



**IMPORTANT DEVELOPMENTS IN THE RUSSIAN LEGISLATION  
EFFECTIVE FROM JANUARY-FEBRUARY 2018**



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## 1. ANTI-CORRUPTION LEGISLATION

From 1 January 2018, information on the liability of a person in the form of dismissal due to the loss of confidence for the commission of a corruption offence, except for the information constituting state secrets, shall be subject to inclusion into the register of persons dismissed due to the loss of confidence. This register shall be published in the state information system on public service in Internet.

The procedure for inclusion of information into the register of persons dismissed due to the loss of confidence, procedure for the removal of the information from the said register, as well as procedure for the maintenance and placement of the register in the state information system on public service shall be determined by the Government of the Russian Federation.

(Federal Law No. 132-FZ dated 1 July 2017).

## 2. BANKING AND FINANCE

### 2.1 Amount of the Bank's Own Equity (Capital)

From 1 January 2018, the amount of own equity (capital) of a bank holding a universal license shall not be less than 1 billion roubles, of a bank holding a basic license - not less than 300 million roubles.

If after 1 January 2018 a bank with a basic license reduced the amount of its equity (capital) below the minimum amount of equity (capital) within 4 consecutive months, such a bank shall within 6 months upon expiry of the said period replace its status with the status of a non-banking credit organisation or obtain the status of a microfinance company and simultaneously terminate the status of a credit organisation and cancel the license to conduct banking operations.

(Federal Law No. 92-FZ dated 1 May 2017).

### 2.2 Economic Standards for Microfinance and Microcredit Companies

From 1 January 2018, the instructions of the Bank of Russia come into force that set economic standards for microfinance and microcredit companies:

- a microcredit company that attracts funds of individuals, including individual businessmen, who are founders (participants, shareholders) thereof, and(or) legal entities in the form of loans;
- a microfinance company that attracts funds of individuals, including individual businessmen, and(or) legal entities in the form of loans, and a microfinance company that issues and place bonds.

(Order of the Ministry of Finance of Russia No. 78n, dated 25 May 2017; Instructions of the Bank of Russia No. 4382-U and No. 4384-U, dated 24 May 2017; Order of the Ministry of Finance of Russia No. 42n, dated 30 March 2012 become inoperative).

### **2.3 Requesting Information from Recipients of Financial Services**

From 1 January 2018, the civil legal relationships arising between a microfinance organisation and the recipient of financial services in connection with the conclusion of the contract for POS-microloans shall be subject to the provisions on requesting information from the recipients of financial services.

The basic standard for the protection of the rights and interests of individuals and legal entities that are recipients of financial services provided by members of self-controlled organisations in the financial market, which unite microfinance organisations (approved by the Bank of Russia on 22 June 2017) provides for:

- the list of information to be requested by a microfinance organisation from the financial service recipient prior to the conclusion of the consumer loan agreement;
- the list of information required for assessing the debt burden of the financial service recipient who applied to a microfinance organisation with an application for a consumer loan for more than 3,000 roubles.

### **2.4 Provision of Information to the Recipient of Financial Services**

From 1 January 2018, microfinance organisations shall provide the financial service recipient in his/her personal account the information on the individual terms and conditions of the consumer loan agreement, payment schedule, as well as structure and amount of the current debt.

Besides, the basic standard for the protection of the rights and interests of individuals and legal entities that are recipients of financial services provided by members of self-controlled organisations in the financial market, which unite microfinance organisations (approved by the Bank of Russia on 22 June 2017) introduces requirements to the procedure for recording and storing by the microfinance organisation of telephone conversations and messages transmitted through telecommunication networks, including mobile telephones.

In addition, from 1 January 2018, certain requirements to the official website of a microfinance organisation come into effect. The website shall contain a section describing its structure, and the total duration of breaks in its functioning shall not exceed 4 hours per a month.

The list of requirements to employees of the microfinance organisation that directly interacts with the recipients of financial services, as well as to checking the compliance of these employees with the specified requirements, is expanded.

## **2.5 Obligatory Requirements to Founders, Corporate Bodies and Officials of Financial Organisations**

From 28 January 2018, the unified requirements to the business standing of shareholders and managers of banks, insurance organisations, non-state pension funds, microfinance organisations, management companies of investment funds and mutual investment funds shall apply.

The respective amendments are introduced to the Federal Law 'On Banks and Banking Activities', Law of the Russian Federation 'On the Insurance Organisation in the Russian Federation', Federal Law 'On Non-State Pension Funds', Federal Law 'On Countering the Legalisation (Laundering) of Proceeds from Crime, and Financing of Terrorism', Federal Law 'On Investment Funds', Federal Law 'On the Central Bank of the Russian Federation (Bank of Russia)', Federal Law 'On Insolvency (Bankruptcy)', and Federal Law 'On Microfinance Activities and Microfinance Organisations'.

(Federal Law No. 281-FZ, dated 29 July 2017).

## **3. STATE PROCUREMENTS**

### **3.1 Procurement from Small and Medium Enterprises**

From 1 January 2018, the threshold values of revenues and assets of legal entities that are obliged or may make purchases from small and medium enterprises (SMEs) are reduced.

It is established that specifics of the participation of small and medium enterprises in the procurement of goods, works, and services by certain types of legal entities shall apply in respect of, inter alia:

- legal entities specified in Article 1.2 of Federal Law No. 223-FZ dated 18 July 2011 'On Procurement of Goods, Works, Services by Individual Types of Legal Entities'<sup>1</sup> the annual revenue of which (for credit institutions - value of assets) from sale products according to the annual accounting (financial) statements for the previous calendar year exceeds 500 million roubles, and provided that they do not meet the conditions of classifying as SMEs;
- autonomous institutions the total value of contracts which for the procurement of goods, works, services for the preceding calendar year exceeds 250 million roubles.

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<sup>1</sup> Including state corporations, state-owned companies, public-law companies, natural monopolies, organisations engaged in regulated activities in the area of electricity supply, gas supply, heat supply, water supply, sewerage, sewage treatment, processing, utilisation, neutralisation, and landfill of solid municipal waste, autonomous institutions, as well as business companies where participation of the Russian Federation, constituent entity of the Russian Federation, municipal unit in the charter capital exceeds 50 % in total.

### 3.2 Uniform Rules for Describing Medicines for Medical Use

From 1 January 2018, the specific requirements to the description of the medicines for medical use which are purchased for the state and municipal needs in documentation on purchase of the medicines shall become effective.

In particular, the description contained in the procurement documentation shall indicate: the dosage form of the medicine, medicine dosage strength with supply capacity of medicine in multiple dosage strength and double quantity, the residual shelf life of the medicine expressed in time units of measure (for example, 'not earlier than 1 January 2020' or 'at least 12 months from the date of the contract conclusion', etc.).

In order to describe the medicines in the procurement documentation it is allowed to indicate:

- the trade names if the medicines are necessary for appointment to the patient based on medical indications (individual intolerance, vital indications) according to the decision of the medical commission of the medical organisation;
- the way of the medicine administration (injections or infusions) if the medicines are intended for parenteral use;
- the age of a child (from 0, from 3 months, from 12 months, etc.) if the medicines intended solely for use in paediatric practice.

The characteristics of medicines contained in the instructions for the use that refer to a particular manufacturer of the medicine are not allowed for indication, in particular:

- equivalent dosages of the medicine that provide for the need to divide the solid dosage form of the medicine;
- dosage of the medicine in certain units of measure, where it is possible to convert into other units of measure (for instance, 'IU' (international unit) can be converted into 'mg', or 'percentage' can be converted into 'mg/ml', etc.);
- fill volume of the medicine primary package, except for solutions for infusions;
- presence (absence) of excipients;
- fixed temperature regime for the medicine storage in the presence of an alternative one;
- presentation (primary package) of the medicine (for example, 'ampoule', 'bottle', 'blister', etc.);
- number of units (tablets, ampoules) of the medicine in the secondary package, as well as the requirement to supply a specific number of packages instead of the specific amount of the medicine;
- requirements for indicators of pharmacodynamics and(or) pharmacokinetics of the medicine (for example, effect start time, maximum effect, effect duration).

(Decision of the Government of the Russian Federation No. 1380, dated 15 November 2017).

### **3. 3 Requirements to Banks Issuing Guarantees to Secure Applications and State Contracts**

From 1 January 2018, customers when making purchases for state and municipal needs shall accept bank guarantees that meet the requirements set by the Government of the Russian Federation.

The list of banks that meet such requirements shall be kept by the Ministry of Finance of the Russian Federation based on the information received from the Bank of Russia, and shall be posted on the official website of the Ministry of Finance.

(Federal Law No. 267-FZ dated 29 July 2017).

## **4. INTELLECTUAL PROPERTY**

From 1 January 2018, the protection of related rights of directors of theatrical works shall be enhanced.

The production made by directors of performances in a form that allows its repeated public performance subject to preserving the recognisability of a particular production by the audience, is defined as a special performance output.

A director is granted with personal non-property rights (right to the performance inviolability) to the public performance, not limited to their protection while using the production in recorded form, in broadcasting or transmitting through cable, in bringing the production to the public.

The start date of protection of the exclusive right of the director to the production depends on the time of the first public performance of the production.

Repeated public performance of the production by a person who made the first public performance upon the consent of the director before 1 January 2018, shall not be treated as a violation of Article 1317.2.10 of the Civil Code of the Russian Federation, unless the contract of the director with the said person expressly provides for one-time public performance of the production or limited number of performances.

## **5. INTERNET AND MEDIA**

### **5.1 Internet-messengers**

From 1 January 2018, the internet messengers shall be obliged to:

- identify by mobile phone number of the users, whose electronic messages they transmit;
- within 24 hours from the receipt of the relevant request from the competent authority, limit the possibility of the user to enjoy the messaging service;



- provide the technical possibility for users of the instant messaging service to refuse to receive electronic messages from other users;
- ensure the confidentiality of transferred electronic messages;
- ensure the possibility of transferring electronic messages on the initiative of state authorities;
- not allow the transfer of electronic messages to users of the instant messaging service in cases and in the procedure determined by the Government of the Russian Federation.

The ID information about the subscriber numbers shall be stored by messengers in the territory of Russia only.

Such information can be provided to third parties upon the consent of the user, except for the cases provided for by law. The instant messaging service organiser shall be obliged to provide a proof of the respective consent.

(Federal Law No. 241-FZ dated 29 July 2017).

## **5.2 Requirements to the Information to Be Published by Online Media**

From 1 January 2018, the online media shall ensure that the following information is published on its website:

- name (title) of the publication;
- founders (co-founders);
- full name of the editor-in-chief;
- e-mail and phone number of the editorial board;
- content mark (in certain cases).

The founder of a mass media shall be obliged to notify the registering authority on the termination, suspension, and resumption of media activities.

The procedure for re-registering the media is replaced with making changes to the registry entry. An extract from the register will be issued instead of a certificate of registration of the media.

Persons who cannot be editors-in-chief of media will include citizens serving a sentence in detention facilities or having a criminal record for committing crimes using the mass media or information and telecommunication networks, including the Internet, or for committing crimes connected with extremist activities.

The media may be excluded from the register in case of the death of an individual or liquidation of a legal entity that is the founder of the media.

A separate state fee of 8,000 roubles will be charged for the issue of a permit to distribute the products of foreign periodicals in Russia.

In addition, the state fee for the state registration of a media, for making changes to the registration entry (including those related to changing the subject or specialisation of the media) will be charged regardless of the form of distribution of a media (currently the amount of the state fee differs in relation

to the state registration of a periodical printed publication, news agency, radio, television, video program, newsreel program and other media).

(Federal Laws No. 239-FZ and No. 253-FZ dated 29 July 2017).

## 6. INFORMATION SECURITY

### 6.1 Protecting the Critical Information Infrastructure of the Russian Federation from Hacking

On 1 January 2018, Federal Law No. 187-FZ dated 26 July 2017 "On the Security of the Critical Information Infrastructure of the Russian Federation" comes into force.

The critical information infrastructure includes information systems, information and telecommunications networks, automated management systems for critical information infrastructure facilities, and telecommunication networks used to organise interaction between such facilities.

The main principles of ensuring the security of critical information infrastructure, powers of the President of the Russian Federation, the Government of the Russian Federation and the Russian state authorities in the area of ensuring the security of critical information infrastructure, the rights and obligations of facilities, the procedure for implementing security assessments, the procedure for categorising and maintaining a register of significant critical information infrastructure facilities are defined.

Measures to ensure the security of critical information infrastructure of Russia and information on the state of its security against hacking constitute a state secret.

The procedure for preparation and use of the resources of the unified telecommunications network of Russia to ensure the operation of significant critical information infrastructure is approved by the Government of the Russian Federation.

Telecommunication operators shall ensure the implementation of the procedure, technical conditions for the installation and operation of means designed to search for hacking signs in telecommunication networks and their security as approved by the Federal Law 'On the Security of the Critical Information Infrastructure of the Russian Federation', if installed in the telecommunication network used to organise interaction between facilities of critical information infrastructure of the Russian Federation.

Thereat, the provisions of the Federal Law 'On the Protection of the Rights of Legal Entities and Individual Businessmen in the Conduct of State Control (Supervision) and Municipal Control' that establish the procedure for organising and conducting inspections shall not apply during the state control in the area of ensuring security of significant facilities of the critical information infrastructure of the Russian Federation.

(Federal Laws No. 187-FZ, No. 193-FZ dated 26 July 2017).

## **6.2 Criminal Liability for Undue Influence on the Critical Information Infrastructure of the Russian Federation**

From 1 January 2018, there will be the criminal liability for:

- creation, dissemination and/or use of computer programs or other computer information that is knowingly intended to unduly influence the critical information infrastructure of the Russian Federation, including for destruction, blocking, modification, copying of information contained therein or neutralising the means of protecting the said information;
- unlawful access to protected computer information contained in the critical information infrastructure of the Russian Federation, including with the use of computer programs or other computer information that is knowingly designed to unduly influence the critical information infrastructure of the Russian Federation, or other harmful computer programs, if it caused harm to the critical information infrastructure of the Russian Federation;
- violation of the rules for the operation of the means of storing, processing or transmitting protected computer information contained in the critical information infrastructure of the Russian Federation or information systems, information and telecommunications networks, automated control systems, telecommunications networks related to the critical information infrastructure of the Russian Federation, or the rules for access to the said information, information systems, information and telecommunication networks, automated control systems, telecommunication networks, if it caused harm to the critical information infrastructure of the Russian Federation.

(Federal Law No. 194-FZ dated 26 July 2017).

## **7. MEDICINE AND PHARMACEUTICALS**

### **7.1 Law on Telemedicine**

From 1 January 2018 the Federal Law 'On the Introduction of Amendments to Certain Legislative Acts of the Russian Federation on the Application of Information Technologies in the Area of Health Protection' No. 242-FZ dated 29 July 2017 comes into force (except for certain provisions).

Telemedicine technologies are defined as information technologies that provide for remote interaction of medical officers between each other and with patients, for identification and authentication of them, for documenting their actions during consultations, and for remote medical supervision of a patient's health.

Medical assistance with the use of telemedicine technologies shall be organised and provided according to the procedure established by the competent federal executive authority, the procedures for the provision of medical care and based on medical care standards.

Consultations to a patient or his/her legal representative can be provided by a healthcare professional with the use of telemedicine technologies for the following purposes:

- prevention, collection, analysis of patient complaints and history data, evaluation of the effectiveness of medical and diagnostic measures, medical supervision of the patient's health;
- making a decision on the need in a face-to-face attendance (examination, consultation).

When providing consultations with the use of telemedicine technologies, the doctor can correct the previously prescribed treatment, if the diagnosis is established by him/her and the treatment is prescribed at the face-to-face attendance (examination, consultation).

Documenting of the information on the medical assistance to a patient using telemedicine technologies, including making entries into the patient's medical documents, shall be performed using a strengthened qualified electronic signature of a healthcare professional.

A patient or his/her legal representative may receive medical documents (copies thereof) and extracts therefrom, including in e-form, on request sent, inter alia, in e-form.

The Uniform State Information System in the area of public health will be created.

## **7.2 List of Vital and Essential Medicines for Medical Use**

On 1 January 2018, the following lists approved by the Order of the Government of the Russian Federation No. 2323-r, dated 23 October 2017:

- list of vital and essential medicines for medical use;
- list of medicines for medical use, including those prescribed by the decision of medical commissions of medical institutions;
- list of medicines for people with hemophilia, cystic fibrosis, pituitary dwarfism, Gaucher disease, malignancy of lymphoid, hematopoietic and related tissue, multiple sclerosis, persons after the transplantation of organs and(or) tissues;
- minimum range of medicines needed for medical care.

The new lists are supplemented with a number of medicines and dosage forms for medicines already included in the lists.

## **7.3 Information on the Interconvertibility of Medicines for Medical Use**

From 1 January 2018, information on the interchangeability of medicines for medical use will be included in the state register of medicines (i.e. for the purposes of state and municipal procurements).

It is also allowed to use the results of determining the interconvertibility of medicines for medical use.

(Federal Law No. 429-FZ, dated 22 December 2014; the Order of the Ministry of Healthcare of the Russian Federation No. 80n, dated 09 February 2016).

## 8. TAX LAW

### 8.1 "Tax free"

From 1 January 2018, Russia implements a 'tax free' system, which involves the VAT refund when exporting goods by citizens of foreign countries (other than EAEU countries) purchased by them in Russia in retail organisations.

Non-Russian nationals may apply for compensation of the tax amount within 1 year after the purchase of goods provided that the goods are exported from Russia within 3 months from the date of their purchase.

When selling goods to non-Russian nationals for at least 10 thousand roubles including VAT within one calendar day the seller shall issue the document (check) for compensation of the tax amount, with indication of the required information.

The tax amount is not compensated when purchasing excisable goods and other goods according to the established list.

The refundable tax amount is determined as the difference between the VAT amount calculated by the retailer when selling the goods and the cost of the service for compensation of the tax amount. A zero VAT rate is established with regard to services for the tax refund.

The procedure for justifying the application of the zero tax rate by organisations providing the said services, conditions for the tax refund, a list of documents confirming the right to tax refund, as well as requirements for the retailers the list of which will be established by the competent authority, are determined.

(Federal Law No. 341-FZ dated 27/11/2017).

### 8.2 VAT Zero Rate

From 1 January 2018, the zero rate of VAT applies:

- to sales of goods exported under the re-export customs procedure, previously placed under the customs procedure of processing in the customs territory or the customs procedure of a free customs zone, free warehouse, when providing the necessary documents;
- to sales of goods (processed products, wastes and/or residues) received (accumulated) as a result of processing, or goods manufactured (made) from goods placed under the procedures of a free customs zone, free warehouse.

In order to justify the application of the zero VAT rate in conducting of operations for export sales of goods sent in international mail to foreign persons taxpayers shall submit the documents according to the established list.

Taxpayers may apply a rate of 10% or 18% instead of the zero rate when performing works (rendering services) in connection with transportation of exported goods, subject to submitting the respective application to the tax authority at the place of their registration not later than the 1st day of the tax period when they intend not to apply a zero rate. The period for applying the tax rates provided by the application must be at least 12 months. It is possible not to apply a zero tax rate only with respect of all operations performed.

Different tax rates may not be applied depending on who is a buyer of the relevant goods (works, services).

(Federal Law No. 350-FZ, dated 27 November 2017).

### **8.3 Investment Tax Deduction for Corporate Profit Tax**

From 1 January 2018, taxpayers may reduce the amount of tax (advance payment) payable to the budget of a constituent of the Russian Federation by no more than 90% of the current period expenditures for the purpose of completion, further equipping, reconstruction, modernisation and technical re-equipment of fixed assets.

The amount of the investment tax deduction cannot be more than the difference between the estimated amount of corporate profit tax for the tax (accounting) period and the estimated tax amount when applied the tax rate of 5% (unless another rate is determined by a decision of the constituent of the Russian Federation).

Certain categories of taxpayers cannot apply the investment tax deduction.

If at least one of the parties to the interdependent party transaction applies an investment tax deduction for corporate profit tax during the tax period, such a transaction shall be recognised as controlled when the amount of revenue under the transaction for the corresponding calendar year exceeds 60 million roubles.

(Federal Law No. 335-FZ, dated 27 November 2017).

### **8.4 Gambling Tax**

From 1 January 2018, the minimum and maximum gambling tax rates are doubled.

In addition, the taxable objects shall be deemed processing centres of interactive betting of totalisators and betting offices. The tax rate for these objects can be established by the laws of the constituent entities of the Russian Federation within the range of 2.5 to 3 million roubles.

The application for registration of objects taxable with the gambling tax must be submitted to the tax authority no later than 5 days before the date of their installation.

(Federal Laws No. 354-FZ and No. 358-FZ dated 27 November 2017).

## **8.5 Favourable Tax Regime in the Territory of the SEZ in the Kaliningrad region**

From 1 January 2018, in the territory of the special economic zone (SEZ) in the Kaliningrad region new tax incentives will apply, in particular:

- zero VAT rate for domestic air transport services with a point of departure or destination located in the territory of the Kaliningrad region;
- exemption from excise taxation for certain transactions with excisable goods; the specifics of the calculation and payment of excise duty in the release of excisable goods for domestic use are established;
- the corporate profit tax rate will be 0% during 6 tax periods starting from the period where the first profit was received from the implementation of an investment project and 10% - during the next 6 tax periods;
- reduced tariffs of social insurance contributions for payers included in the register of SEZ residents in the Kaliningrad region for the period up to 2025 inclusive, subject to statutory specifics, are introduced.

(Federal Law No. 353-FZ dated 27/11/2017).

## **8.6 Double Taxation Convention between Russia and Brazil**

From 1 January 2018, the Convention between the Government of the Russian Federation and the Government of the Federative Republic of Brazil 'On Avoidance of Double Taxation and Prevention of Evasion from Taxation with Respect to Income Taxes' dated 22 November 2004 (together with the Protocol, dated 22 November 2004) shall apply.

(Federal Law No. 300-FZ, dated 30 December 2008; the Memorandum of the Ministry of Finance of the Russian Federation dated 24 November 2017).

# **9. INDUSTRY**

## **9.1 Classification of Products as Products Manufactured in Russia**

From 1 January 2018, more stringent requirements for industrial products are established in order to classify them as products manufactured in Russia; in particular, the requirements for the percentage of foreign components in the manufacture of machine tools; the number of operations performed on the territory of the Russian Federation in the production of self-propelled single-bucket excavators and loaders, crawler cranes, conveyors for the food industry, etc.

(Decision of the Government of the Russian Federation No. 719 dated 17 July 2015).



## **9.2 Rules and Criteria for Classifying Products as Industrial Products that Have No Analogues Produced in Russia**

On 1 February 2018, the Rules and Criteria for Classifying Products as Industrial Products that Have No Analogues Produced in Russian Federation approved by the Decision of the Government of the Russian Federation No. 1135 dated 20 September 2017, come into force.

Criteria for classifying products as industrial products that do not have analogues produced in Russia are defined as differences between the product parameters and parameters of industrial products produced in Russia. Thereat, parameters of products are deemed parameters related to the functional purpose or the list of functions, the scope of application, quality characteristics (for example, reliability, ergonomics, energy efficiency, production effectiveness, safety, environmental, production, operational parameters, metrological characteristics and other parameters of products).

The Ministry of Industry and Trade of Russia shall classify products as products that have no analogues produced in Russia subject to the examination and issue an opinion on the respective classification of products within 30 business days after submission of the respective application to the Ministry.

Examination of products shall be carried out by organisations included in the list of organisations that carry out expert examination of the differences between product parameters and parameters of industrial products manufactured in Russia.

The maximum amount of payment for providing the obligatory examination of the differences between product parameters and the parameters of industrial products produced in the Russian Federation is established, in particular, for:

- determination of the parameters of the declared products relating to the functional purpose or the list of functions performed, the scope of application, the quality characteristics;
- search for industrial products produced in the territory of the Russian Federation that are similar to the declared products.

## **9.3 Ban for Production and Turnover of Low-Alcohol Tonic Beverages Except for Those Produced for Exports**

From 1 January 2018, a ban for the production and turnover of alcoholic products with an ethyl alcohol content of less than 15% of the volume of finished products containing tonic substances (components) is introduced, except for the products produced for the purpose of export from the Russian Federation.

Besides, a ban for the movement across the territory of the Russian Federation of unmarked alcoholic beverages in the amount of more than 10 litres per a person is introduced. The violation of this ban entails a fine in the amount of 3,000 to 5,000 roubles with confiscation of the respective products.

The license for the retail sale of alcohol products or licenses for the retail sale of alcoholic beverages when providing public catering services will include the coordinates of the planimetric points of



the stationary commercial facility or a stationary public catering facility where the alcohol products are permitted for sale.

It is specified that only organisations that have in their ownership, economic management, operational management or lease for the term of 1 year or more the production and storage facilities shall be entitled to produce alcoholic products.

(Federal Law No. 278-FZ dated 29 July 2017).

## 10. TECHNICAL REGULATION

From 1 January 2018, a number of sections have been excluded from the uniform list of products that are subject to obligatory certification:

4361 'Electronic and physical functional, nuclear and radioisotope devices, blocks and units',

4362 'Devices, installations, systems for measurement and control of ionising radiation',

4363 'Radioisotope instruments',

4364 'Detectors of ionizing radiation',

6937 'Operating equipment for nuclear power plants',

6938 'Pumps for nuclear installations and radiochemical production',

6940 'Radiation machinery',

6968 'Radiation protection equipment',

6981 'Special technological equipment', and

7010 'Isotope products'.

Certificates of conformity issued before 1 January 2018 shall be valid until the expiration of their validity.

## 11. STATE CONTROL (SUPERVISION)

### 11.1 Risk-Oriented Approach in the Organisation of Certain Types of State Control (Supervision)

From 1 January 2018, a risk-oriented approach in organising and implementing state control (supervision) over business activities will apply. Under this approach, in some cases, the choice of intensity (form, duration, periodicity) of inspections and other control measures is determined by

referring the activities of a legal entity, individual businessman and(or) production facilities used by them in the performance of such activities to a certain risk category or a certain hazard class (category).

The current Rules for classifying the activities of legal entities and individual entrepreneurs and (or) their production facilities to a certain risk category or a certain hazard category (category), as well as a list of types of state control (supervision) that are implemented using a risk-based approach are approved by the Decision of the Government of the Russian Federation dated 17 August 1981 № 806.

(Federal Law No. 246-FZ dated 13 July 2015).

## 11.2 Checklists for Scheduled Inspections

From 1 January 2018, in the course of scheduled inspections of legal entities and individual businessmen, the controlling authorities will use checklists in certain cases, in particular, in case of:

- control over the medical devices circulation;
- federal state supervision in the area of medicines circulation;
- state control of the quality and safety of medical activities;
- state supervision in the area of civil defense;
- state supervision in the area of protecting the population and territories from natural and man-made emergency situations;
- federal state supervision in the area of hydraulic structures safety;
- federal state supervision in the area of industrial safety;
- federal state energy supervision;
- federal state supervision over compliance with the labour legislation and other regulatory legal acts (in respect of employers - legal entities and individual businessmen which refer to the moderate risk category).

(Decisions of the Government of the Russian Federation No. 840, dated 14 July 2017, No. 864, dated 22 July 2017, No. 930, dated 4 August 2017, and No. 1080, dated 8 September 2017).

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Best Regards,

GRATA International Law Firm (Moscow)

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