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1. ISSUES AND RECOMMENDATIONS OF FIAC WORKING GROUPS

Foreign Investment Advisory Council

1. The Development of Digital, Low-carbon and Knowledge-based Economy

Issue 1. Problems involved in implementing "green certificates" in the Russian energy sector from the perspective of power consumers that produce consumer goods – based on the example of Unilever Rus enterprises, which converted from renewable energy to 100% electricity in 2018-19.

By 1 September 2019 all Unilever enterprises on five continents (excluding Australia and New Zealand) had converted from renewable energy to electric power, largely by means of international green certificates (Renewable Energy Certificates), free bilateral agreements with companies generating renewable energy on the wholesale market, and own generation at new enterprises.

In the absence of a legal framework (rules) for the circulation of such certificates in Russia (the system is expected to be approved in April 2020), Unilever Rus, as a player on the wholesale power and capacity market, acted via Mosenergosbyt, which entered into free bilateral agreements with renewable energy suppliers on our behalf for the purchase/sale of power on the wholesale market. The supplier's delivery point clusters (DPCs) (specific wind and solar power plants – in our case, Fortum and Hevel) were tied to specific DPCs of the customer (Unilever Rus production facilities in St. Petersburg, Tula, Ekaterinburg and Omsk) as well as the volumes of power purchased, types of power plants and forms of renewable energy. Currently the purchase price of green energy in our DPCs is a premium on the price of power on the wholesale market, and this, with a fixed purchase volume, essentially supports and structures reliable future demand for renewable energy generators.

This scheme has been acknowledged and verified by our international auditors as well as by Russian experts (the Committee for Environmental Protection and Natural Resources of the Russian Union of Industrialists and Entrepreneurs [RUIE]), who stressed the need to guarantee one-time sales of green energy by the generating company and/or energy provider. Such a guarantee can be provided by reissuing (transferring) green certificates and recording the transfer in the register of certificates. The register must be subject to strict external audits to rule out the risk that the same certificates will be repeatedly transferred within the register.

The urgent need for a system of green certificates is recognized by both generating companies and power-consuming companies. In 2019, the Market Council developed the concept of such system, after which the Russian Ministry for Economic Development developed and introduced for public discussion draft Federal Law "On Amending Federal Law "On the Power Sector" and Certain Legislative Acts of the Russian Federation Due to Introduction of Green Certificates".

Recommendations:

In the opinion of FIAC's working group, the proposed draft law needs to be enhanced to ensure compliance with the following key principles when implementing the system of green certificates:

- Participation in the system of tradable green certificates is voluntary for both producers and consumers of green energy;
- The system of tradable green certificates is independent from other stimulus measures aimed at promoting green energy and vice versa;
- Green certificates are not treated as exchange traded securities (these risks exist, considering that the above draft law provides for electronic trading in green certificates);
 - Compatibility with the current international green certification system.

Issue 2. Regulating the GHG emissions.

In accordance with Instruction of the President of the Russian Federation No. Pr-2323 of 11 November 2019, paragraph 7 of the plan to implement initiatives to enhance government regulation mechanisms for regulating the GHG emissions and the Paris Agreement adopted on 12 December 2015 by the Conference of the Parties to the UNFCCC on its 21 session, the Russian Government is drafting Federal Law "On Government Regulation Mechanisms for Regulating GHG emissions and On Amending Certain Legislative Acts of the Russian Federation".

The working group supports and understands the necessity of speedy drafting of the document, as its absence may ultimately limit the possibility of inclusion of the Russian Federation in the groups of economic, technological and ecological leaders on international and regional levels, as well as its perspectives for international cooperation. We believe, however, that the draft law requires significant enhancement, as its current version will not allow the achievement of the declared goal.

The draft law provides a framework only and does not include any measures to establish declared conditions enabling sustainable development with low GHG emissions and increased competitiveness and stability of the Russian economy amid global transfer to sustainable climate development.

For example, none of the types of activities listed in Article 4 serves as a regulation of the GHG emissions. Even incentives supporting activities to reduce GHG emissions may not in substance regulate the emissions.

The draft law proposes monitoring emissions and establishing target GHG emission indicator for the Russian Federation as a whole. The purpose of monitoring, however, is not to determine actual (additional) reduction of the GHG emissions, which is in fact necessary to assess the emissions reduction rate, but to count (identify) sources of the GHG emissions related to the activities of regulated entities and to determine the GHG emissions from these sources in order to provide the regulator with the respective data on an annual basis.

There are also concerns about Article 8 of the draft law limiting the regulated entities' responsibility to filing the GHG reports and stipulating liability only for untimely or inaccurate reporting. It follows that, in contrast to the regulated entities, the Russian Federation has target indicators and necessity to reduce the emissions. The question is who will contribute to the reduction of the GHG emissions if such a requirement is not issued to any specific party. As the logic goes, the established target indicators should be achievable without any special measures undertaken neither by the entities nor by the Government. Such indicators, however, may not be seen as the goal, as without special measures and actions undertaken by the Government net-zero GHG emissions (balance of anthropogenic emissions from emission sources and the GHG sinks absorption), being a long-term goal of the Paris Agreement, may never be reached.

At the same time, carbon accounting goals established in Article 9 are not achievable, as the reports filed by the regulated entities do not provide reliable information on the GHG emissions (at the very best, only in terms of the regulated sources and types of GHG, which is certainly not all GHG emissions).

The working group is positive about the introduction of the concept of carbon credits. However, it is important to understand that such credits may not be seen as the results of projects implementing, as the result is the reduction of the emissions or additional GHG absorption. A carbon credit is essentially a certificate confirming the GHG emissions reduction (additional absorption) due to project implementing. In addition, from our point of view, such primary activities with carbon credits as issue and redemption, are not covered in the draft law, which makes the introduction of carbon credits meaningless.

In general, the draft law does not protect the Russian entities, but creates additional risks as it puts Russia in a position of a country that ignores the Paris Agreement and does not take any measures to mitigate climate change in disregard for the requirements of the Paris Agreement. Such regulating of the emissions will create extremely uncomfortable conditions for the Russian exporters on the world markets and world investors may step away from the Russian entities and the Russian market as a whole. This may result in stagnation of the Russian economy back from the global trend on decarbonization and transition to low-carbon development pattern.

Recommendations:

- 1. Enhancement of the draft law based on the above-mentioned comments in cooperation with the FIAC working group.
- 2. Introduction of the economic stimulation mechanism of the GHG emissions reduction through the emission quotas for regulated entities along with the introduction of the carbon tax/fee for exceeding such quotas.

Issue 3. On Amendments to the Labor Code of the Russian Federation to Establish Guarantees for Working Women in Rural Areas.

Federal Law No. 372-FZ of 12 November 2019 "On Amendments to the Labor Code of the Russian Federation to Establish Guarantees for Working Women in Rural Areas" (the "Law") entitles working women in rural areas to a 36-hour working week (unless a shorter working week has been established by other legislative acts), and they are entitled to the same salary as for a full working week.

The Law provides women with social guarantees that were previously approved by Ruling No. 298/3-1 of the Supreme Court of the RSFSR of 1 November 1990 "On Urgent Measures to Improve the Situation of Women and Families and to Protect Motherhood and Childhood in Rural Areas" (the "Decree"). The main purpose of these measures was to increase the birthrate in rural areas, as the Decree's preamble indicates: "The Supreme Court of the RSFSR, understanding the importance of resolving issues concerning the family, motherhood and childhood, in view of the critical demographic situation in rural areas, and in fulfillment of decisions of the Congress of People's Deputies of the RSFSR, rules that the first stage of a comprehensive program for the protection of motherhood and childhood in the Republic shall be as follows." In addition, the Decree specified the occupations (crop production, livestock and poultry farming and the fishing industry) that qualified women for benefits. Thus, only women in agricultural jobs qualified. At the time, this was understandable and justified due to the high proportion of manual labor and harsh conditions, including weather conditions.

While the retention of these benefits and their inclusion in the Labor Code do have some justification, we believe that simply copying thirty-year-old provisions into the Labor Code without regard for the changed conditions and nature of work and new safety procedures and without regard for developments in technology that have reduced the amount of manual labor as well as other factors could harm Russia's investment climate as a whole and adversely affect the labor market.

The adopted Law contains no additional details or criteria that would clearly identify the group of women who qualify for benefits, other than the term "rural area," for which there is no clear definition in current Russian law.

Moreover, the Law has a direct regulatory impact on business (requiring that shift schedules at production facilities be revised and that additional employees be sought in order to maintain the previous level of labor productivity, etc.), and this impact was not assessed when the Law was developed and adopted.

For one thing, the Law takes no account of a trend that has been under way for some time: an improving ecological situation in cities that has been achieved by moving manufacturing facilities outside city limits. In effect, the Law indirectly harms urban ecology, since an entrepreneur relocating production outside city limits will incur continuing expenses in addition to those involved in moving or in building a new facility in a rural area.

If all women working outside city limits qualify for benefits, this will lead to higher female unemployment, since employers will find it profitable to hire men, who do not qualify for such benefits (essentially, a form of discrimination) and will work 40 rather than 36 hours a week for the same pay.

Moreover, the law does not consider the whole range of such various alternative social support measures for women employed in the entities outside urban areas as the provision of voluntary medical insurance, life and health insurance, food and education (including education abroad) allowance, access to sports infrastructure and other.

Recommendations:

The Russian Labor Code should be amended to define the term "rural area" based on the socioeconomic level of communities (high-tech production facilities, infrastructure, communications, transport, etc.) and to establish an exhaustive list of occupations that qualify workers for benefits based on their specific labor activities.

Issue 4. On experimental legal framework in Moscow.

Pursuant to Federal Law No. 123-FZ "On the Experiment to Establish Special Regulation to Create Necessary Conditions to Develop and Implement Artificial Intelligence Technology in the Moscow Federal City, a Subject of the Russian Federation, and on Amending Articles 6 and 10 of the Federal Law "On Personal Data" dated 24 April 2020 (the "Law"), an experimental legal framework has been introduced in Moscow on 1 July 2020 for a period of 5 years.

The Law establishes goals, tasks and key principles of the introduction of the experimental legal framework and governs the relationships arising therefrom.

In particular, the Moscow government is authorized to establish the terms and procedure for the development and implementation of the AI technologies and the procedure for using its deliverables.

Legal entities or individuals registered in Moscow and engaged or planning to engage in the development, implementation, sale or distribution of the AI technologies may participate in the experiment.

The status of the participant is assigned on the day the applicant is included in the register maintained by the authorized body.

The coordinating council is established in order to determine strategic areas and monitor the experimental legal framework. Based on the results of the experiment, the coordinating council will provide the Government of the Russian Federation with the proposal on whether amending the legislation is feasible.

The Law establishes that processing of personal data received as a result of anonymization is aimed at improving the effectiveness of the state or municipal control during the Moscow AI experiment:

- Processing of personal data received as a result of anonymization of personal data is allowed for the purpose of improving the effectiveness of the state or municipal control and for other purposes contemplated by Federal Law No.123-FZ;
- Processing of the special category of personal data (health information of citizens) is allowed for the purpose of improving the effectiveness of the state or municipal control and for other purposes contemplated by Federal Law No. 123-FZ.

Risks:

- The goal on the improvement of the effectiveness of the state or municipal control established in Article 7 of the Federal Law No. 123-FZ that allows processing of personal data, including special categories of personal data, is general in nature and does not provide any specifics;
- There are concerns regarding early adoption of Federal Law No. 123-FZ without prior discussion, analysis, application and implementation of the following:
- Mechanism preventing transfer of personal data to parties not participating in the experimental legal framework;
- Procedure for destruction of personal data by a participant of the experimental legal framework when the participant status ceases to apply or the period of the experiment expires;
 - Specific responsibility for neglecting the rights of the subjects of personal data;
- Standard reasonable requirements to the participants of the experimental legal framework on the protection of personal data received during the project;
- The level of protection of personal data processing by the participants of the experimental legal framework may differ significantly putting them in an unfair competitive position;
- Personal data processing under single infrastructure significantly increases the risks of data loss and trapping of personal data by intruders;
- There are concerns regarding technical capability to ensure compliance with Article 4.7 of Federal Law No. 143-FZ prohibiting storage of personal data outside the Moscow federal city, a subject of the Russian Federation.

Recommendations:

Use draft law No. 950900-7 to support imposing of a moratorium on the adoption of Article 7 by 1 July 2025. This will provide necessary time for developers of AI systems to eliminate (minimize) technical errors in their systems, ensure sufficient testing and reviews during elimination of possible system errors and technical inaccuracies and prevent the use of personal data from intrusion upon the citizens' privacy. During the moratorium, legislative gaps related to responsibility of legal entities and officials for misuse of AI technologies and non-compliance with data processing procedures will be eliminated.

Issue 5. Automation and robotization of industrial enterprises.

In fulfillment of the Russian Government's instruction based on FIAC's Plenary Session, recommendations on measures to stimulate automation and robotization of enterprises in the context of the National Project for Enhancing Labor Productivity are being developed in cooperation with the Productivity and Efficiency Department of the Ministry of Economic Development.

The experience of introducing industrial robotics in developed countries showed that, to promote large-scale robotization and automation in industry, measures to support an enterprise's initial industrial robotization project are critical in ensuring that the first experience is not a negative one and that the right goals are set for further modernization. It was determined that one such critical element is a process audit to assess an enterprise's potential for industrial automation and robotization and determine priority groups of processes where automation and robotics will yield the greatest economic benefits.

Recommendations for process audits at enterprises involved in the National Project were developed in cooperation with the Russian Ministry of Industry and Trade and the Ministry of Communications and were favorably received. Such process audits may be included in the support program, thus amplifying the effect

of digitization initiatives at National Project participants and laying a systemic foundation for large-scale automation and robotization in industry. To ensure that enterprises have the resources for process audits, the current regulations of development institutions must be analyzed with a view to subsidizing expenses that National Project participants incur for process audits as a basis for the industrial automation and robotization of production processes to enhance labor productivity.

Market participants prepared and submitted to the Productivity and Efficiency Department of the Ministry of Economic Development (https://www.economy.gov.ru/material/departments/d29/) recommendations on the regulations on process audits in order to implement industrial automation and robotization of production processes to enhance labor productivity. Matters of government financing of process audits have been deferred due to the pandemic. According to ABB, further development of the process audits program requires involving a wide range of market participants, including automation and robotics manufacturers, industry associations, representatives of the Federal Center of Competences, national development institutions and companies participating in the National Project. One of the key objectives is to establish a platform facilitating open discussions of the market stakeholders. Currently, active industry associations does not satisfy the requirements of the antimonopoly legislation. On its part, ABB suggested that the Ministry establish a working group under the aegis of the Productivity and Efficiency Department to prepare the final version of the regulation on the robotics audit program. One of the possible steps to implement the regulation may be a test process audit on one of the enterprises participating in the program. ABB Russia is currently considering such test process audit in Kaliningrad region with the involvement of the ABB Engineering Center specialists and engineering partners of ABB in Russia.

For information

Proposals on implementing robotics and automation for the National Project "Labor Productivity"

Robotics and automation are widely used globally to enhance labor productivity, cut on costs and increase the competitiveness of enterprises. The share of industrial robotics in the GDP growth in the countries with a developed industrial robotics market reaches up to 10%, which is comparable with the share of the entire oil and gas sector in the structure of the Russian GDP (approximately 10%). In our country, the share of industrial robotics in the GDP growth is negligible and accounts for only a fraction of a percent in the GDP growth. This demonstrates the non-use of a huge potential of industrial robotics which has already proved its effectiveness in many countries.

Number of robots per 10,000 employees in an industry is used for comparing countries by the level of industrial robotization. Robot density reflects market saturation and the level of industrial automation. In 2018, robot density in Russia reached 5 robots per 100 employees being comparable to that in Indonesia and the Philippines. In contrast, the global average is 99 robots per 10,000 employees, while in China the indicator is 140 robots per 10,000 employees, in the USA - 217, in Japan - 327, in Germany - 338, in South Korea - 774 and in Singapore - 831.

Such low use of robotics in the Russian industry is an indication of certain system difficulties faced by the enterprises when implementing robotic cells:

- Low management awareness of economic efficiency of implementing robotic cells;
- Lack of qualified personnel in the area of robotics;
- · Absence of the open methods for assessing the potential of industrial robotization;
- Absence of the data base of implemented robotic solutions by industry and performed operations in Russia and abroad;
- Absence of available debt financing of projects to modernize production using robots (RUB 5-15 million);
- High costs of pre-project feasibility studies to receive financing and justify small projects.

These challenges may be addressed under the National Project "Labor Productivity".

Industrial robots are widely used in the industrial production of most of the developed countries. Robotic cells (with the use of articulated or cartesian robots, delta robots, SCARA robots and other) may perform such functions as welding, cutting, metalworking, coloring, coating, assembling, machine tending, food transfer and packaging and other operations related to replacement of hard, monotonous and hazardous manual work.

It is international practice to provide additional support measures by the government authorities in order to increase the use of robotics. Measures that would make such class of technologies available for the industrial enterprises may also be applied in Russia. In order to promote the use of robots in each area,

barriers for each sector should be addressed individually and needs and specifics of robitization of these industries should be considered. Implementation of robots increases competitiveness of domestic enterprises, reduces costs and allows transfer of workers from routine to more intellectual operations. Inclusion of robotics in the program for enhancing labor productivity will provide enterprises with advanced production tools, adapt employees and improve their competencies which will ultimately increase their competitiveness on foreign markets. Stimulation of the enterprises' demand for robotic solutions will also increase the number of local developers of robotic-cell technologies (integrators) and will have positive impact on the robotics market as a whole.

Proposals on implementing robotics and automation for the National Project "Labor Productivity" are based on the results of the discussion held with extensive participation of the members of the National Association of the Robotics Market Participants.

Recent global trends in technological processes automation development determining the possibility of labor productivity enhancement

Shift to the fourth technology paradigm (Industry 4.0) accelerates embedding of robots, cobots (collaborative robots) and other modern machines and industrial automation tools in the production processes ensuring significant increase in the capacity of enterprises. This triggers the issues of communication compatibility, determinancy, transparency of the network M2M connectivity, assessment of general equipment efficiency, transition to predictive diagnostics and technical maintenance and gives rise to a need for the required level of information safety and safety of human-machine interaction.

Currently, there is a global tendency for the development and implementing of flexible production systems aimed at transition to the production of single batches of products at the current characteristics and potential of the mass production. This tendency implies a conceptual change in the approaches to design, development, production and maintenance of manufacturing lines and cells. Modern automation and robotization technologies provide opportunities for simultaneous production of different types of products on one technological site or line, thereby enabling significant increase in productive capacity and efficiency.

One of the key objectives aimed at transition to modern production technologies is the process audit of the level of automation and robotization of the existing enterprises. Process audit should involve assessing and preparing of recommendations on criteria describing the enterprise's technological level and its readiness for implementing perspective production technologies (refer to Annex 1).

Preliminary recommendations:

The National Project "Labor Productivity" consists of 3 federal projects, each of which involves measures to increase the use of robots and automation of technological projects to enhance labor productivity. A program of process audits is one of the recommended measures to minimize the risks of enterprises arising from implementing the initial robotic-cell technologies and to support development of new technologies by local integrators. Similar projects are used as well in the countries with high robotization rates (for example, Robotliftet, a program of the Swedish Agency for Economic and Regional Growth).

Identifying the need of the participants of the program to enhance labor productivity for the implementation of robotic automated systems through the process audit of enterprises. The initiative may be implemented through the Federal Center of Competences in Labor Efficiency with the involvement of the players of the market of industrial robotics and means of industrial robotization, especially robotic cells integrators. As a result, participating enterprises will receive shaped images of industrial robotized flows in accordance with best international practices, including the specification, results of technology testing, evaluation of the required cash investments, timing of the project and payback period and a full list of materials to create the investment project.

We also recommend distinguishing separate segment "Robotization and automation of production processes" when preparing documents under the National Project "Labor Productivity". The wording "automation and use of end-to-end technologies" implies the use of robots. Such use, however, is not directly denoted, which may result in ambiguous interpretations and future limitations on the implementation thereof.

In addition, timing of the activities established in the passport of the federal project should be extended for the segment "Robotization and automation" to ensure proper arrangement of such activities.

The National Association of the Robotics Market Participants is ready for future collaboration with the Russian Ministry for Economic Development and the Federal Center of Competences in Labor Efficiency in terms of implementing the National Project "Labor Productivity".

Annex 1

Recommendations on the structure of the process audit of the automation level of enterprises

1. Use of the industrial robotics

Increased robotization of enterprises and replacement of manual labor on hazardous, monotonous and hard operations have appreciable effect on the reduction of the cost of manufactured products and, consequently, on the increase of the enterprise's efficiency and competitiveness. In its turn, this results in the increased volume of manufactured goods and number of workplaces that become more comfort and efficient.

Process audit should involve evaluation of the enterprise and the following steps:

- Analysis of the existing technological processes;
- Testing by the integrators/auditors of the use of the industrial robotics in the existing technological processes using digital twins;
 - Payback analysis on the basis of the calculations received during testing;
 - Recommendations on required changes;
 - Training of the enterprise's specialists.
 - 2. Functional safety

An integral part of the industrial robotization and automation should become an increase of the technological processes safety and reduction of this risk of personnel injury and death, which directly relates to the increased production capacity. This requirement may be satisfied through the use of modern industrial safety standards and technologies. This may include functional safety standards aimed at protection of the personnel working with complex robotized and automated machining centers. Increased interaction of a human and a machine should at all times be followed by the increased human protection thus ensuring the development of collaborative technologies of human-machine interaction. Process audit should involve evaluation of the enterprise and the following steps:

- Analysis of whether technological equipment satisfies the existing functional safety standards;
- Assessment of the level of the functional safety training of the operating personnel;
- Assessment of the existing measures to mitigate risks of near-accidents;
- Assessment of whether technological equipment satisfies the existing standards;
- Recommendations on required changes:
- Identification of opportunities to increase functional safety of technological equipment;
- Evaluation of the budget required to increase functional safety of an enterprise, including improved training of personnel involved in production.
 - 3. Networking

It should be noted that increase of the efficiency and capacity through implementing flexible production systems will be directly dependent on the level of the digitalization of the enterprise's infrastructure allowing for integration of the production level and the level of information technologies. In particular, communication compatibility, determinancy and networking reliability become the most essential aspects of such integration.

Until now, communication inside and between the machines and production units was established through various proprietary communication protocols. In this case, data transfer between the devices and components of different produces requires the use of specialized converters and gateways putting additional pressure on the operating personnel of industrial enterprises related to the heterogeneous network infrastructure maintenance. Existence of multiple industrial proprietary communication protocols makes it much harder to create a unified network of information and process systems slowing down digital transformation of enterprises under the development of the fourth technology paradigm. This issue may be resolved through a shift to the open standard communication protocols to ensure seamless data transfer between the devices of different producers from the field level to the cloud computing level. Use of such technologies makes it possible to dramatically increase the speed and volume of production data transfer and significantly enhance labor productivity.

Process audit should involve evaluation of the enterprise and the following steps:

- Analysis of industrial communication protocols used for M2M connectivity;
- Assessment of the share of M2M communications using industrial communication protocols in the total amount of communications:
 - Assessment of the extent of the use of proprietary industrial communication protocols;

- Assessment of the extent of the use of open industrial communication protocols Assessment of the network connectivity between the technological and production management levels;
- Recommendations on the improvement of transparency of network connectivity between the technological and production management levels;
- Personnel training on the modern methods to establish network connectivity on an industrial enterprise.
 - 4. Overall equipment efficiency

Modern high-performance means of automation that ensure collection of operational data in real time through the industrial field channels make it possible for the employees operating high-tech equipment to refine and accelerate the assessment of the overall equipment efficiency (OEE) that directly characterize the capacity of the industrial enterprise. Enterprises should be assessed for the availability of automated means of collecting and analyzing data on energy consumption and operating processes of technological equipment.

Process audit should involve evaluation of the enterprise and the following steps:

- Analysis of the existing supervisory control and data acquisition (SCADA) systems;
- Analysis of the availability of industrial communication protocols infrastructure at the technological equipment;
- Analysis of the integrated means of diagnostics of technological equipment in terms of the availability of information characterizing the efficiency;
- Recommendations on the establishment of the system of monitoring and assessment of the overall equipment efficiency;
- Personnel training on the modern methods to assess the overall efficiency of the technological equipment.
 - 5. Predictive diagnostics and technical maintenance

Enterprises should be assessed for the opportunities to transit to technical maintenance of complex technological equipment, for example, flexible industrial robotic cells, using automated means of predictive diagnostics.

Predictive maintenance is based on the intellectual technical maintenance scheme activated even before a failure in a machine or a system occurs.

Combination of technical and economic production data and information from the measuring sensors allows predicting the possibility of a shutdown (failure). Consequently, further technical maintenance activities may be postponed, though the components at high risk of failure may be timely identified and repaired before failure occurs.

Maximum production efficiency with minimum maintenance costs may be achieved only through technical maintenance that is ultimately concentrated on the condition of the equipment.

Process audit should involve evaluation of the enterprise and the following steps:

- Assessment of the regulations and rules on diagnostics and technical maintenance in place;
- Analysis of the availability of data on the condition of technological equipment for further analysis;
- Assessment of the availability of means of control and measurement of parameters that characterize the condition of the technological equipment;
 - Analysis of statistical data on technological equipment failures:
 - Recommendations on the transit to technical maintenance on condition;
 - Evaluation and planning of the budget for implementing predictive diagnostics;
 - Recommendations and evaluation of the budget for personnel training and retraining.

2. Localization and Regional Development

Issue 1. Excessive requirements for the localization of production in Russia.

Russia enacted an import substitution policy by Decree No. 719 of the Russian Government of 17 July 2015 "On the Verification of the Manufacture of Products in the Russian Federation." It provides that the main criterion for treating products as Russian-made is the location of key manufacturing processes in Russia. This requirement applies to almost all key industries, and the list of manufacturing processes and regulated industries continues to expand.

Initially, the main criterion for treating automotive products as Russian-made comprised a list of mandatory manufacturing processes to be localized in the Russian Federation or EEU. The approach was criticized by automakers since it neither reflected the specific conditions in which industry segments are developing nor followed global technology trends.

In its Decree No. 667 of 25 May 2019, the Government approved amendments to Decree No. 719, introducing a new system of evaluating the level of localization by scoring processes involved in the production of key parts and components for automotive vehicles. Automakers become eligible for various types of state support depending on their total score.

The approach, offering automakers more freedom in choosing processes for localization, is progressive, but it still has a number of weaknesses.

1. List of manufacturing processes.

The new list of manufacturing processes is not optimal. For example, an excessive number of newly introduced processes involve production of automotive electronics, which was not even mentioned in the previous version of the list. Since there had been no requirement to manufacture electronic units in the Russian Federation, most automakers were not prepared to localize their production. The importance of electronic systems and related software for today's vehicles means that the development of such software is costly and involves lengthy fine-tuning and testing. It is highly inefficient in economic terms to develop separate versions of software for the Russian market and transfer the intellectual property rights to a company registered in Russia. It is also unlikely that Russian software will be the only software installed in vehicles manufactured around the world by international companies. It should also be noted that production of electronic systems for vehicles is generally underdeveloped in Russia.

The list of manufacturing processes also includes Russian-made paint materials, while even Russian manufacturers refuse to use them.

2. Accounting for vehicle class specifics.

The list of manufacturing processes takes no account of vehicle class specifics (passenger cars, trucks and buses), though their output, which is the main cost driver, may differ a thousandfold. It thus makes no economic sense to localize production of such complex components as engines and gear boxes for trucks in the current circumstances.

Due to the fact that versions of the same component for passenger cars and trucks (for example, windscreen, body kit parts) may differ significantly in size and complexity, investments in their production and thus also their profitability may also differ dramatically, so a different score should be assigned to the same processes localized in different segments of the automotive industry.

3. Localized production of components

The list does not mention components whose production has been financed before (automobile glass, sound insulation, wiring, fifth-wheel assemblies and hitch mechanisms), which depreciates the investments made. Investors are also concerned about possible depreciation of their investments if changes are made to Government Decree No. 719 in the future.

Currently, the Ministry of Industry and Trade is working to roll out the scoring system to other machine-building industries (manufacture of agricultural, road-building and specialized machinery). It is quite possible that this approach will be used in other industries.

Recommendations:

Inform the Ministry of Industry and Trade and the Ministry of Economic Development about the position of international investors looking to expand their businesses in Russia on specific parameters of the scoring system and suggest reasonable adjustments thereto.

Issue 2. Facilitating exports to the CIS and neighboring FSU countries (by monitoring changes in technical regulations in these countries).

Many Russian and foreign companies today export Russian-made products to the CIS and neighboring FSU countries.

These countries' requirements for products (e.g., marking, food safety control, state standards for food products, limits/standards/prohibitions with respect to the use of certain ingredients) vary greatly.

EAEU countries (Armenia, Belarus, Kazakhstan and Kyrgyzstan) apply the same requirements as Russia, which makes it easier to export goods to these countries.

Technical regulations adopted in other CIS countries, such as Azerbaijan, Moldova, Mongolia1, Tajikistan, Turkmenistan 2 and Uzbekistan, have special provisions that must be taken into account when manufacturing products. Joint efforts have been made to establish interstate standards. These efforts made it easier to solve this problem. On the other hand, Moldova, for example, has recently harmonized its technical regulations with European standards that are different from EAEU standards.

Georgia, which is not a member of the CIS, is also focused on harmonizing its technical regulations with European standards. Not all countries are WTO members, which makes it impossible to automate the process of collecting information about new non-tariff barriers.

It is therefore necessary to monitor changes in technical regulations of countries that are not members of the EAEU. However, language barriers and a lack of special knowledge and competencies are serious problems.

Most companies work in these countries through distributors, which means they do not have employees to monitor regulatory changes. As a result, Russian manufacturers are far too often unprepared for new changes that come into force. This gives rise to a risk of loss (risk of write-off) and might lead to an outright refusal to supply goods to certain countries in order to mitigate risks. Needless to say, these issues are even more challenging for small and medium-sized businesses.

This situation remains unresolved in 2019 as Russian exporters are now facing new requirements and are uncertain how to meet them.

The solution is to establish mechanisms for the exchange of information about recent developments in food legislation at the interstate level, ensure regular monitoring and issue newsletters on changes in technical regulations being drafted and enacted in these countries.

Based on a meeting of FIAC's executive committee on 10 October 2019, the Ministry of Industry and Trade, in cooperation with the Russian Export Center and the business community, should develop the concept of an early warning system to provide updates on requirements for goods imported from Russia to neighboring FSU countries. Such functions can be performed by Russia's trade missions abroad.

This work will be continued in 2020 together with the Department of Foreign Trade Regulation and Export Support of the Ministry of Industry and Trade.

Issue 3. Need for certification of Russian suppliers of livestock products to develop non-commodity exports from the Russian Federation.

Export-oriented production is included in the priority agenda of the national agricultural policy. The Ministry of Agriculture of the Russian Federation developed a complex of support measures to unlock the export potential of Russian producers; the measures are being implemented as part of the International Cooperation and Exports national project.

Producers are encouraged by the state measures: exports of certain non-commodity products are increasing and the geography is expanding. For example, exports in 2018 totaled 539,000 tons, worth USD 1,168 million, representing year-on-year growth of +17.3% in physical terms and +11.3% in monetary terms.3

At the same time, Russian manufacturers encountered certain challenges while expanding their export geography to the EU. In accordance with EU veterinary requirements, if exported goods contain ingredients of animal origin, the suppliers of such ingredients must be certified and registered as exporters in the EU veterinary control systems. In other words, if a Russian chocolate maker wants to export its produce to the EU, the respective Russian supplier of powdered milk (an ingredient of the exported chocolate) must be

¹ Participates in certain CIS structures as an observer

² Associated member

³ According to the Confectionery Industry Association

registered in the EU veterinary control system. Certain difficulties are caused by the absence of a health certificate issuer in the Russian Federation (as required in some countries).

Many Russian exporters have found themselves in a situation where 1) their suppliers are not interested in getting certified for compliance with EU veterinary requirements due to the absence of export plans; 2) regional administrations of the Federal Service for Veterinary and Phytosanitary Supervision (Rosselkhoznadzor) carry out certifications in violation of the established deadlines. These factors significantly limit the Europe-oriented export potential of Russian manufacturers.

The actions proposed to address the existing situation are as follows:

- 1. Russian Government: establish an authority responsible for the issuance of health certificates.
- 2. Ministry of Agriculture: accelerate implementation of a register of controlled goods exporters to countries which are not members of the EAEU.
- 3. Ministry of Agriculture: raise awareness of Russian agricultural producers; encourage them to register as exporters or get certified for compliance with the veterinary requirements of major export destinations in the agroindustrial complex.
- 4. Ministry of Economic Development: implement educational programs for SMBs (agroindustrial complex) to keep up with the current requirements/certifications in the field of energy efficiency, sustainable development, environmental safety and HACCP.

Issue 4. Recommendations on improving tax law to support investments.

Federal Law No. 335-FZ of 27 November 2017 added Article 286.1 "Investment Tax Credits" to the Russian Tax Code, permitting certain taxpayers to reduce the amount of tax (prepayment) they pay to federal and regional budgets.

An investment tax credit allows a reduction in profits tax payable to the federal budget and the budget of the relevant constituent entity of the Russian Federation. An investment tax credit may reduce regional tax by a maximum 90% of expenses for the acquisition of fixed assets and of expenses for upgrading, reconstructing and otherwise improving fixed assets. In such cases, the minimum tax that must be paid to the regional budget is 5% of the profits tax base.

Federal tax may be reduced by 10% of expenses for the acquisition fixed assets and of expenses for upgrading, reconstructing and otherwise improving fixed assets. The Tax Code places no minimum on tax payable to the federal budget, and this means that an investment tax credit may reduce federal tax to zero.

However, such profits tax reductions entail a number of restrictions and requirements for taxpayers – above all, a lack of flexibility in applying or not applying the tax credit to assets and the additional administrative burden involved in double accounting and the calculation of maximums and minimums.

Matters yet to be regulated include a depreciation procedure for accounting purposes, a procedure for calculating and paying assets tax and the ability to deduct the acquisition cost of fixed assets when such assets are written off/sold.

From an economic point of view, the tax credit does not ultimately have an effect of 90%-100% of the cost of investments, but much less, depending on regional indicators and conditions. In fact, if expenses are not taken into account in determining the investment tax credit in subsequent tax (reporting) periods under Article 286.1.9 of the Tax Code, it can have the reverse effect, when the amount of a credit is less than subsequent profits tax and assets tax consequences. There are also concerns about the strict requirement that unpaid taxes be restored and that fines and penalties be paid when fixed assets are sold, which fails to take into account companies' investment cycles and effectively prevents the renovation of manufacturing facilities. For example, manufacturers of fast-moving consumer goods are constantly upgrading their production lines and introducing new solutions to meet consumers' growing demands with respect to the consumer properties of such goods.

At the regional level, costly investments (fixed assets in groups 8-10) may not be taken into account. The right to establish taxpayer categories is interpreted very broadly, and restrictions may be applied not only to types of economic activity, but also to aspects of corporate structure (the presence of separate legal entities in a region, an investment project's regional revenues as a percentage of the company's total revenues).

Recommendations:

We recommend the following as part of developing the mechanism of investment tax credits:

- 1. For certain fixed assets, allow taxpayers to choose the expenses that are used in calculating an investment tax credit and are subject to the restrictions in Article 286.1 of the Russian Tax Code.
- 2. In paragraph 2 of clause 8 of Article 286.1 of the Russian Tax Code, eliminate the restriction of three subsequent tax periods during which a taxpayer may change its decision to apply (or not to apply) an investment tax credit, and also allow unpaid taxes to be restored in an amount proportional to the period during which an investment tax credit was used.
- 3. Establish a depreciation procedure for accounting purposes and a procedure for calculating and paying assets tax, and allow the tax base to be reduced when fixed assets are written off/sold.
- 4. Amend clause 9 of Article 286.1 of the Russian Tax Code to give taxpayers the unconditional right, when expenses exceed the maximum, to take them into account in determining the investment tax credit in subsequent tax periods.
- 5. Amend clause 12 of Article 286.1 of the Russian Tax Code to allow taxpayers to sell/liquidate fixed assets without restoring unpaid taxes and paying fines and penalties at the end of the three-year period after the fixed assets are recognized.
- 6. Amend clause 4 of Article 286.1 of the Russian Tax Code so that investment tax credits can be applied to all fixed assets in depreciation groups 3-10.
- 7. Amend subclause 3 of clause 6 of Article 286.1 of the Russian Tax Code to limit an entity to setting criteria only by type of economic activity.
 - 8. Delete subclause 4 of clause 6 of Article 286.1 of the Russian Tax Code.
- 9. The investment tax credit mechanism needs improvement, and this situation creates uncertainties for investors deciding whether to expand production now and in the next 1-2 years. At the same time, current benefits affecting the regional portion of profits tax will no longer apply from 1 January 2023. This situation, against an economic background complicated by the spread of the coronavirus infection, is having a negative impact on the investment climate.

We recommend that paragraph 5 of clause 1 of Article 284 of the Russian Tax Code be amended to allow lower rates of corporate profits tax payable to Russian constituent entities to be used until their expiration date – only for projects to which such benefits apply until 1 January 2023.

3. Improvement of Tax and Customs Law and Administration

Improvement of Tax Law and Administration

In 2019-2020, the working group for the improvement of tax and customs law and administration focused on the following issues.

Issue 1. Substantiation of intra-group services.

In tax audits in 2019 and 2020, the tax authorities have been particularly scrutinizing service agreements between a Russian legal entity and its foreign parent company or affiliate. The tax authorities claim that such services are not real or justified, reclassify payments for them as passive income (distribution of capital or dividends, for example) and assess withholding tax on it in Russia.

The questions asked during tax audits make it clear that the auditors tend to assume a deliberate lack of good faith when the parties to a transaction are related, and they treat every transaction with a related party as a means of tax optimization rather than a rational business transaction.

An analysis of the Survey of Litigation on the Application of International Treaties and Legal Abuses in Cross-Border Transactions, prepared by the Federal Tax Service, indicates that the tax authorities are inclined to take such an approach.

The Russian tax authorities require more extensive justification of expenses for intra-group services than is the case in international practice and is accepted by the tax authorities of many countries, and this creates substantial additional tax risks for businesses in Russia.

Such an approach, requiring excessive documentation and ignoring the economic substance of services, is not only at odds with international practice and difficult (in effect, impossible) to administer, it also prevents the use of global expertise, disrupting established relations within a group of companies. This makes the Russian divisions of such groups less competitive and ultimately prevents them from contributing to the national tasks of attracting investments and increasing exports.

Based on the outcomes, including those resulting from the activities of the working group, the Russian Federal Tax Service issued a letter on 20 August 2020 to clarify to the subordinate tax authorities certain issues related to the application of the concept of intra-group services.

Recommendations:

We believe it desirable to continue efforts towards improving the regulation on how intra-group services should be substantiated, based on international practice.

Issue 2. The need for foreign companies providing electronic services to Russian taxpayers to be registered for VAT purposes in Russia

In 2019, a Tax Code provision was enacted to require foreign companies not registered in Russia to discharge the VAT payment obligation by themselves and register with the tax authorities if they provide electronic services to Russian customers.

This provision posed a whole range of practical issues for foreign companies and hindered large companies from providing electronic services to their Russian divisions.

In view of the above, the authorities considered the practicality of applying the previously used tax-agent mechanism to electronic services provided in intra-group transactions.

As a result of repeated discussions with representatives of the Ministry of Economic Development and the Federal Tax Service, the Federal Tax Service issued a letter of 24 April 2019 which did not formally change the procedure of paying VAT pertaining to electronic services, but indicated a possibility for the taxpayer not to make a VAT payment if the purchaser of their services had withheld and paid VAT using the tax-agent mechanism. This letter improved the situation, but a complete legislative solution of the issue is still pending.

Recommendations:

We recommend that the working group continue to discuss amendments to the Russian Tax Code related to restoring the tax-agent mechanism applied to electronic services provided under intra-group transactions and consider introducing the qualified tax-agent institution for electronic services.

Issue 3. The need for stable legislation on, and predictable rules of changing, the tax burden, including excises, of foreign investors in Russia.

In the last three years, a practice has developed in tax disputes that is inconsistent with the principles of tax law. Many large international companies in Russia have been hit with substantial additional tax assessments as a result of tax audits of previous periods.

This adverse practice has not always been the case. Until 2013, arbitration courts, guided by Article 3 of the Tax Code, interpreted all uncertainties, ambiguities and contradictions in legislative acts on taxes and levies in favor of taxpayers.

This approach changed dramatically after 2013, when a number of new trends emerged in the work of the tax authorities, causing serious concerns of business, namely:

- new rules and concepts could be applied to a transaction that was completed before they had been introduced into tax law and doctrine;
- numerous transactions were reclassified by the tax authorities, which also often applied the criterion of economic substance (justification) to reclassify taxpayers' actions;
- the burden of proving the circumstances, on which government authorities based disputed decisions, was shifted to taxpayers.

Each of these three traits of the current practice pose an equal threat to the ability to do business in Russia. Businesses today lack transparent criteria for determining how their actions will subsequently be classified. In this situation, any business (and investment) activity is seen as involving a high level of risk, making Russia less attractive for investors.

The problem is not the poor quality of regulation (gaps, contradictions), but the application of principles that are not found in the law or an arbitrary interpretation by the fiscal authorities of provisions that are set down in law.

Recommendations:

We recommend formulating precise criteria for economically justified transactions carried out by taxpayers. We also believe that consideration should be given to establishing an institution of reasoned opinions outside of the tax monitoring procedure.

Issue 4. Refining the regulations that govern the provision of investment tax credits and consideration of the option to extend regional income tax breaks.

In 2018, Article 286.1 "Investment Tax Credits" was added to the Russian Tax Code, permitting certain taxpayers to reduce the amount of income tax (prepayment) they pay to federal and regional budgets.

However, this mechanism is rarely used now because of significant restrictions imposed on taxpayers that apply investment tax credits. These restrictions, aggravated by the upcoming, from 1 January 2023, termination of the regional income tax credits widely used by investors, lead to a significant deterioration in the investment climate.

The proposed income tax reduction entails a number of restrictions and requirements for taxpayers, and above all, a lack of flexibility in applying or not applying the tax credit to assets and the additional administrative burden involved in double accounting and the calculation of maximums and minimums.

When refining the investment tax credit mechanism, we consider it appropriate to stipulate the following: grant the taxpayer the right to choose expenses for certain fixed assets to be used in the calculation of investment tax credit; remove the restriction in the form of three consecutive tax periods after which the taxpayer can change its decision to apply (or opt out of applying) the investment tax credit mechanism; as well as provide for the possibility for the taxpayer to restore unpaid taxes in the amount proportional to the period during which it used the tax credit mechanism, adjust provisions of the relevant Tax Code article to give the taxpayer the right to sell/liquidate fixed assets upon the expiration of a 3-year period after the fixed assets were entered in accounting records without restoring the respective amounts of unpaid taxes and paying interest and penalty, and address a number of other technical issues in the application of this article.

The investment tax credit mechanism needs improvement, and this situation creates uncertainties for investors deciding whether to expand production now or in the next 1-2 years. At the same time, the currently available tax breaks on the regional portion of income tax will stop applying from 1 January 2023. This, coupled with the difficulties in the economy due to COVID-19, has an adverse impact on the investment climate.

Apart from that, we suggest discussing the possibility to amend paragraph 5 of clause 1 of Article 284 of the Russian Tax Code to allow lower rates of corporate income tax payable to Russian constituent entities to be used until their expiration date – but only for projects which are duly entitled to these tax breaks until 1 January 2023.

Recommendations:

We suggest considering a package of potential changes to the tax legislation in order to harmonize the use of the current tax break.

Improvement of Customs Law and Administration

Issue 1. Improvement of the institution of AEOs in the EAEU.

1.1. Remote access to information in the accounting systems of AEOs.

Under clause 1.7 of Article 433 of the Customs Code of the Eurasian Economic Union, in order to be registered as an authorized economic operator and be issued a type-one certificate, a legal entity must have "a goods accounting system that meets the requirements established by the customs law of member countries, making it possible to compare the information provided to the customs authorities during customs operations with information on business operations and giving the customs authorities access (including remote access) to such information."

The form and procedure for providing remote access to information in an accounting system are not established by customs law. However, FIAC member companies interested in being registered as authorized economic operators have come up against certain requirements of the customs authorities, such as the requirement that, during field customs inspections, remote access be provided directly to accounting and information systems rather than to the information alone.

Currently, in order to process data concerning, among other things, the management of import and export operations, FIAC member companies in most cases use global corporate-wide automated systems based on an SAP hardware-software solution (SAP G-ERP). Servers are often located in data centers outside the Russian Federation.

In order to meet the information security requirement to protect critical corporate information systems, companies use special organizational, software and technical protection tools, including access restrictions and the identification and authentication of users accessing such systems.

For authorization purposes, we suggest considering methods of remote access in the form of a "data mart" system as well as other methods providing access to information in an accounting system without any direct link to internal corporate information systems.

Authorized customs officers can be given access to the required information, retrieved directly from an SAP G-ERP accounting system, on customs and business operations involving goods that have been cleared through customs by a company using AEO status by means of user authentication with individual logins and passwords, using a web interface that automatically provides access via a secure communication channel.

Recommendations:

We request that, for foreign trade operators interested in AEO status and for the customs authorities, the Federal Customs Service consider preparing a survey of standard forms of remote access to information in AEOs' accounting systems in addition to direct remote access to accounting systems as well as a list of information to which remote access is provided.

Issue 1.2. Requirements for reporting by AEOs.

Order No. 2077 of the Federal Customs Service of 20 December 2018, which approves the AEO report format, contains information on all business transactions related to the movement of AEOs' goods – in particular, receipt, storage, release into production and sale.

Much of the required information is unnecessary, since, under Article 433 of the EAEU Customs Code, the customs authorities must be given remote access to AEOs' information systems before they can be registered as authorized economic operators. It is an excessive burden on businesses to require that they additionally submit such information.

At the same time, EAEU regulations and national laws make requirements of AEOs, including that their accounting systems comply with Federal Law No. 402-FZ "On Accounting" of 6 December 2011 and with Russian tax law, which requires that the goods declaration number and commodity number in the declaration be indicated in accounting systems only upon initial receipt.

The report form envisaged by Appendix No. 2 is not optimal for enterprises engaged in continuous production, where the movement of raw and other materials is daily and continuous and system accounting is done by production lot without any link to goods declaration numbers and commodity numbers in goods declarations.

Thus, the proposed format of the report (in particular, Appendix No. 2, which additionally includes information on the storage, movement and sale of goods) introduces additional requirements for an AEO's accounting system, thus creating additional administrative barriers and entailing additional financial costs for the organization and operation of the AEO's accounting system.

Recommendations:

1. The Federal Customs Service of Russia should amend its order by removing information – provided by AEOs via remote access – which is contained in the databases of other federal executive bodies, as well as information unrelated to the simplified procedures applied by AEOs, from the list of information annually provided by AEOs.

Issue 1.3. An extended list of simplifications, including for goods subject to mandatory identification marking.

Article 4, paragraph 3, of the Agreement on Identification Marking in the EAEU (concluded in Almaty on 2 February 2018) states that, once marking has been introduced, goods imported into the customs territory of the EAEU are to be marked prior to being placed under the customs procedures of release for domestic consumption and re-import and also, in cases stipulated by the laws of EAEU member states, prior to the customs procedure of free customs zone. Goods may be marked after being placed under the customs procedures of release for domestic consumption and re-import in warehouses specified in Article 6, clause 1-c, of the Agreement, if this is permitted by the laws of EAEU member states.

Under current law, goods must be marked before they are put into circulation. In some cases, mandatory marking outside Russian customs territory is impossible due to the technological limitations of production lines or the economic unfeasibility of re-equipping production lines when insufficient quantities of products are procured for the Russian consumer market. The Russian Government is authorized to approve the rules for marking goods subject to mandatory identification marking as well as the specifics of marking individual goods (Article 5, part 1, clause 3.1, of Federal Law No. 381-FZ).

Decree No. 515 of the Russian Government of 26 April 2019 establishes the rules for marking goods subject to mandatory identification marking. Under these rules, foreign-produced, imported goods are regarded as "put into circulation" when the customs authorities release them for domestic consumption. Clause 4 of these rules states that goods are marked by creating and applying means of identification (machine-readable codes) to goods, packaging or another physical medium intended to bear means of identification in the locations where they are manufactured, packaged (repackaged) or stored. One special simplification for AEOs under the EAEU Customs Code gives them the ability to store foreign goods under customs control on their premises and outdoor sites. The FIAC working group asks the Federal Customs Service to consider allowing AEOs to mark goods with means of identification on their sites and premises that have type II or type III certification.

In collaboration with the Federal Customs Service of Russia, the Ministry of Finance prepared a draft resolution of the Eurasian Economic Commission providing for such simplification.

We ask the Ministry of Economic Development to assist in preparing the resolution and submitting it to the Eurasian Economic Commission.

Issue 2. Enhancement of state measures to support the processing of goods for domestic consumption and processing in the customs territory.

In addition to the production in Russia of components for the domestic market (or conversion to Russian raw materials), localization may also involve efficient production for the global market (expanded exports from Russia). Incentives for localizing production may include lower administrative barriers for exports of finished goods. The traditionally high share of imported goods in many segments of the Russian market – a result of low domestic supply and growing domestic demand - is a sure indicator of high growth potential for domestic production in terms of both consumer demand and import substitution. Moreover, goods produced in Russia may be viewed as competitive on the EAEU market. Yet growth in production is hindered by a number of factors, one of the most important being the structural imbalance between import duty rates, with rates for raw and other materials exceeding those for finished products. This imbalance is an economic barrier to growth in domestic production, because importing finished products is cheaper than producing them in Russia. The result is a decline in the competitiveness of domestic products on both domestic and foreign markets. The problem primarily involves raw and other materials that are not produced in EAEU countries and cannot be replaced by other materials without a substantial loss in the final products' consumer properties. The adjustment of customs duty rates for specific items in the Common Customs Tariff is a complicated, laborious and time-consuming process requiring a sophisticated analysis of all the economic implications. It may involve risks of false declaration and is thus not always an effective solution for this problem. In our opinion, this situation can be resolved by making more active use of the special customs procedure of processing for domestic consumption, as provided in Article 188 of the EAEU Customs Code. This would contribute to import substitution (the customs procedure of processing for domestic consumption). Under these procedures, raw and other materials used in processing are fully

exempt from import duties, taxes and non-tariff regulatory measures. Processed products are placed under the customs procedure of release for domestic consumption, subject to import duties at the relevant rates, without the application of non-tariff regulatory measures. Chapter 26 of the Customs Code of the Customs Union sets clear, unambiguous and exhaustive requirements for foreign trade operators to ensure proper use of the procedure of processing for domestic consumption and to prevent unfair declaration for purposes of evading import duties. This procedure may be used only on the basis of a special document issued by an authorized body of an EAEU member country and containing information on both the recipient and the conditions for use of the procedure. There are also numerous requirements with respect to the manner. conditions, timing and volumes of processing as well as the identification of goods and processed products, including the requirement that processed products cannot be restored to their original condition in a costeffective manner. Thus, Chapter 26 of the Customs Code of the Customs Union establishes and allows for the effective use of a customs procedure designed to attract, support and develop high-tech production in the Eurasian Economic Union, regardless of any imbalance in the customs duty rates for raw materials and finished products, while ensuring an appropriate level of control over the correct use of the procedure. Foreign trade operators note two main problems preventing these procedures from being more widely used: 1) The lack of criteria that would allow an authorized body to determine whether a means of identifying foreign goods in processed products is acceptable. 2) The limited number of goods that qualify for the customs procedure of processing for domestic consumption.

The identification of foreign goods in processed products is an important issue for other customs procedures as well, including the procedure of processing in the customs territory, and also for the growth of exports.

The following should be noted in connection with the identification of foreign goods in processed products. Under Article 192 of the EAEU Customs Code (and also Article 167), the following methods may be used to identify foreign goods in processed products: 1) seals, stamps and digital and other labeling affixed on original foreign goods by the declarer, processor or customs officials; 2) a detailed description, photographs or scaled-down representation of foreign goods; 3) a comparison of preselected specimens and samples of foreign goods and processed products; 4) use of the current labeling of goods, including serial numbers; 5) other methods, depending on the nature of the goods and the form of processing, including a review of detailed information provided about the use of foreign goods in processing and about the processing technology as well as customs control of processing operations. Unfortunately, for most industries, the methods specified in clauses 1)–4) are unacceptable because the raw materials used in the manufacturing processes: 1) are not or cannot be clearly identified (chemical and food raw materials, small parts and spare parts); 2) disappear during the manufacturing process (evaporation, chemical transformation); 3) are difficult to separate or identify due to the specifics of the end product (food products, complex equipment).

Under Articles 124 and 147 of Federal Law No. 289-FZ of 3 August 2018 "On Customs Regulation in the Russian Federation and Amendments to Certain Legislative Acts of the Russian Federation" (hereinafter, Federal Law No. 289), the identification of foreign goods in processed products may be based on the assumption that foreign goods placed under this customs procedure in previous periods were the first to be used in processing. In our opinion, however, there should be more detailed guidelines to be followed by foreign trade operators in obtaining processing permits and selecting an acceptable method of identification based on examples when such permits were successfully obtained.

Under Article 188 of the EAEU Customs Code, the customs procedure of processing for domestic consumption may be applied to only a limited number of goods determined by the national laws of Customs Union member countries. In the Russian Federation, this list is established by Article 146 of Federal Law No. 289 and Government Decree No. 565 of 12 July 2011 (hereinafter, the "Decree"). The list is limited to only about 50 goods that are clearly intended for the production of electric trains and aircraft. As a result, the procedure of processing for domestic consumption is not used in practice, thus blocking the development potential of local high-tech manufacturing with high added value and discouraging new investments in such manufacturing. It is important to note that the customs regime of processing for domestic consumption is widely used throughout the world and is an effective means of developing local industry and attracting investments. Thus, for example, under Belarusian and Kazakh law, the procedure of processing for domestic consumption may be applied to all goods in the Customs Union's Unified Goods Classifier for Foreign Economic Activity, except those that may not be imported into the customs territory of the Customs Union and/or do not qualify for processing in the customs territory (a list of such goods was approved by Decision No. 375 of the Customs Union Commission of 20 September 2010 "On Certain Issues Concerning the Application of Customs Procedures"). The customs procedure of processing for domestic consumption is thus attractive for companies investing in the Russian economy. However, this procedure is limited to the list of goods established by the Decree, making it impossible to apply the procedure to certain goods.

Recommendations:

- 1. The Ministry for Economic Development, in cooperation with concerned government agencies and the business community, should consider modifying the procedure for determining which goods may be processed for domestic consumption (as approved by Government Decree No. 565 of 12 July 2011) by establishing a list of goods that do not qualify, in order to expand the application of the procedure of processing for domestic consumption.
- 2. The Federal Customs Service and the Russian Export Center, in cooperation with concerned federal executive bodies, should prepare detailed guidelines, based on successful examples, with step-by-step instructions on how to obtain permits to process goods in the customs territory.

Issue 2.1. Revising tax law to expand access to procedures of processing in the customs territory.

Further improvement in the administration of processing in the customs territory will create additional growth drivers for non-commodity exports. One important area of such work is sustained improvement in the procedure for identifying foreign goods in processed products.

Customs law provides for the equivalent replacement of goods in order to simplify the process of identifying and controlling imported commodities. However, widespread use of the equivalent replacement of goods in connection with the customs procedure of processing in the customs territory requires amendments to the Russian Tax Code.

As part of the equivalent replacement procedure, equivalent EAEU goods are processed and then replaced with foreign goods. This gives rise to tax risks, as the foreign goods are imported after processing, which is contrary to the provisions of the Russian Tax Code. To eliminate inconsistencies, paragraph 3 of clause 1.1 of Article 164 of the Russian Tax Code should be reworded as follows:

"of goods exported under the customs re-export procedure that were placed under the customs procedure of processing in the customs territory and/or goods (processed products, waste and/or residues) received (formed) as a result of the processing of goods placed under the customs procedure of processing in the customs territory."

Recommendations:

The Ministry of Finance, together with the Federal Customs Service, should consider amending the Russian Tax Code to expand opportunities for the equivalent replacement of goods under the customs procedure of processing in the customs territory.

Issue 3. Amendments to Order No. 27 of the Ministry of Finance of 18 February 2020.

Order No. 27 of the Ministry of Finance of 18 February 2020 "On the Competence of the Customs Authorities to Perform Certain Customs Operations and Specific Functions with Respect to Goods" (hereinafter, the "Order") entered into force on 2 July 2020.

The Order significantly expanded the list of products that must be cleared at Central Excise Customs posts. The list now includes many non-excisable goods, such as food raw materials and ingredients (including for baby food), baby food products, specialized therapeutic and preventive nutrition, and medicines, making logistics and customs clearance considerably more complicated and costly for socially significant goods and raw materials for food production, industrial goods and pharmaceuticals.

1. Under clause 1 of Appendix No. 1 to Order No. 27n of the Ministry of Finance of 18 February 2020 (hereinafter, the "Order"), some goods are classified as "goods under the same commodity heading as excisable goods in the Unified Commodity Classifier for Foreign Economic Activity of the Eurasian Economic Union (hereinafter, the 'EAEU Classifier') as well as goods indicated in Appendix No. 3 to this order."

The EAEU Classifier does not, however, separate goods into excisable and non-excisable. The term "excisable goods" is established in Article 181 of the Russian Tax Code, which makes no reference to EAEU Classifier codes.

As an example, Appendix No. 3 to the Order lists codes 2106902000, 2106909200, 3302101000, 3302104000 and 33021090000, under which raw materials are imported for the production of beverages. There are trace amounts of alcohol in the raw materials (a minimal %) that evaporate as a result of chemical processes during production and do not remain in the end product. These headings also cover raw materials that have no alcohol content and are not excisable in the terms of Article 181 of the Russian Tax Code.

It is thus unclear what goods are meant in this clause, and the list of excisable goods must be specified, including the EAEU Classifier code.

2. Clause 10 of the Order places the goods indicated in Appendix No. 3 to the Order within the exclusive competence of certain customs posts. Thus, posts that are not Central Excise Customs posts and are not indicated in Appendix No. 4 to the Order cannot perform any customs operations of a general nature (including inspection, placement in temporary storage, etc.).

Clause 3 of Appendix No. 1 to the Order states that goods imported in the same shipment as excisable goods and goods indicated in clause 2 of Appendix No. 1 to the Order are within the competence of Central Excise Customs posts.

In practice, goods indicated in Appendix No. 3 may be carried in a single vehicle, but without excisable goods in the understanding of Article 181 of the Tax Code. For example, flavoring agents for the industrial production of beverages (Commodity Classifier code 3302 10 400 0) with an alcohol content of less than 9% and other components for the production of beverages that are not excisable and not indicated in the appendices to the Order. In this case, the shipment must be divided, and a declaration for goods in Appendix No. 3 must be filed with a specialized excise customs post (electronic declaration center), while a declaration for the remaining goods must be filed with a general customs post). As a result, two declarations must be filed for one shipment of goods, and customs fees and fees for the customs representative's services must be paid twice. It is also unclear in this case whether one temporary storage warehouse can receive the entire shipment of goods, since the actual control posts are not Central Excise Customs posts and cannot perform customs operations (e.g. inspections) for goods in Appendix No. 3, and goods not indicated in the Order are not within the competence of Central Excise Customs posts. In the future, this could result in a division of customs flows, making logistics and supplies of components for manufacturing more complicated and costly.

3. Clause 15.7 of the Order states that the Order does not apply to demonstration samples and samples for certification testing (taking into account quantitative restrictions on goods in the relevant category).

According to this clause, samples of excisable goods and certain types of goods indicated in appendices 1, 3 and 5 to the Order cannot be cleared at Central Excise Customs posts. We regard this as illogical and as greatly complicating the importation and customs clearance of such shipments. This also makes the usual commercial shipments of excisable and certain other goods along with samples of such goods impossible.

- 4. In using Appendix No. 3, the customs authorities are guided exclusively by the Classifier code, but the same code may apply to both excisable goods and goods that have no relation to excisable goods. The Classifier code may also apply to goods that have no relation to goods indicated in the appendix. For example, Appendix No. 3 includes code 8543 70 900 0: "Devices for heating tobacco, consisting of an electronic device used to produce tobacco steam by heating tobacco, without burning or smoldering, for inhalation by consumers." However, the same Classifier code covers electrostatic devices (e.g., for flocking machines), electroluminescent devices largely in the form of strips, sheets and panels, static eliminators, etc. This appendix, in conjunction with the Order and Appendix No. 4, thus substantially limits the number of customs authorities, including actual control posts, that can handle a wide variety of goods that have no relation to excisable goods, making the logistics for many goods, including pharmaceuticals and biologically active supplements, complicated and expensive.
- 5. Under Appendix No. 3 to the Order, based on the EAEU Classifier code, the Order also applies to registered pharmaceuticals, even though, under Article 181 of the Tax Code, pharmaceuticals registered by an authorized federal executive body and entered and/or included in the State Pharmaceutical Register are excluded from the list of excisable goods. Clause 20 of the Rules for the Proper Storage and Transportation of Pharmaceuticals for Medical Use, approved by Order No. 646n of the Ministry of Health of 31 August 2016, prohibits food, tobacco products and beverages other than drinking water from being stored in premises used to store pharmaceuticals.

Also, point 20 of the Rules for the Proper Storage and Transportation of Pharmaceuticals for Medical Use, approved by Order No. 646n of the Ministry of Health of 31 August 2016, requires that premises and/or areas for the storage of pharmaceuticals maintain the temperature and humidity levels indicated in a pharmaceutical's documentation: its registration file, instructions for medical use and instructions on the packaging. In practice, no temporary storage warehouse in the jurisdiction of Central Excise Customs is licensed for pharmaceutical activities involving the storage of pharmaceuticals for medical use.

Recommendations:

- 1. The Ministry of Finance should issue a list of EAEU Classifier codes for goods that are excisable and clarify the scope of the Order by excluding non-excisable goods from clause 1 of the Order.
 - 2. The Ministry of Finance should reword clause 1 of the Order as follows:

- 1. Establish that Central Excise Customs posts, except for the Specialized Central Excise Customs Post (code 10009130) and the Far Eastern Specialized Central Excise Customs Post (code 10009260) (hereinafter, the "Specialized and Far Eastern Specialized Customs Posts) are competent to perform customs operations for excisable goods and goods indicated in appendixes 1, 3 and 5 to this order (hereinafter, "certain types of goods), unless otherwise stipulated by this order, with the exception of cases in which competence to perform customs operations for excisable and other types of goods is regulated by other regulatory acts adopted in accordance with Russian law.
- 2. The Ministry of Finance and the Federal Customs Service should issue clarifications allowing customs control measures to be taken on the instruction of Central Excise Customs and permitting temporary storage at other customs posts.
 - 3. The Ministry of Finance should consider making the following amendments:
 - 1. Reword clause 3 of Appendix No. 1 as follows:

"Goods imported in the same shipment as excisable goods or goods indicated in Appendix No. 3 and/or in clause 2 of this list."

- 2. Reword clause 15.7 as follows:
- "7) for demonstration samples and samples for certification testing (taking into account quantitative restrictions on goods in the relevant category) as regards the restriction of the customs authorities' competence."
- 4. The Ministry of Finance should consider eliminating Appendix No. 3 to the Order or updating the list of goods indicated in this appendix or establish additional conditions for the application of this appendix.
- Status (1 September 2020): An order of the Ministry of Finance that would amend Order No. 27n of the Ministry of Finance of 18 February 2020 has been prepared and publicly discussed, and a regulatory impact assessment has been done.

Issue 4. Simplification of the confirmation procedure for a zero rate of VAT on exports to foreign countries, including EAEU member countries.

The simplification of export procedures is one of the most important steps that can be taken to boost production in Russia and attract investments. Submitting an export confirmation to the tax authorities for the approval of 0% VAT is a very involved procedure. There are still difficulties with exports to Customs Union countries. Under Appendix No. 18, Part II, clause 3.3, to the EAEU Treaty, exporters must provide the original statement of import and payment of indirect taxes, marked by the tax authority in the importer's country. This requirement is almost impossible to fulfill without a permanent and reliable counterparty in Customs Union countries that is willing to handle all these formalities for its Russian partner. As a result, many Russian enterprises turn down deals with Belarusian, Kazakhstani and Armenian companies, thereby reducing turnover in the Customs Union.

In view of the planned implementation of a unified system for the unique identification of foreign trade operators in the EAEU (Regulation No. 11 of the Board of the EAEU Commission of 20 January 2020), we think consideration should be given to using the unified system for tax purposes, among other things, as well as to simplifying the procedure for verifying exports in the EAEU.

Recommendations:

- 1. Consider using the unique identification of foreign trade operators in the EAEU (Regulation No. 11 of the Board of the EAEU Commission of 20 January 2020) for tax purposes, among other things, as well as simplifying the procedure for verifying exports in the EAEU.
- 2. Draft amendments to Appendix No. 18 to the Agreement on the Formation of the EAEU and/or a list of statements to eliminate the need for VAT payment statements marked by the tax authority of the importer's country and for copies of shipping documents bearing the seals of counterparties in Customs Union countries.

Issue 5. Risk-oriented approach to imports of controlled goods.

Currently, when products subject to state veterinary or phytosanitary control (goods with a high phytosanitary risk) are imported into EAEU customs territory, the visible part of the cargo is inspected in each container. It is important to note that major companies that are foreign trade operators generally import controlled products in large lots (50 or more containers at a time), and it is costly in terms of time and money to present these containers for inspection. The requirement that 100% of an incoming lot be inspected increases the cost of end products and greatly slows operations with such cargo in ports of entry.

According to the Federal Service for Veterinary and Phytosanitary Oversight, a number of importing companies have never violated import rules or have violated them so rarely that the risk can be considered negligible.

Pursuant to Government Decree No. 806 of 17 August 2016 "On the Use of the Risk-Oriented Approach," a risk-oriented approach is to be applied to state control, including veterinary and phytosanitary control.

This involves categorizing and ranking foreign trade operators and their cargo using a risk management system as a basis for determining what state control measures will be applied and their scope.

The Federal Service for Veterinary and Phytosanitary Oversight, in cooperation with the Federal Customs Service, carried out a pilot project, as part of the risk-oriented approach, to reduce the number of containers of controlled products that must be presented for inspection. This experiment, however, applies only to fish products subject to state veterinary control and cleared by the Northwest Customs Administration and to controlled products cleared in the free port of Vladivostok.

At the same time, Decision No. 318 of the Customs Union Commission of 18 June 2010 envisages the selective examination or search, involving the phytosanitary risk management system, of goods classified as quarantine products with a high phytosanitary risk

Clause 26 of Order No. 1996 of the Federal Customs Service of 30 September 2011 states that an authorized official of the customs authority decides whether quarantine products with a high phytosanitary risk should be examined or searched by the Federal Service for Veterinary and Phytosanitary Oversight or its regional bodies, based on whether the risk level for each lot of such products is high, increased or acceptable.

The risk level and lots of quarantine products to be examined or searched is determined automatically by the automated risk management system's software during state phytosanitary control upon import.

Until software is introduced to automatically determine the risk level and lots of quarantine products to be examined or searched, an official selecting goods to be examined or searched by the Federal Service for Veterinary and Phytosanitary Oversight is to be guided by the list of quarantine products subject to inspection by the Federal Service or its regional bodies.

In fulfillment of Regulation No. 1125-r of the Russian Government of 29 June 2012 and Government Decree No. 806 of 17 August 2016, we request that the following measures be considered:

- 1. The Federal Customs Service should develop and implement an automated information system to manage risks involved in state phytosanitary control when the products specified by Order No. 1996 of the Federal Customs Service of 30 September 2011 are imported.
- 2. Until an automated risk management system is introduced, the Federal Customs Service, in cooperation with the Federal Service for Veterinary and Phytosanitary Oversight, should develop a set of criteria for assessing the phytosanitary risks involved in importing controlled products with a high phytosanitary risk, similar to the criteria currently applied as an experimental part of the risk-oriented approach, to products subject to veterinary control.
- 3. The Federal Customs Service, in cooperation with the Federal Service for Veterinary and Phytosanitary Oversight, should extend the risk-oriented approach to controlled products entering via seaports by applying it in other customs administrations and by expanding the list of controlled products in view of the recommendations of business associations.

Issue 6. Use of transportation expense deductions in determining customs value.

At present, companies tend to get many requests from the customs authorities to support their applications to deduct expenses for the transportation of goods in the Customs Union from the customs value of those goods, and they are also asked to provide documentary evidence of such deductions under the basic terms of delivery that provide for the international transportation of goods at the seller's expense (DDU, DAP, DAP, CIP, CIF, CPT and CIP). As a result, companies have to make extensive customs value adjustments.

Among the documents requested by the customs authorities, the following are listed: a contract for the transportation (freight forwarding agreement, if any), loading, unloading or reloading of goods; an invoice for the transportation, loading, unloading or reloading of goods; and bank documents (if the invoice has been paid).

Under clause 2.2 of Article 40 of the EAEU Customs Code, the customs value of imported goods should not include expenses for the transportation of such goods through EAEU customs territory from the place of arrival of such goods in the customs territory of the EAEU, provided that these expenses are separated from the price actually paid or payable, are declared by the declarer and are documented.

The list of documents confirming the declared customs value of goods is given in Appendix No. 1 to the Procedure for Declaring the Customs Value of Goods, approved by Decision No. 376 of the Customs Union Commission of 20 September 2010 "On the Procedures for Declaring, Controlling and Adjusting the Customs Value of Goods" (the "Procedure").

The scope of Decision No. 376 of the Customs Union Commission of 20 September 2010 is limited solely to the procedure for declaring the customs value of goods, while the procedures for controlling and adjusting the customs value of goods are determined by Decision No. 42 of the Board of the Eurasian Economic Commission of 27 March 2018 "On the Specifics of Customs Control of the Customs Value of Goods Imported into the Customs Territory of the Eurasian Economic Union."

Under Decision No. 376 of the Customs Union Commission of 20 September 2010, three basic conditions must be met in order for deductions from the customs value of declared goods to be accepted by the customs authority:

- expenses for the delivery of goods within the EAEU must be separated from the price actually paid or payable, i.e. the amount of transportation expenses must be presented in the invoice on a separate line;
 - the amount of such expenses must be declared by the declarer in the declaration of customs value;
- information on the amount of expenses for the delivery of goods within the EAEU must be documented.

At the same time, under Decision No. 376 of the Customs Union Commission of 20 September 2010, the following documents may be submitted by a declarer as documentary evidence of the composition of customs value:

- a contract for the transportation (freight forwarding agreement, if any), loading, unloading or reloading of goods; an invoice for the transportation, loading, unloading or reloading of goods; and bank documents (if the invoice has been paid);
 - or documents (information) on transportation tariffs;
- or accounting documents in which the cost of transportation is reported (if the goods are transported in the declarer's vehicles).

In this formulation, the listed documents should not be submitted simultaneously in verification of customs value, and the declarer, subject to the above list, may provide any available documents.

Under clause 9 of Ruling No. 18 of the Supreme Court in full session of 12 May 2016 "On Certain Issues with Respect to the Application of Customs Law by the Courts" (the "Ruling"), the customs value of imported goods should be calculated following the principles established in the Agreement on the Application of Article VII of GATT 1994 and should be based on criteria compatible with commercial practice.

Given that, the customs authorities may require a declarer to provide documents verifying the composition of a declared customs value, but only those documents that the declarer has or should have by virtue of law or business practice.

In particular, a declarer is not obligated to have and may not have documents confirming the conclusion of a contract for the transportation (freight forwarding agreement), loading, unloading or reloading of goods; an invoice for the transportation, loading, unloading or reloading of goods; or bank documents (if the invoice has been paid) under the basic terms of delivery that provide for the international transportation of goods at the seller's expense (DDU, DAP, DAP, CIP, CIF, CPT and CIP).

Clause 7 of the Ruling establishes that a declarer may provide the customs authority with evidence of the transaction by which goods were purchased in any form not contrary to the law, including in the form of a commercial invoice as well as documents (information) on transportation tariffs in the form of an information letter from the seller of goods.

It would thus be advisable to prepare clarifications for the customs authorities and foreign trade operators, including a list of documents necessary and sufficient to verify the composition of the customs value of declared goods and support applications for the deduction of transportation expenses in the Customs Union from the customs value of goods as well as documentary evidence of such deductions under the basic terms of delivery that provide for the international transportation of goods at the seller's expense (DDU, DAP, DAP, CIP, CIF, CPT and CIP).

Recommendations:

The Federal Customs Service of Russia, together with concerned business associations, should clarify the list of documents necessary and sufficient to verify the structure of the customs value of declared goods and

support applications for the deduction of transportation expenses in the Customs Union from the customs value of goods as well as documentary evidence of such deductions under the basic terms of delivery that provide for the international transportation of goods at the seller's expense (DDU, DAP, DAP, CIP, CIF, CPT and CIP).

4. The Development of Consumer Market and Technical Regulation

I. Launch of an end-to-end tracking system in the Russian Federation and the EAEU market.

Issue 1.1. Effect of multiple tracking systems.

In recent years, various government agencies in Russia have implemented electronic systems that use, inter alia, additional marking to monitor and record the movement of goods in the consumer market (tracking systems): the Unified State Automated Information System (EGAIS), product identification marking (so-called CIMs and RFID marks), the Mercury electronic veterinary certification system, cash register equipment, documentary tracking, etc. A number of systems are subject to EAEU supranational regulations.

The FIAC working group strongly supports the fight against counterfeit products, while pointing out a number of factors that cast doubt on the effectiveness of the proposed measures.

- So far, decisions to introduce marking systems have been based on pilot projects and confidential
 progress reports for the government prepared by system operators. There is a lack of analytical
 market data, including on whether illicit trade in industrial goods has exceeded certain limits; no
 discussions are held with dedicated federal executive bodies and industry representatives;
- The implementation of these systems entails significant costs for market participants (equipment purchases, development/customization of IT solutions, training staff and partners). Technological solutions are not enough in certain industries where production and logistics processes need redesigning (for example, canceling deliveries to small retail outlets or renting more warehouse space). Given the additional expenses, the cost of consumer goods is likely to grow substantially (up to 2%), and the supply of certain categories of products will decrease, as it is not technically feasible to meet system requirements;
- At the end of a pilot project, its takes companies 12 to 18 months on average to eliminate any pilot project errors and align their internal systems with the new legislative requirements. The same applies to the moratorium on fines. The Eurasian Economic Commission provides a transition period of 12 to 18 months for even minor changes in marking requirements to enable companies to improve their package management and equipment purchases. In the above case, system requirements are enforced as soon as the pilot project is completed;
- Numerous as they are, all these systems cannot address certain industry issues, such as unreported sales within the EAEU;
- Meanwhile, two systems are expected to apply to some categories simultaneously. For example, there is an experiment to mark dairy products from 15 July 2019 through 31 December 2020 (the pilot project was extended by Government Decree No. 371 of 30 March 2020), and the transition to mandatory marking is scheduled for January 2021 (under Government Decree No. 806-r of 30 March 2021). At the same time, dairy products are subject to the requirements of the Mercury veterinary tracking system that have applied since 1 July 2019. A current solution designed to integrate the two systems, as required by the Government, involves duplicating operations in both of them. In reality, dairy companies will be burdened with performing additional functions in the CIM system, be subject to double checking by state bodies and incur double the administrative (and criminal) liability. Companies are categorically opposed to a situation in which one product category is controlled by two or more systems that are integrated by burdening market participants with additional duties and costs. We regret to say that paragraph 7 of Prime Minister Medvedev's instructions following FIAC's 33rd Plenary Session of 15 October 2018 (on the need to harmonize the requirements of electronic tracking systems) received little attention;
- Even if such systems continue to evolve without overlapping control over certain categories of goods, wholesalers and retailers trading a wide range of consumer goods (including SMEs) will bear the additional pressures of having to operate several systems simultaneously. As a result, they will struggle to maintain their financial indicators and consumer service level.

Issue 1.2. Launch of a tracking system in the EAEU market.

Today Russia is actively developing a system of control (identification) marking. Eleven categories of goods are subject to marking, and there is public discussion of the need to extend this system or to experiment with marking for new categories – above all, the food industry – in addition to the categories already included in the list.

Launching tracking principles in EAEU states is not an even process, with the Eurasian Economic Commission only beginning to formulate its general approach. The key requirements at the EAEU level are general in nature and provide member states with broad powers in terms of system design and the list of

controlled goods, leaving critical issues of business process organization and free movement of goods unaddressed (e.g. the need to develop unified technical marking standards or regulations governing product tracking systems).

The Agreement on Product Identification Marking in the Eurasian Economic Union allows countries to unilaterally introduce marking systems after a notification procedure without input from other EAEU member countries (Article 7 of the Agreement). Thus, the EEC can prescribe EAEU-wide lists of goods to be marked, although each member state may approve its own national lists and related requirements. Storage, transportation and sales requirements may be different or altogether missing in different states, but the exporting state will have to comply with the importer's requirements, which will hit manufacturers with heavy costs for segmenting production and managing trade flows based on the "marking" status of goods. This approach is inconsistent with the EAEU's digital agenda for ensuring the "seamlessness" of the EAEU. Despite the intent, voiced in the Agreement's preamble, to ensure the lawful turnover of goods, countries will end up fighting the unlawful circulation of goods in various market segments on their own, undermining any coordination between government policies and failing to resolve the problem at the level of the EAEU as a whole.

Today, neither Russian law nor the EAEU has a method of analyzing the feasibility of control (identification) marking to avoid burdening market players with excessive additional costs, although the costs for food manufacturers will be considerable. Dairy enterprises, for example, estimate an additional RUB 45 billion in costs in the first year – 25 billion in capital expenditures and 20 billion (excluding VAT) for marking. Producers of mineral water have estimated growth in cost at around RUB 5-6 per liter in connection with the introduction of marking.

We believe that each proposal of any EAEU member state to expand the list of goods to be marked must be published and assessed by market participants to determine whether it is reasonable and other members are ready to introduce marking for the proposed category. Expanded lists should be approved by a consensus of all EAEU member states.

Companies insist that all EAEU member states must be subject to a common and unitary product tracking system based on an exhaustive and transparent set of principles and criteria to follow when deciding whether to apply the system to new categories of consumer goods. We regret to say that paragraph 5 of the instructions of Prime Minister Dmitry Medvedev following FIAC's 32nd Plenary Session of 15 October 2018 (concerning the need to harmonize the requirements of electronic tracking systems used in Russia and the EAEU) has so far received little attention. The implementation of a number of tracking systems gives rise to significant risks preventing free movement of consumer products around the EAEU. Decision No. 56 of the Eurasian Economic Council of 10 July 2020, designed to improve the organization of this process at the supranational level, offers little hope that the situation will be rectified.

APPENDICES

a. Product identification marking in the Russian Federation.

Since 2017, a number of federal laws and other regulations have come into effect which introduced the concept of mandatory marking, entitled the Government to approve lists of goods to be marked, and specified the conceptual framework and a model of system functioning as well as a general list of goods to be marked and marking fees of 50 kopecks (except vital and essential drugs for medical use). CRPT-Operator and the Russian Government have signed a PPP agreement (approved by Instruction No. 899-r of the Russian Government of 8 May 2019) for a term of 15 years.

Since 2018, Russia has implemented pilot projects to mark various categories of goods. Marking became mandatory for tobacco products, pharmaceuticals and footwear on 1 July 2020. Various proposals are being debated to expand the proposed list to cover other foodstuffs. However, the Feasibility Assessment Methodology for applying marking to specific categories has still not been adopted. Despite a series of consultations between the Ministry of Industry and Trade and the business community (begun in December 2019), the latest available version of the document contains many serious conceptual gaps that must be addressed before the methodology can become a legitimate and effective tool.

It is worth mentioning that the explanatory notes to the draft ruling provided no economic rationale for the marking code fee of 50 kopecks, while each company's extra operating costs to pay code fees are roughly estimated at billions of rubles per annum.

The draft Federal Law "On Amendments to the Criminal Code of the Russian Federation (Concerning the Allocation of Responsibility for Violating the Requirements of Identification Marking)" needs to be analyzed to determine the danger to society presented by the new crimes and the appropriateness of the penalties imposed. The same applies to draft amendments to the Administrative Offenses Code. In a situation where legislative requirements are in constant flux, companies are vulnerable to penalties.

b. Mercury electronic veterinary certification system.

Electronic veterinary certification ("EVC") of products of animal origin came into effect on 1 July 2018. As soon as the step-by-step procedure of including products in the EVC system was approved, the burden on the system declined dramatically, preventing significant system failures in processing electronic supporting veterinary documents (eSVDs) in the early stage of EVC functioning. However, to align market operations with those of the EVC system, a lot of issues have to be resolved manually, which creates various problems for the business community. During the preparation stage and the discussions between the regulator, system designer and business representatives, the system's technical features were extended, but they require further improvement. The legal framework is still inadequate, leaving a number of issues unresolved, including the issues of sanctions and of disconnecting users when they violate the SVD preparation procedure.

c. Documentary tracking system in the EAEU

The ratification of the Agreement on Tracking Goods Imported into the Customs Territory of the Eurasian Economic Union (hereinafter, the "Agreement") is now underway in EAEU member states. Once ratified, the Agreement will introduce a system of tracking certain categories of imported goods based on supporting documents. Government Decree No. 913 of 23 June 2020 extends the experiment until 31 December 2020. This means that a great many businesses will have to switch to electronic document flow by then. Yet there is uncertainty as to how the mechanism of approving the list of goods to be tracked will work: under the draft federal law "On Amendments to Part One and Part Two of the Russian Tax Code" of 27 June 2019 (on establishing national documentary product tracking system https://regulation.gov.ru/projects#npa=93083), it is to be approved by the Government of the Russian Federation (Article 105.32.2), whereas under Article 2 of the Agreement, the Eurasian Economic Commission is the approving body. Thus, national regulations are in conflict with supranational regulatory acts, giving rise to additional barriers in mutual trade. When used in combination with the marking system, this method, though advanced and better aligned with the needs of business, clearly creates duplicated systems and doubles the burden on business. The functions of the system and resulting costs for market participants are still to be determined.

The documentary tracking system should obviously be seen as an alternative to the control identification marking system, and the two systems need to be compared to select the best option based on all relevant criteria.

We thus believe it essential for the Government and business community to develop and submit proposals to improve digital data exchange between business and the government on statutory reports, declaration, certification and other statutory compliance matters by creating a centralized information service ("one-stop shop") guided by the principles of:

- 1. Streamlining data exchange between corporate IT systems based on standard attributes via a single sign-on
- 2. Reducing (not increasing or duplicating) the number of data transmissions between corporate and government IT systems
- 3. Minimizing the costs incurred by businesses and the government to integrate, gather and store data as part of implementing new IT systems
- 4. Creating mutual benefits, i.e. not only lifting the burden of new costs and requirements, but also providing businesses with free access to aggregated market data (subject to the protection of commercially sensitive information) to optimize their business planning processes, and creating a common free catalog of consumer goods
- 5. Liability (and penalties for violations) for only one system, even when several systems are integrated

In view of the above, working group member companies have prepared the recommendations below.

Recommendations:

- 1. Legislate the principle of a common and unitary product tracking system in the Russian market, harmonize the approaches, ensure integration of all such systems via a single IT platform, and avoid any additional burdens for member companies.
- 2. Establish, at the level of the EAEU, that one category of goods must not be subject to control by two or more tracking systems at the same time.

- 3. Harmonize approaches to product tracking throughout the EAEU before they are implemented nationally; switch to a consensus-based procedure of extending the list of goods to be tracked.
- 4. Design a procedure for marking imported goods released into free circulation in the EAEU following customs clearance and for sales of goods on wholesale and retail markets.
- 5. In cooperation with the business community, develop criteria for deciding whether to use tracking systems for specific product categories, including a single reliable indicator of the percentage of counterfeit and/or contraband products (based on comprehensive quantitative studies), the cost-effectiveness of system implementation, given the product cost, and the anticipated economic effect.
- 6. Ensure that decisions on the inclusion of each specific product category are made in stages, based on:
 - a. a feasibility assessment
 - b. evaluation of the results of a pilot project
 - c. a regulatory impact assessment (including the implications for small and medium-sized businesses)

Ensure that the impact of including a specific category in the marking system is assessed; introduce a procedure for discussing and agreeing the report with the relevant federal executive bodies and participating companies.

- 7. Develop a roadmap with specific deadlines for introducing traceability requirements for each planned product category (a transition period for mandatory marking of at least 18 months following approval of a report on the successful completion of a pilot project in the specific product category); carry out pilot projects with sufficient transition periods during which fines do not apply (a moratorium on fines for system participants of at least 12 months after an information system is adopted; prevent disproportionate liability, including criminal, for minor violations of system procedure by participating businesses). Ensure appropriate deadlines, agreed with business, for phasing out the remaining unmarked products for each link in the supply chain.
- 8. To prevent unfair competition and manipulation of the market, ensure that commercial information is adequately protected by system operators and that there is serious liability for information leaks.
- 9. Discuss and agree the format and volume of data on the movement of goods generated from the tracking and marking system with the concerned industry associations (including manufacturers, wholesalers and retailers).
 - 10. In order to eliminate the black market and provide incentives for good faith market players:
 - a. provide a package of fiscal and non-fiscal incentives for small businesses circulating marked/tracked goods:
 - b. reduce the risk profile/burden of control and oversight for good faith market players circulating marked products by focusing the authorities' efforts on eliminating the black market.
- 11. Eliminate any legal uncertainties associated with the Mercury system's functioning, and improve the technical efficiency of certain aspects of the system, including by amending Order No. 589 of the Russian Ministry of Agriculture of 27 December 2016.

II. State policy on a healthy lifestyle.

Issue 2.1. Strategic planning to prevent noncommunicable diseases and promote a healthy lifestyle.

Under Presidential Edict No. 204 "On National Goals and Strategic Development Objectives of the Russian Federation through 2024" of 7 May 2018, sustainable natural population growth and an increase in life expectancy to 78 years (80 years by 2030) are priority goals of national social policy. In this context, health protection and promotion of a healthy lifestyle become high priorities and have thus been included in the national Demography and Health Care programs.

The Strategy for the Promotion of a Healthy Lifestyle and the Prevention and Control of Noncommunicable Diseases until 2025 was adopted by Order No. 8 of the Ministry of Health of 15 January 2020. The Strategy is the product of successful efforts by concerned government structures, science and business. The Strategy focuses on broad efforts to educate the public about a healthy diet; the Strategy's implementation mechanism involves limited interaction with associations of employers. At the same time, the Strategy leaves out a number of doubtful measures whose effectiveness has not been universally accepted in world practice.

Another document supporting a healthy lifestyle is the passport of the priority project "Promoting a Healthy Lifestyle," which was included in the nationwide Demography project as a section entitled "Developing

Incentives for Citizens to Lead Healthy Lifestyles, Including Healthy Diets and Breaking Bad Habits" and approved by the Presidium of the President's Council for Strategic Development and Priority Projects (Minutes No. 8 of 26 July 2017).

One of the priority project's measures is an awareness campaign involving manufacturers in promoting a healthy lifestyle. The campaign is a pilot project for the marking of qualified goods to verify that they conform to the principles of a healthy lifestyle. So far, however, no scientific basis has been provided for the nutrient profiles underlying the proposed marking pilot project or for the list of products selected, thus leaving these criteria open to debate. The proposed criteria conflict with, for example, the criteria of optimal and excessive nutrient content developed by the Federal Service for Surveillance of Consumer Rights Protection and Human Wellbeing, jointly with the Nutrition and Biotechnology Federal Research Center, in fulfillment of Paragraph 53 of the Implementation Plan for the Strategy to Improve the Quality of Food Products in the Russian Federation through 2030. This lack of coordination between various government bodies may result in the parallel development of two conflicting systems of criteria, thus disorienting business and consumers and ultimately discrediting the concept of a healthy lifestyle.

At the same time, the Russian State Duma has adopted the Federal Law "On Amendments to the Federal Law 'On the Quality and Safety of Food Products' and Article 37 of the Federal Law 'On Education in the Russian Federation," which defines such basic concepts as "healthy diet," etc.

The member companies of the FIAC working group believe that the formulation of state policy on a healthy lifestyle requires serious cooperative efforts in doing an expert assessment of documents and ensuring that policymakers consider the issues raised by business, drawing on input from all stakeholders. The approaches to various related projects should be unified as a prerequisite for further discussion.

The working group supports the government's efforts to develop a systemic approach to promoting an active/healthy lifestyle and preventing noncommunicable diseases. Today many leading companies, following recommendations by the WHO and other global health regulators, have made voluntary health commitments and advocate a maximally balanced approach taking into account the current state of the industry and motivating companies to take additional measures based on self-regulation and a broad industry consensus.

Recommendations:

- 1. Include representatives of the FIAC working group in the Health Ministry's Interdepartmental Council for Public Health.
- 2. Consider integrating the best practices of the working group's member companies in the general government strategy for promoting a healthy lifestyle and preventing non-communicable diseases.

Issue 2.2. Circulation of organic products on the Russian market.

On 1 January 2020, Federal Law No. 280 of 3 August 2018 "On Organic Products and Amendments to Certain Legislative Acts of the Russian Federation" (hereinafter, Federal Law No. 289) entered into force, regulating the manufacture, storage, transportation, marking and sale of organic products for local consumers.

The law introduced a number of requirements affecting the circulation of organic products. To keep consumers informed, organic products are to be marked with a standardized graphic image (symbol) along with a bar code containing information on the manufacturers and the types of organic products they manufacture. For this purpose, the Ministry of Agriculture is to create and maintain a unified state register of organic product manufacturers. The law prohibits the word "organic" from being used on packaging in any form and in any language. It also fails to provide for a transition period. Law No. 280 does not recognize the international system of organic certification.

For many years prior to the adoption of national organic regulation, over 80 Russian manufacturers and importers provided Russian consumers with organic products verified by documents and marking in accordance with international standards. As of 1 January 2020, the market of organic products was worth tens of billions of rubles.

According to experts, adaptation to the new national requirements will take at least a year after all the necessary subordinate acts enter into force and a sufficient number of organic certification agencies are accredited. Considering the seasonal nature of agricultural raw materials, the time required will be even longer. It should be noted that:

1. The crucial subordinate acts concerning the format of the graphic image and the procedure for maintaining the register were adopted in the last month of 2019, but entered into force only on 1 January 2020. As of 1 February 2020, the register had not gone into use.

2. National certification of organic products was impossible before 1 January 2020 because certification agencies for organic raw materials and finished products were accredited only in December 2019. There are currently only three such agencies, and there is a serious shortage of attested experts in this area. Certification agencies can't handle the volume of applications from manufacturers and importers. Today hundreds of companies are on these agencies' waiting lists for organic certification, but they are essentially getting nowhere.

Epidemiological measures to prevent the spread of coronavirus infection have further complicated the situation because all certification activities (along with the requisite field inspections) have been suspended.

For this reason and also because transition to the new packaging will take half a year after a request to produce it is made, it would be reasonable to assume that organic products in the old packaging (marked in accordance with international standards) will be replaced gradually by products in the new packaging (in accordance with Russian organic regulation), and this process cannot be completed before mid 2021 without disrupting business and lowering the quality of life for Russian consumers. Nevertheless, the Ministry of Agriculture has refused to consider a moratorium on fines for unavoidable violations involved in the circulation of organic products as well as on certain requirements that lack the necessary legal and technical basis.

Another concern is that such regulation directly affecting product marking, adopted on the national level, is a barrier to the free movement of such products throughout the EAEU.

Recommendations:

To ensure that the regular supply of organic food products for consumers is impacted as little as possible and minimize the losses of the food-processing industry and the supply chain in the current situation, we recommend the following:

- 1. Amend the Law to permit the legal circulation of imported organic products and raw materials supported by international certificates until at least 31 December 2022
- 2. Provide for a 3-year transition period during which concerned companies can complete the organic certification procedure and switch to the new marking; create a unified register of organic product manufacturers
- 3. Take measures to create a competitive and professional environment to ensure that the national organic certification system has a sufficient number of qualified experts

Issue 2.3. Supplying patients with specialized nutrition products on an outpatient basis to raise the quality of life and optimize public health care spending.

The supply of therapeutic food for patients is a continuing problem in Russian health care due to low awareness in the medical community, a lack of clinical guidelines and standards of treatment, and inadequate legislation on providing therapeutic food to both hospital patients and outpatients.

The targets set by Presidential Edict No. 204 "On National Goals and Strategic Development Objectives of the Russian Federation to 2024" of 7 May 2018 are an increase in life expectancy to 78 years and 80 years by 2030 as well as a reduction in mortality among the working-age population, in deaths from circulatory diseases and tumors, including malignant, and in infant mortality. It is clear that it will be difficult to reach these targets without a comprehensive and state-of-the-art approach to treatment.

Numerous international and domestic surveys confirm that well-balanced and timely nutritional support using specialized therapeutic food will not only improve quality of life, but also reduce the number of complications, facilitate post-operative recovery, enhance the efficiency of expensive high-tech treatment, reduce the number of patient days and in-patient treatment costs and accelerate recuperation.

In 2016, the Social Economics Center did a pharmacoeconomic research study, "Specifics of Enteroalimentation for Certain Categories of Patients" which found that the economic effects of enteroalimentation included budget savings and shorter hospital stays. According to the study, savings could total RUB 13 billion a year. A similar program was implemented in St. Petersburg in 2015 to supply specialized therapeutic food financed by the St. Petersburg Government for patients in need of nutritional support. As a result, we have seen a significant decline in readmissions (from 6-7 to 1.5 a year) and treatment costs (by 60%).

We think it would be advisable to consider taking the following measures:

- 1. Analyze current law on providing patients with specialized therapeutic food;
- 2. Draft proposals for amending current legislation;
- 3. Develop an education program for medical specialists;
- 4. Create an awareness-raising campaign.

Recommendations:

1. Form a working group, drawing on the ministries of health, labor and economic development, the business community, patient organizations and the medical community, to discuss issues involved in providing outpatients with specialized therapeutic food.

III. State trade policies

Issue 3.1. Fundamental principles of the state regulation of trade.

The amendments to the Law "On Trade," in effect since 15 Julyn2016, have brought about a radical restructuring of the entire system of relations between suppliers and retailers. This law has seriously complicated the situation of all market players from retailers to suppliers. With consumer demand declining, suppliers no longer have enough flexibility to use retail networks for promotion and logistics.

Retail and supply relations shifted to a front margin model, and price competition intensified, limiting the ability to promote goods on the market. It is thus small and medium-sized businesses, both retailers and food suppliers, which have encountered the greatest difficulties.

The Federal Antimonopoly Service did not publish the essential clarifications on how to apply the amended law until September and November 2016, reducing the already short transition period and forcing market players to revise the terms of supply agreements on very short notice (thousands of revised agreements for each retail network). Additional clarifications by the Federal Antimonopoly Service limited the ability of both retailers and suppliers to temporarily reduce prices as a way of promoting sales.

Players on the food market were seriously inconvenienced by the large-scale inspections that regulatory agencies initiated after 1 January 2017 to ensure that suppliers and retailers complied with the amended law. The inspections, however, revealed no major violations. The process of self-regulation that in 2014-15 partially enabled market participants to find helpful solutions and restrain price growth was suspended. Only gradually, as new business practices developed under the amended Law, were market players able to resume the dialog on self-regulation. There were early successes: self-regulation helped market players effectively address the problem of returned bakery products. Today the dialog between retailers and suppliers is focused on adapting the Code of Good Practices and the Commission's efforts to implement the Code to the new conditions.

Since the Law was amended, however, the retail situation has not yet regained equilibrium. Market players (suppliers and retailers) remain dissatisfied with the business climate created by the amended Law "On Trade." We observe a continuing trend of politically driven and non-expert proposals for further "improving" the Law.

In 2018 Federal Law No. 446 "On Amendments to Article 5 of the Federal Law 'On the Development of Agriculture' and to the Federal Law 'On the Principles of the State Regulation of Trade in the Russian Federation" (28 November 2018) was adopted, prohibiting the return of foodstuffs with a shelf life of up to 30 days. The explanatory note stated that the law was designed to substantially lower the costs of domestic producers that had to utilize such products and to move away from the practice of forcing retailers to accept returns. It was not taken into account, however, that a significant number of manufacturers have an interest in allowing their products to be returned in order to keep shelves stocked and optimize logistics, especially in remote areas (because retailers order goods in a quantity a little above the projected demand). We believe that federal executive bodies should analyze a) the impact that prohibiting returns has on the costs and efficiency of the entire supply chain and b) various means used by good-faith market players to get around this prohibition.

Other new legislative initiatives were designed to ban contractual penalties and control prices. Other topics have been publicly discussed, such as the regulation of markups, direct imports, in-house production and own trademarks, the introduction of shelf quotas for local manufacturers and the limitation of food quality inspections and shopping center hours. All of this raises real risks that state regulation of the economy will continue to intensify and that legislative interference with economic relations between players on the food market will be counterproductive in terms of the development of a modern market economy.

The working group's position is that any further toughening of trade law, especially tougher state regulation of prices/markups, will not only create serious complications for the consumer market, but also inevitably be perceived as a retreat by the Russian leadership from market principles.

Recommendations:

- 1. In dialog with suppliers and traders, finish work on a federal strategy for the development of trade in Russia that establishes clear and predictable conditions of business and investment for market players in the medium term and ensures the priority of self-regulatory mechanisms over legislative regulation of relations between counterparties on the consumer market.
- 2. Include Federal Law No. 446 of 28 November 2018 "On Amendments to Article 5 of the Federal Law 'On the Development of Agriculture' and to the Federal Law 'On the Principles of the State Regulation of Trade in the Russian Federation" (the prohibition of returns) in the impact assessment plan for 2021.
- 3. The Russian government should not support any additional legislative restrictions on free contractual relations between players on the consumer market and consider supporting the development of a system of self-regulation on the national food market (including a system of incentives).
- IV. Building an integrated regulatory environment of the Eurasian Economic Community and its effect on the consumer market.

Issue 4.1. Unreasonable barriers to importing and moving specialized therapeutic and preventive products, including clinical and children's nutrition products, to and around the EAEU.

When the Decision of the Board of the Eurasian Economic Commission "On Amendments to the Unified List of Goods Subject to Veterinary Control" came into force on 22 February 2019, new positions (products) under EAEU Classifier codes were included in the list, and a number of positions were revised.

In furtherance of the Decision and in conjunction with the regulatory impact assessment procedure, the EAEU's Legal Portal published draft amendments to Decision No. 317 of the Customs Union Commission "On Amendments to Unified Veterinary (Veterinary and Sanitary) Requirements for Goods Subject to Veterinary Control (Oversight)" (see https://docs.eaeunion.org/ria/ru-ru/0103315/ria_05022019, hereinafter, the "Draft Decision"). Pursuant to the Draft Decision, the toughest veterinary control measures should be applied to new products on the List; for example, a veterinary certificate and an import permit must be obtained, and producers must be included in the Register of Third-Country Enterprises.

The amendments apply to groups of products under codes 1901 90 910 0 and 1901 90 990 0 of the EAEU Classifier and will have a significant impact on imports to Russia of goods in Group 2106 (UVSR positions 81, 81(1), 81(2)), which include specialized therapeutic and nutritional food products, including children's foods, as well as a number of dietary supplements. Imports of these products, depending on the category, account for 90% of total imports to the EAEU. The restrictions will also cover related ingredients: vitamins, minerals and supplements, ingredients with casein, lactalbumin, high serum protein, chemically pure lactose content, etc.

It is noteworthy that most of the above products and ingredients have no components of animal origin in Group 04 of the EAEU Classifier (dairy products) or any other group in Section 1 of the EAEU Classifier (products of animal origin) and have never been treated as food products exposed to veterinary risk. Moreover, such products have never been subject to veterinary control in EAEU countries.

The logic of the Draft Decision suggests that the new descriptions of goods are not covered by the current exemption from veterinary control for finished food products with less than 50% content of animal origin when the goods are supplied to the Russian Federation and the Republic of Kazakhstan. This regulation is in line with the commitments assumed on joining the WTO and set down in Decision No. 810 of the Customs Union Commission "On Exemptions from Veterinary Measures for Goods in the Unified List of Goods Subject to Veterinary Control (Oversight)" of 23 September 2011 ("Decision No. 810") and in Decision No. 317 of the Customs Union Commission "On the Application of Veterinary and Sanitary Measures in the Eurasian Economic Union" of 18 June 2010 (Appendix 1 to the Unified Veterinary Requirements for Goods Subject to Veterinary Control (Decision No. 317, UVSR).

Such an approach sets a precedent for violating WTO requirements across the EAEU, with the burden subsequently cascading to manufacturing and logistics operations in member countries that assumed those obligations (to date, Russia and Kazakhstan). These concerns proved justified in June 2020, when the Ministry of Agriculture issued a draft order "On Amendments to the List of Controlled Goods That Must Be Accompanied by Supporting Veterinary Documents, Approved by Order No. 648 of the Ministry of Agriculture of 18 December 2015," which incorporated the requirements of Decision No. 11 into Russian law.

As per the background report to Decision No. 11, the amendments to the unified list of goods subject to veterinary control and the Draft Decision discussed through the RIA procedure were designed to address the issue of control over imported cheese-like products ("produced by the technology of making cheese from milk-containing products, where animal fat is replaced with vegetable fat"). The restrictions, however, also apply to medical and therapeutic foods, including vital foods for children and adults in need of specialized medical nutrition (for example, those with severe allergies or metabolism disorders or recovering from life-threatening illnesses), the components required to produce specialized food products and other foods domestically, etc. The range of goods in Product Position 2106 and their quantities are probably too great to perform a full-scale impact assessment, and "cheese-like products" in that context pale into insignificance.

To implement the proposed veterinary control measures (for example, requirements for importers of high-risk products, such as livestock or unprocessed carcasses, to be included in the register of importers and obtain import permits), complex arrangements are required which can take years before deliveries are launched. This threatens not only the domestic food industry as a whole, but also public health in EAEU member states where such specialized products are a vital means of maintaining quality of life.

Given the above, we believe that the Draft Decision, as proposed, is impractical, imposes excessive requirements on the subject of regulation and activities of market participants, and may severely affect the circulation of product groups necessary for the stable performance of the food industry in the EAEU and socially significant categories of food products.

Recommendations:

- 1. Add an exemption to the Draft Decision for products with less than 50% content of animal origin that are supplied to the Russian Federation and the Republic of Kazakhstan, and replace the term "milk components" with the term "Group 04 products".
 - 2. Reduce control measures for products to a simple "veterinary certificate" requirement.
- 3. Provide an exemption from veterinary control for specialized products, including baby foods, vitamins, minerals and supplements (vitamin and mineral complexes and premixes), flavoring agents, protein concentrates (of animal and vegetable origin) and mixes thereof, dietary fibers, food supplements (including complex supplements), dietary supplements, food products used as ingredients to make baby foods, stabilizers, flavorings, icings, pastes and fillers.
- 4. Establish a transition period for the decision of at least two and a half years after its official publication date.

Issue 4.2. Reduction of risks entailed by the impact of the EAEU's Technical Regulation "On the Safety of Chemical Products" (TR EAEU 041/2017) on the operations of FIAC member companies.

EAEU Technical Regulation 041/2017 "On Safety of Chemical Products" was adopted by Decision No. 19 of the Council of the Eurasian Economic Commission of 3 March 2017. Pursuant to the Decision, EAEU Technical Regulation 041/2017 comes into force on 2 June 2021, subject to the development and approval of a procedure for creating and maintaining the EAEU register of chemical substances and mixtures and a notification procedure for new chemical substances (second-level documents) by 1 December 2018. A delay in adopting second-level 2 documents means that the effective date of EAEU Technical Regulation 041/2017 would have to be postponed.

This regulation will be a big hurdle for releasing chemical products into the market and, consequently, adversely impact the operating environment in all industrial sectors. Also, Russian national goals and strategic development objectives will inevitably be affected as a result of reduced production output and slowed product development and localization by foreign entities (domestic production of chemical and other products could be suspended). It will also raise barriers to the release of advanced innovative products in the Russian market, deliveries of raw materials and the free movement of goods, services, capital and labor resources in the Eurasian Economic Union.

These problems are a result of the following:

- The number of substances subject to registration has grown due to the requirement to register raw
 materials to produce food products, household chemicals, perfumes, cosmetics, medical devices,
 pharmaceutical products and products of other industries not currently subject to registration, as
 well as due to the requirement to register chemical mixtures;
- It takes longer (a year and a half) to market products (and raw materials);
- Substantial funds and resources will have to be spent on product validation;

- There is a risk of loss of confidential information on mixture compositions, which constitutes intellectual property;
- While there is no laboratory infrastructure in Russia to support testing, foreign protocols are not accepted.

The impact that the EAEU Technical Regulation "On the Safety of Chemical Products" will have on companies was discussed at a plenary session with ex-Prime Minister Dmitry Medvedev and Minister of Industry and Trade Denis Manturov. As a result, the Ministry of Industry and Trade was instructed to formulate proposals, with input from concerned federal executive bodies and the business community, for eliminating potential barriers involved in complying with standards of safety under EAEU Technical Regulation 041/2017 "On the Safety of Chemical Products."

On 25 December 2019, the Ministry of Industry and Trade hosted a meeting with the officials of the Federal Consumer Rights and Welfare Service (Rospotrebnadzor), the Ministry of Health, the Ministry for Economic Development, members of the expert community and the FIAC. The points of view of all concerned parties were heard during the meeting and entered in the minutes. The Ministry of Industry and Trade advised that Resolution No. 42 of the Eurasian Economic Commission Board of 29 March 2019 "On Amendments to EAEU Technical Regulation 041/2017 "On the Safety of Chemical Products" had been approved in December 2019, with the Republic of Kazakhstan appointed responsible for drafting the amendments. It was proposed that business, in the framework of the working group, collaborate with the Ministry of Industry and Trade on amending EAEU Technical Regulation 041/2017.

The working group submitted its opinion on Kazakhstan's draft amendments to the EAEU Technical Regulation 041/2017 in conjunction with the process of regulatory impact assessment. The working group generally supports the proposed amendments, but believes that Technical Regulation 041/2017 should not apply to products and raw materials used to manufacture them in cases where the such products or materials are regulated by other regulatory acts of the Eurasian Economic Union. This proposal may be realized in a second set of amendments to EAEU Technical Regulation 041/2017 by adding an Appendix No. 1 that includes the following items:

- Medical products (including those for in vitro diagnostics);
- Smoking and non-smoking tobacco goods;
- Finished animal feed (pet food), raw materials used in producing it and feed additives;
- Chemical products used as raw materials for the production of food, cosmetics, medicines, household chemicals and goods for medical purposes.

Recommendations:

- 1. Support the proposals to make the amendments to EAEU Technical Regulation 041/2017 that have been developed by the Republic of Kazakhstan;
- 2. Consider the possibility of a drafting a second set of amendments to EAEU Technical Regulation 041/2017 for the further improvement of regulation;
- 3. Set up a working group under the Ministry of Industry and Trade, involving experts and representatives of business, for regular joint work.

Issue 4.3. Proposed amendments to the Technical Regulation of the Customs Union "On the Safety of Products of Light Industry" (TR CU 017/2011).

The proposed amendments focus on issues that have been raised by experts at a number of Russian institutions, including the Russian Quality System (Roskachestvo), but that are not lobbied by anyone, as they involve a labor-intensive, multistage process and require financial support from the government before being included in the agenda of the Eurasian Economic Commission.

Examples of current issues:

- Denim and corduroy are illegal, as they have an air permeability of 20 dm3/cm2/s at best, while the Technical Regulation requires a minimum of 50 dm3/cm2/s. This was shown by tests of denim products that Roskachestvo conducted in 2018.
- Headwear, scarves and gloves are also subject to air permeability requirements, although the air permeability of such products is obviously not a key factor in winter. They were thus exempted from the air permeability requirements specified in Technical Regulation 007/2011 for children's clothes.

Based on the results of FIAC's Executive Committee meeting of 9 October 2019, a joint meeting was held at the Ministry of Industry and Trade on 25 December 2019 with representatives of the Ministry of Economic Development, the Federal Agency for Technical Regulation and Metrology and expert companies (the Textile and Light Industry Innovative Research and Production Center and the Central Research Institute of the Garment Industry). At the meeting, the Ministry of Industry and Trade instructed the Textile and Light Industry Innovative Research and Production Center to prepare EAEU draft decisions that are needed to move the packet of documents forward. On 19 May 2020 the center received the answer that the preparation of EAEU draft decisions is not within its competence. An inquiry was sent to the Ministry of Industry and Trade as to whether another expert organization could be appointed to prepare EAEU draft decisions, but no answer was forthcoming. Nor was there any response to a request that the Ministry of Industry and Trade arrange another joint meeting.

Recommendations:

- 1. Set up a joint meeting with the Ministry of Industry and Trade for further discussion in order to speed up the process of resolving this issue.
- 2. Bring the requirements that Technical Regulation 017/2011 makes of denim and corduroy fabrics into line with the requirements of GOST 21790-2005 and actual air permeability indicators for denim and corduroy.
- 3. Exempt headwear, scarves and gloves from the air permeability requirements for clothing for adults (Technical Regulation 017/2011) as they are for children's clothing (TP 007/2011).

5. Health Care and Pharmaceutical Industry Development

Issue 1. Protection of intellectual property (IP) rights to patented reference (original) pharmaceuticals.

1.1. Prevention of unfair competition and violation of rights to results of intellectual activity in the circulation of pharmaceuticals due to production and supply of pharmaceuticals manufactured illegally using registered inventions.

There are companies that systematically launch generics (including biosimilars) with a breach of existing patents on reference (original) pharmaceuticals. Government agencies place orders for generic drugs manufactured illegally using patented inventions.

Such practice results from existing legislative gaps. Federal Law 61-FZ "On the Circulation of Pharmaceuticals" allows for the registration of generic drugs or biosimilars before the patents on reference (original) drugs expire. If the respective pharmaceuticals are included in the List of Vital and Essential Drugs ("VED List"), unscrupulous manufacturers may register maximum manufacturer's price and offer the pharmaceuticals for state or municipal procurement. Current legislation does not require producers of generic drugs applying for registration with the State Register of Pharmaceuticals to commit to withholding their product from civil circulation until the expiry of effective patents for original drugs. Therefore, contracting authorities and consumers are misled and believe that simultaneous existence of reference and generic pharmaceuticals on the market is appropriate, whereas low prices for generic drugs are misleading for contracting authorities and affect the determination of the initial maximum price of a contract (IMPC).

As a result of actions taken by unscrupulous market participants, patent holders get entangled in lengthy proceedings to protect their rights. Some lawsuits involve central or municipal contracting authorities, as well as federal and regional authorities and bode badly for producers that invest in the localization of drug manufacturing. Over the recent years, member companies of FIAC's Working Group for Health Care and Pharmaceutical Industry Development (hereinafter, "the Working Group") brought dozens of patent-related lawsuits.

The need to improve regulations governing exclusive rights to invented pharmaceuticals and law enforcement practices in the area was emphasized in clause 6 of Instructions for the Russian Government, including Instruction No. DM-P13-7063 of Russian Prime Minister Dmitry Medvedev adopted during FIAC's 31st session held on 23 October 2017.

A decision was approved during a meeting between the Russian Minister of Economic Development and FIAC members (Minutes No. 28-MO of 2 October 2018) to amend Federal Law No. 61-FZ "On the Circulation of Pharmaceuticals" to ensure the creation of a unified register of active pharmaceutical ingredients (hereinafter, the "Unified Register"). When registering a drug, the Russian Ministry of Health will consult the Unified Register. The term of the registration certificate for a generic should begin on the date when patent rights to an invention relating to the reference drug expire or when the right to use the invention is transferred by the rights holder under a license agreement. To implement this provision, the Federal Service for Intellectual Property (Rospatent) set up a working group in July 2019 that comprised representatives of the pharmaceutical industry and federal authorities to develop approaches to establishing and creating this register. At the working group's request, on 24 January 2020, the Ministry Health brought before the Russian Government a draft Federal Law "On Amendments to Federal Law 'On the Circulation of Pharmaceuticals'" to authorize the creation of a unified register of active pharmaceutical ingredients protected by patents to inventions. Previously, the draft was approved by the Ministry of Economic Development. It included comments by federal executive bodies concerned. In the accompanying letter, the Ministry of Health pointed out that changes to national laws concerning the registration of pharmaceuticals would require amendments to similar provisions of the Eurasian Economic Union (EAEU).

In collaboration with with the Ministry of Health and Rospatent, the Ministry of Economic Development drafted the proposed amendments to regulatory legal acts of the Eurasian Economic Commission (hereinafter, "the Commission") for the creation of a unified register of patented active pharmaceutical ingredients of the EAEU, its application for the state registration of pharmaceuticals for human use in the EAEU member states, as well as for the issue of registration certificates for pharmaceuticals containing patented active pharmaceutical ingredients. The certificates are not valid until the patent's expiry. The Ministry of Economic Development submitted the proposals of the Russian side to the Commission for discussion with FIAC members.

FIAC's Health Care and Pharmaceutical Industry Development Working Group appreciates the contribution of the Russian Ministry of Economic Development to the preparation and adoption of the above bill and is ready to support the Ministry's initiatives in 2020 on amending the EAEU legal framework. The Working Group members note that the Russian Ministry of Health has successfully implemented Article 37 of Federal

Law No. 61-FZ "On the Circulation of Pharmaceuticals" of 12 April 2010 by making information about all applications for state registration of pharmaceuticals publicly available on the official website of the Russian Ministry of Health.

However, other aspects of unfair competition and violation of rights to results of intellectual activity in the pharmaceutical industry also need to be addressed.

Recommendations:

- 1. Any pharmaceutical registered during the term of protection may not be approved for sale without its patent holder's consent or before the patent's expiry. Information on existing patents and drug release dates must be included in the unified state register of pharmaceuticals for human use.
- 2. The state registration of the manufacturer's maximum price for pharmaceuticals is equivalent to the release of a drug for sale and is permitted only with the consent of the patent holder or upon the patent expiry.
- 3. Russian legislation should be aligned with legal acts of the Eurasian Economic Commission to make sure that information on the protection of intellectual property rights to drugs by patents effective in EAEU member states is indicated upon the registration of drugs and that the applicant confirms that the new drug to be registered is not in breach of any third-party rights protected by a patent or a license.
- 4. Legal provisions should be added to legislation governing the circulation of pharmaceuticals in the Russian Federation and the EAEU to ensure that registration certificates for newly registered drugs take effect after the expiry of patents on registered active pharmaceutical ingredients.

1.2. Unlawful use of the findings of pre-clinical and clinical studies submitted by an applicant for drug registration (data exclusivity).

1.2.1. Problem

The exclusive nature of data is understood as a ban on the use of information about the findings of preclinical and clinical studies of the reference (original) pharmaceutical for the registration of generic drugs (biosimilars).

Upon accession to the WTO and in accordance with clause 1295 of the Working Group's Report on Russia's Accession to the WTO, the Russian Federation committed itself not to register products subject to data exclusivity provisions under Article 39 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) within six years after those products were initially registered. An exception from the above is that a party may register subsequent products if it provides its own data about the pre-clinical and clinical studies that meet the same criteria as the data provided upon the initial registration.

Clause 18 of Federal Law No. 61-FZ met that requirement, but it was amended by Federal Law No. 429-FZ of 22 December 2014 that considerably shortened the previously agreed six-year data exclusivity.

Under the new version, an application for state registration of a generic or biosimilar may be submitted to the Russian Russian Ministry of Health in four and three years, respectively, after the state registration of a reference pharmaceutical in the Russian Federation.

It is strange that biopharmaceuticals are less protected than other drugs, although the former are more sophisticated and require heavier investment in pre-clinical and clinical studies.

Under Federal Law No. 61-FZ "On the Circulation of Pharmaceuticals" (paragraph 1u of Part 1 of Article 33), the state register of pharmaceuticals must contain information on the date of the drug's release for sale. Currently, such information includes registration confirmation period (five years) or "no definite term." We suggest adding one more line to the state register of pharmaceuticals to present information on the release date of generics or biosimilars depending on the reference pharmaceutical's exclusivity period.

Considering that the EAEU common pharmaceutical market has operated since 2016 and that national registration procedures for pharmaceuticals will not be applied after 1 January 2021, the EAEU, in accordance with its established procedure, should consider adding a data exclusivity provision to regulations governing the state registration of pharmaceuticals within the EAEU, including the requirement that the EAEU unified register of registered pharmaceuticals indicate the protected data exclusivity period.

Recommendations:

1. Part 18 of Article 18 of Federal Law No. 61-FZ "On the Circulation of Pharmaceuticals" should be amended to prohibit the use of information on pre-clinical and clinical studies of pharmaceuticals presented by the applicant for the purposes of their state registration without the applicant's consent for six years following the date of state registration of a drug.

- 2. The state register of pharmaceuticals should include information about the period of exclusivity of findings of pre-clinical studies of pharmaceuticals and clinical studies of reference drugs.
- 3. The state registration procedure should include an assessment of exclusivity status of the findings of pre-clinical and clinical studies.
- 4. 4) Regulatory documents of the Russian Ministry of Health in particular, the Administrative Regulation on the State Service of State Registration of Pharmaceuticals for Medical Use should be amended to ensure the proper legal protection of the findings of pre-clinical and clinical studies within six years after a reference drug is initially registered. Data exclusivity status should be reviewed when generics/biosimilars are registered, and state registration should be denied if data exclusivity period is in effect.
- 5. One more line should be added to the state register of pharmaceuticals to indicate the date of generic or biosimilar drugs' release into circulation relative of the reference drug's exclusivity period.
- 6. The EAEU regulations governing the circulation of pharmaceuticals should be amended to prohibit the use of information about pre-clinical and clinical studies of pharmaceuticals presented by the applicant for the purposes of their state registration without the applicant's consent for six years after the date of state registration of a drug.

1.3. Possible legislative amendments that would introduce compulsory licensing.

1.3.1. Problem

Proper protection of intellectual property rights is fundamental to the successful development of an innovation-based economy and to long-term investment. There is a direct correlation between the intellectual property protection index and the venture capital & private equity country attractiveness index. Therefore, concerns are raised about initiatives to amend existing legislation in terms of compulsory licensing that involve the introduction of additional limitations to the rights of the patent holders in the course of administrative procedures, as well as less specific and broader opportunities than the international treaties provide for third parties using a patent-protected invention to manufacture medicines for export sales without a patent holder's consent.

Global experience shows that proposals for compulsory licensing should be considered very carefully in view of the risks encountered by the governments of Thailand, Brazil, India, Indonesia, Malaysia and other countries. Namely, it would affect the cost of treatment. Frequent inability to reduce the price of a generic produced under a compulsory license, resulting in generics being purchased at prices close to, or even higher, than those of reference (brand-name) drugs. Besides, it is impossible to quickly market a drug manufactured under a compulsory license, as it is necessary to adopt new technology and streamline the production process, as well as to confirm quality, safety and efficiency of this drug.

Until now, the use of compulsory licenses in court proceedings, including pursuant to the appeal of the Russian Ministry of Health or regional health care ministries (departments) or other legal subjects, has been minimal, which suggests that there has been low demand for this mechanism. However, today there are instances of exclusive licenses being issued under Article 1362 of the Russian Civil Code, which indicates the efficiency and functionality of this mechanism. As a result, in our view, there is no need to introduce other additional mechanisms to restrict the rights of patent holders.

On 22 November 2019, the Russian Government submitted draft Federal Law No.842633-7 On Amendments to Article 1360 of the Russian Civil Code (hereinafter, "the Draft Law") to the State Duma of the Russian Federation. The Draft Law establishes a new version of Article 1360 of the Russian Civil Code suggesting that the Russian government may, when absolutely necessary for defense and security purposes to protect the life and health of citizens, allow an invention, useful model or industrial prototype to be used without the patent holder's consent if the latter is notified in the shortest possible time and paid appropriate consideration. The method of determining the amount of compensation and the payment procedure are approved by the Russian government.

Maintaining the affordability-quality balance of drug supply while preserving investment incentives for the pharmaceutical industry remains one of the key objectives, therefore the Working Group members believe that any initiative permitting the use of inventions without a rightholder consent should be subject to weighted and precise analysis due to the following reasons:

• The Draft Law segregates life and health protection from defense and security and narrows the subject of regulation to the national security only and, therefore, limits the powers of the Russian Government. At the same time, in accordance with Federal Law No.390-FZ On Security, the security or national security not only embraces national security but also public security, environmental security, personal security and other types of security established by legislation. Therefore, the

existing version of Article 1360 of the Russian Civil Code insures mutual conformity of adopted laws to the full extent and reflects full powers of the Russian Government vested in it in accordance with Article 10 of Federal Law No.390-FZ On Security.

• The Draft Law suggests changing the form of implementing the provisions of Article 1360 of the Russian Civil Code by vesting the Russian Government with the right to decide upon the use of inventions instead of the existing power to permit using an invention without a rightholder's consent. At the same time, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which is an international treaty and an integral part of the Russian legal system, establishes a case-by-case approach to such cases and stipulates that, before such use, the suggested user should have made attempts to obtain a rightholder's consent on reasonable terms and such attempts have failed over a reasonable time. In turn, this requirement may be eliminated in case of a country-wide emergency or other critical circumstances or in case of the non-commercial use by the state.

The Working Group also would like to draw your attention to the fact that Article 1359 of the Russian Civil Code already provides for an administrative mechanism for exercising the right of the Russian Government to use exclusive rights to an invention for the purpose of resolving situations related to the use of the invention in emergency circumstances (natural disasters, catastrophic event, accidents, etc.) on condition that the patent holder is notified of such use as soon as possible and paid adequate compensation. Such emergencies may include epidemics, epizootics, etc.

Therefore, the working Group believes that the proposed amendments are not fully consistent with the provisions of the existing Russian legislation, including TRIPS, are redundant and may deteriorate the investment attractiveness of the Russia's innovations market thus decreasing the patent activity in the Russian Federation and negatively affecting the Russian R&D, as well as significantly restricting the patients' access to the most recent developments in most R&D and innovative industries, including health care.

Recommendations:

The FIAC's Working Group recognizes the importance and necessity of supporting the compulsory licensing within the existing civil law framework. In addition, under current legislation, the interests of the parties are protected through court proceedings that enable all the arguments and reasons underlying the compulsory license claim to be carefully considered and, where legally permitted, a decision to be taken in favor of issuing such a license. The existing court practice in relation to health care and drug supply in particular demonstrates the effectiveness of the compulsory licensing model established by the existing legislation.

Issue 2. Enhancement of the regulatory environment for medical products.

2.1. On the need to ensure that EAEU rules allow for the circulation of medical products within national jurisdictions until their registration certificates expire.

2.1.1. Problem

There is a transition period until 31 December 2021 provided for by the Agreement on Common Principles and Rules for Circulation of Medical Products (Medical Devices and Equipment) within the Eurasian Economic Union of 23 December 2014 and the resulting Decision No. 46 of the Council of the Eurasian Economic Commission "On Rules for Registration and Examination of Safety, Quality and Effectiveness of Medical Products" of 12 February 2016. During the transition period:

- The manufacturer (or its authorized representative) may, at its own choice, register the medical product in accordance with the EAEU Rules or the legislation of the Eurasian Economic Union member state.
- Medical products registered in accordance with the legislation of the EAEU member state circulate on the territory of this state.
- Documents confirming the registration of medical products and issued by the authorized health administration body of the EAEU member state in accordance with the legislation of this state expire on the pre-determined date but not later than 31 December 2021.

Therefore, to circulate in the EAEU after 2021, all medical products currently circulating on the EAEU market in accordance with local rules are subject to the comprehensive registration procedure in accordance with the EAEU Rules for Registration and Examination of Safety, Quality and Effectiveness of Medical Products by 31 December 2021. Second-level documents on medical products circulation, including the Rules for Registration and Examination of Safety, Quality and Effectiveness of Medical Products approved by Decision No. 46 of the Council of the Eurasian Economic Commission of 12 February 2016 (hereinafter, the "Rules"), have already entered into force. However, it should be emphasized that the new medical products

registration mechanism was launched only at the end of 2019. Therefore, the transition period within which producers will have to re-register all their medical products in accordance with the new Rules reduced to two years.

It has been estimated that, under the new Rules, the release of medical products to the EAEU market, including all the tests and the registration itself, may take up to 18 months on average.

In the meantime, in the Russian Federation there are currently more than 36,000 registered medical products which will have to be re-registered by 31 December 2021 under the EAEU Rules. In addition, given the prospect of the new unified EAEU legislation, producers have kept a number of medical products from releasing to local markets, which means they will also have to release the new products to the EAEU market within the determined period.

In this context, the logical conclusion is that the determined transition period (ending on 31 December 2021) is reasonably not enough to perform all the necessary procedures to ensure timely registration of all medical products circulating in EAEU member states. Amendments to the effective EAEU legislation could remedy the situation, but another obstacle is the existing challenges of EAEU inter-state approvals, which will complicate adopting the required amendments within the remaining time before the end of the transition period.

Recommendations:

- 1. Establish in a EAEU decision that medical products (medical devices and equipment) registered before 1 January 2022 may continue circulate in the covered jurisdictions until the registration certificate and/or shelf life expiry.
- 2.2. Decriminalization of the circulation of medical products that cannot endanger life and health (amendments to Article 38 of Federal Law No. 323-FZ "On Principles of Public Health Care in the Russian Federation" of 21 November 2011 and Article 6.33 of the Code of the Russian Federation on Administrative Offenses).

2.2.1. Problem

According to the Federal Service for Surveillance in Healthcare (Roszdravnadzor), measures implemented by its subordinate expert organizations in 2016 to control the circulation of medical products included over 500 expert examinations of medical products: technical tests and toxicology studies, expert reviews of documents for medical products, expert reviews for compliance of the medical products in circulation with the data in the respective registration files. In 83.9% of cases, the quality requirements were not met; only in 9% of those cases of non-compliance, however, medical products threatened life or health.

A typical violation of producers of medical products is when the characteristics and other data on the medical products they sell differ from those presented in the registration file, which means that the producers have failed to notify the regulator of the changes in due time. As a result of documentary non-compliance, medical products that are as such safe and effective are treated as 'poor-quality' and are put on hold, which, in its turn, causes lower tax revenues to the budget of the Russian Federation, reduced consumer access to medical products and poorer health care quality.

In light of the above, we believe it appropriate to legalize the circulation of the medical products that bear no risk of damage to life or health, even if there are inconsistencies in their registration files. This will ensure stable tax proceeds from the circulation of such medical products and alignment of the Russian legislation and international regulations adopted in the EAEU (Decision No. 141 of the Council of the Eurasian Economic Commission "On Approval of the Procedure for Authorized Bodies of the Member States of the Eurasian Economic Union for Measures to Suspend or Forbid Application of Medical Products that Endanger Life and (or) Health, Poor-quality, Counterfeit or Falsified Medical Products, and On Their Withdrawal from Circulation in the Member States of the Eurasian Economic Union" of 21 December 2016.) Another proposal is to introduce a special element of an administrative offense, namely the late notification of an executive body of the necessity to amend the registration documents for the medical product.

The Draft Law was prepared by the Ministry of Health considering the comments of the FIAC Health Care and Pharmaceuticals Working Group and submitted to the Russian Government after certain stages of interdepartmental approval procedure.

Recommendations:

- 1. Russian Government should accelerate the approval of the draft law to amend Article 38 of Federal Law No. 323-FZ "On Public Health Care Principles in the Russian Federation" and its submission to the State Duma.
- 2. Amend the existing term of 'a poor-quality medical product' in Article 38.13 of Federal Law No. 323-FZ so that it indicates the potential danger of using the product.
- 3. Amend Article 6.33 of the Code of the Russian Federation on Administrative Offenses so that it includes a provision on liability for untimely amendments to the registration file for the medical product.

Issue 3. Increased availability of innovative drugs under the state drug supply program for Russian citizens.

3.1. Problem

For the purposes of this document, "innovative drugs" are defined as patent-protected drugs that are first-in-class or the only option for treating severe acute or chronic diseases that lead to deterioration of quality of life, permanent disability or premature mortality of Russian citizens.

Innovative treatment technologies, including those developed at the level of genes (gene therapy), cells (cell therapy) and tissues ("tissue engineering") and offered by modern medicine open up great opportunities for patients and the health care system. Availability of innovative pharmaceuticals reduces the burden of severe life-threatening chronic diseases affecting life expectancy and quality and facilitates progress towards objectives of national projects. In this regard, the inclusion of innovative pharmaceuticals in state pharmaceuticals supply programs should be seen as an investment and their impact on life quality and expectancy should be assessed in the medium and long run.

The High-Cost Nosologies State Program (hereinafter, the "HCN Program"), which was adopted in 2008 under Decree No. 1416 of the Russian Government, has made a revolutionary breakthrough in the availability of innovative drugs for treating the most severe diseases with significant medical costs. However today, the program needs to be further developed and improved. The criterion of "no negative impact on the existing program budget during the first year and three-year planning period" when considering proposals to include drugs in the list of high-cost drugs (Decree No. 871 of the Russian Government of 28 August 2014) creates a significant and often impassable barrier to innovation, especially for unique drugs of the last generation, which are really capable of fundamentally changing the treatment paradigm, and not only save, but also significantly prolong the patient's life and improve its quality.

Another significant barrier to innovation on the Russian market is the existing procurement system. In accordance with the provisions of Federal Law No. 44-FZ of 5 April 2013, the purchase of medicines is carried out mainly through electronic auctions by reducing the initial (maximum) price. The auction method helps to get the lowest offer price only if there are several participants offering a drug with the same international non-proprietary name (INN) and is most suitable for procurement of generic drugs and biosimilars. An innovative drug has a unique INN. Therefore, competitive bidding procedures do not reduce the price, but require temporary and organizational costs for the auction on the client's part. The Working Group welcomes measures aimed at making a list of pharmaceuticals procured by brand names as set out in the government's Resolutions No. 965 dated 30 June 2020 "On Amendments to the Rules for Establishing the List of Medical Drugs Procured in Accordance with Their Brand Names and on the Administration of Pharmaceuticals of Particular Brand Names" and No. 1164 dated 3 August 2020 "On Amendments to the Resolution of the Government of the Russian Federation No. 1289 Dated 30 November 2015" and calls for expanding the list of diseases to which this approach applies provided there are sufficient health grounds.

There is a proven global practice for the procurement of innovative drugs, which is aimed to create a sustainable access of patients to drugs in the most complex therapeutic areas, such as oncology, immunology, rare (orphan) pathology, neurology (e.g. Alzheimer's disease, multiple sclerosis) and others, the treatment of which is still associated with a high level of unmet needs. This approach is based on the possibility to conclude various agreements with manufacturers through direct negotiations, which helps to find optimal solutions that, on the one hand, meet health care needs by achieving best treatment results, increase the availability of state-of-the-art medicines for patients, optimize the financial, organizational and time costs of the state; on the other hand – provide greater predictability for manufacturers of innovative drugs, including in terms of volumes and period of production.

Furthermore, such long-term approach to planning the procurement of innovative drugs protected by patents should include alternative forms of procurement (other than e-auctions), such as risk-sharing and cost-sharing contracts, which will not only make innovative treatment more affordable for the patients, but also will lead to lower budget costs for the drug supply. A decrease in prices considering supply volume and timing, as well as additional supplier's liabilities related to risk sharing if the treatment does not prove to be

positive, seem to be economically feasible for procurement of pharmaceuticals using the federal or regional budget or compulsory health insurance funds, which is important in the context of cost containment and the need to receive reimbursement for costly treatment.

Therefore, it is also reasonable to provide for a differentiated price-fixing mechanism to be used to improve the way in which the Lists of Pharmaceuticals are formed, where in some cases, in compliance with the current restrictions and conditions for influencing the budget when forming the lists, manufacturers are ready to reduce prices in Russia below the minimum in reference countries, but are forced to weigh such decisions with risks of price erosion and significant financial losses in foreign markets.

Such a differentiated approach may include fixing the maximum manufacturer's price under current rules when including a drug in the List of Vital and Essential Drugs ("VED List") for human use and a separate actual maximum manufacturer's price when including a drug in the HCN Program, which is not public and not included in the State Register of Maximum Manufacturer's Prices, but is the maximum for the actual manufacturer's price for supplies under the above Program. One of the implementation mechanisms may include specifying the responsibility for the manufacturer's non-compliance with the stated price in the rules for list preparation as grounds for excluding a drug from the list of high-cost drugs at the regular/extraordinary review.

Recommendations:

- 1. Introduce a differentiated approach to the assessment of innovative drugs when preparing lists of pharmaceuticals for human use and the minimum assortment of pharmaceuticals needed to provide medical care, taking into account their long-term impact on the quality of life and life expectancy and excluding the criterion of negative impact on the budget for this category of drugs.
- 2. Develop and implement a mechanism allowing the transfer of pharmaceuticals with registered analogues in the Russian Federation from the HCN Program to other drug supply programs in accordance with their profile (in-patient, outpatient segment), while maintaining their availability in accordance with the actual need.
- 3. For innovative patent-protected drugs provide for a differentiated mechanism for fixing prices provided by legislation and price regulation.
- 4. Create a legitimate interdepartmental platform under the patronage of the Russian Ministry of Health to negotiate with manufacturers the conclusion of various purchase agreements for innovative drugs. The government bodies have already worked successfully with manufacturers at joint platforms, for example, within the interdepartmental commission established to negotiate and conclude special investment contracts under the patronage of the Russian Ministry of Industry and Trade.
- 5. Develop a legal instrument that would enable the formalization of proposals and recording of obligations of the parties when concluding agreements supported at the interdepartmental platform.
- 6. Amend and improve laws with respect to procurement of pharmaceuticals^ introduce long-term contracts between the state and manufacturers of pharmaceuticals, risk-sharing contracts and cost-sharing contracts, as well as procurement of reference pharmaceuticals under the patent protection without e-auctions.
- 7. Introduce a flexible mechanism for planning budgets for government programs based on the assessment of medical technologies, as well as the real needs of patients reflected in the unified register of patients entitled to subsidies, and using digital technologies for data procession.

Issue 4. Rules for the special circulation of medical devices in an emergency and (or) in the event of a threat of the spread of a disease that poses a danger to others.

In emergency situations, prevention of emergencies, prevention and treatment of diseases that pose a danger to others, diseases and injuries resulting from exposure to adverse chemical, biological, radiation factors, it becomes necessary to use medical devices that were not previously circulated on the territory of the Russian Federation and do not have state regulatory approval.

Operating in the context of the COVID-19 pandemic, Government Resolutions No. 430 of April 3, 2020 "Peculiarities of the circulation of medical devices, including state registration of a series (batch) of medical devices" and No. 804 of June 2, 2020, "On amendments to circulation of medical devices, including state registration of a series (batch) of a medical device" will expire on January 1, 2021.

The entry into force of this legislation in April 2020 allowed innovative manufacturers of medical devices and equipment to supply diagnostics and devices for the patients with COVID-19 in May 2020, which in turn contributed to the timely detection of cases, implementation of measures to prevent the spread of infection,

use of the latest therapeutic and diagnostic techniques for COVID-19 and associated diseases to prevent the development of fatal complications.

However, all diagnostic tests registered according to this procedure in the Russian Federation specified for quality virus detection and do not make it possible to determine the quantity, titer of antibodies to SARS-CoV-2. The development of quantitative tests to determine antibody titer goes hand in hand with the development and use of a vaccine. Such tests will be available in the US and the European Union in 2021.

Only if quantitative tests are available, plasma transfusion to patients with COVID-19 can be carried out in accordance with the serological status of the donor, which affects the outcome of the course of the disease and can save lives.

Since the validity of Resolutions No. 430 and No. 804 expires in December 2020, no quantitative test can be used on the territory of the Russian Federation, and it will take 18 months to obtain a registration approval according to the traditional procedure in the Russian Federation. Thus, quantitative testing will only become available in the Russian Federation in 2022.

Recommendations:

We recommend that by the decision of the Government of the Russian Federation establish valid until December 31, 2021 with the possibility of extending the Government Decree "Peculiarities of the circulation of medical devices", with the inclusion in the list of additional medical devices, including digital solutions, that allow remotely assessing the health indicators of patients requiring constant medical supervision, adjusting therapy, and, as a result, reducing the risks of costly complications for the state budget and optimizing the work of medical professionals.

Issues being monitored:

Issue 5. The functioning of the drug track and trace system during the COVID-19 pandemic. The harmonization of requirements to the drug track and trace system in the common EAEU market.

5.1. Problem

Member companies of FIAC's Working Group support efforts of the Government of the Russian Federation in creation and implementation of efficient and operating system to monitor the movements of pharmaceuticals for medical use that is in line with safety requirements and development of health care and pharmaceutical industries.

According to the existing laws, entities engaged in the circulation of pharmaceuticals must apply special means of identification to the packaging of pharmaceuticals and enter pharmaceutical information in the T&T system since 1 July 2020.

Due to the reporting requirements, a T&T systems to monitor movements of pharmaceuticals implemented in the Russian Federation is the most ambitious and the most complicated system of this type ever existed.

The FIAC Health Care and Pharmaceutical Industry Working Group welcomes measures of the the Government of the Russian Federation set out in Resolution No. 955 dated 30 June 2020 "On Putting Pharmaceuticals for Human Use into Public Circulation" that allow companies in the period until 1 January 2021 to import and sell unmarked drugs produced before 1 October 2020. However, in the opinion of companies represented on the FIAC Working Group, the proposed procedure is too complicated and does not meet the challenges facing entities selling pharmaceuticals:

- Additional drugs are needed during the COVID-19 pandemic to treat COVID-19 and its complications. Most production lines equipped with marking systems for Russia cannot quickly and considerably increase their capacity in excess of their current targets. Therefore, lines without marking systems should be used to produce additional drugs, but it may take long to obtain permission for their import if one follows the procedure established by the Government's Resolution No. 955 dated 30 June 2020. This can limit health establishments' and patients' access to these drugs.
- Due to measure to fight the COVID-19 epidemic, including a quarantine and the closure of borders both by countries of equipment manufacture and the Russian Federation, it is impossible to complete planned supplies of equipment for the track and trace system and organize the arrival of specialists to perform installation and commissioning work, and therefore all production lines are unlikely to meet the deadlines for the introduction of marking systems.
- In early August 2020, Russia's leading pharmaceutical associations reported data transfer issues linked to a misalignment of the T&T system, the uniform catalog of medicinal drugs and the state

register of manufacturer price caps. Drugs that were produced before July 1 and imported in Russia but not customs-cleared and approved for sale are kept at customs warehouses.

In view of the above-mentioned complications, companies represented on the Working Group suggest introducing a simplified notification procedure for the importation of unmarked drugs in Russia in the period until 1 January 2021.

The Working Group also notes the importance of addressing issues related to drug marking within the EAEU. In accordance with Agreement on Common Principles and Rules of Circulation of Medicinal Products within the Eurasian Economic Union of 23 December 2014, the pharmaceuticals sold on the EAEU territory must have a special mark in accordance with the unified requirements to the pharmaceutical marking (Article 8).

The Agreement on Marking Goods with Identification Signs in the EAEU of 29 March 2019 provides for the introduction of identification signs unified in the EAEU. Mandatory requirements for manufacturers and importers of pharmaceuticals in the Russian Federation in respect of products, which circulation is regulated by EAEU's legal acts and which may freely circulate on the EAEU common pharmaceutical market, should be in line with Article 30 of Treaty on the Eurasian Economic Union of 29 May 2014, which states that a common pharmaceutical market should be based on the following principles: adoption of common rules in the field of circulation of pharmaceuticals and harmonization of member states' legislation with respect to control (supervision) over the circulation of pharmaceuticals.

Thus, the Working Group believes that the drug marking system should function in the common pharmaceutical market and meet the interests of manufacturers of all EAEU countries rather than isolate the EAEU from other international markets.

Recommendations:

- 1. Russia should introduce a simplified notification procedure for the importation of unmarked drugs for the period until 1 January 2021 due to the COVID-19 pandemic, the growing need for certain types of medicines and anti-epidemic measures taken by Russia and other countries.
- 2. The Russian government should harmonize with the Eurasian Economic Commission a consistent set of mandatory requirements in respect of pharmaceutical marking with means of identification in accordance with Article 30 of Treaty on the Eurasian Economic Union of 29 May 2014, which states that a common market of pharmaceuticals should be based on the following principles: the adoption of common rules in the field of circulation of pharmaceuticals and harmonization of member states' legislation with respect to control (supervision) over the circulation of pharmaceuticals.

Issue 6. Expanding drug supply system for Russian citizens.

6.1. Problem

The structure of the pharmaceutical market is now strongly imbalanced, in that the compensation of most of treatment expenses is at the expense of the patient and this situation has not changed for many years. The state budget covers just over 35% of all expenses for pharmaceuticals (more than RUB 380 billion in 2019), while patients cover the rest. Prescription drugs account for about 50% of drugs sold to patients.

The expansion of the scope of the government drug coverage program, especially in the out-patient segment to include all the citizens together with the subsidized categories will facilitate increase of treatment efficiency and mortality decrease. In order to resolve this problem, one of the instructions of the Russian President of 17 December 2018, issued based on the results of the meeting on the effectiveness of the drug supply system on 16 November 2018 in St. Petersburg, was to ensure submission by the Russian Government of recommendations to modernize the drug supply system for citizens, including concerning the implementation in certain constituent entities of the Russian Federation of relevant pilot projects aimed at analyzing different approaches to the establishment of the universal drug supply system.

In addition, according to Edict No. 254 of the President of the Russian Federation "On the Strategy for the Development of Russian Health Care to 2025" of 6 June 2019, among the priorities for solving the main problems of the development of health care are improvement of drug supply mechanisms, as well as the mechanism of pharmaceutical pricing. Since July 2019, the Russian Ministry of Health has held a number of meetings on the drug supply modernization, including with participation of the representatives of the FIAC's Working Group for Health Care and Pharmaceutical Industry Development.

At the same time, financing of pilot projects at the regional level, selection of preferred diseases, types of drugs and a regulatory framework governing relations between manufacturers of medicines and regional health authorities, and medical organizations involved in the pilot project remain among the most difficult and unresolved tasks that must be addressed for the successful implementation of this initiative. In addition, pilot projects and subsequent establishment of the universal drug supply system will ensure that the goals

of the Health Care National Project to reduce mortality and increase life expectancy by 2024 are met. The Working Group welcomes decisions by the Russian government to provide patients entitled to benefits with VEDs starting 1 January 2021 and establish a federal register of people eligible to receive drugs, medical devices and specialist clinical nutrition products purchased with federal or regional budget funds as set forth in the Federal Law No. 206-FZ dated 13 July 2020 "On Amendments to Certain Legal Acts of the Russian Federation Concerning the Provision of Citizens with Pharmaceuticals, Medical Devices and Specialist Clinical Nutrition Products."

What is more, based on the results of the meeting with Russian Prime Minister Mikhail Mishustin on 14 February 2020 and in order to improve oncological care, the Ministry of Health and the Ministry of Finance were instructed to submit proposals on amendments to the Russian legislation to ensure a possibility for outpatients to continue administration of medical drugs of particular trademarks which were prescribed to such outpatients and administered while they stayed in hospital provided there is a respective decision of the medical panel. The Working Group welcomes measures adopted by Order No. 1n of the Russian Ministry of Health dated 9 January 2020 "On the Approval of the List of Pharmaceuticals for Medical Use to be Dispensed for One Year to Outpatients Who Suffered an Acute Cerebrovascular Accident or a Heart Attack, or Who Had Coronary Artery Bypass Surgery, Coronary Artery Angioplasty and Catheter Oblation in Connection with Cardiovascular Diseases" and calls for extending this approach to other groups of socially important diseases.

As far as orphan diseases are concerned, the list of drugs provided by Russia's constituent entities was limited until recently to "life-threatening and chronic progressing rare (orphan) diseases that shorten citizens' lives or cause disability" as set out in Government Directive No. 403 dated 26 December 2012. Under Federal Law No. 299-FZ dated 3 August 2018 and Federal Law No. 452-FZ dated 27 December 2019 "On the Principles of Healthcare for Citizens of the Russian Federation," seven rare (orphan) diseases were included in the expensive-to-treat-diseases program and the Russian Ministry of Health was authorized to supply patients covered by the program with pharmaceuticals. That reduced the financial burden on regions and gave patients with rare diseases guaranteed centralized access to therapy. Obviously, the remaining listed 17 rare diseases also should be added to the program.

Apart from that, Instruction of the Russian President No. Pr-1080 dated 8 July 2020 to establish an additional fund of RUB 60 billion within the federal budget for specific purposes, including for treating children with severe rare (orphan) diseases, will help improve children's access to medicines.

However, a lack of clear criteria for the expansion and content of regional and federal programs considerably limits access of patients with rare diseases that are outside the scope of the above-mentioned programs to much-needed therapy despite the health sector's considerable achievements in the area and availability of registered drug therapies in Russia.

Recommendations:

- 1. Supplement federal programs under the Health Care National Project with indicators reflecting improved drug supply, particularly in the outpatient segment. Cardiovascular diseases and cancer should be considered as a priority.
- 2. In order to facilitate the activities of the Healthcare Working Group of the State Council of the Russian Federation, engage FIAC member companies as experts in optimization of drug supply and development of pharmaceutical industry.
- 3. Ensure introduction of amendments to the Russian legislation stipulating a subsidized drug supply at the expense of the compulsory health insurance program to ensure a continuous drug therapy in case of transfer from hospital to the outpatient segment.
- 4. Expand the list of socially significant diseases that make patients eligible under state pharmaceutical provision programs to continue receiving prescribed brand-name drugs after they are discharged from hospitals for treatment in outpatient clinics.
- 5. Specify and adopt criteria for conditions that are included in the list of rare (orphan) life-threatening and chronic progressing diseases that shorten patients' lives or cause disability, and approve federal and regional programs to subsidize drugs for this category of patients.

6. Financial Institutions and Capital Markets

Forming the infrastructure of the Russian financial market and banking sector and carrying on legislative activity in regulating it

Issue 1. Problems of amending Currency legislation- issue resolved.

In February 2013, amendments entered into force to the Administrative Offenses Code concerning certain operations on the residents' accounts opened outside Russia. The banking community is drafting an amendment to clarify certain issues, i.e., a Russian resident's qualification concerning currency regulation, and the expansion of the list of operations which Russian residents can perform on the accounts opened outside Russia.

On 22 July 2013 and 5 May 2014, the Association of European Businesses sent letters to the Russian Ministry of Finance on amendments which should be made to Russian currency legislation. On 13 August 2013 and 9 June 2014, replies were received from the Ministry of Finance to the effect that the Association's proposals would be considered when drafting the amendments to Russian currency legislation.

On 4 July 2014, the RF President signed the federal law 218-FZ which introduced amendments to the currency control legislation and extended the list of cases when funds can be credited to resident individuals' accounts at banks outside Russia. The list does not include funds from securities, rent, grants and some other operations.

Recommendations:

Draft Law # 607024-6 "On the Alteration of Article 12 of the Federal Law "On the Currency Regulation and Currency Control" that was sent to the Chairman of the State Duma of Russia on 22.09.2014 (responsible Financial Market Committee) contains the following provisions:

"Along with the cases as indicated in the first passage of this part, credited to resident individuals' accounts at banks based in OECD or FATF member countries may be the following nonresidents' funds:

"...funds obtained by a resident individual upon a carve-out of foreign securities, as well as funds in the form of an accrued (coupon) interest payable under the terms of issue of resident individual-owned foreign securities, as well as other revenues on foreign securities (including dividends, disbursement against bonds and promissory notes, and payments upon impairment of the share capital of an issuer of foreign securities)..."

Status 2015 - 2016:

On 18 February 2015 draft law # 607024-6 passed the first reading in the State Duma.

The Association of European Businesses sent a letter of support to this draft law with some comments to the State Duma's Committee on the Financial Market (on 27 October 2014).

On 28 November 2015 the draft law "On amending articles 3.5 and 15.25 of the Russian Code of Administrative Offenses and articles 12 and 23 of the Federal Law "On currency regulation and currency control" (hereinafter - the law) came into force. The law introduces long-awaited changes to the existing list of permitted transactions for transferring funds into foreign bank accounts of Russian currency control residents. In this issue we briefly highlight the aspects of these amendments that may impact individuals.

Amendments introduced to the law on currency regulation and currency control and the Code of Administrative Offenses (Federal Law No 173-FZ of 10 December 2003 "On currency regulation and currency control," the Russian Code of Administrative Offenses No 195-FZ of 13 December 2001).

The law expands the list of permitted transactions for transferring funds to foreign bank accounts opened by Russian currency control residents in countries that are OECD or FATF members. The list of permitted transactions will now include the following:

- Transferring of monetary funds received as a result of alienation of foreign securities listed on a Russian stock exchange or a foreign stock exchange that appears on the list of foreign exchanges approved by item 4 article 27.5-3 of federal law No 39-FZ "On security markets" of 22 April 1996. The paragraph will come into force as of 1 January 2018. As of today the list includes 21 foreign exchanges, including the New York, London and Swiss stock exchanges;
- Transferring of monetary funds received as income from the transfer of monetary funds and/or securities to be managed under fiduciary agreement (where fiduciary is considered a non-resident). This provision came into force on 28 November 2015.

Note that under the amendments, Russian currency control residents will only be able to transfer income derived from the sale of foreign securities directly to their foreign bank accounts starting from 2018. It is worth noting that in the absence of additional clarifications, the amendments fail to clarify whether the transfer of monetary funds received as a result of the redemption of bonds into a foreign bank account will be a permitted currency transaction or not.

At the same time from 28 November 2015 Russian currency control residents are now permitted to transfer the income received from a foreign fiduciary manager to their foreign bank accounts. Federal law No 39-FZ "On securities markets" defines securities management as the fiduciary management of securities and monetary funds designated for carrying out transactions with securities and (or) entering into agreements for derivative financial instruments.

The amendments to the Russian Code on Administrative Offenses will enter into force starting from 1 January 2016 and will introduce penalties for violating the terms and procedures for submitting notifications on movement of funds on accounts opened in banks located outside of Russia by individuals who are considered as Russian currency control residents. The burden of the administrative penalties is limited to RUB 20,000. Individuals are expected to submit their notifications on the movement of funds on foreign bank accounts by 1 June of the year following the reporting year (e.g. on or prior to 1 June 2016 for the year of 2015).

Issue 2. Standard loan agreement for small and medium-sized enterprises - issue resolved.

By late May 2015, the Standard Loan Agreement for micro, small and medium businesses was ready. Two documents, including detailed explanations, were presented to the banking community as a result of joint efforts by the European Bank for Reconstruction and Development and the Association of Regional Banks:

- 1. Model general terms and conditions of a loan agreement for small and medium businesses.
- 2. Model specific terms and conditions of a loan agreement for small and medium businesses.

Importance:

During the two project years, statutory changes and the local banks' best practices have been taken into account; local banks' loan agreements have been summarized; typical problem situations that banks face when in court, have been analyzed. As a result, banks have been provided with a high-quality Standard Loan Agreement template that they will be able to use in their operations, thereby mitigating legal risks and building a foundation for improving the potential of portfolio securitization for small and medium businesses in the future. The document was also presented to the Russian Central Bank for informational purposes. The Central Bank welcomed those efforts.

Status 2015: the project is complete. Recommendations: monitor statutory changes; amend the agreement, as may be necessary.

Issue 3. Conversion - issue resolved.

a. Creating a legally effective mechanism for converting of subordinated loans into the authorized capital of banks

Conversion issues are important for Russian market participants, since they may have an impact on attracting debt and equity financing.

In 2012 – 2013 the Central Bank of the Russian Federation (the "CBR") has revamped the rules applicable to subordinated debt provided to Russian credit organisations in an effort to make them Basel III compliant. Basel III specifies the criteria for debt instruments issued by a bank to qualify as Additional Tier 1 Capital (i.e., additional to the Common Equity Tier 1) which include, inter alia, the requirement for such instruments to contain loss absorption features through

- (i) conversion to common shares at an objective pre-specified trigger point or
- (ii) a write-down mechanism which allocates losses to the instrument at a pre-specified trigger point on a 'going concern' basis.

CBR Regulation No. 395-P1 is currently the principal act regulating the issuance of subordinated debt instruments for the purposes of their inclusion into calculation of capital of Russian credit organisations.

¹ "On the Method for Calculation of the Amount and Assessment of Adequacy of the Net Worth (Capital) of Credit Organisations (Basel III)" dated 28 December 2012, as amended by CBR Directive No. 3096-U dated 25 October 2013, ("Regulation 395-P").

Regulation 395-P provides that a subordinated loan would be "transformed" into common equity through a prepayment of the subordinated loan by the borrowing bank and channeling of the proceeds of such prepayment for payment of the bank's capital increase.

Accordingly, the conversion of a subordinated loan into equity would currently require:

- a. compliance with certain corporate procedures and regulatory approvals relating to the issuance of additional common stock into which the subordinated loan is be converted and increase of the charter capital of the bank; and
- b. the actual prepayment of the subordinated loan which is, in turn, subject to a consent of the territorial department of the CBR to be issued after the state registration of the share issuance relating to such capital increase or, in the case of limited liability companies, the adoption of the decision on charter capital increase and amendments to the bank's charter.

The current conversion mechanics therefore lack automatism and may not be capable of being completed in full, with the result that the subordinated lender would be forced to accept a write-down of its loan in the absence of cooperation and required corporate action on behalf of the borrowing bank, its shareholders and governing bodies. Such obstacles may restrict fundraising by banks, and EBRD has been researching this issue and identified inconsistencies and potential ways to resolution, which it presented to MED and CBR in a detailed note.

Recommendations:

Among the obstacles under the current regulations which will need to be resolved in order to allow conversion of subordinated loans to equity for loss absorption are the following:

- restriction on set-off debt (article 11 of the Banking law currently restricts setting off the liabilities of a Russian bank against the payment of its charter capital which precludes a direct debt to equity conversion);
- corporate law requirements (corporate approvals by shareholders needed that may not be enforceable, mandatory offers may be triggered, etc.)
- the need for regulatory consents/clearances by CBR, FAS, Government Commission on Strategic Investments etc.
 - the procedure for definition of conversion pricing needs to be clarified; etc.

Status 2015-2016:

Further to the introduction of Basel-III rules for banks' capital calculation, and in particular loss absorption requirements for subordinated loans in 2014, EBRD prepared an overview of the existing legislation, regulation and procedures for simplification of subordinated debt conversion into ordinary shares (participation interests in the charter capital) as one of the ways for covering losses by subordinated debt accounted as tier 1 or tier 2 capital of a bank. The overview and recommendations have been provided to the Ministry of Economic Development and the Bank of Russia for a discussion.

Several important concepts have been subsequently implemented and reflected in the Federal Law No. 432-FZ dated 22 December 2014 and regulatory acts adopted pursuant to it, specifically, the amendments made to the Regulation No. 395-P by Instruction of the Bank of Russia No. 3600-U dated 15 March 2015.

As a result, the following essential improvements have been achieved:

- The conversion of subordinated loans is no longer subject to the requirements of federal laws governing the procedure for obtaining approvals from the Bank of Russia and the FAS of Russia, for the acquisition of thirty or more percent of ordinary shares of a joint-stock company credit institution;
- No involvement of the state financial supervisory body to determine the price for the placement of shares is required;
- The conversion of subordinated loans is no longer subject to requirement to exercise preemptive rights by the persons having preemptive rights to acquire additional shares of the bank;
- In the event of a failure by the borrower bank to fulfil the relevant obligations in relation to the conversion, the CBR could exercise its authority and issue a conversion demand therefore forcing the bank to complete the conversion as potentially, if the trigger events are not remedied, the CBR may need to revoke the banking license.
 - There is more transparency envisaged in the conversion process; etc.

Further analysis revealed that the remaining issues, which need to be clarified for further stream lining of the practical application of the subordinated debt related regulation include:

- Conversion procedure permissibility of offsetting claims under subordinated loans;
- Setting priority for the write-down / conversion among several subordinated debt instruments;
- Enforceability of the shareholders' obligation to perform necessary and timely actions for the conversion;
 - Defining price setting mechanism for conversion shares;
 - Permissibility of a write-up of written down amounts under certain circumstances;
- In addition, the need to obtain consent from the Government Commission for Control over Foreign Investment in certain cases as well as some other questions may need further clarification.

Issue 4. Banking secrecy regulation- issue postponed.

Presently, banking secrecy issues are regulated by the provisions of Article 857 of the Civil Code of the Russian Federation and Article 26 of the Federal Law "On Banks and Banking Activities." Article 857 of the Civil Code provides for the following rule, "Information protected by banking secrecy may only be provided to customers themselves or to their representatives, as well as presented to a credit bureau on the grounds and in the manner prescribed by the law. Government authorities and their officers may only have such information provided in cases and according to the procedure prescribed by the law." Therefore, the current version does not enable transfer of banking secrecy data to other persons with the customer's consent.

This legal gap limits development of banking services in the Russian Federation due to the following reasons:

First of all, many customers (both foreign- and Russian-based) chose to centralize treasury functions within a group of companies. On the one hand, it enables greater cash flow manageability from the group's parent company, and, on the other hand, helps to cut corporate administrative costs to maintain individual treasuries for each company.

Secondly, for many structured bank products (for example, syndicated lending), it is necessary to transfer information protected by banking secrecy among entities participating in providing such products to the customer (for instance, between the bank servicing the borrower's account and the lender banks).

And, thirdly, in the current environment, many banks (both foreign- and Russian-based) strive to reduce their administrative costs to cut the cost of bank products for their customers, and they consider outsourcing some technical functions (for example, IT or archiving) to professional service companies.

We would like to draw your attention to the fact that the customer has information classified as banking secrecy in the meaning of the Federal Law "On Information, Information Technologies, and Information Protection", and that they should be entitled to dispose of that information at they think fit.

Recommendations:

With this in mind, we suggest that it should be made possible to transfer any information protected by banking secrecy to other persons with the customer's consent or at the customer's request in the laws of the Russian Federation the ability, namely, to revise Article 857, clause 2 of the Civil Code to read as follows:

"Information protected by banking secrecy may only be provided by customers themselves or by their representatives, as well as presented to a credit bureau on the grounds and in the manner prescribed by the law. Information protected by banking secrecy may also be provided to other parties with the consent of the customer. Government authorities and their officers may only have such information provided in cases and according to the procedure prescribed by the law."

Issue 5. Changes in the legislation on Personal Data (Law № 242-FZ dated 21.07.2014) -postponed.

Federal law 242-FZ - challenges for business

Banking community expresses its concern with the adoption of the Federal Law "On Amendments to Selected Legislative Acts of the Russian Federation with Regard to Clarification of Data Processing of Personal Data across Information and Telecommunications Networks" # 242-FZ dated 21.07.2014 (hereinafter, the "Law"). The Federal Law # 152-FZ dated 27.07.2006 "On personal data" in its current versions covers all operators of personal data without any exceptions which effectively means that all Russian and foreign companies operating in the Russian Federation will have to company with the Law.

Moreover, Federal Law # 526-FZ dated 31.12.2014 "On amendments to clause 4 of the Federal law "On Amendments to Selected Legislative Acts of the Russian Federation with Regard to Clarification of Data Processing of Personal Data across Information and Telecommunications Networks" which entered into force on 31.12.2014 has sped up entering of the Law into force. According to the amended Law operators of personal data will have to comply with the new requirements to storage of personal data of Russian citizens from 1 September 2015 already.

We believe that these initiatives may result in deterioration of the investment climate in Russia due to a conflict with the requirements of common world market practices, infringement of the rights and interests of end-users (citizens of the Russian Federation), and significant logistical costs that are expected burden corporate investors. Following a number of meetings and discussions regarding the above-mentioned Law, many companies have highlighted a number of legal, economic and technical issues that may arise in connection with entering of the law into force on 1 September 2015.

We deem it necessary to clarify the procedure for and the scope of application of the Law. In case the legislator aimed to introduce specific requirements regarding personal data processing in Internet, then the Law requires certain amendments to limit its application to the designated purview. Also following the changes to the personal data protection legislation it may make sense to revise the definition of personal data which is currently formulated too broadly.

Status 2016:

Pursuant to Federal Law 242-FZ, the Central Bank, subject to the provisions of Regulation 397-P, requires foreign banks to place and store their databases in the territory of the Russian Federation.

The Working Group of the European Business Association on enforcement of Federal Law 242-FZ has prepared a letter to the Central Bank requesting to elaborate on paragraph 1.2 of Provision 397-P, and hold a meeting with representatives of the banking community.

We received a reply letter from the Central Bank of the Russian Federation, signed by Alexey Yu. Simanovsky, exhorting strict compliance with existing legislative norms and Central Bank instructions.

We intend to hold a round of consultations within the banking community and, possibly, prepare another letter to the Central Bank of the Russian Federation requesting a meeting to discuss that matter.

Issue 6. Localization of Data basis.

Direction of the Bank of Russia No. 3753-U dated August 7, 2015, On [Amendments to] Regulation of the Bank of Russia dated February 21, 2013, No. 397-P "On Procedures for the Creation, Maintenance and Storage of Electronic Databases (the "Direction"), which came into effect in September 2015, instructs credit institutions that electronic databases containing information about the assets and liabilities of credit institutions and the movement of such assets and liabilities, as posted to analytical and synthetic account registers, should be maintained in the territory of the Russian Federation. The explanatory note to the Direction says that the amendment in question is necessitated by adoption of Federal Law dated July 21, 2014, No. 242-FZ, regarding localization of databases containing personal data of citizens of the Russian Federation.

Concurrently with that, implementation of the Direction (in the absence of additional clarifications from the Bank of Russia) may give rise to situations where credit institutions will be obliged to move databases to Russia even if such databases do not contain personal data of citizens of the Russian Federation, or if personal data localization demands do not apply based on clarifications provided by the Ministry of Communications of the Russian Federation and the Federal Service for Supervision of Communications, Information Technology and Mass Media of the Russian Federation. Therefore, the Direction imposes stricter demands on credit institutions that it does on the other parties to civil transactions.

Proposal: conduct a meeting and consider the possibility of issuing clarifications on application of paragraph 1.2 of Regulation No. 397-P dated February 21, 2013, as amended by Direction of the Bank of Russia No. 3753-U dated August 7, 2015.

On 25 May 2016 Larisa Mamolina, Central Bank, Credit Institutions Licensing and Financial Rehabilitation Department took part in the FIAC working group meeting and updated the group on CBR's position regarding Regulation 397-P. She clarified the term of database: § 41 of Law on Banks and Banking says that databases should reflect all completed operations and other transactions executed by the credit institution, any base of the credit institution that reflects all those operations. As for how banks maintain it, whether it is distributed, or whether there is only one database or there are several databases – there are no specific CBR regulations in that respect. Banks define what they understand by a "database". In CBR's understanding, it is about bases reflecting data stipulated by the existing legislation, first and foremost. After the meeting with foreign banking community representatives Bank of Russia is actively working on issuing

of official interpretations. CBR is also considering publication of this document when ready. At the moment it's not clear in what form it will be provided, and if banks with foreign equity participation will enjoy any special terms – the document is at the stage of coordination of official explanations and all departments involved in their preparation are providing their comments. But on 13 July 2016 AEB received letter from CBR's deputy Chair Simanovsky with strict recommendations to follow the current version of Regulation 397-P.

The FIAC banking working group intends to raise this issue during FIAC ExCo in October and is preparing recommendation for final Communiqué.

Issue 7. Unilaterally Accounts Closure – issue resolved 2017-2018.

This issue was raised at the meeting with the Chairman of the State Duma of the Russian Federation, with the members of the Investment Council on 12 March 2015. On 29 April 2015 FIAC working group on Financial Institutions and Capital Markets sent an official request to the State Duma Chairman on regulations on accounts closure. On May 26, we received a reply from the Duma's Civil Law Committee. The Committee took note of our request and will take it into consideration while working on the changes to the second part of the Civil Code. We mentioned certain disadvantages, risks for the banking community due to the fact that the opportunities for unilateral closure of accounts were very limited. We can form a small banking sub-group regarding this issue for the purpose to prepare proposals.

There exists some uncertainty with respect to the current procedure for the closure of "inactive" bank accounts with non-zero balances, and with respect to the procedure in accordance with which the bank can exercise its right to unilaterally terminate a bank account agreement.

In particular, the current version of paragraph 1.1 of Article 859 of the Civil Code of the Russian Federation authorizes the bank to unilaterally repudiate a bank account agreement, if all of the following conditions are met at the same time:

- 1. the balance of the customer account is equal to zero for a period of 2 years;
- 2. no operations are conducted with the customer account for a period of 2 years;
- 3. the customer has been notified in writing of the need to replenish its account;
- 4. no funds have been credited to the account for a period of 2 months after such notice has been served.

Even though paragraph 1.1 of Article 859 of the Civil Code of the Russian Federation says that the parties may stipulate otherwise in the agreement, in practice there exists uncertainty as to the extent of freedom that the parties may enjoy in terms of contractual regulation of agreement termination procedures.

There are at least two different constructions of the wording of paragraph 1.1 of Article 859 of the Civil Code ("unless otherwise stipulated by the agreement"). One construction is that this provision only permits the parties to set a short period for repudiation of the bank account agreement and/or set a minimum account balance. The other construction is that the wording "unless otherwise stipulated by the agreement" forbids the bank to reduce the period for repudiation of the agreement or otherwise modify the terms of the agreement, but merely authorizes the bank to waive its unilateral repudiation right.

Therefore, there currently remains some uncertainty regarding the extent of freedom enjoyed by the parties in terms of contractual procedures governing unilateral termination of the bank account agreement at the initiative of the bank.

Recommendations:

The current version of Article 859 of the Civil Code of the Russian Federation materially restricts the right of the credit institution to unilaterally terminate the bank account agreement, inter alia, with respect to "inactive" bank accounts where no operations are conducted, and the customers cannot be reached. According to the existing legislation, in such situations the bank continues to bear a public duty to service such accounts regardless of whether they generate any cash flows, which entails incurrence of unavoidable perpetual costs.

The amendments that we propose are designed to expand the freedom of contract in relations between the credit institution and its corporate customer. In particular, they authorize the parties to incorporate into the bank account agreement the right of the bank to unilaterally terminate such agreement on the terms set forth therein. There are separate procedures governing non-zero-balance accounts and protecting customer funds.

On October 27, 2015, the Banks and Financial Markets Group of the Foreign Investments Advisory Council sent to N. N. Gonchar, Chairman, State Duma Committee on Financial Markets, a letter with detailed

proposals regarding amendments to be introduced to Article 859 of the Civil Code of the Russian Federation regarding termination of bank account agreements, and to Direction of the Bank of Russia dated July 15, 2013, No. 3026-U. Unfortunately, no response from the State Duma of the Russian Federation has been received to date.

On 18 May 2016 a meeting of FIAC banking group representatives with Russian Ministries took place in Ministry of Economic development. The main topic was Accounts closure. Thereafter the discussion on modification of §859 of the Russian Civil Code continued on 25 May 2016 at the FIAC banking working group meeting attended by representatives of Russian Authorities. Deputy head of legal department of Central bank Andrey Borisenko commented on the working group's proposals on modification of the §859 of the Russian Civil Code. After that meeting FIAC working group updated their proposals and sent new version to the State Duma, CBR, Ministry of Economic Development. On 3 June Annett Viehweg, chair of the banking working group, delivered a report on unilateral accounts closure. The list of instructions after the FIAC ExCo signed by First Deputy Prime-Minister of Russia Igor Shuvalov included following: on Russian Ministry of Finance (A.G. Siluanov) Russian Ministry of Economic Development (A.V. Ulyukaev) -jointly with the Bank of Russia and the banking community, analyze whether it is advisable to simplify the procedure for the unilateral closure of accounts by credit institutions. Report the results to the Government of the Russian Federation by 1 October 2016.

This issue will be raised at the FIAC Plenary session on 17 October.

Current status as of September 2017:

The FIAC efforts resulted in the Russian lawmaker adopting the new wording of Article 859 of the Civil Code of the Russian Federation as suggested by the working group to regulate unilateral closure of customer bank accounts. Pursuant to this wording of the Article, credit institutions will be able to unilaterally terminate the bank account agreements with legal entities and individual entrepreneurs provided that no operations are conducted with such accounts even if the balance is positive. Under the previous wording, for the right to repudiate an agreement to arise, the bank account had to be zero-balance for a long period of time, which basically made this provision unworkable. The new regulation is expected to have a positive impact on the franchise quality, reduce the number of inactive abandoned accounts, which, in turn, will lead to more favourable conditions for regulatory compliance (in terms of combatting money laundering and terrorist financing and other efforts) and will reduce unreasonable costs related to maintenance of inactive abandoned accounts.

Issue 8. Access to state funds and strategic companies for foreign (non-state) financial institutions - issue resolved 2018/2019.

The banking community is concerned with the discussions held at the level of the Russian government in respect of selection criteria for banks authorized to accept deposits from some of the state-controlled companies. The Association of European Businesses and the FIAC calls for the Russian government to avoid any discrimination of the Russian banks with foreign capital.

Foreign banks participating in the FIAC working group, as well as members of the Association of European Businesses also worry that they may be left out of that list regardless of the fact that they have the highest credit ratings among the banks operating within the Russian Federation.

As experience confirms, stable and uniform rules both for national and foreign banks operating in a country are a key to successful long-term foreign direct investments and clients' confidence in banking. Actually, Russian subsidiaries of major global companies need both local and foreign partner banks to pursue full-fledged activities in the country.

The Association of European Businesses and the FIAC calls for the Russian government to avoid any discrimination of the Russian banks with foreign capital that would adversely affect the development plans of foreign investors in Russia.

It is worth mentioning that the volume of loans granted by foreign-based banks and their Russian subsidiaries to the Russian state-owned companies BY far exceeds the volume of liabilities attracted from the same category of clients. Global banks' ability to support Russian companies with credit resources on favorable terms will be significantly impacted by removing Russian subsidiaries of global banks from the list of authorized providers of such services.

In October 2015 Association of European Business sent an official letter to First Deputy Prime-Minister I.Shuvalov regarding the intention of the Government to forbid state-owned companies to keep their liquid funds in foreign banks. On 19 November 2015 in its response to the query initiated by the AEB and banking community the Financial Policy Department of the Ministry of Finance said that requirements applicable to credit institutions where business companies strategically important for the defense industry complex and national security of the Russian Federation and companies directly or indirectly controlled by the state may

keep their accounts are stipulated by Federal Law dated July 21, 2014, No. 213-FZ. Pursuant to part 3 of Article 2 of Federal Law 213-FZ, the Central Bank publishes on its web site a list of credit institutions which meet the requirements set forth in Federal Law 213-FZ. The list includes subsidiary credit institutions of foreign banks. The Federal Law does not envisage any restrictions on the financial operations with foreign banks.

Status 2016:

Resolution of the Government of the Russian Federation dated May 5, 2016, No. 389, established requirements applicable to credit institutions holding, in accounts and deposits, the funds of the federal budget, budgets of constituent entities of the Russian Federation, state extra-budgetary funds, and funds of state-owned companies and corporations. The most critical of those requirements are those related to:

- capital adequacy, and
- control by the Bank of Russia/Russian Federation, or application of capital-building measures imposed by the Deposit Insurance Agency.

There currently exist several draft laws and Government decrees which also stipulate requirements to be met by credit institutions before they are permitted to maintain bank accounts or accept cash on deposits from various types of business units. Thus, one of the draft Government decrees dealing with proposed amendments to regulations on competitive selection of Russian credit institutions authorized to hold regional operator accounts sets forth, as one of eligibility criteria, establishment by the Bank of Russia/Russian Federation of direct or indirect control over candidate credit institutions, or implementation by the Deposit Insurance Agency of capital-building measures with respect to such credit institutions.

Participants of the 30th session of the Foreign Investment Advisory Committee (FIAC) held in Russia on October 17, 2016, suggested that current requirements be replaced with market-driven regulation mechanisms based on credit institution risk ratings. The Government representative also proposed to use national ratings assigned by the Analytical Credit Rating Agency (ACRA).

The List of Instructions by the Prime Minister of the Government of the Russian Federation of the FIAC 30th session (17 Oct 2016) contains an instruction to the Ministry of Finance of the Russian Federation to consider, by December 1, 2016, together with all affected federal executive bodies, the Bank of Russia, and representatives of the banking community, the possible expansion of the list of credit institutions authorized to hold government funds.

Recommendations:

In the light of the above, the FIAC suggests that the Ministry of Finance of the Russian Federation should organize a discussion of that issue with representatives of the banking community within the framework of its Working Group on the Russian Banking Sector and Financial Markets. We also request that the Ministry of Finance of the Russian Federation communicate to the FIAC contact details of the individuals responsible for carrying out that instruction so as to enable efficient interaction.

The FIAC working group is in contact with Minfin (Financial Policy department). The working group sent several official requests to Minfin with concrete proposals what should be amended in the proposed initiatives (KC-2811-16-ол от 28.11.2016 and KC-1511-16-дс от 15.11.). On March 2, 2017 the working group sent additional request to Minfin on the review of requirement to the structure of banks' property established by the Decree of the Government dated 05.05.2016 N 389 and also to provide clarifications on current draft law №1120209-6. Furthermore the working group sent on official request on CBR, Minfin and MinEc to organize a joint meeting on Restrictions for foreign banks in Russia and invite Minfin's, Minec's and CBR's and foreign banks' representatives.

2017 Status:

The laws adopted in order to regulate banking services for companies and unitary enterprises of strategic importance, including depositing their own funds, establish an open list of requirements for credit institutions. Among other things, the Government of the Russian Federation may introduce additional requirements by its decree. According to the existing draft of the relevant Decree of the Government, such additional restrictions may include measures that are not related to economic market criteria, in particular, political and other administrative measures. Consequently, in order to ensure transparency and maintain a competitive environment in the financial market, it is proposed that this issue should be addressed together with the market participants, for instance, through discussions within the relevant FIAC working group with the participation of government officials.

Issue 8.1. Banking tax and custom guarantees- issue resolved in 2018 / 2019.

The banking community expresses its concern with certain drafts of regulatory documents that introduce new criteria to determine the maximum amount per bank guarantee and the maximum amount for all the active guarantees issued by the same bank or the same credit institution that can be accepted by customs authorities to secure payment of customs duties, taxes, as well as by tax authorities to ensure payment of taxes, namely:

- 1. Draft order of the Russian Ministry of Finance "On fixing maximum amount of per bank guarantee and the maximum amount for all active guarantees issued by the same bank or the same credit institution that can be accepted by customs authorities to secure payment of customs duties, taxes";
- 2. Draft decree of the Government of the Russian Federation On fixing maximum amount of per bank guarantee and the maximum amount for all active guarantees issued by the same bank that can be accepted by tax authorities to ensure payment of taxes".

The new criteria significantly reduce a list of organizations that may offer their services to major companies and foreign trade participants for issuing bank guarantees to be accepted by customs and tax authorities. Due to the new criteria, the sharp decrease in the number of market participants becomes less of an issue of financial stability indicators for banking institutions and more of a decision to be made by government authorities, which can open the door to the concentration of credit risk in the banking system and build up an additional pressure for the banks in terms of regulatory compliance and, as a result, it may affect the terms and conditions of lending for corporate clients. With reduced competition in the bank guarantees market issued for the benefit of tax and customs authorities, the scene may be set for an artificial increase in the costs of such guarantees, which, in turn, will lead to higher costs for manufacturers and participants of foreign trade activity.

Recommendations:

This issue is essential for the financial market organizations, including foreign institutions. Participants of the FIAC working group would welcome any forms of discussion and exchange of opinions, as well as live meetings with Russian Authorities to discuss the bank guarantees issue.

Status 2018:

The working group has been engaged in an active dialogue with the Ministry of Finance in respect of comments and additions to the Resolution of the Government of the Russian Federation "On the introduction of amendments to the resolution of the Government of the Russian Federation No. 874 of July 24, 2017 'On the maximum amount of one bank guarantee and the maximum amount of all concurrently valid bank guarantees issued by one bank in order for bank guarantees to be accepted by tax authorities for the purpose of ensuring tax payments". In February 2018, FIAC's working group sent its comments on this document, and is currently drafting a detailed proposal with amendments, which will be sent to the Ministry of Finance shortly. On March 31, 2018, the Government issued Resolution No. 386 "On the introduction of amendments to the resolution of the Government of the Russian Federation No. 874 of July 24, 2017 'On the maximum amount of one bank guarantee and the maximum amount of all concurrently valid bank guarantees issued by one bank in order for bank guarantees to be accepted by tax authorities for the purpose of ensuring tax payments", which takes the working group's comments into account. Further on, the working group will continue its discussions with the Ministry of Finance and the Ministry of Economic Development regarding bank guarantees to be issued in favor of customs authorities, as well as placement of federal budget funds into bank deposits.

In general, amendments proposed by the Ministry of Finance positively change distribution of limits between market participants and reduce the credit risks of the beneficiary (the State) under such guarantees. As was mentioned during the meeting, it is expected that this approach will be reflected in legislative acts that establish limits/criteria for operations with instruments where the state acts as a beneficiary, particularly: guarantees securing customs payments, government procurements, and allocation of funds of the Federal Budget/Treasury.

Previously, the capital adequacy was the criterion for credit institutions' access to financial instruments, for which the government or governmental authorities acted as a party or a beneficiary, namely, bank guarantees issued to secure payment of taxes, customs duties, tender guarantees for participating in governmental procurements and in placements of Federal Budget funds.

Over the past two years, the FIAC working group has actively maintained that, due to improvements in the rating sector, credit ratings, as a measure of credit institutions' financial soundness, are the most appropriate criterion for setting limits for such instruments.

Currently, following viable cooperation with the Ministry of Economic Development and the Ministry of Finance, concepts are being harmonized for setting criteria of banks' access to working with governmental authorities or companies with government involvement and for defining the maximum amount of a banking instrument issued to the benefit of governmental authorities.

Achievements:

- 1. The result of viable cooperation between the Ministry of Economic Development, the Ministry of Finance and the FIAC working group for development of Russia's banking sector and financial markets was Government Resolution No. 539 dated May 3, 2018, in which the credit rating assigned by Russian rating agencies was the major parameter for setting a limit for bank guarantees issued to secure payment of taxes.
- 2. In addition, Government Resolution No. 706 was passed on June 20, 2018, which determines the rules for credit institutions' interaction with companies that are critical for Russia's military-industrial complex and security, which Resolution mentions a credit rating assigned by a Russian rating agency as the major criterion and establishes the requirements for the capital ratio at the level necessary for obtaining a general-purpose banking license.
- 3. The Russian Government has also drafted a Resolution and an Order that use the above criteria for issuing bank guarantees to secure payment of customs duties and to secure bids and performance of contracts.

Intentions:

The FIAC working group members intend to continue constructive engagement with the Ministries to implement this (rating-based) approach for credit institutions' cooperation with governmental authorities.

Issue 9. Accounting policy of a lending institution in respect of placement of deposits under the general agreement - Time deposit accounts: accounting and requirements for transfer of information about deposit transactions to the Federal Financial Monitoring Service (Rosfinmonitoring).

The working group for the development of the banking sector and financial markets of Russia of the Foreign Investment Advisory Council (FIAC) has contacted the Bank of Russia (the "Bank") in connection with lending institutions' accounting policy regarding placement of deposits under a general agreement.

Problem

Pursuant to the current version of Bank of Russia's Regulation No. 579-P "Concerning the Chart of Accounts for Lending Institutions and the Procedure for its Application", dated February 27, 2017, and the current accounting policy of the Bank, when the Bank's corporate clients (the "Client") place deposits under the general agreement on deposit transactions (the "General Agreement"), "the Bank shall, as part of analytical accounting, keep personal accounts reflecting the term of deposits, interest rates, and types of currency."

According to the Bank's practice, deposits are placed on the basis of a deposit agreement application (the "Application") received from the Client in accordance with the General Agreement with the Client, which Application sets forth the term, interest rate, amount and currency of the deposit agreed with the Bank. The Bank opens a new analytical account for each deposit newly placed by the Client, including when placing money for a short-term (overnight) deposit. Such an approach considerably increases the scope of information to be transferred by the Bank to the authorized bodies as part of compliance with provisions of Bank of Russia's Regulations No. 311-P, 562-P μ 321-P, as well as regulatory risks in connection with possible delays in complying with the aforementioned provisions and provision of incorrect information. It should be mentioned that pursuant to clause 9.1 of Chapter 9 of Bank of Russia's Instruction No. 153-I dated May 30, 2014, termination of a deposit agreement, including in the case established in the third paragraph of clause 5.2 of Article 7 of Federal Law No. 115-FZ, constitutes grounds for closing a deposit account. The Bank makes an entry on the closing of the respective personal account in the Register of Open Accounts on the date when there is a zero balance on the deposit account, unless otherwise provided for in the deposit account agreement. In practice, two conditions should be met in order to close a deposit account: a zero balance on the deposit account agreement.

At the same time, upon expiry of the term of the deposit and upon the actual fulfillment of the Application, the Bank does not terminate the General Agreement with the Client but closes the Application, which is actually a deposit account agreement. The Bank is responsible for closing the deposit account as a result of closing of each Application, which means, if the Client regularly makes "overnight" deposits, a daily opening and closing of a new sub-ledger account 42102 (deposits by non-governmental commercial organizations for the term of up to 30 days).

Status:

Taking into account practice of lending institutions, the analysis of the possibility of a multiple use of subledger accounts for making deposits was carried out, subject to observance of the time of such deposits and types of currency. The analysis has shown that automated banking systems may be adapted for using the already opened accounts for newly placed deposits; however, the existing wording of clause 9.1 of chapter 9 of Instruction BR No. 153-I does not provide such a possibility.

Proposal:

FIAC's working group for the development of the banking sector and financial markets offers to submit a proposal to the Bank of Russia regarding the amendment of the second paragraph of clause 9.1 of Chapter 9 of Instruction BR No. 153-I by including the possibility of establishing other terms of closing of the deposit account in the General Agreement (in the current version, other terms may be established only by a deposit agreement).

Current status:

FIAC's working group sent a letter to the Bank of Russia (on January 30, 2018) with a request to express the Bank of Russia's position with respect to the obligation to close the deposit account upon expiry of the term of the deposit and the possibility of using previously opened deposit accounts, provided that the analytical account does not simultaneously register deposits with different terms, and also requested Bank of Russia to schedule a meeting on this matter. This issue is being considered by the Bank of Russia (status as of April 2018).

Issue 10. Changes in the legislation on information security: Implementation by banks with foreign participation in 2018 of the Financial System Information Security Outsourcing Standard – postponed.

The working group for the development of the banking sector and financial markets in Russia of the Foreign Investment Advisory Council (FIAC) has been drafting an application to the Bank of Russia with respect to the developed Financial System Information Security Outsourcing Standard, which will enter into force on July 1, 2018.

Questions:

It is not clear how Service Providers' licensing requirements are applied, provided that they are foreign organizations, particularly:

- a. Is a license required if the national legislation of the country where the foreign organization operates does not require that such type of activity should be licensed?
- b. Is it sufficient (i.e., licensing under the local legislation is not required) if a foreign service provider has a relevant international license? For example, clause 6.6 on page 18 refers to the PCI DSS international standard (but does not refer to the local standard) as sufficient to outsource the processing of such payment cards.

Proposal:

- We believe that the Standard should include provisions according to which it is sufficient for service providers located and registered outside the Russian Federation to hold certificates as part of the International Information Security Certification as an alternative to licensing requirements and regular audits. We believe it is necessary to add at least the possibility of outsourcing an information security function to organizations that have licenses confirming their compliance with ISO 27000 standards.
- We also believe that it is necessary to consider the inclusion of other international standards as sufficient for outsourcing the respective functions if there is a relevant international license.

Questions:

- 1. According to the Standard, service providers should undergo regular audits, but in the case of a foreign organization, how will the Bank of Russia assess the results of the audit carried out by a foreign auditing organization at the service provider's place of registration?
- 2. Section 6.6 on page 17 refers to the requirement to form the list of protected information to be transferred for processing when entering into an agreement with a service provider.

In practice, this requirement cannot be fulfilled. Data transmission interfaces, the same as the volume of transmitted data, changes over time in the course of the systems' development. The number of fields in an interface may reach up to 100, and this requirement implies, in particular, documenting of fields. Time and

efforts associated with compliance with this requirement will increase in arithmetic progression with the increase in the number of interfaces.

Proposal:

We believe it is necessary to change this clause by replacing the word "list" with the words "reference to types and groups of protected information..." The word "list" implies a detailed description of each field of the interface. Such a detailed description for the purposes of the Standard is not required because documenting "types and groups of protected information" is sufficient to determine requirements applicable to protection of information.

Questions:

3. The Standard addresses only one direction of outsourcing when a company independently chooses a service provider for itself. There are also alternative interaction options, for instance, when a company is part of an international group and, according to the interaction model established by the group, uses global services and globally approved service providers.

Within the framework of this interaction model, quality control of the service provided is carried out mostly by the parent company itself because it is interested in creating a highly efficient and safe medium in its subordinate divisions.

Proposal:

We believe it is necessary to include such interaction model in the Standard.

Issue 11. Calculation basis for fines on credit institutions – changes to §74 of the Federal Law on Central Bank of Russia.

On October 16, 2018, the State Duma of the Russian Federation approved draft federal law #484811-7 "On Amending Article 74 of the Federal Law 'On the Central Bank of the Russian Federation (Bank of Russia)' in the first reading.

As per the Explanatory Note, the primary goal of the Draft Law is to increase effective pressure of the Bank of Russia on unscrupulous credit institutions by ensuring that the fine for violating the requirements of the Russian law is commensurate with the economic benefit received by such a credit institutions from their clients' suspicious transactions.

It is also stated that implementation of the Draft Law will enable the Bank of Russia to apply sanctions in the form of restrictions and prohibitions as most extreme measures within its supervisory activities. This should help in reducing the client outflow from credit institutions, and as a result, mitigating their loss of business reputation.

The working group would expressed its doubts regarding validity of the approach to increase the fine amount in respect of any offenses, as we believe that it is reasonable to increase liability of credit institutions by segments, in the AML/CFT area, so that the liability would be aligned with the gravity of the offence committed. (for reference: currently, the fine amounts to 0.1 percent of the minimum size of the charter capital, while it is proposed to collect 0.1 percent of the total charter capital for ANY offences. For major banks, it means a hundredfold increase and fines amounting to hundreds millions of rubles (or several millions euro).

At the same time, we believe this Draft Law needs to be substantially revised in order to differentiate the proposed measures.

With this in mind, the working group proposed to keep intact the current provisions of Article 74 of the Federal Law #86-FZ "On the Central Bank of the Russian Federation (Bank of Russia)" dated July 10, 2002, while adding an independent part to regulate how liability for serious violations in AML/CFT is imposed on credit institutions.

On May 1, 2019 modifications to the article 74 of the Federal Law on Central Bank of Russia took in force. Recommendations of the working group were partially implemented. However, in September 2019 the working group prepared a letter to the CBR with further amendments and proposals.

Issue 12. Improvement of Regulation in the sphere of Anti-Fraud in Money Transfers in order to introduce effective mechanisms and fraud reduction. – Moldova schemes.

On September 26, 2018, the law on anti-fraud monitoring systems and freezing unauthorized money transfers, the so-called Anti-Fraud Law, came into force (Federal Law #167-FZ dated June 27, 2018 on amending the Federal Law "On National Payment System"). While implementing Anti-Fraud Law, credit institutions realized that the applicable regulation requires further improvement.

The working group developed specific proposals for improving anti-fraud regulation in money transfers in order to introduce efficient mechanisms to reduce volumes of such fraud.

Here are the three proposals:

- 1. Making it possible for credit institutions to establish their own list of signs of an unauthorized money transfer. Among other things, they should be allowed to use different models for individuals and legal entities. This will enable credit institutions to build a more flexible system to counter fraudulent transactions. The current regulation does not give them such rights, therefore, subject to special legislation in the relevant area, the actions of credit institutions might be challenged.
 - 2. As for individuals, the procedure banks should use regarding payment cards has not been clarified.
- 3. There is no procedure for banks to obtain the client's prior consent to making a payment from a legal entity's account in the case when such consent is received through special secure communication channels, for example, internal authorization systems without using the remote banking (host-to-host) interface.

The working group is interested in further meaningful cooperation with the Bank of Russia in order to create efficient mechanisms to reduce volumes of frauds in money transfers and to protecting the interests of depositors.

Status 2019/2020:

The Working Group expresses its concerns regarding the persistence of the number of dubious transactions of clients carried out by credit institutions. Such situation is associated with the lack of sufficient legal grounds for banks to refuse to execute a client's order or to suspend a transaction even if there is a suspicion that the transaction is carried out for the purpose of laundering proceeds or financing terrorism (hereinafter referred to as ML/FT).

One of the types of dubious transactions mentioned above are transactions based on executive documents, according to which money may be debited and withdrawn from the client's account, including outside the Russian Federation (a so-called "Moldovan Scheme"). Credit institutions have no legal grounds for refusing to conduct such transactions, and the operations themselves are subject to Federal Law No.229-FZ "On the Enforcement Proceedings" dated October 02, 2007 (hereinafter, the "Law 229-FZ").

In its letter No.011-12-4/9325 dated December 11, 2019, the Central Bank in response to the appeal of the Working Group identified this issue as multifactorial, requiring large-scale changes in the legislation.

On March 10, 2020, the Working Group sent a request to the State Duma of the Russian Federation addressed to A.G. Aksakov, Chairman of the Financial Market Committee, expressing its concern regarding the persistent number of dubious transactions of clients conducted by credit institutions and the lack of sufficient legal grounds for banks to refuse to execute a client's order or suspend a transaction, even if there is a suspicion that the transaction is aimed at laundering proceeds or financing of terrorism.

The WG believes that the tools available to banks to counter ML/FT and the involvement of banks in conducting dubious transactions continues to narrow. The banking community has long been awaiting the settlement of these issues. The Bank of Russia, for its part, expresses its understanding of these problems and reports on its efforts to resolve them at inter-agency platforms, including with the participation of the Ministry of Finance of Russia, the Federal Bailiff Service of Russia, the Federal Financial Monitoring Service and the Supreme Court. The elimination of legal gaps requires the introduction of comprehensive amendments to the current legislation agreed by the concerned departments and market participants.

The WG appealed to the State Duma with a request for assistance in enhancing inter-agency cooperation in order to formulate coordinated legal approaches and create mechanisms to reduce the number and volume of doubtful transactions.

Issue 13. Risks associated with the exercise of the functions of a tax agent by Russian credit and financial institutions; issues of applying concessional taxation and determining the actual right to income of a foreign entity.

Currently, the Russian Tax Code restricts the ability of the Depositary Bank to request additional information from clients when there is doubt whether tax benefits may apply.

The working group deems it appropriate to amend the Russian Tax Code in order to eliminate any uncertainties regarding tax agent's right to request additional information on the ultimate beneficiaries of income from clients.

The proposed amendments enhance the depositary's ability to obtain additional information. With them, clients will not be able to refuse information to the Depositary Bank for reason that the Russian Tax Code does not provide for such an option.

Additional information will enable more accurate conclusions whether it is possible to apply tax benefits as provided for in double tax treaties.

Tax legislation imposes obligations on Russian organizations transferring income to the benefit of foreign entities to confirm that such foreign entities have "beneficial ownership of income" (BOI). If the beneficiary does not have BOI, the tax benefits stipulated for in international treaties for the avoidance of double taxation do not apply to such income. Meanwhile, the existing legislation (Article 7 of the Russian Tax Code) does not establish an exhaustive list of criteria to be met by foreign entities in order to be recognized as a BOI entity, and, as a result, Russian organizations that act as tax agents become exposed to tax risks. Among other things, if a tax agent makes an incorrect decision regarding foreign entity's BOI, the Russian tax authorities will require the tax agent to pay the amount of tax to the budget of the Russian Federation that it failed to withhold at its own expense.

Therefore, it is necessary to supplement Article 7, paragraph 2 of the Russian Tax Code with an exhaustive list of criteria that any entity must meet to be recognized as an entity with beneficial ownership of income. Moreover, it is necessary to add a phrase to Article 7, paragraph 2 of the Russian Tax Code to the effect that tax agents may determine whether their counterparty has BOI or not using the procedure developed by the Russian Ministry of Finance.

Eliminating uncertainty will reduce the likelihood of disputes with tax authorities in connection with performance of tax agent functions.

On August 8, 2019, the working group sent a written petition to the Ministry of Finance together with draft amendments to the Russian Tax Code intended to improve the mechanism used by tax agents to determine whether a foreign organization has beneficial ownership of income. Minfin provided official feedback 27.08.2019 №03-08-05/65594 and stated that our proposals will be considered by the Tax department.

In order to reduce risks of a tax agent, the Working Group proposed the following amendments to the Tax Code of the Russian Federation.

1. We propose to reduce the maximum period for a tax authority to carry out control measures in relation to the amounts paid to foreign entities, from 3 years to 6 months, during which period the tax agent will be able to obtain guarantee coverage from its client - a foreign entity for the amount of potential tax risk associated with such payments. Such guarantee coverage may be provided, incl. in the form of a guarantee deposit, guarantees for the period of control measures.

Unfortunately, tax authorities currently do not have enough resources to carry out such activities to such extent and at such time frames. They talk about it directly.

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2. We propose to limit the right of depositories/credit institutions when they perform functions of a tax agent by using only standard income tax rates subject to withholding tax. If the beneficial owner of the income (including a direct client of the depository or a client of a foreign nominal holder) applies for a reduced (concessional) tax rate, the decision on its application, in our opinion, should be made by the authorized tax authority within the framework of a specific tax refund procedure which should be clear with respect to time frames and document composition. In this case, the tax agent may act as an intermediary between the tax authority and a foreign entity and facilitate the collection and provision of documents required for inspection.

At the same time, we would like to note that if the percentage of refund is as low as it is now, this will reduce the overall investment attractiveness of Russia, which should not be allowed under the current conditions, etc. Or

3. Option 3, which provides that clarifications will nevertheless be issued and/or a standard form of certification of the right to apply reduced rates for double taxation agreements will be approved, in which case the tax agent will be exempted from liability. This option, together with a proposal for some kind of guarantee mechanisms or the introduction of a procedure for collecting tax from a foreigner (if, for example, it turns out that the foreigner gave incorrect assurances) may be the most feasible and acceptable for all parties.

It is proposed to bring this topic from the Working Group for discussion at the FIAC Executive Committee in 2020.

Additionally, on August 3, 2020, the FIAC working group sent proposals to Russia's Ministry of Finance and Federal Tax Service (FNS) on how to address this issue and requested a working meeting to discuss the working group proposals. The meeting between the designated FNS departments and the representatives of the FIAC working group and the National Finance Association (NFA) is scheduled for September 15, 2020.

According to the FIAC, it is possible to pursue additional tax administration measures in all of the following areas simultaneously:

- to refine the procedure for applying the concept of a beneficial owner of income for the taxation purposes in Russia; to harmonize a list of criteria to determine presence or absence of beneficial ownership of income; to develop a uniform confirmation template, and to establish a single list of supporting documents;
- to introduce a mechanism into the Tax Code of the Russian Federation in order to collect income tax from Russian-source income and to impose tax sanctions on foreign investors directly, if, after the depository acting as a tax agent withholds the tax based on confirmation from the foreign investor, the tax authorities challenge the reduced tax rates applied to such income;
- to exempt Russian depositories from tax liability for fulfilling their obligations as tax agents when paying income on securities of Russian issuers recorded by depositories in the owners' securities accounts.

The proposed changes will:

- improve transparency and clarity of the applicable tax rules and, accordingly, make a positive impact on appeal in investments into Russian economy for foreign investors, while maintaining a possibility to ensure that taxes from the corresponding revenues are collected to the Russian budget;
- eliminate risks of terminating the activities of the Russian depositories should significant amounts of taxes be collected from them in respect of the income transferred by them to foreign investors, while maintaining a possibility to ensure that taxes from the corresponding revenues are collected to the Russian budget;
 - reduce the labor costs for tax authorities in connection with audits of bona fide taxpayers;
- prevent any situations when depositories administrative costs to collect and analyze the documentary evidence certifying that foreign investors are entitled to reduced tax rates under relevant agreements exceed the income amounts that may be received in the form of depository fees, etc.

It was proposed to submit this topic for discussion from the working group at the FIAC Executive Committee in September 2020.

Issue 14. Changes in the legislation on National payment system – issue resolved 2020.

The working group prepared and sent through the National Payment Council (NPC) the following comments to draft law No. 603192-7 "On amendments to the Federal Law 'On the National Payment System" (the "Draft Law").

Article 1, part 3, paragraph a of the Draft Law provides adding part 1.1 to establish that it is possible to accept orders with encoded payment for execution to Article 8 of Federal Law No. 161-FZ dated June 27, 2011 "On the National Payment System" (the "Law").

According to Article 8, part 1 of the Law, the client's order to transfer funds must contain information that enables transfer of funds within the framework of the applicable forms of cashless payments (the "transfer details"). Given this provision, it remains unclear with respect to the proposed amendment whether specific details of the transfer or a separate client's order to transfer funds may be provided in the form of code.

At the same time, if part 1.1 providing for acceptance of orders with encoded transfer details is added to Article 8 of the Law, amendments will be required to the Regulation on Rules for Transfer of Funds No.

383-P approved by the Bank of Russia on June 19, 2012, as well as to the Rules for Indicating Information in Details of Orders for Transfer of Funds to Effect Payments to the Budget System of the Russian Federation No. 107n approved by order of the Russian Ministry of Finance dated November 12, 2013.

Additionally, given that banks currently lack technology for processing the aforementioned orders, the effective date of his new rule should be at least 9 months after the law is officially published.

(A) The "Payment application" category was not disclosed in the draft amendments, which makes it impossible to distinguish it from the "Electronic means of payment" category, which is understood as remote (digital) banking systems.

As a result, any restrictions imposed on use of payment applications (such as prohibited access to analogues of handwritten signatures, codes, passwords, and other information used to certify the client's right to manage funds) can be extended to electronic means of payment, if such restrictions are interpreted accordingly, which will, in turn, make it impossible to use them if and when it is impossible without such access.

Therefore, it seems necessary to clarify the goals of the new regulation (for instance, to extend it only to some technical solutions purchased from third-party suppliers) and word the Draft Law text accordingly to prevent any situation when it becomes impossible to use remote banking systems (electronic means of payment) any longer.

(B) Currently, residents of the Russian Federation are allowed opening and using bank accounts established outside the Russian Federation. The proposed amendments establish a general ban for residents to use any payment services provided by foreign organizations, including credit organizations, which are allowed to open accounts. It also becomes essentially impossible for non-residents to use remote banking systems (electronic means of payment), since such use implies the need to resort to intermediary services, a Russian operator that must observe a number of guite burdensome conditions, in each case.

At the same time, the very foreign bank maintaining accounts of Russian clients may be qualified as a foreign payment system, and, as a result, it will have to perform a number of actions, including drawing up payment system rules in Russian in order to be able to provide services to Russian customers.

We believe that the purpose of the new regulation is to prevent sale and other distribution of banking services using remote banking systems in the territory of Russia and not to establish an absolute ban on any access of residents of the Russian Federation to foreign banking services. Consequently, we deem it expedient to establish clearer boundaries of the new restrictions and to focus them on public distribution of banking services within the territory of the Russian Federation.

The Working Group sent a request to the Russian Central Bank's National Payment System Department on February 27, 2020, asking for clarifications from the Central Bank on the following issues: a) Category "Payment application" - that in a situation where the payment application provider and the money transfer operator (for example, a banking institution) are one and the same person, this category ("Payment application"), as well as the statutory provision associated therewith (in particular, the provisions of Article 8 of the Federal Law "On the National Payment System" - a ban on the provision of information, information obligations, etc.) are not subject to application; b) Requirements for the activities of a foreign payment service provider (Article 9.1 of the Federal Law "On the National Payment System"); c) Requirements for the operation of foreign payment systems (Article 19.2 of the Federal Law "On the National Payment System").

In April 2020 Central Bank of Russia provided official comments and clarifications in accordance with the official request by the FAIC working group. These clarifications will be used by the banking community as official position of CBR.

Issue 15. Critical Information Infrastructure.

Members of the FIAC working group express their concern over the Draft Decree of the President of the Russian Federation "On Measures to Ensure Information Security in the Economic Domain When Using Software and Hardware at Critical Information Infrastructure (CII) Facilities" and the Draft Resolution of the Government of the Russian Federation "On Approval of Requirements for Software and Hardware to be Used at Critical Information Infrastructure Facilities and Transition Procedure to Predominant Use of Russian Software and Hardware."

Despite the intent behind the Projects being to improve the CII information security, their implementation in their current version may introduce risks of large-scale interruptions in the CII facilities operations, as the practical requirements of the Projects are difficult to fulfill for objective reasons (and, in some cases, are virtually impossible) to the extent of the proposed terms and the possibility to replace many types of foreign software and IT hardware. It is roughly estimated that the credit organizations will have to spend over 700

billion rubles as one-off payments to replace them (and with tighter deadlines, the amount may be even larger). With operations continuity in mind and taking into account the constant transaction load of credit organizations, the average replacement period will take up at least 3 years if there are ready-made models and 5 to 7 years with such processes as searching, selecting, testing, reviewing, budgeting, opening projects, concluding contracts, and other necessary steps.

Moreover, the mechanisms foreseen in the Projects will affect development of competition in the Russian software and hardware market, as well as incentives to improve the products and introduce new designs. The new rules will lead to monopoly positions for some companies, stagnation and backwardness of domestic software and IT hardware business, and, as a result, the CII entities will be forced to purchase substandard products at inflated prices.

In this regard, the working group took an active part in preparing a written petition within the framework of the Association of Banks of Russia addressed to the Bank of Russia in order to support the following amendments thereto:

- to postpone entry of the Projects requirements into effect for 4 years (as of January 1, 2025 and January 1, 2026, respectively);
- to clarify scope of the Projects, extending their provisions exclusively to significant CII facilities that belong to the first category of significance;
- to allow using software developed by credit organizations themselves and not listed in the relevant register;
- to develop state support measures for Russian software and hardware developers in order to enable them to meet the demand for products within the required timeframe, as well as actively introduce innovations;
- to develop and approve a procedure for an authorized government body to consider and address applications from credit organizations regarding their right to use self-designed software, as well as legalizing software and hardware of foreign design without Russian equivalents.

Current status: based on the outcome of a letter written in response to an appeal from the Association of Banks of Russia, the Bank of Russia announced that it plans to send a proposal to the Russian government to postpone the transition to the predominant use of Russian software and hardware at critical information infrastructure facilities until 2025. This issue remains relevant, and the working group plans to hold consultations with financial associations in order to establish a common stance.

7. Natural Resources and the Environment

Environmental and other issues

Issue 1. Splitting processes for registering waste disposal facilities and obtaining waste disposal licenses.

Under the Law "On Production and Consumption Waste," a newly built waste disposal facility may be used only after it is entered in the State Register of Waste Disposal Facilities (SRWDF) and its operator obtains a license for this facility or makes changes to an existing one to include this facility. By law, such registration should take a month, but in practice it takes from two to four. Licensing a new facility by applying for a new license or changes in an existing one may take from four to six months (*pursuant to Law No. 99-FZ, 33 business days to reissue the license). During this period, the new facility may not be used.

Recommendations:

Amend waste management regulations, the licensing law and Law No. 174-FZ "On State Environmental Expert Reviews."

Introduce changes in procedures and timelines for commissioning new waste disposal facilities to facilitate:

- Registration of new facilities in the SRWDF to allow operators to start them sooner.
- Licensing of new facilities, by applying for a new waste management license or updating an existing one, to allow operators to start them sooner.
- Introduce legislative amendments requiring operators to specify target waste types in facility design documentation, rather than a list of waste as is the case at present, to simplify the subsequent licensing process.

Issue 2. Wastewater discharges to land or drainage areas.

The current version of Law No. 7-FZ does not provide for an explicit ban on wastewater discharges to drainage areas; a fee for a related environmental impact, originally specified in Article 16.1, has only been canceled. Environmental authorities now interpret this law as prohibiting such discharges. Many companies with wastewater treatment systems discharging to drainage areas, which account for more than 40% of all companies according to official statisticians, are concerned about this regulatory approach. Companies located far away from water bodies are forced to invest heavily in upgrading their water disposal systems and installing long sewer lines, doing more environmental harm than from disposal to land.

Under Article 1.19 of Russia's Water Code, wastewater includes rainwater, snowmelt and infiltration water coming from the entire drainage area of enterprises. As required by Article 16.1 of Federal Law No. 7-FZ that took effect on 1 January 2016, uncontaminated rainwater from enterprises' non-industrial sites (where there are no potential sources of pollution such as residences, offices and warehouses) must be collected, purified and discharged into a body of water. Companies that are operating drilling sites complying with project documentation approved by the competent authorities have to spend significant amounts of money on building or upgrading water disposal/treatment systems and installing sewer pipes to connect to water bodies, doing an additional harm to the environment. Rainwater from non-industrial sites may be contaminated only by suspended substances that are filtered/purified through soil. Such filtering approaches to non-contaminated wastewater discharges to land/drainage areas are common in EU member countries.

Recommendations:

- Amend Article 1.19 of Russia's Water Code. It is proposed to amend the definition of 'wastewater,'
 i.e. to replace the wording 'runoff from a drainage area' with 'runoff from a contaminated industrial
 area.' This will legislate for discharges of nominally clean water, rainwater, snowmelt and infiltration
 water from non-hazardous/non-industrial sites to land/drainage areas, removing such types of
 wastewater from the definition of wastewater.
- Establish standards for measuring and managing a negative environmental impact from discharges to land.
- Establish pricing mechanisms for permissible levels of discharges to land.

Issue 3. Licensing waste management activities performed by more than one legal entity at the same waste disposal site.

In accordance with Article 9.2 of Federal Law No. 89-FZ of 24 June 1998 "On Production and Consumption Waste," as amended on 29 July 2018, an individual entrepreneur or legal entity may not collect, transport, process, dispose of, neutralize or place I-IV hazard class wastes at a waste neutralization site and/or a site used for I-IV hazard class wastes, where another individual entrepreneur or another legal entity, possessing a valid license, conducts activities to neutralize and/or place I-IV hazard class wastes. Interpretations of this provision, however, differ, leading to a confusion between the term 'industrial site' defined as a site for licensed waste management activities and the terms 'waste disposal site' and 'waste neutralization site.' Pursuant to Article 9.2 of Federal Law No. 89-FZ, legal entities are prohibited from any waste management activities at any site on which another legal entity (site operator) is already engaged in any single type of waste management activity (for example, placement of waste). Consequently, provision of waste neutralization services on legal grounds is impossible. Thus, this statutory provision has no ecological effect only placing unjustified restrictions on the waste processing industry.

Recommendations:

- Amend Article 9.2 of Federal Law No. 89-FZ of 24 June 1998 "On Production and Consumption Waste," as amended on 29 July 2018, as follows:
 - "An individual entrepreneur or legal entity may not conduct activities related to the disposal of I-IV hazard class wastes to a waste disposal site, where another individual entrepreneur or another legal entity, possessing a valid license, conducts activities related to the disposal of I-IV hazard class wastes."
- Add Article 9.3 to Federal Law No. 89-FZ of 24 June 1998 "On Production and Consumption Waste" reading as follows:
 - "3. A person possessing a license for neutralization and/or placement of I-IV hazard class wastes may engage contractors to conduct certain elements of waste placement and/or neutralization activities, as well as waste collection, transportation, processing and disposal activities, provided all license requirements are fully met and contractors' activities are properly overseen. The responsibility for the activities of contractors at a waste neutralization and/or placement site lies with the person receiving a license to conduct activities at that site."

Issue 4. The right not to enter into a waste management agreement with the regional operator.

Article 24.7.6 of Federal Law No. 89-FZ of 24 June 1998 "On Production and Consumption Waste" does not provide for the right of legal entities running municipal solid waste treatment facilities/systems not to enter into an agreement with the regional waste management operator.

This means that in practice, a remotely located site equipped with such systems that comply with applicable standards and are operated by licensed contractors may not be legitimately used for waste management.

In addition, the same clause of Federal Law No. 89-FZ of 24 June 1998 states that legal entities may refuse to enter into an agreement with the regional operator, provided that they operate, either as the owner or on other legal grounds, a waste disposal facility within the boundaries of a land plot where municipal solid waste is produced or at an adjacent land plot.

However, this rule does not apply when a waste disposal facility is located remotely from a land plot where municipal solid waste is produced. This means that legal entities may not be allowed to dispose of waste to their waste disposal sites and they have to incur unjustifiable costs, paying to regional operators as part of their single fee for waste disposal to municipal landfills, the service that may never be actually provided.

Recommendations:

- Amend Article 24.7.6 of Federal Law No. 89-FZ of 24 June 1998 "On Production and Consumption Waste" to include the following: "Legal entities engaged in activities that produce municipal solid waste have the right not to enter into an agreement with the regional operator if they operate, as the owner or on other legal grounds, a waste disposal facility on the State Register of Waste Disposal Facilities or a waste neutralization system complying with applicable standards."
- Amend Article 24.7.6 of Federal Law No. 89-FZ of 24 June 1998 "On Production and Consumption Waste" to remove the provision reading that a waste disposal facility should be located at an adjacent land plot, which places unjustifiable and excessive restrictions on the owners of waste disposal facilities.

Issue 5. Amend rules for the implementation of EPR schemes.

In accordance with clause 1 "zh" of List of Instructions No. Instr-113 issued in pursuance to the Presidential Address to the Russian Federal Assembly of 15 January 2020, the Russian Ministry of Natural Resources and Environment is working on a draft of the Concept for Improving the Institution of Extended Producer and Importer Responsibility (hereinafter, the "Concept" or "EPR").

The working group engaged in the development of the Concept is headed by Ms. Viktoria Abramchenko, Deputy Prime Minister of the Russian Federation. As decided by the working group, the Concept is being drafted with the participation of the Ministry of Economic Development, Ministry of Industry and Trade, Ministry of Natural Resources and Environment, Rosprirodnadzor and subgroups representing other agencies.

The FIAC Working Group agrees that the EPR mechanism needs improvements as the regulatory authorities do not have sufficient information about the amount of goods or packaging released by producers or importers into the market while some of them evade environmental tax.

However, it is important to take into account the successful implementation of EPR schemes by FIAC member companies and make sure that their accomplishments are not lost for the future. That is why we are concerned about the following proposals to change EPR schemes:

- Introducing a 100% recycling requirement while maintaining environmental tax for goods and packaging produced/imported, which will actually bar producers/importers from implementing EPR schemes on their own or through specialized associations;
- Moving the liability for the recycling of waste from the use of goods and packaging or the environmental tax liability from producers/importers of packaged goods to producers of this packaging in order to broaden EPR administration

Recommendations:

The above proposals fail to address poor administration practices currently in place while barring producers/importers from implementing EPR schemes on their own or through associations, as well as introducing quasi-tax on all goods and packaging manufactured or imported and taking no account of best international and Russian EPR practices. The FIAC Working Group for Natural Resources and the Environment believes that it is necessary to improve the transparency of work on the draft Concept and invite FIAC representatives to take part so that they could contribute their views based on 2019 decisions by the FIAC Executive Committee and the FIAC Plenary Session.

It is highly inexpedient to introduce fundamental EPR changes leading to quasi-tax in the current challenging business environment aggravated by the COVID-19 pandemic, currency volatility and other factors. It is also important to understand that the current economic downturn can be lengthy and it will take time for many companies to recover from losses. That is why we believe it is necessary to adjust the Concept for the position of the business community.

It is important for FIAC member companies to maintain a favorable business environment in Russia, in particular, to enable producers and importers to implement the EPR on their own and continue the work of non-profit organizations established for these purposes by FMCG producers, provided a projected gradual increase in recycling quotas continues allowing to consistently build up investments in waste collection and recycling infrastructure as part of independent EPR implementation schemes.

To proceed with the draft Concept, a consensus is needed among FIAC member companies⁵.

Issue 6. Revise wastewater discharge standards.

The current version of the Methodology for Establishing Permissible Levels of Substances and Microorganisms Discharged by Water Users to Water Bodies approved by Order No. 333 of the Russian Ministry of Natural Resources and Environment of 17 December 2007 requires that post-treatment

⁵ Recommendations/position of Unilever PLC:

1. Rates of environmental fees should be differentiated within packaging groups by complexity/simplicity of processing.

2. Responsibility for recycling waste from the use of goods and packaging and for paying environmental fees should be shifted from the producers and importers of packaged goods to the producers of the packaging.

3. Extended manufacturer responsibility should apply to retail companies, including those delivering consumer goods via systems of e-commerce.

wastewater discharged to water bodies be a better quality than water collected from them. To comply with this exorbitant requirement, companies incur significant capital and operational expenditures for wastewater treatment. In particular, it takes more than RUB 500 million to build one copper removal facility to treat collected water, while related annual operational expenditures average out at RUB 30 million. In addition, such cost-intensive projects help little to substantially improve water in the water body as its quality depends on multiple factors, including activities carried out on other adjacent sites and the local environmental situation.

Recommendations:

- Amend water treatment standards to take into account background concentrations of pollutants in a water body above permissible levels in collected water. In particular, it is recommended to allow companies to use permissible discharge limits equaling the background concentration of pollutants in a particular water body if contaminant concentrations in collected water exceed permissible levels due to environmental and anthropogenic factors. In this case, companies will not do any additional environmental harm while being relieved from the excessive burden to produce posttreatment water of a better quality than collected water.
- Introduce the respective amendments to Decree No. 469 of the Russian Government of 23 July 2007 and Order No. 333 of the Russian Ministry of Natural Resources and Environment of 17 December 2007.

Issue 7. Inclusion of cement plants as energy utilization facilities in local waste management schemes.

The cement industry has developed a unique technology of using waste as an alternative fuel for the production of clinker to partly replace natural gas or coal in the fuel mix and utilize a range of wastes, including leftovers from the segregation of municipal solid waste. An oxidizing environment and high temperatures in the burning zone of cement kilns provide safe conditions for the destruction of waste. A distinctive feature of this process is the lack of secondary waste: ash residue that reacts with raw materials used for cement production, generating clinker as an intermediate product. Using waste as an alternative fuel and raw material in the manufacture of cement helps reduce a negative environmental impact, including CO2 emissions, and reduce the consumption of natural resources.

The technology for waste disposal in cement kilns is on the list of BAT in both Russia and the EU. It is considered to be the best available alternative to the burial of waste at landfill sites or waste combustion according to the current waste management hierarchy. The cement industry has capabilities to start using waste as an alternative fuel within a short period of time. However, it is necessary to include cement plants in local waste management schemes and add the utilization of leftovers from municipal solid waste segregation to the list of regulated activities.

Federal Law No. 450-FZ "On Amendments to Certain Legislative Acts of the Russian Federation" of 27 December 2019 amended Federal Law No. 89-FZ "On Production and Consumption Waste" of 24 June 1998 to:

- Extend the definition of the term 'utilization' as follows: "The use of municipal solid waste as renewable energy (secondary energy resources) after the extraction of commercial components at waste treatment facilities which comply with requirements set out in Article 10.3 of this Federal Law (energy utilization)."
- Add energy utilization to the list of regulated activities.
- Add energy utilization tariffs to the list of regulated tariffs.

Given their wording, these provisions should apply to the utilization of leftovers from municipal solid waste segregation at cement plants. However, more clarification is needed.

Recommendations:

1. The Ministry of Natural Resources and Environment and Russian Environmental Operator should attend the matter to provide for the inclusion of Russian cement plants as energy utilization facilities in local waste management schemes and federal/regional programs implemented pursuant to the Federal Project on the Development of a Comprehensive Municipal Solid Waste Management System to provide incentives for the construction of waste management systems at cement plants.

Amend the related bylaws to include regulations for "energy utilization" of leftovers from municipal solid waste segregation at cement plants.

Issue 8. Adjustment.

Adjustment to the Rules for Cold Water Supply and Wastewater Disposal, approved by Government Decree No. 644 of 29 July 2013 "On Approval of the Rules for Cold Water Supply and Wastewater Disposal and on Amendments to Certain Acts of the Government of the Russian Federation".

Court proceedings have become more frequent relating to charges by wastewater disposal organizations for negative impact on centralized drainage systems (CDS). The cases result from vague wordings in the list of substances barred from discharge into CDS in Appendix 4 to the Rules. The charge for the negative impact on CDS may total tens of millions of rubles per user. The wording ambiguity in Appendix 4 to the Rules was partially removed by Government Decree No. 728 of 22 May 2020; yet, the risk of users being wrongfully charged for the negative impact on CDS due to legislative imperfections persists.

To improve the regulatory framework for treating certain substances as prohibited from discharge into centralized drainage systems and to prevent an excessive cost on users of CDS, we propose that the provision in item 4 of Appendix 4 to the Rules be clarified in order to eliminate the risk of its liberal interpretation.

Recommendations:

Amend Appendix 4 to the Rules for Cold Water Supply and Wastewater Disposal, approved by Government Decree No. 644 of 29 July 2013 "On Approval of the Rules for Cold Water Supply and Wastewater Disposal and on Amendments to Certain Acts of the Government of the Russian Federation" as follows:

- 1. In item 4, replace "substances prohibited to be discharged in waterways" (other than those listed in Appendix 5) with "pollutants included in the list approved by Government Decree No. 1316-r of 8 July 2015 which are prohibited to be discharged in waterways (other than those listed in Appendix 4(1) and Appendix 5 to the Rules indicated herein)"
 - 2. Add the following note:

"Note.

In the event a regulatory standard is set for the substances specified in items 1, 3 and 4 of the list (other than those listed in Appendix 4(1)) as regards their content in CDS drinking water, those substances are not prohibited to be discharged into CDS unless the established standard is violated."

Issue 9. Categorization of facilities with a negative environmental impact.

Pursuant to Article 4.2 of Federal Law No. 7 "On Environmental Protection" of 10 January 2002, facilities producing a negative environmental impact are broken down into four categories depending on the magnitude of the impact (significant, moderate, insignificant, minimal). As per the Article, criteria for the categorization of facilities shall be set on the basis of the following:

- Magnitude of environmental impact from various business and/or other activities;
- Level of toxicity, cancerogenic and mutagenic properties of pollutants in harmful emissions and discharges, and hazard classes of production and consumption wastes.

Nevertheless, the criteria for assigning Categories I, II, III or IV to facilities with a negative environmental impact, approved by Russian Government Decree No. 1029 of 28 September 2015, classify facilities to those four categories almost solely on the basis of types of economic activities conducted thereat with no account of their actual negative impact.

Therefore, the criteria for assigning Categories I, II, III or IV to facilities with a negative environmental impact in accordance with Government Decree No. 1029 of 28 September 2015 should be based on the actual environmental impact of substances emitted to the environment, by class, and on other objective parameters. The adopted categorization principle, by type of OKVED activity, fails to stimulate users of natural resources to apply BAT and reduce the overall environmental impact, as it will not enable them to step a level down in the categorization.

Recommendations:

It is recommended to revise the criteria for assigning Categories I, II, III or IV to facilities with a negative environmental impact in order to account for the negative environmental impact of a particular facility irrespective of the type of economic activity conducted thereat and amend Government Decree No. 1029 of 28 September 2015 correspondingly.

Issue 10. Removing oil spill response plans from the list of documents subject to the SEER.

The SEER requirement for oil spill response plans is excessive and does not help increase the environmental safety of operations, since:

- 1. Oil spill response plans are primarily "operative documents" developed in accordance with emergency response regulations to provide for measures to contain and clean up spills of oil and oil products.
- 2. In accordance with Decree of the Russian Government No. 1189 "On the Setup of Measures to Prevent and Clean Up Oil and Oil Product Spills on the Continental Shelf, Inland Sea Waters, Territorial Sea and Adjacent Zone of the Russian Federation" of 14 November 2014, an oil spill response is a type of emergency response and rescue operations. Emergency response and rescue operations are aimed at protecting the environment and mitigating negative impacts from an accident that has caused an oil or oil product spill and thus cannot be considered to be causing a negative environmental impact that is subject to the SEER.
- 3. Under Federal Law No. 7-FZ "On Environmental Protection," any contemplated business and other activities must be given an environmental impact assessment. Information provided in oil spill response plans is intended rather to mitigate or prevent such impact.
- 4. Pursuant to Federal Law No. 174 "On Environmental Expert Review," documents subject to the SEER such as oil spill response plans must contain conclusions of an environmental impact assessment; however, Decree No. 1189 of the Russian Government does not set this requirement for oil spill response plans. The need to undertake a separate EIA for an oil spill response plan for the sole purpose of ensuring formal compliance with Federal Law No. 174-FZ reveals conflicting legislative requirements for oil spill response plans while placing an additional financial burden on companies and affecting the economics of projects.
- 5. Introducing amendments to oil spill response plans remains an open issue, because Federal Law No. 174 requires a repeat SEER for any amendments, including a change in membership on the Emergency Prevention and Response Commission or the replacement of an oil spill response vessel indicated in the existing SEER report. Currently, amendments may make the plan illegitimate, requiring a repeat review.

A SEER report should contain conclusions whether an environmental impact from the activity in question is permissible. As it is hardly possible to conclude that oil spill containment and cleanup operations can have an impermissible environmental impact, being primarily intended to mitigate any negative impact, an environmental assessment of an oil spill response plan makes little sense. It appears to be even more excessive in view of the amendments to Article 16.1 of Federal Law No. 155-FZ resulting from the new Federal Law No. 207-FZ of 13 July 2020, whereby marine oil spill response plans may not go ahead unless a comprehensive training is completed and a related conclusion obtained allowing to contain and clean up spills.

Issue 11. The need to adopt legislation regulating the work of employees who are temporarily provided by an employer that is not a private employment agency to other legal entities under staff leasing agreements.

Description:

Federal Law No. 116-FZ of 5 May 2014 "On Amendments to Certain Legislative Acts of the Russian Federation," which entered into force on 1 January 2016, prohibits outstaffing and restricts the use of staff leasing agreements in Russia.

In pursuance to Law No. 116-FZ, only private employment agencies may lease staff, i.e., provide their employees, on a temporary basis and with the employees' consent, to a host. Organizations that are not private employment agencies may provide employees to third parties only in certain cases in accordance with the terms and procedure prescribed by federal law. This law has not yet been adopted, and the delay has created a range of risks for foreign investors operating in Russia.

Recommendations:

Accelerate the adoption of the following laws to regulate the work of employees temporarily provided by an employer that is not a private employment agency to other legal entities under staff leasing agreements:

 Federal Law "On Amendments to Chapter 53.1 of the Labor Code of the Russian Federation," designed to set up a legislative framework for the temporary provision of employees to third parties under staff leasing agreements. • Federal Law "On Amendments to Article 18.1 of the Law of the Russian Federation "On Employment in the Russian Federation" pursuant to the adoption of the Federal Law "On Amendments to Chapter 53.1 of the Labor Code of the Russian Federation" that are designed to set up a legislative framework for the temporary provision of employees to third parties under staff leasing agreements.

Issue 12. Amend Order No. 154 of the Ministry of Natural Resources and Environment of 18 April 2018 to set criteria and correct factual errors.

The order does not reflect the actual quantity of air pollutants emitted from industrial activities and includes a number of enterprises whose emissions constitute only 0.01% of a total negative environmental impact caused in Russia.

Recommendations:

Correct the errors that have resulted in the unjustified listing of enterprises in the food industry, and remove such enterprises from the list approved by clause 258 of Order No. 154 of the Ministry of Natural Resources and Environment of 18 April 2018 (item code: 45-0177-001418-P).

Disclose the mechanism of selecting industrial sites for inclusion in the list to make it possible to check the expediency of such decisions, and invite the expert community to discuss possible improvements to this mechanism.

Issue 13. Eliminate barriers to the use of recycled plastic in food packaging.

It is necessary to eliminate restrictions on the use of recycled plastic in food packaging. State Standard (GOST) 32686-2014 prohibits the use of recycled materials for the production of plastic bottle preforms, which constrains projects to expand the recycling of plastic waste and its secondary use.

Recommendations:

Amend the state standard/technical regulation to allow secondary plastic pellets to be used in the manufacture of food packaging.

Subsoil use issues

I. Amending laws to improve the investment climate for subsoil use projects (Laws No. 2395-I of 21 February 1992 "On Subsoil Use" and No. 57-FZ of 29 April 2008 "On the Procedure of Foreign Investment in Businesses of Strategic Significance for National Defense and State Security").

Issue 1. Procedures for subsurface site division.

There has long been concern about the absence of provisions allowing license holders to divide subsurface sites into smaller parts and obtain the respective number of licenses without engaging in the bidding process. From the beginning of Russia's transition to a market economy, this issue has been repeatedly raised in practice. We believe that amending subsoil use regulations to allow the division of subsurface sites will only improve the sustainability and efficiency of subsoil use, leading to increased government tax revenues. Subsoil users have to address multiple challenges in their development operations which are related to both technical aspects and mandatory compliance with mining license terms, including the application of certain mining technologies and economic challenges restraining development operations across the entire field such as raising money from several investors for projects in different parts of the field, separating a part of the field to apply a special tax regime or calculating total profit for the entire field.

Recommendations:

Conceptual proposals:

- 1. Allow the use of all available options to change the boundaries of a subsurface site for sites of federal status that are deemed such based on Article 2.1 of the Law "On Subsoil Use" and contain hydrocarbons, subject to the following restrictions that are aimed at preventing selective development operations set up to mine only for high-grade natural resources:
- Transfer of federal status to newly created/changed subsurface sites irrespective of whether they meet criteria outlined in Article 2.1.2 of the Law "On Subsoil Use" by the amount of reserves;
- Introduction of amendments to Article 20 of the Law "On Subsoil Use" to prohibit a waiver of the right to subsoil use in respect of any parts of a subsurface site after its division;
- Stipulating that changes in the boundaries of a subsurface site may be made solely upon application from the subsoil user:
- Stipulating that the Russian Government, with the participation of the competent executive government bodies of the federal level, should hold the decision-making authority over the division of subsurface sites and have the right to deny such applications.
- 2. Specifying permissible options to change the boundaries of subsurface sites complying with applicable requirements, which may be established by bylaws
 - Ensuring that a subsurface site holds reserves on the state register of natural resources;
- Ensuring that a newly created subsurface site has natural resources and commercial potential based on the results of a state expert review;
 - Stipulating that a subsurface site may be divided only based on its geological properties;
- Stipulating that a division of a subsurface site should be in compliance with subsoil sustainable use/protection and mining safety requirements.

Legislative proposals:

1. Amend Article 7 of the Law to add the following provisions:

"For the purpose of ensuring efficient and safe activities at subsurface sites provided for exploration and development activities or the prospecting, exploration and extraction of natural resources under a combined license by the decision of a federal authority in charge of management of reserves on the state register or its local authority upon application from the subsoil user, a subsurface site, provided to the subsoil user in accordance with this Law, may be divided into two sites or more.

Where a subsurface site is divided into two sites or more, the newly created sites are provided for use to the subsoil user and the license held by the subsoil user is reissued to grant the subsoil user the respective licenses."

2. Amend Article 10.1.2 of the Law "On Subsoil Use" to add the following provisions: "... as well as the decision made by a federal authority in charge of management of reserves on the state register or its local authority to divide a subsurface site into two sites or more, with the newly created subsurface sites to

be provided for use to the subsoil user and the license held by the subsoil user reissued to grant the subsoil user the respective licenses."

- 3. Provisions governing the establishment and revision of the boundaries of subsurface sites provided for use, approved by Decree of the Russian Government No. 429 of 3 May 2012, should also be amended to include provisions governing the division of subsurface sites, while the title of the Decree should be changed accordingly.
- 4. Amend clause 20 of Order No. 315 of the Russian Ministry of Natural Resources and Environment of 29 September 2009 to include the following provisions: "if a subsurface site is divided into two sites or more in accordance with the Law of the Russian Federation "On Subsoil Use."
 - 5. Introduce other necessary amendments to implement our conceptual proposals.

Issue 2. Seismic surveys at adjacent subsurface sites.

It is necessary to establish procedures for subsoil users to agree on seismic surveys that are carried out as part of exploration activities beyond the boundaries of their licensed site with subsoil users operating adjacent licensed sites.

Recommendations:

- 1. The Ministry of Natural Resources and Environment should study, at the level of an interdepartmental working group, mechanisms for issuing separate licenses after the discovery of more than one deposit at a subsurface site and adjusting the boundaries of adjacent licensed sites, including by merging sites operated by the same subsoil user.
- 2. The Russian Geological Expertise Agency should develop procedures for subsoil users to obtain approvals for seismic and other exploration activities from (i) subsoil users operating adjacent sites when such activities can extend to their sites if seismic vessels should enter them and (ii) from the Federal Subsoil Use Agency in instances where a targeted site is unlicensed.
 - 3. Amend Article 7 of the Law "On Subsoil Use" to include Part 9 reading as follows:

"To carry out detailed exploration, exploration activities may include seismic surveys at both the licensed subsurface site provided to the subsoil user and adjacent subsoil sites in accordance with project documentation as approved. In instances where adjacent subsurface sites are provided to other subsoil users or are unlicensed, seismic surveys are carried out with the approval of these subsoil users or the Russian Geological Expertise Agency as applicable. The approval procedure is established by respective rules issued by the Russian Geological Expertise Agency.

Issue 3. Exploration and production.

Foreign investors may participate in the development of continental shelf subsurface sites of federal status only as subpartners in companies controlled by the Russian Federation. To participate in the development of other subsurface sites of federal status, foreign companies need special permits issued on a case-by-case basis. In practice, such permits should be granted exclusively to joint ventures established by Russian and foreign companies in accordance with Russian law. This practice is common in many oil-producing countries and is acceptable to international oil and gas majors. On the whole, foreign investors are willing to engage in mutually beneficial collaboration with Russian companies to develop Russian fields, however, a number of specific provisions of applicable Russian laws effectively hamper such collaboration.

Global oil and gas companies engage in their core activity as both investors and operators of oil and gas development projects. Most of major oil and gas projects are implemented by special-purpose vehicles established by project partners specifically for their project. A special-purpose vehicle is normally created as a new legal entity.

Russia's Law "On Subsoil Use," which requires subsoil users to have prior five-year experience in developing subsurface sites on Russia's continental shelf to be eligible for the development of a subsurface site of federal status, effectively excludes special-purpose vehicles from such subsoil users, as special-purpose vehicles created by Russian government-controlled companies with the participation of foreign investors are newly created legal entities established for a specific project and cannot have any prior experience in development activities by definition. A possible solution is to take into account the experience of joint venture founders and/or their subsidiaries in developing a subsurface site on the continental shelf. Prior offshore development projects both in Russia and abroad may be taken into account. Also, it may be feasible to legislate for subsoil user status for subsurface site operators. It is important for investors that a special-purpose vehicle established by project partners has the status of both operator and subsoil user, which is the mining license holder.

Recommendations:

Amend the Law "On Subsoil Use" to allow taking into account the years of offshore development experience of the founders of a legal entity established to carry out development activities on Russia's continental shelf as a subsoil user or their subsidiaries against the five-year experience requirement for such newly created legal entities.

Amend the Law "On Subsoil Use" to define in more detail development activities at subsurface sites on Russia's continental shelf and "subsoil use" activities on Russia's continental shelf that are taken into account in calculating the years of experience.

Amend the Law "On Subsoil Use" to define the operator as a subsoil user and grant the operator the respective legal status.

Issue 4. Exploration.

The possibility that the subsoil use right held by legal entities with foreign ownership or foreign investors may be terminated after the discovery of a field of federal status (Article 2.1 of the Law "On Subsoil Use") is a big disincentive for foreign investors to invest in exploration activities in Russia.

Mechanisms for the compensation of costs related to the exploration and appraisal of newly discovered fields are not efficient because such compensation would not cover costs incurred in other projects in the event of failure to make a new discovery (for instance, dry wells). Oil and gas and mining companies invest in the exploration of multiple subsurface sites that may be located in different regions and even in different countries, and by far not all of them happen to contain commercial reserves. Major companies have large-scale investment programs in place spanning a big number of subsurface sites. Such investment projects are by nature risky ventures, with the risk becoming too high due to additional concerns over the possible termination of the subsoil use right after a discovery. Moreover, international oil and gas and mining companies invest in exploration projects precisely because they expect to participate in the subsequent development of new discoveries.

While Federal Law No. 57-FZ of 29 April 2009 "On the Procedure of Foreign Investment in Businesses of Strategic Significance for National Defense and State Security" defines the term 'foreign investor,' the Law "On Subsoil Use" does not provide a clear definition for 'a subsoil user representing a legal entity with foreign participation.'

While the former law uses the term 'control,' the Law "On Subsoil Use" uses the word 'participation.' In addition, the former law defines the term 'control' and specifies its criteria, while the latter law contains no definition of 'participation' nor does it specify any criteria for such participation. Thus, this term may even be interpreted as ownership of one share, because neither the law nor its bylaws set any criteria for 'participation' (as opposed to Federal Law No. 57-FZ of 29 April 2009).

Recommendations:

Amend the Law "On Subsoil Use" to exclude the possibility that subsoil users, including legal entities with foreign ownership, controlled by the Russian Government either directly or through government-controlled companies may be denied the right to develop a newly discovered field of federal status or such right may be terminated on the grounds of a potential threat to national defense and state security. This provision would be similar to the exemption granted to government-controlled companies by Federal Law No. 57-FZ of 29 April 2008 "On the Procedure of Foreign Investment in Businesses of Strategic Significance for National Defense and State Security."

Amend the Law "On Subsoil Use" to stipulate that prior to announcing a bidding contest or auction for exploration rights, including exploration under a joint license, the Government of the Russian Federation or an authorized body thereof shall conduct a study to issue an opinion about the presence/absence of a threat to national defense and state security in instances where the subsoil user is a company with foreign ownership and its exploration activities result in a discovery meeting the criteria stipulated by Article 2.1.3 of the Law "On Subsoil Use." This opinion of the Russian Government or an authorized body thereof shall be published as part of an official announcement of a bidding contest or auction for exploration rights. If the Russian Government or an authorized body thereof has concluded that there will be no threat to state defense of state security in cases mentioned above and has published such conclusions as part of their official announcement of a bidding contest or auction, a subsoil user with foreign participation may not be denied the right to conduct exploration and development activities at the field or have its right to subsoil use under a joint license terminated.

There may be other mechanisms to protect foreign investors participating in joint ventures that are established to develop a newly discovered field.

Issue 5. Classification of fields of federal status.

The following trends can be observed today in Russia's mineral industry:

- Easy-to-find fields are running out;
- Production shift from depleting high-grade and easier-to-extract deposits to lower-grade deposits which are harder to extract;
- Exploration shift to remote areas with harsh geological and environmental conditions and a lack of infrastructure.

Such trends highlight the need to provide incentives for subsoil users to prospect new large fields the development of which will be economically attractive, bring about substantial investment inflows, create new jobs in remote areas and increase the adoption of new, more advanced technologies in the industry.

However, Russia's current legislation contains a number of provisions restraining investments in exploration activities, including exploration enhancement programs. For instance, there are criteria for assigning federal status to subsurface sites introduced in the Law "On Subsoil Use" following the adoption of the Federal Law "On the Procedure of Foreign Investment in Businesses of Strategic Significance for National Defense and State Security." Currently, federal status is assigned to sites containing more than 50 tonnes of vein gold reserves and more than 500,000 tonnes of copper reserves; however, there are some solid minerals whose mere showings are assigned federal status. In view of the above trends in Russia's mineral industry, including lower commercial yields of precious metals from ores, such subsurface sites have too little potential for commercially viable development. Regulatory mechanisms do not stimulate companies to discover or conduct detailed exploration of medium or large-sized fields that could increase Russia's total mineral reserves.

In view of the above, it makes sense to review deposit size criteria for federal status assignment so that this status could truly indicate the strategic significance of the field and encourage investments into its exploration.

Recommendations:

Amend Article 2.1.2 as follows: "2) located in the territory of a constituent entity or constituent entities of the Russian Federation and containing the following according to the state balance of natural reserves starting from 1 January 2006:

- Recoverable oil reserves of 70 million tonnes or more;
- Natural gas reserves of 50 billion cubic meters or more;
- Vein gold reserves of 250 tonnes or more;
- Copper reserves of 7 million tons or more".

II. Liberalization of exports of geological information.

We welcome the Administrative Regulations of the Federal Service for Oversight of Natural Resource Use on state services in issuing conclusions/permits for exports of subsoil information by region and deposit of energy and mineral resources, of mineralogical and paleontological collection materials, and of excavated animal bones and raw minerals. However, even if these regulations are adopted, a foreign investor that obtains a permit from the Federal Service for Oversight of Natural Resource Use will still have to obtain a license to export any geological information, including information that is not secret. Foreign investors currently have trouble obtaining such licenses, often resulting in project delays and postponed investment decisions.

The Eurasian Economic Commission's Decision No. 30 of 21 April 2015 approved the List of Goods Whose Import to, or Export from, the Customs Territory of the Eurasian Economic Community Requires Authorization (hereinafter, the "List"). The List's title indicates that it is a list of goods. Clause 2.23 – Subsoil Information by Region and Deposit of Energy and Mineral Resources – is thus inconsistent because, based on the analysis of the term 'information' in Article 2 of Federal Law No. 149-FZ of 27 July 2006 "On Information, Information Technology and the Protection of Information," it seems clear that information does not qualify as goods. This is confirmed by the lack of a code for information in the Unified Goods Classifier for Foreign Economic Activities.

The licensing of exports of geological information that is not a state secret makes it extremely difficult to implement joint exploration and development projects in Russia. For information to be processed in foreign data processing centers, a company has to obtain a license, which often results in the suspension of work for an extended period.

Recommendations:

To lower administrative barriers, information that clearly cannot be regarded as a state secret under clause 67 of the List of Information Regarded as a State Secret (approved by Edict No. 1203 of the President of the Russian Federation of 30 November 1995, as amended by Edict No. 90 of the President of the Russian Federation of 11 February 2006) should be removed from the List, i.e. information obtained during joint work performed by foreign individuals and legal entities on particular fields or sections thereof and information obtained on legal grounds by foreign investors from Russian partners.