will serve as an invaluable resource for international companies operating in Russia, empowering them to make informed decisions in a complex regulatory environment.



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#### **TMT**

## Trial of Track & Trace system for radio-electronic products

Due to the general trend with the expansion of the Track & Trace digital labelling system called "Chestny ZNAK" as part of mandatory labelling requirements for more and more groups of products on the Russian market (see more details), a voluntary labelling experiment

is currently being conducted for certain groups of radio-electronic products<sup>1</sup>.

As recently updated<sup>2</sup>, the experiment includes the following stages:

	Timeline	Type of radio-electronic products
Stage 1	1 December 2023 – 30 November 2024	Various lighting equipment (e.g., luminaires, portable electric lanterns, different lamps, lightemitting diode (LED) light sources, rectifiers and static converters)
Stage 2	10 June 2024 – 30 April 2025	Laptops, smartphones and different types of telephone sets
Stage 3	1 July 2024 – 31 August 2025	Different types of printed circuit boards (PCBs)

<sup>1</sup> Resolution No. 1993 of the Government of the Russian Federation dated 25 November 2023 "On conducting an experiment to label certain types of radio-electronic products with means of identification on the territory of the Russian Federation".

<sup>2</sup> Resolution No. 656 of the Government of the Russian Federation dated 23 May 2024 "On amendments to Resolution No. 1993 of the Government of the Russian Federation dated 25 November 2023".

With respect to Stage 3, the Ministry of Industry and Trade is expected to approve methodological recommendations and the schedule of this stage of the experiment by 31 August 2024.

The pilot project is open to manufacturers, importers, retailers and wholesalers of the listed radio-electronic products. To participate, applicants must submit an application to the operator of the "Chestny ZNAK" system (the Centre for Advanced Technology Development or CATD). During the pilot period, labelling codes are provided free of charge. The experiment is expected to make it possible to test technologies to apply means of identification to goods, work out the procedure for interaction between market participants with the labelling system and exclude the

possibility of the use of counterfeit goods. Based on its results, a decision will be made on the advisability of introducing mandatory labelling of radio-electronic products.

Considering the history of experiments with the Trace & Track system for other types of products (e.g., medicines, clothing, tobacco products and dairy products), it is reasonable to assume that the labelling of radio-electronic products is likely to become mandatory once the experiment ends. Thus, manufacturers, importers and sellers of lighting equipment, laptops, smartphones, telephone sets and PCBs are advised to closely monitor the on-going experiment and its outcome so that they can be prepared for further compliance with mandatory labelling requirements.

#### Extension of the data storage obligations of the Moderators

In 2014, under the so-called "Yarovaya laws", the legal status of an "organizer of information dissemination on the Internet" (a "Moderator") was introduced in Federal Law No. 149-FZ dated 27 July 2007 "On Information, Information Technologies and Information Protection" (the "Information Law"). The Moderators are entities that work to ensure the functioning of information systems and/ or programmes for electronic computing machines, which are designed and/or used to receive, transmit, deliver and/or process the electronic messages of Internet users. In essence, the definition is quite broad and may encompass various communication services, as well as any websites or mobile applications that facilitate user-to-user communication, including chat forums or the functional ability for users to leave reviews and for other users to comment on such reviews.

The Moderators are mostly subject to lawful interception obligations with respect to certain data about its users located in Russia<sup>3</sup> and must store the electronic messages of Internet users for six months and so-called "meta data" (i.e., information on the reception, transmission, delivery and/or processing of electronic messages) as well as information on users for one year on the territory of the Russian Federation. The Moderator is obliged to provide this information to authorized state bodies that perform operational investigative activities or ensure the security of the Russian Federation (e.g., the Russian Federal Security Service). There are also additional obligations when the Moderator provides for messages to be encoded.

In addition to the information on a user's electronic message and the "meta data" of such

<sup>3</sup> It can be determined whether user data is located in Russia using network addresses identified as Russian at the time of registration or authorization (mainly IP addresses allocated by Russian telecommunications operators); receipt by the Moderator of geographical data indicating the location of a user on the territory of the Russian Federation (e.g., data from a GPS device); the provision of the details of documents issued in Russia at the time of registration; the provision of contact numbers of Russian telecommunications operators or information about the location of the person received from an authorized entity.

messages, the actual list of information about the users that is subject to the Moderators' data storage obligation is envisaged in Resolution No. 1526 of the Government of the Russian Federation dated 23 September 2020 (the "List"). This includes the user's ID in the Moderator's communication service, IP address, registration data, authorization data, information about changes or additions to the user's telephone number or email address. as well as other information provided by the user during registration, information about paid services provided by the Moderator with payment details (the amount of fees, currency used, and payment system details) and information on the termination of registration.

In 2024, the List was augmented with supplementary user data, which must be stored in Russia for the period stipulated by the Moderator and may be disclosed to the Russian authorities in accordance with lawful interception procedures<sup>4</sup>. It now also includes factually recorded information about users in the event that the communication service offers the option of the electronic monitoring of geolocation as well as the reception, transmission and/ or processing of the electronic messages of such users without registration and authorization. Thus, the Moderator data storage obligation now undoubtedly covers details about unregistered and authorized users, including geolocation data.

Additionally, the Moderators now also store details about the acceptance, transmission, delivery and processing of electronic messages carried out with the use of electronic payment system technologies, including information about means of payment, monetary transactions and the correspondent identifier of the payment system. The data to be recorded includes the currency, amount,

paid service or goods (if any), and other data specified when conducting a monetary transaction. Transactions must also include the identifier of the payment system, currency, amount, paid service or goods (if any), and other data specified when carrying out a monetary transaction.

There are also further plans to extend the Moderators' data storage obligations with regard to user data. Recently, the Ministry of Digital Development, Communications and Mass Media proposed that currently available information about user IP addresses in the List be supplemented with the details of the ports used by the user and the Internet communication service used to register, authorize and terminate the user<sup>5</sup>.

According to an explanatory note from the regulator, an analysis of law enforcement practice shows that the lack of advanced information about IP addresses and user ports at state agencies makes it impossible to identify a specific user if network address translation (NAT) technology is used, or to find users of IP addresses allocated to users of virtual servers (VDS/VPS), virtual private networks (VPNs) and proxy servers. Consequently, if adopted, the amendments to the List would facilitate the investigative activities of the Russian authorities when accessing user data stored by the Moderator.

As such, we see a growing trend towards the List being expanded with additional information about communication service users for the purposes of law enforcement and lawful interception. It is crucial that companies with the legal status of a Moderator pay close attention to any legislative changes that may affect them to ensure that they are prepared to comply with any necessary changes.

<sup>4</sup> The amendments were introduced by Resolution No. 342 of the Government of the Russian Federation dated 20 March 2024 "On amendments to Resolution No. 1526 of the Government of the Russian Federation dated 23 September 2020".

In May 2024, the draft amendments to Resolution No. 1526 of the Government of the Russian Federation dated 23 September 2020 were published for public discussion on the regulation.gov.ru portal. It is currently undergoing a regulatory impact assessment (available <a href="here">here</a> in Russian only).

### Possible utilization fee for foreign telecommunication equipment in Russia

According to recent public statements from the Russian Minister of Digital Development, Communications and Mass Media and information from reputable mass media outlets, the Russian government is currently considering an initiative to introduce a utilization fee for foreign manufacturers of telecommunications equipment to level out prices with domestic manufacturers. This mechanism is expected to be a part of telecommunications sector development strategy in Russia until 2035 and should serve as one of the methods to finance measures to support the production and introduction of domestic telecommunications equipment. In particular, in order to expand support for the production and introduction of domestic telecom equipment, a proposal has been made to co-finance domestic developers' expenses on the development of equipment, as well as to provide soft loans to domestic equipment manufacturers to stockpile components for the future production of equipment.

The legal concept of "utilization fees" was first introduced in Russian law in 2012. At present, it only exists in relation to vehicles imported to or manufactured in the Russian Federation to ensure free utilization for their end owners<sup>6</sup>. It applies to wheeled vehicles (chassis), self-propelled machines and their trailers and is paid by both foreign and domestic manufactures. The purpose of the utilization fee is to ensure environmental safety, including the protection of human health and the environment against the harmful effects of vehicle operation, taking into account their technical characteristics and wear and tear.

In terms of how the initiative would affect the telecommunications sector, no further comments on the governmental proposal are available so far. Yet, market participants fear that the introduction of this measure could lead to a significant increase in equipment costs and a reduction in the quality of telecommunications services.

On a separate note, one could argue that such regulatory measures are a violation of the national treatment standard, which ensures competitive equality and prohibits discriminatory treatment between domestic and foreign investors and investments under the General Agreement on Tariffs and Trade (GATT 1947), since they will only apply to foreign manufacturers. The Russian Federation is subject to the provisions of GATT 1947 due to its active membership in the World Trade Organization (WTO). Nevertheless, we recommend monitoring such legal developments and proposals if your company imports telecommunication equipment to Russia due to the general localization and "technological sovereignty" trend in the light of the current geopolitical situation.

<sup>6</sup> See Article 21.1 of Federal Law No. 89-FZ dated 24 June 1998 "On Production and Consumption Waste".



# Life Science and Pharmaceuticals

#### Potential changes to the data exclusivity regime

Draft Law No. 635933-8 on amendments to the data protection regime that applies to the results of clinical trials (the "Draft Law on Clinical Trials") has been submitted to the State Duma of the Russian Federation.

The Draft Law on Clinical Trials proposes making it impossible to apply the exclusivity regime for clinical trials data in the registration of medicines intended for use in (i) emergencies and (ii) pandemics, as well as in the event of (iii) a shortage or (iv) the risk of its occurrence.

The current regulations do not provide a clear answer about whether data protection measures apply to the relationships that arise from the state registration of pharmaceuticals in Russia, particularly in cases of drug shortages or confirmed risks of shortages, as well as during emergencies (e.g., related to the spread of infectious diseases). According to Article 13 of the Federal Law "On the Circulation of Medicines", the registration of drugs intended for use in military actions, emergencies and the prevention and treatment of dangerous

diseases is conducted based on procedures established by the Russian government.

To implement this, two government resolutions were adopted: Resolution No. 441 (3 April 2020) and Resolution No. 593 (5 April 2022), which create exceptions to the general registration process in order to ensure rapid access to the necessary medications. However, neither resolution mentions whether data protection measures may be applied. This absence is consistent with the purpose of data protection, which is to extend the monopoly of original drug developers without hindering access to the necessary treatments for the healthcare system and patients.

In practice, questions may arise regarding the legality of registering reproduced or biosimilar drugs under Resolution No. 593, especially during confirmed shortages, which could potentially lead to conflicts involving the Ministry of Health, the Prosecutor's Office and the courts. Current judicial practices have been adverse in this regard and pose significant risks for the application of data protection measures,

even in cases of critical drug shortages, which could result in the refusal to register or annulment of registrations obtained under the aforementioned resolutions.

Such conflicts may deter manufacturers from supporting the domestic healthcare system amidst international sanctions, which could ultimately lead to drug shortages and increased social tension. To mitigate these risks, a proposal has been made to amend the relevant sections of the Federal Law to prevent the artificial unavailability of medications for the Russian population.

The purpose of the Draft Law on Clinical Trials is to fill the legislative gap from the lack of regulation of the data protection regime of clinical trials during the state registration of medicines in the event of a defect. As such, the Draft Law on Clinical Trials is designed to prevent the risk of the artificial unavailability of medicines for the Russian population.

If adopted, the Draft Law on Clinical Trials would enter into force on the day of its official publication.

### Acceleration of market launches for generic pharmaceuticals

Draft Law No. 592805-8 on amendments to the Civil Code of the Russian Federation concerning the free use of medicine-related inventions (the "Draft Law on Generics") proposes amending Article 1359 of the Civil Code of the Russian Federation by supplementing the list of actions that do not constitute an infringement of the exclusive right to an invention.

In particular, according to the Draft Law on Generics, the following actions would not constitute an infringement of the rights to an invention: (i) use of the invention with respect to a medicine for development, (ii) preclinical and clinical research, (iii) testing, (iv) state registration, (v) standardization and quality control, (vi) production, (vii) storage, (viii) transportation and import to the Russian Federation, (ix) registration of the maximum retail price and (x) offering for sale

(e.g., conclusion of supply agreements with distributors and pharmacies).

The current patent restrictions on original medicines do not allow generics to be promptly introduced to the market. At present, manufacturers must wait for the patent to expire before they can initiate the development and state registration of medicines. Thus, according to the Draft Law on Generics, Russian generics manufacturers would be granted the right to carry out all the preparatory actions needed to launch the medicine as soon as the patent of the original medicine expires.

If adopted, the Draft Law on Generics would apply to legal relations arising on or after 24 February 2022 and to obligations that are due after 23 February 2022.

#### Harmonization of Russian and EAEU legislation

Federal Law No. 1-FZ dated 30 January 2024 on the harmonization of Russian legislation with EAEU legislation (the "Law on Harmonization") entered into force on 30 January 2024 (except for certain provisions).

One of the most significant provisions of the Law on Harmonization is the regulation of data protection in clinical trials. Under the newly adopted Law on Harmonization, legal protection is now provided both during the state registration of a medicine and during EAEU registration.

The legal protection period is four years for a generic medicine and three years for a biosimilar medicine, and an application for the registration of medicines may be submitted after these periods expire. The results of the preclinical and clinical trials of the medicine cannot be used for commercial purposes without the consent of the right holder for six years following the registration of the medicine.

Please also see our <u>Legal Regulatory Guide</u> <u>Russia. Q3-Q4 2023</u> on this topic.

In addition, the Council of the EAEU has adopted Unified Rules for Pharmaceutical Inspections of Pharmacovigilance Systems of Pharmaceutical Manufacturers (Decision of the Council of the EAEU No. 29 dated 12 April 2024 on amending Decision of the Council of the EAEU No. 83 dated 3 November 2016). The Rules provide for:

- A unified procedure for pharmaceutical inspections in EAEU member states
- A unified approach to interaction between the authorized bodies of EAEU member states

The unification of the Rules at the EAEU level will level out differences in pharmaceutical inspections in different EAEU member states. Moreover, the adoption of the Unified Rules will minimize cases of repeated inspections of pharmaceutical manufacturers by multiple pharmaceutical inspectors from different EAEU member states.

### EAEU Unified Rules on the Circulation of Veterinary Medicines

The Unified Rules on the Circulation of Veterinary Medicines in the EAEU, which were approved by Decision No. 1 of the Council of the EAEU dated 21 January 2022, entered into force on 13 March 2024.

According to the newly adopted Rules, an application for the registration of a veterinary medicine may be submitted in any EAEU member state at the discretion of the manufacturer or its legal representative. However, there are transitional provisions as follows:

- A) The registration of veterinary medicines, which was started and not completed as of 13 March 2024, shall be carried out in accordance with the national legislation of the EAEU member state.
- B) Until 31 December 2027, it is allowed to register veterinary medicine according to the national legislation of the EAEU member state, but only for circulation in the territory of that EAEU member state. In this case, registration certificates are valid for five years.
- C) Registration certificates for veterinary medicine that were issued before 13 March 2024 are valid in the EAEU for the periods established by the national legislation of the EAEU member state, but not later than 31 December 2027.
- D) Veterinary medicines registered before 13 March 2024 may be circulated in the EAEU with the labelling placed on the packaging in accordance with the national legislation of the EAEU member state until the date of expiry of their registration certificates.

After the expiry of the transitional provisions, veterinary medicines must be registered in accordance with the EAEU Unified Rules.

### Mandatory labelling of veterinary medicines from 1 October 2024

According to the newly adopted Resolution No. 675 of the Government of the Russian Federation dated 27 May 2024, mandatory labelling of veterinary medicines will start on 1 October 2024. Mandatory labelling will be introduced with the following stages:

- A) Entities engaged in the sale of veterinary medicines must register in the "Chestny ZNAK" system from 1 September 2024.
- B) Manufacturers and importers of veterinary medicines must start labelling goods and submitting information to the "Chestny ZNAK" system about the introduction of goods into circulation from 1 October 2024.
- C) Information on the retail sales of veterinary medicines must be submitted from 1 March 2025.
- D) Data on veterinary medicines supplied to veterinary medical institutions and agricultural holdings must be submitted from 1 September 2025.

However, veterinary medicines manufactured up to 30 September 2024 inclusive that do not have labelling codes may be sold until their expiry date.

Please note that the application of means of identification on the consumer packaging of veterinary medicines (including in the form of stickers) will not require any changes to the documents included in the registration dossier.

NB! Prior to the adoption of a decision on mandatory labelling, an experiment on the voluntary labelling of veterinary medicines was preliminarily conducted from 25 December 2023 to 31 August 2024.



#### Consumers goods

## Proposed regulatory framework for marketplaces in Russia

On 5 March 2024, a draft law proposing a new regulatory framework for marketplaces was introduced to the lower house of the Russian Parliament (the State Duma). It mainly regulates relations between individual sellers, marketplace platform operators and the points of delivery owners (the "**Draft Law**")<sup>7</sup>. Additionally, the Draft Law grants additional warranties to consumers, inter alia, by prohibiting marketplaces from demanding compensation and other payments from buyers in connection with the return of goods, as well as by introducing requirements to ensure the reliability of information about goods and sellers on marketplaces.

The Draft Law specifies the legal status of the following subjects: an aggregator of information on goods (i.e., marketplace) and its owner; an aggregator with a significant market position (i.e., a marketplace with more than a 20% market share); and the aggregator's infrastructure (i.e., points of delivery, sorting centres, and software used in the process of the delivery/receipt of goods sold on the marketplace). In light of such legal definitions, a proposal has been made to introduce mandatory contractual provisions that would be included to agreements concluded by the owners of marketplaces with individual sellers (aggregator's service agreement) and the points of delivery owners (an agreement concluded between an aggregator of information on the goods owner and a point of delivery owner).

In addition, the Draft Law obliges marketplace owners to publish templates of the above agreements on their e-commerce platform and provide a transparent and clear statement

<sup>7</sup> Draft Law No. 568223-8 "On the State Regulation of Trade Activities of Aggregators of Information on Goods in the Russian Federation and on Amendments to the Federal Law 'On the Principles of State Regulation of Trade Activities in the Russian Federation'" (with regard to introducing the legal regulation of the activities of aggregators of information on goods) (available here in Russian only).

of their terms of service, and to prevent marketplaces from imposing unfavourable conditions on sellers. The Draft Law also prohibits the inclusion of any other services (marketing, logistics) in an aggregator's service agreement. The Draft Law pays specific attention to aggregators with a significant market position, since it places additional obligations on such major platforms compared with general aggregator owners.

Under the Draft Law, the Federal Antimonopoly Service ("FAS of Russia") would be the body responsible for monitoring compliance by marketplaces with their regulatory obligations. At present, the FAS of Russia may already monitor major marketplaces that are qualified as "digital platforms" under the Fifth "Digital" Antimonopoly Package<sup>8</sup>, since the moratorium on antitrust inspections of IT companies, including "digital platforms", was recently lifted with respect to certain violations<sup>9</sup>.

If adopted, the Draft Law is expected to enter into force from 1 March 2025 (this date may be rescheduled due to delays in the lawmaking process). Nevertheless, certain provisions of the Draft Law received criticism from the business community and a number of governmental stakeholders. In particular, the Association of E-commerce Companies, the Ministry of Industry and Trade and the FAS of Russia did not support the idea of setting a market share limit for marketplaces and preventing them from opening new delivery

points if this limit is exceeded, since this could be detrimental to the small businesses involved as well as to customers, and could slow down the development of e-commerce in Russia.

As such, due to the negative comments, a delay in the further consideration of the Draft Law or any new amendments in subsequent versions could be expected, including the possible "freezing" of the Draft Law in the Russian parliament. Nevertheless, if your business in Russia meets the criteria of an aggregator of information on goods (i.e., marketplace), we recommend closely monitoring the development of the Draft Law as well as other legal initiatives concerning marketplace regulation because it is steadily evolving and alternative initiatives may be proposed.

<sup>8</sup> On 1 September 2023, the Fifth "Digital" Antimonopoly Package came into force, which regulates the operation of marketplaces by introducing new criteria for dominance in digital markets and formally preventing abuse by marketplaces (Federal Law No. 301-FZ "On Amendments to the Federal Law 'On the Protection of Competition'" dated 10 July 10 2023). See more details about these legislative changes <a href="here">here</a>.

<sup>9</sup> The moratorium on antitrust inspections of IT companies was introduced in 2022 and was supposed to last until the end of 2024. However, it was lifted from 28 March 2024 due to the large number of complaints from small and medium-sized companies as well as consumers about violations by dominant entities (Resolution No. 340 of the Government of the Russian Federation dated 20 March 2024 "On Amendments to Resolution No. 448 of the Government of the Russian Federation dated 24 March 2022"). See more details here.



#### General Regulatory

#### Waste disposal experiment

On 1 September 2024, an experiment on the disposal of waste from goods and packaging will begin (the "Experiment"). Participation in the experiment is mandatory. Under the Experiment, importers (from non-EAEU countries) must fulfil duties related to the disposal of waste from the use of numerous types of goods and packaging. The Experiment will end on 31 December 2025.

With regard to controlled products and packaging imported from 1 September 2024 until 1 September 2025, prior to the day on which they are released by the customs authority for domestic consumption, importers must:

 Pay an environmental fee or provide notification about the independent disposal of waste. In the latter case, they must obtain a bank guarantee or conclude a surety agreement for the payment of the fee. The waste disposal contract must be concluded with a legal entity or sole proprietor from the register of users.

 Submit reports on the weight of imported goods and packaging to the waste accounting system through their personal account.

With regard to controlled products and packaging imported from 1 January 2024 until 31 December 2025, the following must be submitted to the waste accounting system:

- Reporting on the weight of goods and packaging
- Reporting on the self-disposal of waste from goods and packaging

The reporting must be submitted by 15 April 2025 for the period from 1 January 2024 until 31 December 2024 and by 15 April 2026 for the period from 1 January 2025

until 31 December 2025. Importers may send information to the Ministry of Natural Resources by 15 September 2025 about any problems that may arise in the performance of their duties.

In particular, controlled products and packaging include:

- Trousers and breeches made of other textile materials for men or boys
- New pneumatic rubber tyres and tyres for passenger cars, buses, motorcycles, bicycles, as well as for vehicles and machines used in construction, mining or industry
- Household washing machines, including those with a spin cycle
- Lead-acid batteries
- Plastic packaging products made of polypropylene

- Rigid cylindrical aluminium containers with a capacity of no more than 1 litre
- Coated, impregnated or laminated bleached plastic paper and cardboard (except adhesives) weighing more than 150 g per 1 m<sup>2</sup>

If a product is included in the above list, but its packaging is not, this means that the Experiment is still being conducted with respect to it. If a product is not in the above list, but its packaging is, then the Experiment is not being conducted with respect to both items.

The Experiment will initiate another stage in its development, which will require more reporting and qualifications connected with ecological issues. The Experiment is highly likely to become permanent after it ends, and the experiment period offers opportunities to communicate with the authorities and express any relevant concerns, so it would be advisable to be prepared for it in advance.

#### Environmental fines: recap of 2023

The growing control of the Federal Service for Supervision of Natural Resources ("Rosprirodnadzor") over environmental damage started about four years ago (please refer to the benchmark Nornickel case - collapse of a fuel tank near Norilsk, Siberia in the Regulatory Guide for the II-III quarters of 2020).

Based on its Annual Report, in 2023, Rosprirodnadzor filed **1,190** claims for environmental damage against companies and individual entrepreneurs **for a total of RUB 226.82 billion**.

One of the incidents in 2023 accounted for RUB 146.6 billion, or almost two-thirds of the total amount of claims filed. It was a claim against **Svetlovsky Vodokanal** (Kaliningrad Region) for compensation for damages from the discharge of untreated water into the Kaliningrad Bay of the Baltic Sea.

However, there is a considerable gap between the claims and the amounts recovered: **only RUB 3.6 billion** out of RUB 226.82 billion **were recovered** in 2023.

The state authorities are **having challenges collecting fines** due to the violators' lack of sufficient funds and their subsequent bankruptcy.

According to Svetlana Radionova, head of Rosprirodnadzor, the watchdog is implementing a major experiment to consult businesses on compliance with environmental requirements during the early stages of implementing new investment projects. Radionova believes such a preventive approach will be more effective than imposing fines. Nevertheless, this position should not be treated as an exemption from compensation for damages if we are talking about stable businesses.

## Regular payments for subsoil use: dealing with unfair users

Amendments<sup>10</sup> intended to improve the legal framework concerning regular payments for the use of subsoil enter into force on **1 September 2024**<sup>11</sup>.

Subsoil users are charged regular payments for subsoil use separately for each type of subsoil use: (i) geological study for the prospecting and evaluation of mineral deposits, (ii) exploration of mineral deposits and (iii) construction and operation of underground facilities.

The amendments cover a wide range of issues. Let's consider the most significant ones.

First, they aim to deal with "sleeper" licences. The rates of regular payments will be increased if a subsoil user fails to conduct geological exploration of a mining plot within the timeframe envisaged by law and applies for an extension of the licence term. In the base scenario, such a statutory term does not exceed five years for most subsoil plots, seven

years for subsoil plots located in the Arctic and similar zones and 10 years for subsoil plots in internal sea waters, territorial seas or on the continental shelf.

The payments will be **doubled** during the first year of the new licence, **increased 10 times** for the second year and **100 times** for the third and subsequent years compared with the previous year when the term of the initial licence expires. This measure encourages subsoil users to meet their obligations in good faith and ensure the efficient use of subsoil plots.

Second, the amendments propose taking into account slightly different factors while determining the rate of regular payments: climatic, landscape and geographical conditions, the size of subsoil plots, types of minerals, duration of subsoil use, extent of geological study of the territory and degree of risk.

#### New opportunities for subsoil users

There has been a whole range of significant improvements to the Law on Subsoil in Russia in 2024, which market players have long been waiting for.

The following changes<sup>12</sup> became effective on **1 March 2024**:

 Licence holders are granted the right to convert their exploration licences into mining licences without going through the competitive bidding process (i.e., with the authorization of the authorized state bodies) once written-off reserves or spent subsoil waste from previous exploration licence holders have been accounted for on the state balance sheet.

The Russian Minister of Natural Resources and Environment stressed out that such a modification to the rules for obtaining licences for the next stage of subsoil

<sup>10</sup> Federal Law No. 619-FZ dated 19 December 2023 "On Amendments to Article 43 of the Law of the Russian Federation 'On Subsoil".

<sup>11</sup> Except for certain specific cases when its effect will be postponed.

<sup>12</sup> Federal Law No. 598-FZ dated 29 December 2022 "On Amendments to the Law of the Russian Federation 'On Subsoil' and Article 2 of the Federal Law 'On Production and Consumption Waste'".

exploration would redress the historical injustice when companies that held exploration licences and were investing resources to mine had to initiate an auction at which they had to compete for the plot with third parties.

This change is expected to maximize the incorporation of previously used mineral deposits in the Russian economy.

2. The amendments entitle subsoil users with exploration and mining licences to (i) build and operate underground facilities not related to the mining of minerals (including to store carbon dioxide)<sup>13</sup> and (ii) place groundwater in rock formations after extracting useful components (e.g., lithium,

bromine, boron, magnesium and potassium) within the boundaries of the licenced plots. It is essential to understand that this right is conditional upon the preparation of the related project documentation (changes thereto).

This amendment should save costs and enable companies to switch to a "closed-cycle" production process.

3. In addition, a six-month moratorium has been lifted on the re-licensing of a subsoil area following the early revocation of a licence. This involves cases when, for instance, a company holding a licence is liquidated or a licence holder applies for the early termination of a licence.

#### Development of the labelling system

In recent years, Russia has been developing its Honest Sign national track and trace digital labelling system ("Honest Sign"), which ensures control over counterfeit products, in an effort to supervise the transportation of goods throughout the country. A general overview of the system can be found in our newsletter "The Russian Government has

adopted rules for the digital labelling of new products and procedure for access to labelling information" or on the official Honest Sign website (the latter is available in English and Chinese).

The Honest Sign system continues to expand and will encompass the following categories:

- (A) Non-alcoholic beer (from 1 September 2024)
- (B) Bicycles and bicycle frames (from 1 September 2024)
- (C) Cider and pear cider (from 1 September 2024)
- (D) Certain fermented sparkling and non-sparkling beverages with alcohol concentration of no more than 7% (from 1 September 2024)
- (E) Certain biologically active food additives (from 1 September 2024)
- (F) Certain perfumery and cosmetic products intended for hand hygiene with antimicrobial effects declared in the consumer packaging labelling, as well as surface disinfectants and skin antiseptics (from 1 September 2024)
- (G) Medical gloves (from 1 March 2025)

At present, numerous goods are undergoing experiments with labelling:

- (A) Edible vegetable oils packaged in consumer packaging (25 December 2023 31 August 2024)
- (B) Medicinal products for medical use and raw materials used for the production of medicinal products for medical use (29 December 2023 31 December 2024)
- (C) Certain types of canned food (12 February 2024 31 August 2024)
- (D) Certain types of building materials in consumer packaging (15 March 2024 1 December 2024)
- (E) Certain types of alcoholic beverages with alcohol concentration of up to 9% inclusive (1 July 2024 31 August 2025)
- (F) Certain types of medical devices (1 September 2024 31 August 2025)
- (G) Medicinal products for veterinary use (25 December 2023 31 August 2024)
- (H) Animal feed (25 December 2023 31 August 2024)
- (I) Perfumery, cosmetics and household chemicals (15 January 2024 28 February 2025)
- (J) Selected types of printed materials (1 April 2024 31 August 2025)
- (K) Certain types of heating devices (1 April 2024 28 February 2025)
- (L) Selected types of cable and wire products (20 May 2024 28 February 2025)
- (M) Fibre-optic products (1 December 2023 1 December 2024)
- (N) Radio electronic products (1 December 2023 31 August 2025)<sup>14</sup>
- (O) Technical means of rehabilitation (15 October 2023 31 August 2024)
- (P) Certain types of children's goods (20 December 2023 1 December 2024)

Based on all the previous labelling legislative practices, we assume that the experiments will ultimately result in the adoption of obligatory labelling. On 3 May 2024 the Ministry of Industry and Trade also proposed conducting an experiment to label numerous types of groceries. The experiment would include spices, bread snacks, sauces, vinegar, ready-made soups, and certain vegetables.

The government has also proposed that alcohol-containing non-food products with an ethyl alcohol content of more than 10% of the volume of finished products should be labelled with identification marks of the Honest Sign tracing system and be traced using this system.

Furthermore, on 20 March 2024 a ban was enacted on the retail sale of medical products based on information from the Honest Sign system.

Overall, the Honest Sign system is expanding to include vast groups of products and aims to encompass all the main consumer products available on the Russian market. The Honest Sign has proven its effectiveness and is

already being used in numerous product groups.

As a member of working groups on labelling in foreign chambers of commerce, we are keeping an eye on the further development of the Honest Sign system and are ready to advise you on recent developments in the tracing system upon request.

### Russia's recent trend of strengthening state control over alcohol and tobacco turnover

Recent reforms in alcohol and tobacco turnover in Russia reflect the overall trend towards strengthening state control over such goods. The trend is confirmed by the following regulatory measures:

- Enactment of an experiment to apply labelling codes on special federal labels of low-alcoholic beverages. The experiment will take place from 1 July 2024 until 31 August 2025. The experiment involves placing labelling codes in machine-readable form (QR codes) on special federal labels of low-alcoholic beverages from a specific list, which includes certain types of finished alcoholic beverages with alcohol content of up to 9% inclusive, e.g., honey (including carbonated and table) beverages.
- Enactment of the national rules for the sale of alcohol on summer verandas starting from 1 June 2024. The rules clarified the possibility and procedure for selling alcohol on summer verandas. It is essential to comply with the general requirements for the retail sale of alcohol when providing catering services and to have documents in place stating that, in particular, the veranda meets regional requirements in terms of its placement and arrangement.
- Enforcement of technical regulations on alcohol safety starting from 1 July 2025. The

technical regulations include requirements for the packaging and labelling of products, as well as their safety during production, storage, transportation and sale.

- Extension of an experiment to label alcohol imported to the Russian Federation with special federal labels. Importers may apply special federal marks on imported alcohol at customs warehouses in experiment mode until 31 May 2026.
- A draft law banning the production of alcohol-containing non-food products to a separate unit that produces alcohol. The draft law also states that products with an ethyl alcohol content of more than 28% of the volume of finished products shall not be available for purchase and supply at prices below the minimum cost of alcohol with a similar strength for 0.5 litres during its purchase and delivery. In any case, the ban will not affect imports and exports. The draft law also proposes that alcohol-containing non-food products with an ethyl alcohol content of more than 10% of the volume of finished products must be labelled with identification marks of the Honest Sign tracking system and be traced in this system.

The Russian government has also proposed simplifying and accelerating the issuance of a number of licences for the production and

turnover (except retail sale) of ethyl alcohol, as well as alcoholic and alcohol-containing products. Per the draft law, it will take up to 20 business days from the registration date of documents to issue a licence if the application was sent electronically. At present, it takes 30 calendar days to consider applications and could take twice as long for additional examinations. There is also a proposal to reduce the number of documents that applicants must submit to the licensing authority.

As for tobacco regulation, the following restrictive measures have been enacted:

- The Ministry of Finance has proposed a list of risk indicators that must be identified for federal control over the production and turnover of tobacco and nicotine-containing products, as well as raw materials for their production.
- The government has approved regulations on the federal state control (supervision) of the production and turnover of tobacco products, nicotine-containing products and raw materials for their production. The new regulation establishes rules for controlling the production and turnover of tobacco, nicotine-containing products and raw materials for their production. Inspections are carried out by the Federal Service for Control of Alcohol and Tobacco Markets and its regional authorities. The regulation also establishes, inter alia, the procedure for conducting control measures and the out-ofcourt appeal of decisions made by officials.
- The government established that starting from 7 April 2024, parties involved in the turnover of raw materials for manufacturing tobacco and/or nicotine-containing products must register in the Honest Sign tracking system.

 A new type of administrative liability was introduced: the production and turnover of tobacco, nicotine-containing products and raw materials for their production without a licence or using undocumented equipment will start being punished under the new specific article 14.67 of the Administrative Code of the Russian Federation. Punishment for legal entities is guite strict - up to RUB 1 mln with the confiscation of the manufactured products, equipment, raw materials, semi-finished products or other items used for the production and turnover of tobacco products, nicotine-containing products and/or raw materials for their production, or the administrative suspension of operations for up to 90 days from the time of confiscation of the manufactured products, equipment, raw materials, semifinished products or other items used for the production and turnover of tobacco products, nicotine-containing products and/or raw materials for their production.

Thus, tobacco and alcohol regulation is clearly undergoing constant reforms. Despite the newly adopted restrictive measures, the government is trying to maintain a balance of interests among business and consumer safety by enacting some core shifts only after regulatory experiments have been conducted taking into consideration the obstacles and issues that the parties involved in their turnover have experienced.

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