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OF FIAC WORKING GROUPS

Foreign Investment Advisory Council

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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 to 100% renewable electricity in 2018-19.

By 1 September 2019, all Unilever enterprises across five continents (excluding Australia and New Zealand) had converted to 100% renewable electricity, 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 free bilateral agreements is higher than the price of power traded on the wholesale market. Thanks to this price premium and the fact that the amount of electricity purchases is contractually fixed, renewable energy generators can effectively enjoy a more structured and reliable demand for their products.

This arrangement 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), 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, after the Market Council developed a concept for this system, the Russian Ministry for Economic Development released its exposure draft of Federal Law "On Amendments to the Federal Law "On the Power Sector" and Certain Legislative Acts of the Russian Federation in Connection with the 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 GHG emissions.

At present (August 2021), pursuant to Decree No. 2344-r of the Russian Government of 3 November 2016, the Ministry for Economic Development has updated the Long-Term Low GHG Emissions Strategy to 2050 (hereinafter, the "Strategy") and sent it to the federal executive bodies for approval. In addition, Federal Law No.1116605-7 "On Limitation of Greenhouse Gas Emissions" (hereinafter, the "Federal Law on GHG Emissions Limitation") has been approved and published. The Law was drafted by the Russian Ministry for

Economic Development pursuant to Instruction of the President of the Russian Federation No. Pr-2323 of 11 November 2019 and paragraph 7 of the plan to implement initiatives to enhance government regulation mechanisms for regulating GHG emissions and drive the ratification procedure for the Paris Agreement adopted on 12 December 2015 by the Conference of the Parties to the UNFCCC at its 21st session and approved by Decree No. 2344-r of the Russian Government of 3 November 2016.

The working group believes that the updates to the current versions of the documents are important and positive. The updated interpretation of the greenhouse gas (GHG) definition in the Federal Law on GHG Emissions Limitation allows regulating not only the most common greenhouse gases (carbon dioxide and methane), but also other greenhouse gases that are CO2 equivalents (nitrous oxide, sulfur hexafluoride, hydrofluorocarbons, perfluorocarbons, and a number of hydrochlorofluorocarbons).

Note, however, that despite some improvements, the Federal Law on GHG Emissions Limitation is effectively a compromise and provides only a general framework without describing specific measures to reach the stated goals: a sustainable low-emissions future and a more competitive Russian economy amid the global transition to a sustainable economy. The Strategy goals can only be achieved if the Russian Government adopts the bylaws enabling it to exercise the powers vested in it by the Federal Law on GHG Emissions Limitation.

We believe that, while the baseline scenario of the current version of the Strategy sets a target to bring Russia's cumulative net GHG emissions between 2021 and 2050 to a level lower than in the EU, it still does not set ambitious targets with regard to reducing net emissions. Should the Strategy be approved as currently drafted, the lack of ambitious targets will have an adverse impact on all related regulations. If there is no strategic vision to reduce emissions, there will be no motivation to introduce regulations limiting GHG emissions and/or promoting a low-carbon economy.

FIAC agrees that the Strategy and the Federal Law on GHG Emissions Limitation must be approved, but it proposes that more ambitious targets be set with regard to reducing GHG emissions by 2050. Without clear and ambitious GHG reduction targets, Russia will have difficulties in joining the ranks of economic, technology and environmental leaders on international and regional levels and may run a risk of new restrictions on international cooperation.

FIAC members believe that the regulator should closely focus on greenhouse gases with a high global warming potential ("high GWP gases").

The need for additional government support measures aimed at reducing emissions of high GWP gases (gases with extremely high levels of the CO2 equivalent) has become especially urgent after Russia ratified the amendment to the Montreal Protocol on Substances that Deplete the Ozone Layer (aka the "Kigali Amendment"). The ratification proves the long-term need for regulatory mechanisms aimed at cutting the use of hydrofluorocarbons, which are also regarded as greenhouse gases in Appendix A to the Kyoto Protocol (hereinafter, the "Appendix").

In accordance with the Appendix, greenhouse gases include not only carbon dioxide, but also hydrofluorocarbons (HFC), perfluorocarbons (PFC), and a number of hydrochlorofluorocarbons (HCFC), methane (CH4), nitrous oxide (N2O) and sulfur hexafluoride (SF6). The environmental damage caused by these substances is extremely high, e.g., the emission of one ton of freon 23 (HFC) is equivalent to the emission of nearly 15,000 (!) tons of CO2.

Considering that high GWP gases other than methane and nitrous oxide are predominantly imported to Russia as either stand-alone products or as part of other more complex products, it would be appropriate to introduce dedicated rules regulating the way these gases are brought to market (i.e., put into circulation) and used by local consumers. This approach would allow the government to pro-actively regulate GHG emissions without infringing on the economic interests of local industries most sensitive to the regulation of CO2 emissions.

On 1 April 2021, a complete list of HFC that are high GWP gases (List F) was added to the list of regulated substances pursuant to Government Resolution No. 228 "On State Regulation of Consumption and Circulation of Substances that Deplete the Ozone Layer" of 24 March 2014. Moreover, the Russian Ministry of Natural Resources and the Environment issued Order No. 8 of 12 January 2021 "On Establishing a Permitted Annual Volume of Consumption in the Russian Federation of Regulated Substances from List F of the List of Substances that Deplete the Ozone Layer subject to State Regulation, approved by Government Resolution No. 228 "On State Regulation of Consumption and Circulation of Substances that Deplete the Ozone Layer" expressed in CO2 equivalent" (registered with the Ministry of Justice on 18 March 2021, No. 62808; entered into force on 29 March 2021; hereinafter, the "Order on Restriction of Consumption of List F Substances").

FIAC members, while supporting the expansion of the list of regulated substances with List F substances and the issuance of the Order on Restriction of Consumption of List F Substances, point out that the current version of the draft Government Decree "On Amending Government Resolution No. 228 "On State Regulation of Consumption and Circulation of Substances that Deplete the Ozone Layer" of 24 March 2014" (ID 02/07/06-21/00117236, created on 23 June 2021) contains no provisions to limit the putting of high GWP gases into circulation, but rather focuses on accounting for the amount of harmful substances put into circulation. The very fact of setting targets for restricting HFC consumption and accounting for their exact levels cannot result in lower consumption. We believe that in order to reach the targets set in the Order on Restriction of Consumption of List F Substances, it is necessary to include into the main part of Government Resolution No. 228 of 24 March 2014 the provisions that would directly encourage the reduced consumption of these substances and take into account the way they are put into circulation (as in the case of regulated substances from other lists).

We also believe it is important to introduce symmetrical regulation across the Eurasian Economic Union (EAEU) to reach the announced goals and propose starting the relevant discussions with EAEU members.

Recommendations:

1. We recommend that the baseline scenario of the Long-Term Low GHG Emissions Strategy to 2050 be reviewed and an ambitious target for lower GHG emissions be set.

2. The provisions encouraging the reduced consumption of List F substances and taking into consideration the way they are put into circulation should be included in the main part of Government Resolution No. 228 "On State Regulation of Consumption and Circulation of Substances that Deplete the Ozone Layer" of 24 March 2014.

3. Amendments should be drafted and introduced to Federal Law No. 7-FZ "On Environmental Protection" of 10 January 2002 and other regulations to include provisions regulating the putting into circulation of high GWP gases, as defined in the Kigali Amendment to the Montreal Protocol adopted by Russia.

Issue 3. 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 in the case of 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 birth rate 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, benefits were only available for women in agricultural jobs. 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 drafted 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 urban areas

(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.

4. Problems involved in implementing EDS technology in Russia

The implementation of electronic digital signature (EDS) is one of the key drivers of further digitalization of the economy and optimization of business processes. EDS is embraced by many companies across all levels.

However, the early use of EDS has uncovered some major challenges that not only deter companies from wider adoption of EDS, but force them to give up this mechanism altogether. Moreover, a growing number of reports on fraud and abuse associated with the use of EDS erode public trust in advanced digital technologies, significantly impairing their potential uptake.

There is a paradox: this critically important industry remains underregulated, with its regulation being effectively driven by internal rules of certification centers, which, in the absence of significant legal responsibility, are focused mostly on attracting and retaining new clients without due regard to the quality and security of their services.

After analyzing the existing regulation and application practice, EDS users have come up with a number of proposals, which we believe should help improve the current situation and expand the uptake of this important and effective digital technology.

1. Operating procedures of certification centers

At present, each certification center sets its own standards regulating its roles and responsibilities and the way they should be performed (hereinafter, the “operating procedures”) based on its own interpretation of the legal framework, which differs from those that other certification centers may have.

Consequently, while Article 13.33 of the Administrative Offenses Code provides for liability for violations of the procedure for issuing qualified EDS key certificates, this provision cannot be applied, as the relevant procedures are established independently by each certification center based on its own interpretation of the law.

Certification centers therefore may not be held liable for infringing the applicants’ rights, i.e., when an EDS is issued or canceled in violation of the set deadlines.

Proposal:

The Ministry of Digital Development should either conduct mandatory compliance checks of certification centers’ operating procedures and approve them on a case-by-case basis or develop a standard operating procedure for all certification centers.

2. Issuing an EDS based on scanned copies of documents

Checking EDS applications is a major challenge. Certification centers normally require that applicants upload scanned copies of documents to their personal accounts. In practice, the certification center deal with scanned copies of applications. The originals presented by applicants are only briefly checked against scanned copies, if at all. This practice is not safe and creates fertile ground for fraud, enabling unscrupulous parties to use scanned copies of documents.

Proposals:

Certification centers should be legally prohibited from accepting scanned copies of documents and be made obliged to check original documents submitted by applicants (EDS applications, powers of attorney, etc.).

3. Extending a previously issued EDS.

A system of personal accounts used by a number of large certification centers assumes that when an EDS expires, its holder sees a pop-up window with an option to apply for a certificate. A click in the pop-up window is actually enough to extend a previously issued EDS.

In the case of corporate applicants, this approach is risk prone, as the certification center does not verify the powers of a person applying on behalf of the legal entity. Hence, the certificate is effectively issued without the permission of its owner, which is a legal entity. In order to avoid potential abuse by EDS holders, we suggest that extension of a previously issued EDS should only be granted with the permission of the employer.

Proposal:

The procedure for extension of a previously issued EDS should include obtaining a permission from both the EDS holder and their employer.

4. Termination of an EDS.

Surprisingly, termination of an EDS, contrary to its extension, is overly complicated. Certification centers process applications for terminating an EDS only when these are signed either by the CEO of the legal entity or its employee holding the EDS. Certification centers do not process EDS termination applications signed by an authorized representative of the legal entity acting on the basis of a power of attorney. This approach violates the applicant's (entity's) interests, as it unreasonably narrows the range of potential signatories and is not in compliance with current legislation, in particular, Article 40.3.2 of Federal Law No. 14-FZ of 8 February 1998 "On Limited Liability Companies," whereby the company's sole executive body is authorized to issue powers of attorney to act on the company's behalf.

Proposal:

The operating procedures of certification centers should allow the termination of an EDS based on an application signed by an authorized person on the basis of a relevant power of attorney.

5. Tariffs and primary accounting documents.

The description of tariffs published on the official website of a certification center usually differs from that indicated in invoices, acceptance certificates and other primary documents.

Applicants therefore have no certainty about the pricing process and what product they will ultimately get. Certification centers often use marketing tricks to sell the same product branded as different EDS without telling clients they are in fact identical.

Proposal:

All certification centers should provide a clear description of each tariff and its pricing mechanism as well as an exhaustive list of platforms and websites covered by the certificate. The tariff names on the website should exactly match those indicated in invoices, certificates and other primary documents. Documents should contain full details of the certificate's holder. If a certificate is issued to a legal entity, the certification center should also indicate the full name of the individual holding an EDS.

6. Responsibility of a certification center.

There is currently no criminal liability for violations committed in the course of the issuance and circulation of EDS (EDS issued based on forged documents, violations of verification and issuance procedures, etc.). This means that the actions of certification center officers to issue deliberately false EDS certificates are not regarded as socially dangerous. This prompts a risk of gray trading in such certificates and creates opportunities for fraudulent acts involving the use of EDS. Starting 10 January 2021, these activities are covered by Article 13.33 of the Administrative Offenses Code and are punished by a RUB 250,000 fine. This penalty is too lenient, as there are cases when fake EDS were used to sell property worth of millions of rubles.

In particular, missing the deadline for entering EDS termination data in the register entails a RUB 10,000 fine. At the same time, market players have already faced a situation where a certification center does not enter EDS termination data into the register until a month after such termination.

There is only a RUB 50,000 fine imposed on those who have compromised or illegally modified the certification center's keys. These fines are obviously not high enough to prevent willful misconduct or make certification centers abide by law and follow their operating procedures.

We believe that administrative liability for violating the provisions of Federal Law No. 63-FZ "On Electronic Signatures" is not adequate to protect public interests, since an EDS now substitutes for the physical presence of its holder or their legal representatives in the widest range of legal actions.

Proposal:

Criminal liability should be imposed on authorized persons at certification centers for the unlawful use of EDS, violation of EDS termination deadlines or actions to compromise EDS.

7. Problems involved in issuing qualified EDS to foreign nationals.

The amendments to Federal Law No. 63-FZ of 4 April 2011 "On Electronic Signatures" effective from 1 January 2021 introduce two types of qualified electronic signatures:

1. A corporate EDS detailing registration data of the legal entity and information on its director. Such EDSs will be issued by the Federal Tax Service (FTS) only;

2. A personal EDS.

In case of an individual representing a legal entity, a personal EDS can be used only when supported by a machine-readable power of attorney signed by an EDS of the CEO issued by the FTS.

All electronic signatures issued to corporate officials by commercial certification centers are terminated from 1 January 2022.

At present, the FTS as a certification center is not technically capable of issuing qualified electronic signatures to a legal entity where a foreign national performs the functions of the sole executive body. This, in turn, means that employees of such legal entity will not be able to obtain machine-readable powers of attorney entitling them to sign e-documents on behalf of the legal entity.

Thus, starting 1 January 2022 legal entities where foreign nationals perform the functions of the sole executive body are effectively excluded from e-workflow (unable to submit financial statements via telecommunication channels, or use state services). In other words, a significant part of business activities of such legal entities will come to a standstill.

Proposal:

In order to prevent suspension of business activities in January 2022, the technical challenges of issuing qualified electronic signatures to legal entity where a foreign national performs the functions of the sole executive body should be promptly solved.

8. Federal government oversight.

Under Article 16.1.4 of Federal Law No. 63-FZ of 6 April 2011 "On Electronic Signatures", no scheduled audits of accredited certification centers are now performed as part of the federal government oversight. The Ministry of Digital Development is reluctant to perform an extraordinary audit based on a complaint filed against a certification center by its corporate customer. This, as well as lack of mandatory scheduled audits, means that the activities of certification centers are actually not subject to any control or oversight.

Proposal:

Mandatory scheduled audits of certification centers should be regularly performed, and alleged violations committed by certification centers should be promptly investigated.

Issue 5. Automation and robotics solutions in manufacturing.

Pursuant to the Russian Government's instruction following the FIAC's Plenary Session, measures to stimulate deployment of enterprise automation and robotics solutions are being developed in cooperation with the Productivity and Efficiency Department of the Ministry of Economic Development as part of the National Project "Labor Productivity and Employment Support".

The experience of introducing industrial robotics in developed countries showed that measures to support an enterprise's initial industrial robotization project drive large-scale industry robotization and automation, and such measures are critical in ensuring that the first experience is not a negative one and that the right goals are set for further modernization. It has been determined that another crucial driver is a process audit to access an enterprise's potential for implementing industrial automation and robotics solutions 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 industry automation and robotization. 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 players prepared and submitted to the Productivity and Efficiency Department of the Ministry of Economic Development recommendations on the regulations on process audits in order to automate and robotize production processes to enhance labor productivity. Matters of government financing of process audits have been deferred due to the COVID-19 pandemic and update of the National Project "Labor Productivity". A wide range of market participants, including automation and robotics manufacturers, industry associations, scientific and educational institutions, representatives of the Federal Center of Competences in Labor Efficiency (FCC), national development institutions and companies participating in the program to enhance labor productivity, should be involved to ensure further development of the process audits program. One of the key objectives is to establish a platform facilitating open discussions among market stakeholders to finalize the regulation on the robotics audit program. At present, such platform may be established on the basis of the National Association of the Robotics Market Participants (NARMP).

Implementation of the regulation may start from test process audits on enterprises covered by the program. In 2020, ABB supported by the Government of Kaliningrad Region encouraged enterprises of the region undergo process audits to analyze enterprises' interest in robotic solutions. This proposal have been popular with enterprises, and some enterprises are now developing an in-depth plan to deploy robotic production solutions. Based on the experience of effective cooperation with the Government of Kaliningrad Region and results achieved, ABB is now considering expanding the test process audits program to four other Russian regions: Moscow, Kaluga, Lipetsk and Leningrad Regions.

The regulations on process audits may be easier implemented if adopted and integrated into the geo-information system "Digital Labor Productivity Ecosystem". Process audits may be one of the services accessible via the system. At present, there are software robotic solutions that are capable to create a simulation model of an enterprise in virtual environment, simulate the adoption of robotic cells amid the production process and demonstrate the added value created by automation and robotic solutions before they are deployed full-scale.

For information

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

Robotics and automation solutions are widely used across the globe to achieve greater productivity, cut costs, increase work safety and reduce injury rates at industrial enterprises and make them more competitive. Industrial robotics contribute up to 10% to GDP growth in countries with a developed industrial robotics market, which is comparable with the share of the entire oil and gas sector in Russia's GDP. In Russia, the share of industrial robotics in GDP growth is negligible and makes up only a fraction of a percent, which indicates that the vast potential of industrial robotics, which has proved effective in many countries, remains untapped.

The 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 2019, Russia had 6 robots per 10,000 employees, which is comparable to Indonesia and India. For reference, robot density stands at 187 in China, 228 in the US, 346 in Germany, 364 in Japan, 855 in South Korea and 918 in Singapore, with the global average being 113 per 10,000 employees. The low penetration of robotics in the Russian manufacturing sector suggests that local enterprises face certain systemic difficulties when implementing robotic cells:

- Low management awareness of the economic efficiency of robotic cells;
- A lack of specialist workforce, with only 1,000 qualified experts at local enterprises who have the requisite knowledge to monitor the operation of robotic cells; as robot density is expected to rise by 2025, demand for qualified workforce will increase to 40,000 experts;
- No publicly available methods for assessing the potential of industrial robotization;
- No database of implemented robotic solutions by industry sector and operations performed within and outside Russia;

- A lack of readily available debt financing for projects to modernize production using robots (RUB 5-15 million);
- High costs of pre-project feasibility studies to raise financing and justify small projects.

The National Project “Labor Productivity” is set to address these challenges.

Industrial robots are widely used in the manufacturing sector across most of the developed countries. Robotic cells (with the use of articulated or cartesian robots, delta robots, SCARA robots and other) can perform various functions such 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 for governments to provide additional support aimed at the wider use of robotics. Russia can take the similar approach by making such class of technologies available for local industrial enterprises. To encourage the use of robots across multiple sectors, it is necessary to address individual barriers and analyze the needs and robotization processes specific to each sector. Implementing robots will increase the competitiveness of local enterprises, reduce costs and free up workers from routine and repetitive tasks and enable them to focus on more value-added activities. By integrating robotics into their labor productivity enhancement programs, companies will be able to benefit from advanced manufacturing tools, increase productivity, improve the quality of their output, adapt and upskill their workforce, thus becoming more competitive on the world market. Stimulating demand for robotic solutions among various enterprises will also widen the pool of local developers of robotic-cell technologies (integrators) and have a positive impact on the robotics market as a whole.

Recommendations on implementing robotic and automation solutions for the National Project “Labor Productivity” are based on the discussions involving a large number of NARMP members.

Recent global trends in technological process automation driving improved labor productivity

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

Currently, there is a global trend to develop and implement flexible production systems to facilitate transition to single-batch production at the current characteristics and potential of the mass production. This tendency implies a conceptual change in the approaches to design, develop, produce and maintain manufacturing lines and cells. Due to advanced automation and robotic technologies, different types of products may be simultaneously manufactured on one technological site or line, thereby significantly increasing productive capacity and efficiency.

One of the key steps to facilitate transition to advanced production technologies is the process audit to assess the level of automation and robotization of the existing enterprises. Process audit should involve checking against the criteria describing the enterprise’s technological level and its readiness for deployment of advanced production technologies (refer to Annex 1) and preparing the respective recommendations.

Preliminary recommendations:

The National Project “Labor Productivity” consists of two federal projects, each of which involves measures to expand the uptake of robots and promote automation of production processes to enhance labor productivity.

The process audits program is one of the recommended initiatives to minimize the risks enterprises run when first implementing robotic-cell technologies and to support advancement of technologies by local integrators. Similar initiatives are also implemented in highly robotized countries (e.g., Robot Lift, an initiative of the Swedish Agency for Economic and Regional Growth).

The process audit of an enterprise helps identify demand for robotic automation systems of companies participating in the program to enhance labor productivity. The initiative may be implemented by the FCC and manufacturers of industrial robotics, industrial robotization solutions, especially robotic cells integrators. As a result, participants will obtain a full picture of robotized process flows based on best international practices, along with specifications, results of technology trials, assessment of cash investments required, project delivery time and payback period, as well as a full list of materials to develop an investment project.

We also recommend that a separate segment “Production Process Automation and Robotization” be set up when preparing documents for the National Project “Labor Productivity”. “Automation and end-to-end

technologies” implies using robots, though it is not directly stated, which may lead to ambiguous interpretations and restricted implementation thereof.

Moreover, we recommend that the deadlines set for “Robotization and Automation” actions specified in the federal project summary be extended to ensure their proper elaboration.

The National Association of the Robotics Market Participants is eager to collaborate with the Russian Ministry for Economic Development and the Federal Center of Competences in Labor Efficiency to deliver the National Project “Labor Productivity”.

Appendix No. 1

Recommendations on the structure of the process audit of the enterprise automation level.

1. Use of the industrial robotics.

Increased robotization of enterprises and replacement of manual labor in hazardous, monotonous and hard jobs leads to a significant reduction of the cost of goods manufactured and, consequently, improves enterprise efficiency and competitiveness. This, in turn, results in the increased volume of production and more jobs that are more comfortable and efficient.

Process audit involves evaluation of the enterprise in the following steps:

- Analyze the existing technological processes;

- Use digital twins to test industrial robotics in the existing technological processes by the integrators/auditors;

- Analyze payback based on calculations received during testing;

- Recommend required improvements;

- Train employees of the enterprise.

2. Functional safety.

Industrial robotization and automation must implicate improved safety of technological processes and reduced risk of employee injuries and death, which directly leads to an increased production capacity. This may be ensured with the adoption of modern industrial safety standards and technologies, such as functional safety standards aimed at protecting personnel working with complex robotized and automated processing centers. Expanding human-machine interaction must go hand in hand with enhancing human safety thus ensuring the development of collaborative human-machine interaction technologies.

Process audit involves evaluation of the enterprise in the following steps:

- Analyze whether technological equipment is compliant with the existing functional safety standards;

- Assess functional safety competences of the operating personnel;

- Assess the existing measures to mitigate risks of near-accidents;

- Assess whether technological equipment is compliant with the existing standards;

- Recommend required improvements;

- Identify whether functional safety of technological equipment may be improved;

- Estimate the budget required to improve functional safety of an enterprise, including further training of personnel involved in production.

3. Networking.

An increase in efficiency and capacity through implementing flexible production systems will depend on the digital maturity of the enterprise’s infrastructure and whether it can support integration of production and IT units. In particular, such integration is sensitive to communication compatibility, determinacy and networking reliability.

Until now, inter- and intra-machine (production unit) communication 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, which means operating personnel of industrial enterprises bears an additional burden maintaining heterogeneous network infrastructure. Use 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 in the wake of the shift to the fourth industrial revolution paradigm. This issue may be resolved through the

adoption of open standard communication protocols to ensure seamless data transfer between the devices of different manufacturers from the field level to the cloud computing level. Such technologies can dramatically increase the speed and volume of production data transfer and significantly enhance labor productivity.

Process audit involves evaluation of the enterprise in the following steps:

- Analyze industrial communication protocols used for M2M connectivity;

- Assess the share of M2M communications via industrial communication protocols in the total amount of communications;

- Assess to what extent proprietary industrial communication protocols are used;

- Assess to what extent open industrial communication protocols are used - Assess networking between the technological and production management levels;

- Develop recommendations to improve transparency of networking between the technological and production management levels;

- Educate employees on the modern methods to establish networking within an industrial enterprise.

4. Overall equipment efficiency.

Modern high-performance automation solution that collect operational data in real time through the industrial field bus lines make it possible for the employees operating high-tech equipment to refine and accelerate the assessment of the overall equipment efficiency (OEE) that directly characterizes the capacity of an 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 involves evaluation of the enterprise in the following steps:

- Analyze the existing supervisory control and data acquisition (SCADA) systems;

- Analyze whether technological equipment is equipped with industrial communication protocols interfaces;

- Analyze integrated diagnostics means of technological equipment for the availability of information characterizing its efficiency;

- Develop recommendations to establish a system of monitoring and assessment of the overall equipment efficiency;

- Educate employees on the modern methods to assess the overall efficiency of the technological equipment.

5. Predictive diagnostics and technical maintenance

Automated predictive diagnostics solutions should be used to analyze whether an enterprise is able to transfer to technical maintenance of complex technological equipment, for example, flexible industrial robotic cells.

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

When combined with technical and economic production data and information from the measuring sensors, it is able to predict 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 focused on the condition of the equipment.

Process audit involves evaluation of the enterprise in the following steps:

- Assess diagnostics and technical maintenance regulations and rules in place;

- Analyze whether data on the condition of technological equipment is available for further processing;

- Assess whether control and measurement solutions are installed on technological equipment to monitor its condition;

- Analyze statistical data on technological equipment failures;

- Develop recommendations on the transfer to predictive maintenance;

- Estimate and establish the budget to implement predictive diagnostics;

- Develop recommendations and estimate of the budget for personnel training and retraining.

Issue 6. Low-carbon logistics.

Climate change is the most severe environmental crisis of our time. Human activities lead to the highest emissions ever, with no signs of a slowdown. According to bp's annual Statistical Review of World Energy, global cumulative CO2 emissions in 2018 totaled 33.9 billion tons, up 2% compared with 2017. This is mainly due to increased emissions in developing countries. Measures should be taken to ensure 50% reduction of global GHG emissions by 2050 compared with the baseline year (1990) to harness the global warming.

Cumulative pollutant emissions in Russia totaled 32.3 million tons in 2018, of which 17.1 million tons was generated by stationary sources, and 15.3 million tons was generated by vehicles. In 2018 pollutants emitted by vehicles was up 4.6% compared with 2017, and up 13.2% compared with 2000. Vehicle-generated CO2 emissions may surge in coming decades unless restrictions are introduced.

A draft Strategy for the Development of Auto and Urban Electric Transport to 2030 prepared by the Ministry of Transport states that "[auto transport] makes up from appr. 40% to 70%-80% (in large cities) of the total anthropogenic air pollutant emissions". Pursuant to the strategy, "vehicle-generated air pollution causes 15-20 thousand early deaths annually in the country". In addition, cars are a major source of noise pollution.

One of the measures to abate noise and reduce environmental pollution is the development of electric and other alternative means of transport, which is also a key step towards a low carbon economy. According to the International Council on Clean Transportation,1 green (electric and hybrid) cars currently make up 6%-14% of the total cars produced by European manufacturers. Around 7% of the cars sold in Europe are electro cars. As stated in the rating by KPMG, Russia is regrettably lagging behind global leaders in preparedness to e-mobility.

Pursuant to the Government Decree of 5 November 2020, the Ministry of Transport, the Ministry of Industry and Trade and the Ministry of Natural Resources are to draft a federal law to "introduce measures to stimulate the use of environmentally friendly transport". The draft law must be submitted to the government not later than in June 2021, and to the State Duma three months later.

The action plan attached to the Decree states that the Cabinet of Ministers must approve directions for constituent entities of the Russian Federation regarding "the development and approval of comprehensive strategic planning documents for the uptake of electric transport and development of the respective infrastructure" by May 2022. Such documents will determine the minimum share of wheeled electric cars in intracity passenger transportation and for organizations with state participation.

One of the key challenges hindering e-mobility development in Russia is the lack of infrastructure (most importantly, underdeveloped charging network). According to surveys, a sufficient number of charging points available is a second important factor that is considered by electric vehicle buyers in Russia (with price being the most important one). In terms of this metric, Russia ranks 24th (the last but one) in the KMPG rating.

According to KPMG and VYGON Consulting, there are fewer than 500 charging points in Russia, while the number of electric cars is surging (a 71% y-o-y increase) hitting 10,000 cars by the beginning of 2021. For reference, there are 1.3 million charging points in China2, around 170 thousand in Europe, 80 thousand in the USA, 22 thousand in the UK, and more than 16 thousand in Norway.

At present, Russia has no comprehensive plan to support development of electric vehicle market, nor has it a comprehensive public charging points development program. Separate regions introduce isolated incentive initiatives aimed at developing electric transport and charging network. Regional and municipal authorities (e.g., in Ulyanovsk and Vologda regions, in Ufa and Kazan) have made the first move to establish a path for charging network development. Moscow is one of the leading regions, with actively developing electric bus fleet and respective charging network. Energy companies, including Rosseti and RusHydro, are also implementing dedicated charging network development programs.

Some regulations supporting the development of EV charging network have also been put in place. In particular, laws have been passed, which state that electric charge is not power supply services and are not subject to licensing (Federal Law No. 262-FZ "On Amendments to the Federal Law 'On the Power Industry'"). Standards on parking spots for cars within apartment building compounds were enacted in St. Petersburg (Resolution of the Government of St. Petersburg No. 524 of 21 June 2017) that assume one EV parking space per 1600 sq m of the total floor area, but at least one parking space equipped with a charger.

1 International Council on Clean Transportation

2 China: in-house and public charging points, other countries: public charging points only.

Presently, pursuant to the Government Decree of 5 November 2020, the Ministry of Transport, the Ministry of Industry and Trade, the Ministry of Natural Resources and the Autonet working group of the National Technological Initiative are drafting a federal law to “introduce measures to stimulate the use of green transport”. A wider range of stakeholders should be engaged in the discussion of such an important draft law, including foreign car manufacturers and charging solutions manufacturers who have the expertise and unique experience in the field.

International best practice

In 2019, the European Parliament and the European Commission approved Regulation No. 2019/1242,3 proving a 30% reduction of CO2 emissions generated by new trucks by 2030. European regulations require that CO2 emissions generated by new trucks brought to market should be reduced in two stages: by 15% by 2025, and by 30% by 2030.

The development strategies of many international companies include obligations to reduce their carbon footprint. Thus, pursuant to its Carbon Zero Logistic strategy, Unilever committed to reduce the carbon footprint of its transportation by 50% by 2025 and to reach a net zero by 2030. In order to achieve the goals set, the company introduces initiatives to reduce CO2 emissions, including those that optimize routes (via reducing kilometers traveled, avoiding dead run, using fewer trucks, optimizing truckload), update vehicle requirements (increased aerodynamic performance, tire drag reduction, drivers trained in driving at optimal efficiency). However, these arrangements are not enough to achieve the goals set. The next steps to reduce CO2 emissions should include use of railway transportation for long haul traffic only (> 1000 km), a gradual shift to low-carbon or no-carbon fuels (alternative fuels), and switch to electro vehicles for short drives and urban transportation. However, this sector is presently underdeveloped even in central regions (Moscow, St. Petersburg).

Ingka Group (comprising IKEA retail chain and MEGA shopping centers) undertook to reduce industrial emissions by 2030 in pursuance of the Paris agreement and joined the global EV100 initiative which unites companies committed to accelerate transition to electric transport by 2030. Since the delivery of goods is one of the important elements of the Group’s business, the Group assumed a global commitment to switch to eclectic or zero emission vehicles by 2025. IKEA is taking practical steps to implement the strategy. For example, the company has already switched to using only electro vehicles when delivering goods from shopping malls in Shanghai. In Russia, IKEA follows the global strategy and uses its international experience of effective transitioning to the sustainable development model, which suggests a gradual departure from using vehicles powered by fossil fuels. Currently, a pilot project is launched in Moscow and St. Petersburg to deliver goods using electric vehicles.

Schneider Electric has set the goal to achieve a 15% reduction of transportation CO2 emissions within its supply chain by 2025 (compared with the baseline year of 2020). The company is currently using vehicle emission calculation methodology based on its internal guidelines (Transportation Transformation – Performance).

Many countries active in supporting EV and charging network development. For example, China, being a global EV leader, has established a specialized agency4 responsible for developing charging network strategies and standards. Beijing has also developed and implemented Guidance on Accelerating the Construction of Electric Vehicle Charging Infrastructure5 by 2020, which is enough to cover 5 million electric vehicles. The European Energy Performance Building Directive6 provides for a mandatory number of charging points when building new infrastructure facilities. There are also a system of subsidies and grants aimed at supporting charging network development in Europe.7

A developed charging network will encourage sustainable demand for electric vehicles for both private and commercial use. When ICE vehicles of utility service providers, logistics operators, carsharing service providers and public transport are replaced with electric vehicles, it will help to abate noise and reduce pollution in cities, thus enhancing quality of life.

3 Regulation (EU) 2019/1242
4 Chinese Electric Vehicle Charging Infrastructure Promotion Agency, EVCIPA
5 Guidance on Accelerating the Construction of Electric Vehicle Charging Infrastructure
6 Energy Performance Building Directive (2018)
7 The Connecting Europe Facility, CEF

Recommendations:

CO2 emissions calculation

There is currently no unified methodology for calculating CO2 emissions generated by trucks in Russia, and there are certain difficulties with estimating carbon footprint of logistics operations.

FIAC member companies communicate with logistics companies providing transportation services and give their recommendations on route optimization and vehicle use to achieve the CO2 emissions reduction target for logistics. However, as Russia does not have a developed legal framework, requirements of FIAC members are often perceived as recommendations.

We believe that we all need clear legal requirements, unified methodology for calculating vehicle carbon footprint and certain stimuli to encourage logistics companies to transfer to low-carbon logistics.

Supporting green transport development

According to the preliminary analysis, achieving CO2 emission reduction target may require involvement of the following stakeholders:

- Manufacturers of alternative-fuel vehicles and transportation service providers using alternative fuels (to adopt a financial and non-financial reporting system, including am climate risk assessment and risk mitigation strategy);

- Private and public sector players (to develop infrastructure adopted for new vehicles);

- Investors and banks (to ensure transparency in informing about risks inherent in assets);

- Government authorities (economic benefits and incentives to stimulate development of this sector of automotive industry and infrastructure necessary to a step-by-step transition to green fuels; the government should introduce effective, predictable, incremental pricing of carbon emissions).

Companies and entities also require the following systems to be created and maintained to transfer to a low-carbon business strategy:

- Municipal infrastructure for hybrid and green vehicles;

- Establishing a cargo tracking system within a company (or in cooperation with logistics providers and public sector entities), which may be based on GLONASS (checking whether companies live up to their commitments to use low-carbon vehicles can be challenging).

Supporting green vehicle owners

Green vehicles include electric, gas- and hydrogen-powered vehicles. Owners of these vehicles may enjoy preferences, such as reduced toll payable, free parking, use of public transport lanes. Reducing of transport tax should also be considered.

Charging network development

A developed charging network must be established so that electric transportation can develop rapidly in the Russian Federation. The following measures can facilitate its establishment:

- A vision of the charging infrastructure market should be developed based on partnership principles, full transparency and competitiveness, with an aim to provide quality charging services on an arm's length basis;

- Drafting methodological recommendations on charging network creation and development in Russian regions (subject to local specifics) and general requirements with regard to the number of parking spaces equipped with chargers for construction, reconstruction and major repairs projects, as well as for road, housing and shopping and business infrastructure;

- Methodological recommendations on calculation of service fee for owners and operators of charging network should be developed and approved;

- Procedures to connect charging points to infrastructure facilities should be simplified;

- Owners and operators of charging network should enjoy tax benefits (e.g., with regard to income, property or value-added taxes);

- Grants to compensate for the capital investments should be provided, e.g., by subsidizing interest rates on loans issued for construction of charging points;

- The state should partly compensate for market electricity selling tariff, thus ensuring that customers in Russia can buy charging services at special tariffs to encourage sustainable demand for electric vehicles and reduce the total cost of owning an electric vehicle;

- Design and construction standards for office and residential buildings and parking areas should be updated to include charging point quotas (amendments to the set of rules “Urban Development. Urban and Rural Planning and Development”, SP 42.13330.2016; “Parkings”, SP 113.13330.2016), including underground parkings (amendments to the set of rules “Embedded Underground Parkings. Fire Safety Requirements”, SP 154.13130.2013), and operators should be awarded the right to install and maintain such points through a competitive bidding process;

- A special financing mechanism for charging network projects that involve own generation using renewable energy sources and/or use of energy accumulation systems should be developed and introduced;

- Addressing issues related to implementation of the vehicle-to-grid (V2G) technology;

- Mechanisms to support companies replacing their ICE vehicles with low-carbon (electric) vehicles should be developed;

- The legal framework should be enhanced with regard to individuals and legal entities entitled to own electric chargers;

- The legal framework should be enhanced to introduce administrative fines for violating rules for stopping and parking at spots designed for EV charging;

- A major public information campaign should be carried out to promote low-carbon vehicles and raise the awareness about their capabilities, how fast and ultra-fast charging stations work and what are their advantages.

At early stages of charging network development, charging stations should be installed at petrol stations, parking spots, hotel-adjacent areas, in shopping malls, suburban settlements, courtyards of residential complexes, and close to tourist attractions.

It should be noted that charging network will be attractive for business investment only if the electric car market is on the rise and their number is surging. Therefore, measures to support charging network should be considered in conjunction with measures to support EV market development, including additional benefits and EV allowances for customers. Such measures might include VAT refund on EV purchase, or trade-in allowances when replacing an ICE vehicle with an electric vehicle.

2. Localization and Regional Development

Issue 1. Excessive requirements for the localization of production in the Russian Federation and imperfection of the procedure for validating the Russian origin of goods.

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 both manufacturing processes as well as regulated industries continues to expand constantly.

In its Decree No. 661 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.

It is noteworthy that 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.

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.

Currently, Russia's Ministry of Industry and Trade is taking action to expand the scoring system principle to other branches of the machine building. It is probable that, eventually, the foregoing system will be replicated in other industries.

Investors are also quite critical of the procedure for validating the Russian make of goods with an ensuing access to government incentive measures. The aforementioned procedure envisages a multistage attestation of manufactures in accordance with the adopted method and the subsequent issuance of a conclusion by Russia's Ministry of Industry and Trade. The effective procedure seems to be rather cumbersome taking into account the limited effective term of a conclusion and the necessity to terminate it ahead-of-schedule and obtain a new one, where the design of a product is changed for the reason of technical improvement, amendment of legal requirements or the replacement of a spare parts supplier. Taking into account that the legal documents issued by the Chamber of Industry and Commerce and the Ministry of Industry and Trade establish deadlines for fulfilling certain stages when obtaining an assessment act and a conclusion, that are measured in days, it turns out that, in practice, the foregoing process takes about six months and a significant time share is spent for preparing a package of documents required for obtaining an assessment act and its following coordination with the Chamber of Industry and Commerce.

Resulting from a highly excessive and bureaucratic procedure (taking 4-6 months from initial application), manufacturers of Russian products have to postpone localization and export development projects indefinitely because, in the absence of legal validation of the production in the Russian Federation, one becomes ineligible to obtain government support measures, as envisaged for such type of the strategic projects. Consequently, Russia's economy and that of its constituent entities fail to obtain investment, the state budget – tax revenues and the effect on the performance of national projects is negative.

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.

Streamline the procedure for obtaining the validation of production in the Russian Federation by reducing the total of required documents to a reasonable minimum (up to 3-4 weeks without reducing the assessment quality).

Issue 2. 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 property tax and the ability to deduct the acquisition cost of fixed assets when such assets are written off/sold.

From economic viewpoint, 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 property 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 after 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 property 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 the 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 the budgets of Russian constituent entities to be used until their expiration date and only for the projects to which such benefits apply in accordance with the established procedure until 1 January 2023.

Issue 3. Barriers for the development of pet-food production under the current conditions.

The production of pet food is a dynamically growing industry and investments into it have topped USD 3 billion over the past 20 years. FIAC member companies have already built five plants in Russia. Annual turnover of the pet food market exceeds RUB 200 billion, and over 20,000 people are employed in its production and distribution system. In addition, substantial quantities of finished pet food are exported to the non-FSU and CIS countries8. Already now the total annual export exceeds 10.3 billion and, with a due development of raw material sources, the total export would grow by 25%-30 annually, according to companies' estimates.

Currently, companies are implementing multiyear investment projects for the construction of new pet-food production plants or enhancing the existing production capacities, that are worth billions of rubles. Therefore, the strategic planning of raw materials procurement is our top priority.

Pet-food production employs multiple technologies, innovations and dozens of various raw material components and ingredients. FIAC member-companies have always viewed the maximum localization of raw materials production as one of their priorities. Due to the multiyear program for the development of local suppliers pursued by the Working Group members, nowadays, the ratio of domestic raw materials varies from 80% to 90%. It is evident, however, that a 100% indicator is virtually unattainable. Despite all our efforts, market participants critically lack the raw materials of Russian make, which raises concerns not only about the current investment but is also viewed as a risk for stability of the ongoing production.

For example, in the sphere of meat-and-bone meal the share of Russian raw materials in the total supply has increased from 50% to 78% over the past four years, which has reduced an overall deficit to 22.79 thousand tons. The remaining share falls on the types of meat-and-bone meal that is not manufactured in Russia or whose quality fails to comply with mandatory requitements of the member companies of the FIAC Working Group. Therefore, the success of industry operations and development hinges on a stable importation of critically important raw materials in the necessary volumes.

There are concerns about the availability of animal proteins such as rabbit, sheep, duck, quail and goose meal, pork meal with the protein content of 70% or above (offal, cracklings or meat), chicken meal with the protein content of 80% or above (offal or meat). The salmon, beef, and chicken meal with the protein content of 65% or above as well as animal fat and choline chloride are in limited supply (i.e., below the demand), and without their obtainability in the necessary quality and volume it is virtually impossible to manufacture a broad spectrum of the ready-for-use pet foods.

8 The main export destinations are in the CIS (Azerbaijan, Abkhazia, Armenia, Belorussia, Kazakhstan, Kirgizia, Moldova, Uzbekistan, Tajikistan, Turkmenistan and Ukraine), the EU (Poland, the United Kingdom, Germany, Italy, France, Denmark and Finland), Norway, Turkey and Mongolia. Particular attention is paid to the prospects of accessing China's pet-food market.

The restrictions introduced by Rosselkhoznadzor in 2021 on the importation of pet food and feed additives[9] from certain EU countries, for the reason of discovery in the shipments from certain manufacturers of the undeclared GMO components, have significantly deteriorated supply of important raw materials for the industry because they concern not the specific non-complying manufacturers but the country-manufacturer whose supplies have traditionally covered a significant share in the deficit of raw materials and ingredients. Not only animal proteins have been banned but also the whole spectrum of pet food and feed additives including those that are not manufactured or manufactured in an insufficient volume in Russia. The fact, that the components of raw materials made of animals, the meet-and-bone meal included, which by origin cannot include any plant components, have been banned because of discovery of the undeclared GMO components, is particularly amazing.

In our estimate, the suspension of raw materials import from certain European countries has brought about, amongst others, an increase in the deficit of chicken meal with high protein content of up to 25%-30% and also of the salmon meal combined with an overall reduction in the growth rate of local pet food production by, approximately, 6%-10% and a price growth on numerous raw materials.

At the same time a multiple price increase on locally produced meat-and-bone raw materials (only in the past seven months the price of chicken meal has gone up by 35%-55% and of the pork meal by 50%-70%), unfortunately, has not resulted in their abundancy on the Russian market.

In May 2017, in the context of discussing the restrictions on importation of meat-and-bone meal from certain countries, Russia's Ministry of Agriculture established a working group for monitoring the aforementioned market, whose objectives included drafting an import-substitution road map as well as coordinating the interaction of consumers and manufacturers of meat-and-bone meal with a view to increase its production in Russia. However, the road map was neither adopted, nor approved.

We support the resumption of cooperation in the context of the working group under the Ministry of Agriculture for the development, adoption and implementation of a new road map up to the provision of only locally-manufactured raw materials to producers by 2030, because the current restrictions on the importation from certain EU countries of pet foods, feed additives including a broad spectrum of raw materials and ingredients have caused serious problems in the sphere of predictability of operations of all Russian manufacturers of the ready-for-use pet foods. In the event of escalating the restrictions on importation of critical raw materials, the industry risks to lose the production of a notable share of certain pet foods up to a closure of certain plants.

A reduction of pet-food production in Russia will result in a decrease of its share on the EAEU and CIS markets. It will be replaced with imported pet foods and a restoration of Russia's export position will require significant time.

Taking into account the aforementioned as well as that the restrictions imposed on the importation of pet foods and feed additives from certain countries have significantly extended the list of critically important components of raw materials, besides the meat-and-bone meal, we deem it necessary to draft and adopt an action plan for a comprehensive and predictable transfer of the industry on locally manufactured raw materials (with the ability to compensate for deficit through importation) by 2030.

Recommendations:

Resume the working group operations for drafting actions (a road map) of raw materials localization for the production of pet food till 2030 and have it adopted by an order of Russia's Ministry of Agriculture.

Establish favorable conditions for a reliable provision of the current and prospective pet-food production with raw materials of the required volume and quality, including imported raw materials, during the development period of the domestic market for similar raw materials.

9 https://fsvps.gov.ru/fsvps/news/41773.html
Rosselkhoznadzor Directive No. №FS-KS-7/6762 of 15.03.2021. The importation to the Russian Federation of all pet food and feed additives manufactured in Spain has been suspended as of 15 March 2021.
Directive No. № FS-KS-7/13836 of 21 May 2021. The importation to the Russian Federation of all pet food and feed additives from Germany has been suspended as of 15 March 2021.

Appendix 1

Proposals of the members of the FIAC Working Group for inclusion into an action plan for analyzing the current situation on the market of meat-and-bone meal.

Proposals for inclusion in the road man	Deadline	Responsible organizations	Substantiation	Comments
After the enactment of GOST R 59296-2021 Tankage [meat-and-bone meal] for the production of feed for non-productive animals. Technical conditions, its provisions should be included into the list of requirements under the Government Decree No. 982.	Q II, 2021	Industrial unions (National Meat Association, National Union of Hog Farmers, Russian Poultry Union)	It is necessary to improve the quality of locally produced meat-and-bone meal urgently.	
Improve quality control systems at the Russian packing plants manufacturing meat-and-bone meal so that their products comply with the requirements of GOST R 59296-2021.	Q II – Q IV, 2021	Russia's Ministry of Agriculture and the industrial unions	It is necessary to improve the quality of locally produced meat-and-bone meal urgently.	
Russia's Ministry of Agriculture should set up an interdepartmental working group for quarterly analysis of the reports supplied by Russian manufacturers of meat-and-bone meal on the actual volume of meat-and-bone meal realized for the pet food [production].	Q II, 2021	Russia's Ministry of Agriculture	It is essential to monitor import substitution in the sphere of the meat-and-bone meal production.	We deem it essential to mandate Russian manufacturers of meat-and-bone meal to provide quarterly reports on the actual supply of each meat-and-bone meal type meeting the requirements of quality pet-food.
Preserve and develop the alternative supply sources of raw materials (meat-and-bone meal) from third countries that do not support the regime of sanctions against the Russian Federation: establish an accelerated coordination procedure for veterinary certificates;	During 2021	Russia's Ministry of Agriculture, Rosselkhoznadzor	As it is impossible to use for production only the domestically manufactured raw materials as well as taking into account the risks of a reduction of manufacturing capacity for the cat and dog food, it will be necessary to ensure a	Currently, it takes up to two years to establish new markets and new suppliers.

establish a streamlined procedure for adding new entries to authorized producers lists on the basis of guarantees issued by the country-producer.			timely supply of raw materials from third countries. The availability of alternative markets will ensure competitive equity on the domestic market of raw materials.	
Establish alternative supply sources of finished products (cat and dog food) from third countries (that already includes meat-and-bone meal): - establish an accelerated coordination procedure for veterinary certificates; - establish a streamlined procedure for adding new entries to authorized producers lists on the basis of guarantees issued by the country-producer.	During 2021	Russia's Ministry of Agriculture, Rosselkhoznadzor	As it is impossible to use for production only the domestically manufactured raw materials as well as taking into account a significant reduction of manufacturing capacity for the cat and dog food, it will be essential to ensure a timely supply of raw materials from third countries. Currently, it takes up to two years to establish new markets and new suppliers.	Currently, out plants for the production of cat and dog food in the EU and certain other countries, that have been certified by Rosselkhoznadzor, are highly overburdened. According to our preliminary calculations, in order to ensure the required volume of finished goods, we will need to have more than 10 additional plants certified.
Exclude salmon meal from the list of goods subject to a planned ban. Consider introduction of a ban on importation of the aforementioned product upon reaching ninety-percent localization.	Q II, 2021	Russia's Ministry of Agriculture	Currently, it is virtually impossible to substitute local product for imported salmon meal because of its quality. In addition, we request to adopt a complex of incentives supporting an accelerated development of fish meal production in Russia.	

Exclude chicken, rabbit, duck, turkey, and sheep meal from the list of products subject to a planned ban. Consider ban introduction individually for each type of meal upon reaching a ninety percent localization.	Q II, 2021	Russia's Ministry of Agriculture	Currently, such industry as the rabbit breeding is only beginning to develop in Russia. For there is no industrial production of the rabbit meal in Russia, it is virtually impossible to substitute an imported meal for the domestically manufactured product. Russian market for the production and processing of duck is at initial development stage and includes only several manufacturers so far, because, currently, the commercial duck farming is extremely difficult in Russia. Besides, all duck meal manufactured at the aforementioned farms is used for feeding their own livestock and is not available on free market. Significant deficit of the chicken meat-and bone meat persists and surpassing it will take time.	

Issue 4. (Risks of applying the so-called double-standards approach.) The risk of unfounded restrictions due to the measures limiting the unconscionable competition when marketing goods in the Russian Federation, whose consumer qualities, allegedly, are inferior to those of the goods marketed abroad.

The FIAC expresses concern regarding the approach formulated by Russia's supervisory agencies with respect to the so-called double standards approach, whereby the goods of international brands marketed in Russia, according to plans, will be compared regularly with the similar goods marketed in other countries in terms of consumer characteristics, composition and the terms of use. In the event of difference of the goods marketed in Russia and a failure to inform consumers about designating the goods specifically for the Russian market, the foregoing actions of Russian manufactures will be deemed unconscionable competition entailing an increased administrative liability.

The goods manufactured by international companies have identical composition and quality, irrespective of where they are produced and for which country designated. The occasionally arising insignificant differences are caused by such objective reasons as consumer preferences, the conditions of goods production and use but, foremost, by different regulatory standards.

Thus, different mandatory requirements to goods in Russia and other countries often result in that the manufacturers have to adopt their global recipes before accessing the Russian market. It is noteworthy that goods marketed in Russia fully comply with the foreign counterparts in terms of consumer attributes and quality characteristics.

Proposals of certain government agencies as regards the additional informing of consumers concerning goods' designation for the Russian market by way of corresponding labels is excessive from the viewpoint of effective law in Russia and the EAEU. The Common Mark of Products Circulation already demonstrates that the goods, which bear it, have successfully passed all the compliance tests established in the EAEU technical regulations.

Attempts to infer "double quality standards" with respect to the goods that fully comply with the requirements of Russia's and the EAEU law but have insignificant differences from their foreign counterparts question the effectiveness of the system adopted in Russia (and the EAEU) for assessing compliance of goods and the validity of established requirements in the sphere of quality and safety.

The aforesaid attempts form a groundless prejudice of Russian consumers towards the goods manufactured in Russia under international brands, thereby inflicting on goods' manufacturers not only reputational but also material damage in the form of the reduced sales. It may produce negative effect on the investment climate and the rate of production localization in Russia.

Renunciation of forming the policy for discriminating the goods manufactured under international brands in Russia as regards their foreign counterparts would solve the problem. The harmonization of regulatory requirements between Russia, the EAEU and other countries, including the mutual acknowledgement of test results based on the approximation of approaches to the assessment of goods compliance and methods of its laboratory testing, would be an additional important measure. That would not only permit manufacturers of international brands produce fully identical goods in Russia and other countries but would also strengthen Russia's export potential.

Recommendation:

Renounce the practice of discriminating the goods manufactured by international companies in Russia until the harmonization of regulatory requirements between Russia (the EAEU) and its major trade partners, including the mutual acknowledgement of test results, approximation of approaches to the assessment (validation) of goods compliance and methods of its laboratory testing.

Issues being monitored:

Issue 1. 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.

At the same time those 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 regulation in other CIS countries, such as Azerbaijan, Moldavia, Mongolia[10], Tajikistan, Turkmenistan[11], and Uzbekistan, has special provisions that need to be taken into account when manufacturing products. Joint efforts have been made to establish interstate standards. These efforts make it easier to resolve the problem. On the other hand, Moldova, for example, has recently harmonized its technical regulation with the European standards that are different from the EAEU standards.

One should separately mention Georgia, which is not a CIS member and is also focused on harmonizing technical regulation with European standards. Not all countries are WTO members, which precludes automating the collection of information about new nontariff barriers.

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

Most companies operate in the aforesaid countries through distributors, i.e., do not have employees who could monitor all changes. As a result, Russian manufacturers are far too often unprepared for new changes that come into force. It gives rise to a threat of loss (the risks of having to write-off products) and might lead to an outright refusal to supply goods to certain countries in order to mitigate risks. Needless to say, that the foregoing difficulties are even more challenging for small and medium-size companies.

This situation remains unresolved: 2019 saw several new cases of drafting and introducing new requirements, whose implementation raises questions on the part of Russian exporters.

Solution seems to be in establishing mechanisms for information exchange on changes in the food law at interstate level, organizing regular monitoring and issuing freely accessible newsletters on changes in technical regulation being drafted and enacted in the aforesaid countries.

Based on the meeting of FIAC Executive Committee on 10 October 2019, the Ministry of Industry and Trade, in cooperation with the Russian Export Center and business community, were mandated to draft concept of an early warning system to provide updates on the requirements for goods imported from Russia to neighboring FSU countries. Russia's trade missions in foreign countries could perform the aforesaid functions.

In 2021 the issue was transferred to monitoring regime because of reorganization of the Minpromtorg Department that had requested the foregoing system.

10 Takes part in certain CIS agencies as observer.
11 An associated member.

3. Improvement of Tax and Customs Law and Administration

In 2020 and 2021, the Working Group for Improvement of Tax Law focused on the following issues.

Issue 1. Procedure for applying cl. 25 of Federal Accounting Standard (FAS) 27/2021 Accounting Documents and Document Flow in Accounting.

On 1 June 2021, the Ministry of Justice registered the Order of the Ministry of Finance on approving FAS 27/2021. Pursuant to cl. 25 of this Order, an entity is required to keep accounting records and information contained therein and locate respective data bases within the territory of the Russian Federation. The obligation to apply this clause arises from 1 January 2022.

This clause makes it impossible to derive a clear conclusion on whether the accounting data processing center should be transferred to Russia or it is sufficient to locate its copy (mirror) in Russia for the purpose of the clause enforcement. Unfortunately, Information Statement No. Is-accounting-33 of the Ministry of Finance of 10 June 2021 does not resolve the existing uncertainty and related risks, allowing for the storage of data copies in other countries, and does not comment on the possibility to locate copies of the original accounting data specifically in Russia.

The uncertainty arisen from this regulation has a material impact on foreign investors which are exposed to the risk of unjustified costs (excessive localization of infrastructure, when a copy is sufficient) or additional expenses (investment in the creation of a copy) or direct violation of the Russian legislation that is also unacceptable.

It should also be noted that actual primary accounting documents related to activities of the foreign investors are quite often stored in the Russian Federation and many FIAC member companies are under the tax monitoring, giving the tax authorities a direct access to its accounting and tax data, and in certain cases to the electronic archives of primary documents.

Recommendations:

Request an official clarification from the Russian Ministry of Finance on the procedure for applying cl. 25 of FAS 27/2021 and suggest considering the possibility to introduce a transition period for the implementation of this regulation before 1 January 2023, and clarify the possibility to implement this regulation in entities subject to the tax monitoring.

Issue 2. Substantiation of intra-group services.

In tax audits in 2020 and 2021, 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. The position of the Federal Tax Service concerning shareholder services was additionally disclosed in the letter of 12 February 2021.

Recommendations:

We believe it desirable to continue efforts towards improving the regulation on how intra-group services should be substantiated, based on international practice, in particular, certain routine services should be removed from the close control of the tax authorities.

Issue 3. 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 4. 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 5. Further refining the regulations that govern the provision of investment tax credits.

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.

Recommendations:

We suggest continuing further refining of the implementation procedure of this tax regulation with regard to proposals of FIAC members.

Improvement of Customs Law and Administration

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

Issue 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.

2. The Federal Customs Service of Russia should consider reducing the list of information, including the information on expenses provided by AEOs via remote access.

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 and submitted a draft resolution to the Eurasian Economic Commission providing for such simplification.

We ask the Ministry of Economic Development and the Ministry of Finance to assist in adopting the resolution by 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 cost-effective 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 3. Development of the customs monitoring institution.

The Federal Customs Service continues to improve the customs control leading to a gradual shift of the focus to the customs control after the release of goods and to the further simplification of the customs control with respect to good-faith foreign trade operators.

One of the potential areas for interaction of a good-faith business and the customs authorities is the customs monitoring regime, which involves reducing the administrative and control burden on foreign trade operators and ensuring the transparency of customs and domestic business operations by granting the remote access to data in accounting systems of foreign trade operators.

The plan of measures for the period of 2021-2024 on the implementation of the Customs Service Development Strategy by 2030 provides for the introduction of the customs monitoring procedure with respect to authorized economic operators (AEOs). One of the tasks for 2021-2022 set before the Federal Customs Service is to conduct an experiment in the customs monitoring.

FIAC member companies support the development of the customs monitoring procedure. However, with regard to the experiment and subsequent establishment of legal framework for the voluntary disclosure by foreign trade operators of goods accounting system and the simplification of the customs control, we consider it is useful to pay attention to the following.

1. As part of Regulation No. 81-r of the Federal Customs Service of 7 May 2019, an experiment is currently being conducted in the submission of data in electronic form with the use of a data mart. At the end of August 2021, there is an unresolved problem concerning the limit on the amount of data transfer and there is no agreed list of information sufficient for the purpose of the customs control. The initiatives of the experiment participants met with no response. Therefore, the decision to launch the customs monitoring can be adopted upon the successful completion of the experiment attesting to the efficiency of the participants' systems and the agreed approach to the amount of information provided.

2. Necessary and sufficient amount of information in accounting systems reportable as part of the customs monitoring should be determined by regulations. Changes in the list of necessary information in accounting systems should be followed by a sufficient transition period of at least 12-18 months, which is associated with prolonged timing for improving, updating and configuring the ERP accounting systems of AEOs. In particular, the list of information necessary for the customs monitoring and reported by AEOs to the customs authorities via remote access to goods accounting systems, is defined in Appendix 2 (cl. 19 of the draft decree of the Russian Government "On Conducting the Experiment in Customs Monitoring") which has not yet been provided to foreign trade operators.

3. It is required to define through legislation the procedure and terms of providing the information by AEOs upon request of the customs authorities and the procedure in case of failure to provide the information requested, including for technical reasons.

4. Regulations should define ways of providing remote access to the information in accounting systems (web interface, remote access software, Personal Account app, Electronic Data Reporting app) permitted by the customs monitoring.

5. It is necessary to provide multiple information operators to ensure competition in the information exchange services.

6. Information provided within the customs monitoring could omit the data for periods prior to the date of application submission.

7. It is required to revise/improve a balanced set of criteria for the initiation of the customs monitoring procedure and to ensure the public disclosure of the methodology for the calculation of criteria and the possibility to revise them, including on the basis of proposals of the experiment participants.

8. It is necessary to change the wording of cl. 22 of the draft decree of the Russian Government “On Conducting the Experiment in Customs Monitoring” and reword it as follows: “The report of the customs authorities on the customs monitoring is submitted to an authorized economic operator within 5 business days from the date of its preparation by registered mail with the return receipt or in the form of an electronic document via the personal account to independently assess the probability of violation of customs law and voluntarily address the possible consequences (customs duties underpaid).”

9. It is required to revise cl. 34 of the draft decree of the Russian Government “On Conducting the Experiment in Customs Monitoring”, including:

“Customs monitoring terminates early in the following cases:

1. when it is impossible to grant remote access to goods accounting systems of authorized economic operators, send online requests to the economic operator which is subject to the customs monitoring (apply remote technologies)

2. when the customs authorities identify the inaccurate information submitted by AEOs; →eliminate or determine criteria for assessing the credibility of information

3. when assets of AEOs are depreciated (sale of real estate properties, change of a legal entity, establishment of subsidiaries, transfer of funds to third persons’ accounts)→ eliminate or establish clear criteria of the level of depreciation of assets.”

We also request to consider the possibility to regulate the simplifications of the customs control for participants of the customs monitoring, such as:

1. A motivated opinion of the customs authorities, which can be prepared either on their own initiative or on the initiative of a foreign trade operator, reflects the position of the customs authorities on the correctness of calculation (withholding), completeness and timeliness of payment of customs duties and is mandatory for the application by the customs authorities and foreign trade operators.

2. Mutual agreement procedure on the elimination of violations or risks of violations of the customs legislation identified during the customs monitoring excluding the possibility of bringing administrative and/or criminal charges against the entity under review if AEOs voluntarily submit applications on amending (adding) the information included in goods declarations and pay the amount of customs duties, levies and taxes due.

3. The customs authorities encouraging and accepting the results of proper self-inspection performed by foreign trade operators, including before or after the customs monitoring of self-inspection of foreign trade operations of the company to ensure their compliance with the customs legislation.

4. Refraining from the conduct of in-house and on-site customs inspections with respect to periods, when the customs monitoring is conducted (was conducted).

Recommendations:

1. We request you to support the proposals of the Federal Customs Service on the conduct of experiment in applying the customs monitoring and its enactment.

2. We request you to consider the FIAC’s proposals when developing a regulatory framework for the introduction and implementation of the customs monitoring in Russia.

3. We request you to include the experts of FIAC member companies in the working group for determining the requirements / developing an integrated solution for the purposes of the customs monitoring, including the issue of integration with accounting systems of foreign trade operators / use of the remote access to goods accounting systems and for drafting the roadmap of transfer to the customs monitoring taking into account the practical experience of tax monitoring.

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, 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.

- 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);
- 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, by far not always and are included in the when implementing the system of tracked;
- Meanwhile, two systems are expected to apply to some categories simultaneously. Therefore, in addition to the existing Mercury federal information system, the compulsory product identification marking is introduced in the dairy industry beginning 1 June 2021. 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 players 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.

We 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

Additional challenges arise out of the Federal Law "On Amendments to the Federal Law 'On Production and Consumption Waste' and to Article 8 of Federal Law 'On the Fundamental Principles of the State Regulation of Trade in the Russian Federation,'" being currently drafted by the Ministry of Natural Resources, as, in particular, it forbids the sale of goods not registered with the Unified state waste accounting information system.

The business community has already warned that this measure, in its current version, may give rise to significant risks of supply chain disruptions, all the more as no details were given during the draft law discussion concerning the implementation of the suggested obligations to enter changes in “the register of goods and packaging” and concerning the ban on sale.

We also remain concerned about the emergence of another tracking system on the Russian consumer market, in addition to those existing or being developed as it will add complexity to business operations for no good reason.

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.

The roll-out of the system on various categories of goods at the EAEU level will give rise to additional risks of limiting the free movement of goods.

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 within the Common Economic Space.

Given that the marking system may be implemented unilaterally and there are no mechanisms to coordinate the accession of other member states, the tracking principles are being implemented unevenly in the EAEU while the framework principles established by the EEC are not sufficient to synchronize the processes across all member states.

As a result, once the dairy products marking system was implemented in the Russian Federation, the Republic of Belarus announced the intent to introduce the same. However, the integration of the national systems reveals a lacking coordination and non-harmonized requirements between the two, jeopardizing the mutual dairy trade between the Russian Federation and other members-states.

The EAEU lacks an integrated information system which would enable a mutual recognition of national marking codes. National requirements of the member states are not harmonized, their implementation and deadlines take no account of the legislative specifics (for instance, substantial transition periods to implement compulsory tracking requirements) adopted by other member states.

The Russian rules for marking dairy products provide for transition periods (or a complete exclusion) with respect to the compulsory requirements which cannot be met without aggregation and individual tracking until 1 December 2023, while Belarusian laws, supranational provisions (provisions of the EAEU resolutions) and CRPT technical integration terms provide otherwise. Therefore, Russian exporters to Belarus become prejudiced, which creates additional barriers for the circulation of goods within the EAEU, as it is technically impossible to comply over such a short period of time.

Besides the identification marks, Decree No.9 of the Republic of Belarus establishes the requirement either to use additional “protection marks” or to ensure additional traceability via electronic consignment notes. As a result, entities bear additional costs to procure Belarusian “protection marks”, whose acquisition and application are technically challenging.

Therefore, mutual recognition of codes guaranteed by the EAEU Council’s resolutions for each category of goods (and, in particular, by the Draft Resolution “On Marking Certain Types of Dairy Products by Identification Marks”) is only possible by incurring unreasonably high costs by the trading parties to ensure compliance with multiple costly terms.

Eventually, the implementation of one and the same system in different member states creates additional barriers for trade participants and the compliance in one member state does not guarantee a free movement of goods between other EAEU member states.

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. Currently, we are observing how the absence of the marking consensus creates additional barriers for the circulation of goods between the 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 c. 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.

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 (current and developing) 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 simultaneously.

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. Harmonize requirements of the EAEU member states for marking and circulation of goods subject to compulsory marking by identification means, considering the transition periods and requirements established in national regulations and put off the implementation of the traceability obligation, registration and exchange of information in cross-border transactions.

5. Ensure the recognition of the products released into circulation using the national marking system of any EAEU member state and a possibility for their circulation within the EAEU territory without the need to provide additional information on MC cross-border movements.

6. 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;

7. 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.

8. Ensure that decisions on the inclusion of each specific product category are made in stages, based on:

a. feasibility assessment;

b. evaluation of the results of a pilot project;

c. regulatory impact assessment (including the implications for small and medium-sized businesses);

9. 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.

10. 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.

11. 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.

12. 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).

13. In order to eliminate the black market and provide incentives for good faith market players:

d. provide a package of fiscal and non-fiscal incentives for businesses circulating marked/tracked goods;

e. 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;

14. Elect not to establish the Unified State Waste Accounting Information System (otherwise, ensure a full integration of this system into the unified information service (the "one-stop system") based on the above compulsory principles).

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. A problem of organic products circulation upon the enforcement of Federal Law No.280 - FZ dated 3 August 2018.

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 to regulate the manufacture, storage, transportation, marking and sale of organic products at the local market.

In accordance with the Law, local and imported organic products are subject to certification for compliance with the Russian legislation of organic products and subsequent marking with a standardized graphic image (symbol) along with a bar code containing information on the manufacturers and the types of organic products they manufacture that could be reviewed through a unified state register of organic product manufacturers specifically created by the Ministry of Agriculture.

Long before the enactment of Federal Law No.280, business had repeatedly reported to the Russian Ministry of Agriculture on the risks caused by the substantial delay in drafting and adopting the necessary subordinate acts, the related absence of the post-enactment transition period and the resulting non-recognition of the international certification system for organic products with a prohibition to use the word "organic" in any form and in any language.

Before the adoption of the national organic regulation, dozens of Russian producers and importers supplied organic products, documented and marked in accordance with international standards, to the local market. The market of organic products, worth tens of billions of rubles before 1 January 2020, was, in an instant, forced into the gray zone.

Most affected is the imports of organic raw materials and products as it is impossible to inspect foreign end product makers and suppliers of raw materials due to the COVID-19-related restrictions while Russian certification authorities cannot accept the evidence provided by suppliers under the existing legislation.

It is necessary to mention the absence of specific certification mechanisms and procedures with respect to foreign organic product makers, including those from the Eurasian Economic Union, in the Law and exiting standards. Thus, section 13 of the "Requirements for Circulation of Imported Products" of currently valid Interstate Standard No.33980 "Organic Production. Production Regulations, Processing, Marking and Implementation" was drafted for the CIS states which would like to join the standard and takes no account of the specifics of the circulation of products imported from other states. As a result, neither local nor foreign certification authorities are able to comply with the requirements set in this section and certify the imported products under Russian laws.

It should also be mentioned that should such certification be performed the importer's details may not be entered in the Register of organic producers as the system accepts only the details typical for the Russian jurisdiction (OGRN, TIN, etc., clauses 1 and 2, part 2, Article 6, Federal Law 280-FZ). The Legal Support Department of the Ministry of Agriculture confirmed the requirement to provide such details and the impossibility to register foreign producers in March 2021.

Indeed, the uncertainty with respect to imported organic raw materials complicates the investment agenda of the Russian organic producers, including exports to third countries.

In accordance with the instruction of the Prime Minister of the Russian Federation, issued by the results of the FIAC plenary session (No. MM-P13-13685of 28 October 2020, clause 10), the authorized agencies took steps to "develop the competitive professional environment to make sure the national organic certification system has a sufficient number of qualified experts". However, according to the business community, this risk is not insignificant but not the only barrier,

Based on the above, we have to admit that the problem has not been solved – it is still impossible not only to certify producers of organic raw materials on a timely basis but also to enter the details of foreign legal entities (producers) into the Register of Organic Products.

Recommendations:

1. Amend the Law to enable inclusion of the details of foreign producers of organic goods in the Unified Register of Organic Products.

2. Amend the Law to limit the circulation of imported organic products and raw materials supported by international certificates beginning 1 January 2023 but no sooner than 12 months from the removal of the pandemic-related restrictions on international movements.

3. The Ministry of Agriculture jointly with the Federal Service for Accreditation (RusAccreditation) should develop and agree proposals for amending the TC-40 documents concerning the possibility to accept evidence provided by suppliers of products (raw materials) during the international organic certification in order to certify imported organic products and local organic products produced using imported organic raw materials.

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.

The special therapeutic nutrition is important during the outpatient treatment of the following patient groups: children and adults suffering from rare diseases, palliative patients, patients after a massive brain hemorrhage, patients with spinal cord and brain injuries, with complicated neurological conditions (e, .g. ICP) and cancer, senior citizens, especially with chronic diseases that affect the central nervous system (the Alzheimer's disease, the Parkinson's disease, dementia).

As part of the approved national projects “Health Care”(federal projects “The Fight against Cancer”, “The Fight against Cardiovascular Disease” and the “Demography” (federal project “Senior Generation”) and the departmental target program “Development of the Palliative Care”, despite significant budget allocations for diagnostics, expensive treatment and rehabilitation, such vital component as the specialized therapeutic nutrition is missing.

The inadequate provision of therapeutic food for children with disabilities results from the fact that the list of nosoligies involving provision of special foods for children with disabilities is limited to 13. A large number of children fall beyond the scope of the existing legislation.

What is more, families with kids suffering from severe milk protein or food intolerance find themselves in a difficult medical and financial situation as such conditions do not qualify for the disability status, while the adequate therapeutic nutrition is the main component of their treatment. The financial burden is borne by the family. However, the absence of the treatment may inflict severe implications and a long-term drug therapy, as such kids often develop such disabling conditions as the bronchial asthma.

The existing laws provide neither for adults with disabilities.

Today, certain constituent entities of the Russian Federation launch regional pilot projects and programs to provide special therapeutic nutrition to the patients in need, which prove to be relevant and effective. At the same time, complex measures are required to scale up the initiatives to the federal level.

To achieve the set goals, we need to:

- identify and analyze gaps in the regulatory framework of the Russian Federation hindering the access of the Russian citizens to special therapeutic nutrition, draft proposals on their elimination;

- harmonize the EAEU and the EU laws governing the circulation and quality of special therapeutic foods;

- provide special therapeutic nutrition for patients with cancer, after a hemorrhagic stroke and palliative patients (adults and kids) and geriatric patients;

- expand the list of diseases involving provision of special therapeutic foods for children with disabilities;

- provide access to special foods for adults with disabilities (currently, only certain categories of kids with disabilities are entitled to receive special foods under the law);

- provide for the nutritional support during an out-patient treatment and/or rehabilitation or other treatment at home.

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.

Issue 2.4. Introduction of excise duties for certain categories of food products.

The FIAC member companies learned from the media that the Russian Government is considering introduction of the excise duty on foods, specifically on sugar-containing beverages, and increasing the excise duties on alcoholic beverages to attract additional revenue to the budget.

First of all, the FIAC member companies draw attention to the fact that any increase of the administrative and financial burden on the consumer sector will be excessive and, say the least, untimely. The excise duty introduction in the circumstances where the Government is taking measures to contain the product inflation, on the one hand, and, on the other hand, is supporting certain industries appears to be inconsistent. The proposal with a strong negative effect on the sugar market is being considered amidst the 2021 crisis, the period when the Government has to actively support the sugar industry.

The FIAC member companies are confident that the introduction of the excise duties for certain products, in particular, sugar-containing beverages, will be economically inexpedient due to the following:

1. Difficulties in determining the criteria for the products to fall under the regulation.

In order to consider the possibility to implement the excise regulation and administration, sugar-containing beverages must be first defined. Presumably, this group of food products may be regulated by the general requirements of the 'horizontal' technical regulations "On Food Safety" (TR CU 021/2011), "Marking of Food Products" (TR CU 022/2011), "Technical Regulation on Juicy Products from Fruits and Vegetables" (TR CU 023/2011).

These regulations contain neither the "sugar-containing beverage" term nor the "nonalcoholic beverage" term. The latter is only defined in the voluntary interstate standard GOST 28188-2014 "Nonalcoholic Beverages. General Specifications". "A nonalcoholic beverage is a ready beverage made of drinking or mineral water with the total mineralization no more than 2%". The GOST definition does not allow identifying appropriately a nonalcoholic beverage as it relates as well to juice- and dairy-containing beverages.

In accordance with the All-Russian Classifier of Products by Type of Economic Activity (OKPD 2), effective from 1 January 2016, the group of nonalcoholic beverages is assigned to code 11.07.19. "Other Nonalcoholic Beverages". However, there is no breakdown by sugar. In accordance with code EEU TN VED 2202 10, nonalcoholic beverages comprise "mineral and carbonated water containing sugar additives or other sweeteners or flavors". Non-alcoholic beer is also assigned to this code.

In consideration of the above, it is hardly possible to identify "sugar-containing beverages" for the excise regulation purposes and there are serious concerns that all beverages in general may become subject to the excise regulation, which will have a significant negative impact on the industry.

At the same time, the establishment of the excise regulation system from scratch appears to be very challenging as it will require significant additional injections from the RF budget and greater administrative resources, which is hardly possible in terms of the control/oversight reform in the Russian Federation.

2. The impact of the excise duty on the industry.

The sugar consumption volume in Russia remains relatively stable at 40 kg per capita a year, which is substantially lower than abroad.

Today, more than three thousand enterprises produce nonalcoholic beverages and packed water. In accordance with the current definition (Federal Law No.209-FZ of 24 July 2007), most enterprises are small and medium businesses (maximum 15 enterprises hit the large business threshold by headcount and/or turnover). Most enterprises are local producers supplying beverages and drinking water within particular regions. Many enterprises produce both nonalcoholic beverages (including kvas) and drinking water.

Therefore, at least three thousand small and medium businesses will be negatively impacted by the regulation.

As part of the survey conducted by the Higher School of Economics “Analysis of Social and Economic Consequences of the Excise Regulation of Sugar-Containing Beverages in the Russian Federation” (2019), a detailed forecast of social and economic consequences was prepared. Three basic scenarios were used to assess the impact of the additional tax on the regional economy/budget in the Russian Federation:

a. The excise duty is introduced for carbonated sugar-containing nonalcoholic beverages in the amount of RUB 5 per liter.

b. The excise duty is introduced for all nonalcoholic beverages in the amount of RUB 5 per liter.

c. The excise duty is introduced for sugar in the amount of RUB 5 per liter.

(The excise duty is transferred to consumer prices - the most realistic scenario by the experience of the alcoholic beverages and tobacco industries)

If the excise duty is introduced for sugar-containing nonalcoholic beverages, the annual output will decrease by 8%-9%, the employment will go down by 2.6-2.7 thousand people, the annual profit will shrink by RUB 23.5 billion – RUB 24.3 billion, the total annual investments in equity - by RUB 2.5 billion – RUB 2.6 billion. As a result, the total tax revenue of the Russian Federation will go down due to the shrinking input VAT, income and other taxes. According to the Higher School of Economics, the total input VAT will decline by RUB 2.4 billion – RUB 5.2 billion, other tax revenue (including income tax, taxes related to fixed assets, etc.) - from RUB 12.5 billion to RUB 18.9 billion for the first few years. In addition, according to the model, the negative impact on the industry and economy will be accumulating over time and, in the long term, will have a multiplier effect.

The budget replenishment prospects of excise duties on sugar-containing nonalcoholic drinks are limited (usually, within 1% of the total receipts).

Therefore, there are no economic grounds to expect a significant growth of budget revenues from the excise duties - the growth may be neutralized by shrinking tax receipts due to the above factors. As a result of the regulation, the total effect on the federal and regional budgets will appear to be negative.

2. The excise duty on sugar-containing beverages as a tool of the state policy.

It is global practice to position the excise duty on sugar-containing beverages as a means to prevent noncommunicable diseases through reduced sugar consumption. At the same time, the share of sugar consumption by food industry remains relatively low in Russia. In 2017, only 40% of sugar was consumed by production enterprises, while 51.5% was attributed to households and 8.2% was exported. The specifics of the Russian Federation is that 55% of the sugar consumed by households accounts for monosaccharides (pure sugar) and less than 2% - for beverages. The share of nonalcoholic beverage production is 1.5% of the total sugar consumption. Therefore, the introduction of the excise duty will not cause a substantial reduction of sugar consumption.

It should be noted that the strategic planning documents in the field of health care in the Russian Federation (e.g. the Strategy for the Promotion of a Healthy Lifestyle and the Prevention and Control of Noncommunicable Diseases until 2025 (Order No. 8 of the Ministry of Health of 15 January 2020)) do not provide for such measures.

The specifics of the Russian excise policy is that the goods with the proven negative impact on health are subject to additional taxes, such as cigarettes and alcoholic beverages or premium or luxury products. The proposal to introduce an excise duty on sugar-containing beverages contradicts this logics as there is no evidence proving that the consumption of nonalcoholic beverages causes harm to public health; neither they are luxury products.

The international experience demonstrates the counter-productive effect of such measures. In Denmark, Ireland and Finland, the tax for sugar-containing beverages was lifted (in 2013, 2015 and 2017, respectively) due to arising economic challenges and lacking evidence of the positive impact of such taxes on public health. Once Denmark introduced a similar excise duty, the market was overtaken by similar products from other European countries free of such duties. As a result, the government counted that they were losing about EUR 40 million annually due to the unpaid VAT. By the way, the introduction of the excise duty in the Russian Federation may cause overtaking of the domestic market by beverages from bordering countries, including the EAEU member states. In June 2021, Norway announced the removal of the excise duty.

Considering the above, we have valid grounds to conclude that there are no criteria for defining the “sugar-containing beverage” category. The establishment of the excise administration system from scratch will require significant financial and administrative injections and will take indefinite time. At the same time, the potential budget drop-out caused by the excise duty may neutralize the respective tax receipts. If viewed as a tool to prevent noncommunicable diseases in Russia, it will not have effect due to the national sugar

consumption structure; let alone, that it contradicts to the Russian excise policy. The international experience demonstrates a poor effect of similar measures both on the state budget and health care.

The excise duty on alcoholic products

Among various options to replenish the budget, the Government, among other things, is considering an option to increase the excise duty on alcohol by 10%.

Over the last 5 years, the Russian Government managed to significantly improve the tax regulation predictability. In 2018, the Government elaborated the approach which included a promise not to change taxes during six years. On the whole, such measures had a positive impact on business by improving the competitiveness of bona fide producers.

Freezing the excise duty on alcoholic products in 2017-19 with a subsequent indexation for the 3-years' inflation had a stabilizing effect on the major industry indicators without budget drop-outs. At the same time, the legality of the alcoholic market increased on the back of the lower per capita consumption and no negative social implications.

The increase of the excise duty on alcohol will work on the opposite, producing a negative impact on tax payments and deteriorating the investment climate in general. An additional increase of the excise duty by 10% will cause a material drop of the legal alcohol output as soon as in 2022 compared to 2020 (beer - by 11.2%), which will have a direct imprint on the amount of the excise duty paid, in particular due to the growing illegal market.

In accordance with the survey held by the leading experts of the Ye. T. Gaidar Institute for Economic Policy (IEP) "The Justification of the Excise Policy relating to Alcohol Products in the Russian Federation up to 2024" with a detailed assessment of the economic and social impacts of various scenarios, in 2024, the excise payments in the alcohol industry may go down by 10.9%. The shrinking legal alcohol output drives the shadow market exposing public health and lives to risks. In accordance with the IEP estimates, the most appropriate scenario does not involve an increase of the excise duties on alcohol products but their freezing for 2022-24 at the 2021 level. This option provides a wide range of advantages compared to the adopted excise rates, adjusted for inflation by 4%.

The key economic projections related to freezing the excise duties in 2022-24 are as follows:

- The 3.5% growth of projected tax receipts for the period up to 2024 by to make RUB 449.46 billion. Should the excise duty increase by 4% annually, in accordance with the Russian Tax Code, the tax receipts are expected to decline by 10.9% to RUB 387.03 billion.
- A higher employment rate in the alcohol industry (488.4 thousand vs. 473.5 thousand) and a more positive effect on the related sectors (suppliers and vendors), mostly represented by small and medium business, most sensitive during the pandemic.

We believe it is important to follow the previous approach and not to increase the excise duties on alcoholic products in 2022-24 above the level established the Russian Tax Code. It will help alcohol producers maintain production capacities and workplaces, ensure payroll payments, take measures to prevent the spread of the coronavirus and continue to duly fulfill tax obligations in the current tough conditions. At the same time, the possibility to freeze the excise duty on alcoholic products at the 2022 level for the next three years could be an important state contribution during the pandemic to support business forming a localized cluster of Russian companies from related sectors (agriculture, chemical and glass sectors, logistics, trading companies, etc.) and to maintaining the social security in regions.

Recommendations:

1. Russian Government - refrain from increasing the financial and administrative burden on the consumer sector by introducing excise duties on certain food products, in particular, sugar-containing beverages, due to their economic inefficiency.

2. Maintain the previous approach and not to increase the excise duties on alcoholic products in 2022-24 above the level established the Russian Tax Code, and consider the option to freeze them for three years.

III. State trade policies

Issue 3.1. On the risks of introducing state regulation of prices and markups in the consumer market.

In December 2020, Russia introduced the state regulation of prices for sand-sugar and sunflower oil. The regulation was documented by the so-called 'arrangements' between the producers and retail chains on establishing price ceilings for shipments from plants and sale to end consumers. The original term of such

arrangements expired on 31 March 2021 and was extended till 1 June for sugar (currently, the arrangement has expired but is, in fact, still applied by many market participants) and till 1 October for sunflower oil.

In addition, on 30 December 2020, the Law on Trade and the respective Government Decree were amended and now prices may be capped by the Russian Government within the territories of certain constituent entities for maximum 90 calendar days provided the price increases by 10% or more (considering seasonality) during 60 days (previously, 30% during 30 days). Therefore, this measure is more likely to be applied.

On 27 February 2021, the Government instructed the Ministry for Economic Development to organize continuous monitoring and assessment of consumer prices and approved the list of priority consumer products and services for analysis and development of appropriate response measures with the assistance of ministries and agencies.

It would be already fair to say that though the sugar and oil price regulation had such a short-term effect as the shelf price decline, it has, in fact, created a sever imbalance on the respective markets, primarily due to the impossibility to consider a number of significant aspects, and in particular:

a) the arrangements are de jure voluntary and de facto mandatory only for the largest players. Most of unorganized traders and even producers are left beyond such arrangements.

b) The price arrangements miss out the wholesale (distribution) component engaged in logistics, packaging, etc. As a result, purchase prices often surpass dispatch and retail prices. And in most cases it is impossible to refuse working with wholesalers and substitute them with “direct contacts” of producers both for major retailers and, specifically, for small businesses, as it deteriorates the previously established stable models of interaction between suppliers and retailers forcing them to adopt more complicated and less effective ones.

c) Creating a marketing hype In anticipation of the expiry of the arrangements on 1 April and of the respective increase in prices, we saw a significant growth of “speculative” purchases from retailers. Producers failed to meet the skyrocketing demand.

d) The prices were equalized and brand differentiation almost vanished. In particular, the prices for cheap low-margin products, that used to be sold below the state price level, were raised to the maximum.

e) The mechanism suggested after 1 April to subsidize sugar producers for retail deliveries complicated the procedure of making new arrangements, which, in certain cases, caused supply interruptions.

f) The Government decided to prolong the arrangements at the last moment contrary to the multiple public statements. This step reinforces the distrust of the market participants in the authorities’ actions and builds up the unpredictability in terms of business panning both by producers and traders.

g) Complicated relations between producers and retail chains prevents market participants from responding to consumer demand changes in a timely manner. As a result, certain regions (remote, in particular) experienced interruptions and a temporal absence of regulated products.

h) The established price regulation paradigm has been actively exploited by political parties in their election campaigns. Public statements, including those made by the representatives of the ruling party, bring additional implications and anxiety as they turn into sporadic control raids of non-state actors, evidence-free accusations of producers and traders for unjustified overpricing, threats to address the issue in strict adherence by the Law “On Trade” mechanism. The public is misguided to believe that the inflation issues may be resolved by administrative control methods, let alone the prejudice against consumer market participants. Unfortunately, scarce votes in the Government, Central Bank and Accounts Chamber are not enough to shift the price discussion from the administrative regulation to market leverage.

i) Recent publications in media mention the intent of the Federal Antimonopoly Service to adjust the retail mark-ups for socially important goods, either by informal measures for leading Russian traders or by making new changes to the Law “On the Principles of the State Regulation of Trade in the Russian Federation.”

In consideration of the above, the market participants view the situation as alarming and threatening in terms of reinforcement and further expansion of the anti-market trend in the state regulation of prices.

Recommendations:

1. Any state intervention in pricing on the consumer market violates grossly the market economy principles, breaks the established economic relations, deteriorates supply chain balances. The FIAC member companies advocate maintaining the market mechanisms without any state regulation of prices or markups at the consumer market.

2. The further prolongation, expansion and(or) modification of the existing regulation is not acceptable without a full-scale assessment of the actual impact of the measures already taken. Such assessment must be performed upon the instruction of the Russian Government with the mandatory participation of the involved business associations.

3. The Government should depart unconditionally from the arrangements existing de facto and de jure beginning 1 October 2021.

4. The Government should take effective measures against the price regulation politicization both during the current election campaign and in the future. It is important to declare at the highest level that the administrative regulation of prices and markups is absolutely unacceptable and detrimental for the market-driven economy of the modern Russia, and to block possible new legislative initiatives in this respect.

Issue 3.2. Fundamental principles of the state regulation of trade

The amendments to the Law "On Trade," in effect since 15 July 2016, 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.

Despite early successes: self-regulation helped market players effectively address the problem of returned bakery products. 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.

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."

Other topics are publicly discussed on a regular basis, 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.

Meanwhile, the dialog between retailers and suppliers is resumed focused on adapting the Code of Good Practices and the Commission's efforts to implement the Code to the new conditions.

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 2022

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).

4. The Russian government should block possible new legislative initiatives intended to regulate prices and markups.

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 4.2.1. 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 to market products (and raw materials), up to 18 months.
- 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 the 33rd plenary session held in October 2019 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" (List of Instructions No. DM-P13-9288 of the Prime Minister of the Russian Federation of 26 October 2019).

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;
- Raw materials used in producing animal feed and feed additives;
- Chemical products used as raw materials for the production of food, cosmetics, medicines, household chemicals, hygienic products 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;

4. Reword clause 6 of Regulation 1 TR EAEU as follows: "6. Food products, including biologically active supplements and food additives and medical products (including those for in vitro diagnostics), smoking and non-smoking tobacco goods, raw materials for the production of pet food and additives, chemical products used as raw materials for the production of food, cosmetics, medicines, household chemicals, hygienic products and goods for medical purposes".

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 intellectual property involved in the circulation of pharmaceuticals due to the registration, production and supply of pharmaceuticals manufactured illegally using patented inventions.

There is a systematic practice of launching generics (including biosimilars) in violation of existing patents for reference (brand-name) pharmaceuticals. Government agencies continue to procure generics (biosimilars) manufactured illegally using patented inventions.

This practice is the result of gaps in current law. Under EAEU law (Decision No. 78 of the Council of the Eurasian Economic Commission of 3 November 2016 "On the Rules for the Registration and Expert Examination of Medicines for Human Use"), and previously until 1 January 2021 under Russian law (Federal Law No. FZ-61 "On the Circulation of Pharmaceuticals"), generics (biosimilars) may be registered during the term of the patent for a brand-name (reference) drug.

If a drug is included in the List of Vital and Essential Drugs, unscrupulous manufacturers may register the maximum manufacturer's price and offer the drug for purposes of state or municipal procurement. Legislation does not require that the EAEU Unified Register of Registered Drugs or the State Drug Register indicate that generics were registered during the term of the patent for the brand-name drug or indicate the term of the patent. State contractors and consumers are thus led to believe that the simultaneous presence of brand-name and generic drugs on the market is appropriate, and the low market prices for generics mislead state contractors and affect the initial maximum price of a contract.

Due to the actions of unscrupulous market players, patent holders have to resort to lengthy litigation to protect their rights, and state and municipal contractors as well as federal and regional authorities must often be involved in such litigation. The lack of proper legal regulation hinders investments and efforts to increase the local content of manufacturing. In recent years, companies in FIAC's Working Group for Health Care and Pharmaceutical Industry Development (the Working Group) have brought dozens of patent-related lawsuits.

However, the courts lack criteria for granting injunctive relief in such cases, and patent holders' rights to intellectual property continue to be violated while litigation is under way.

FIAC members have repeatedly called for improvements in regulation and law enforcement practice to protect exclusive rights to drug-related inventions. The Russian government has issued instructions, beginning with FIAC's 28th session in 2014, and the issue was addressed at FIAC plenary sessions in 2016, 2017 and 2019.

Most recently, at FIAC's 34th session on 19 September 2020, two instructions were issued on the legal regulation and implementation of a register of pharmacologically active substances (clauses 3 and 4 of Instruction No. MM-P13-13685 of the Prime Minister of the Russian Federation of 28 October 2020). The second instruction also addressed the key issue of the legal enforcement of the register by means of its integration into EAEU law. In August 2020, Deputy Prime Minister Tatyana Golikova instructed that a patent protection mechanism be developed in the framework of the EAEU.

At the 67th meeting of the task force under the expert council of the Eurasian Economic Commission in August 2019, the Ministry for Economic Development presented a proposal to introduce a register of patents for pharmacologically active substances (the Register). As a result of this meeting, it was decided that the Eurasian Economic Commission would send materials to member states so that they could form opinions. The issue was raised again at a session of the Council of the Eurasian Economic Commission on 5 March 2021, and it was recommended that the Register be introduced in Russia so that Russia's experience could be provided to EAEU member states.

The Federal Service for Intellectual Property, Patents and Trademarks (Rospatent) officially presented the proposed Register on 30 June. The Register applies only to patents for pharmacologically active substances. The use of the Register to regulate the circulation of pharmaceuticals was also agreed with the Ministry of Health and the Ministry of Industry and Trade.

The pharmaceutical register of the Eurasian Patent Organization was launched on 1 March 2021. The register is more extensive than Rospatent's register, including not only chemical and biological pharmaceuticals, but also means of applying and manufacturing inventions.

Considering the full extent of drug regulation, the Ministry for Economic Development, jointly with the Ministry of Health and Rospatent, prepared recommendations for amending laws and regulations of the

Eurasian Economic Commission to create a unified EAEU register of pharmacologically active substances and to use it to register medicines for human use in EAEU member states. The Ministry for Economic Development submitted the recommendations to the Commission so that the Russian side's initiative could be discussed with FIAC members. FIAC's Health Care and Pharmaceutical Industry Development Working Group applauds the ministry's contribution to the preparation and adoption of this draft law and is ready to support the ministry's efforts to amend the EAEU legal framework.

The working group appreciates the work that is under way to create a register in Russia and welcomes the launch of the Eurasian Patent Agency's register of Eurasian pharmaceutical patents. However, if the Register is to be effective in protecting intellectual property and spurring investments in innovative drug therapy, it must include all patents issued under Russian law for registered pharmaceuticals. It is important for the Russian and Eurasian patent systems to be complementary and coordinated in terms of the functioning of pharmaceutical patent registers and their integration in the drug registration procedure under EAEU law.

Unfair competition and violations of intellectual property rights, as these apply to drug circulation, are problems that still urgently need to be solved, including by further improving the features and use of drug registers and patents in Russia and the EAEU.

Recommendations:

1. Ensure that drug registration makes use of data in the Eurasian Patent Agency's and Rospatent's registers of drug patents by amending EAEU law to stipulate the following:

1.1. A drug registered during the term of a patent may be put into circulation only with the patent holder's consent or after the patent expires.

1.2. If a patent is still valid, a registration certificate issued for a generic (biosimilar) should indicate that the drug may be put into circulation beginning on the date when the patent expires.

1.3. Information on current patents and the dates on which drugs may be put into circulation should be indicated in the EAEU Unified Register of Registered Drugs and the State Drug Register.

2. State registration of the maximum manufacturer's price of a drug is equivalent to introduction into circulation and is permitted only with the consent of the patent holder or after the patent expires.

3. Rospatent's Register should be implemented in 2021 so that data on its practical use can be collected and provided to EAEU member states

4. Ensure that the Register includes all patents issued under current Russian law for registered pharmaceuticals, including information on the patent protection of both chemical and biological drugs and on patents for the invention not only of drugs, but also of forms, compositions and combinations of drugs and of means of production and forms of application for a specific purpose under Russian civil law. Article 1350 of the Civil Code states that patent protection applies to the invention of substances, of compositions and combinations of substances and of means of production and forms of application for a specific purpose.

5. Include the following in legislation on the contract system for the procurement of drugs for state and municipal needs:

5.1. The requirement that parties involved in government procurement provide letters guaranteeing that third parties' intellectual property rights have not been violated

5.2. The purchaser's right to deny a procurement bid if data in the registers of Rospatent and the Eurasian Patent Agency establishes that the bidder inaccurately stated that third parties' intellectual property rights have not been violated.

6. Ensure that Russian and Eurasian patent systems are complementary and coordinated in terms of the functioning of drug patent registers and their integration in the drug registration procedure under EAEU law.

7. To prevent unlawful actions by unscrupulous market players and violations of patent holders' rights, criteria should be developed and clarifications of higher courts should be prepared to provide lower courts with grounds for granting injunctive relief in cases where patented inventions are illegally used for the manufacture and delivery of drugs.

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:

Data exclusivity means that information on the findings of preclinical and clinical studies of reference (original) drugs must not be used for the registration of generics (biosimilars).

When Russia acceded to the WTO, under clause 1295 of the Report of the Task Force on the Accession of the Russian Federation to the World Trade Organization, it undertook not to register products subject to data exclusivity provisions under Article 39 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) for six years after those products are initially registered. An exception to this is when a party registering subsequent products provides its own data on preclinical and clinical studies that meet the same criteria as the data provided upon initial registration.

This provision was observed under Article 18 of Federal Law No. 61-FZ until the article was amended by Federal Law No. 429-FZ of 22 December 2014, which considerably shortened the six-year data exclusivity period.

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

It is odd that biopharmaceuticals are less protected than other drugs, even though they are more sophisticated and require investment in a much greater number of preclinical and clinical studies.

Under Federal Law No. 61-FZ “On the Circulation of Pharmaceuticals” (Article 33, part 1, clause 1-u), the state register of pharmaceuticals must indicate when a drug is to go into circulation. Currently, this means indicating either a five-year or indefinite confirmation period. We suggest adding an additional line to the state register of pharmaceuticals for information on when a generic (biosimilar) will go into circulation in relation to the reference drug’s exclusivity period.

In view of the fact that the EAEU common pharmaceutical market has been in operation since 2016 and national drug registration procedures ceased on 1 January 2021, proposals should be submitted to the Eurasian Economic Commission to make data exclusivity an element in the regulation of drug registration in the EAEU and to include the data exclusivity period in the EAEU’s unified register of registered pharmaceuticals.

Recommendations:

1. EAEU regulations governing the circulation of pharmaceuticals should be amended to prevent information on preclinical and clinical studies submitted by an applicant for purposes of drug registration from being used without the applicant’s consent for six years after the date of the drug’s state registration.

2. The Unified Register of Registered Drugs and the State Drug Register should include information on the exclusivity period in reaction to the findings of preclinical studies of drugs and clinical studies of brand-name (reference) drugs.

3. The state registration procedure should include an assessment of the exclusivity status of the findings of preclinical and clinical studies.

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

2.1. EAEU rules should 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 under the Agreement on Common Principles and Rules for the Circulation of Medical Products (Medical Devices and Equipment) in the Eurasian Economic Union of 23 December 2014 and the resulting Decision No. 46 of the Council of the Eurasian Economic Commission “On the Rules for the Registration and Expert Examination of the Safety, Quality and Effectiveness of Medical Products” of 12 February 2016. During the transition period:

- A manufacturer (or its authorized representative) may, at its own discretion, register a medical product in accordance with EAEU Rules or the laws of the EAEU member state;

- Medical products registered under the laws of an EAEU member state circulate within that state;

- Documents confirming the registration of medical products and issued by an EAEU member state's authorized health administration body under the laws of that state are valid until their expiration date but not after 31 December 2021.

To circulate in the EAEU after 2021, all medical products currently circulating on the EAEU market under local rules must undergo the full registration procedure under the EAEU Rules for the Registration and Expert Examination of the Safety, Quality and Effectiveness of Medical Products by 31 December 2021. Note that the new registration procedure for medical products was launched only at the end of 2019, even though second-level documents on the circulation of medical products, including the Rules for the Registration and Expert Examination of the Safety, Quality and Effectiveness of Medical Products, approved by Decision No. 46 of the Council of the Eurasian Economic Commission on 12 February 2016 (the "Rules") had entered into force earlier. Thus, the transition period during which producers will have to re-register all their medical products under the new Rules was reduced to two years.

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

In the Russian Federation, over 36,000 registered medical products will have to be reregistered by 31 December 2021 under EAEU Rules (according to the Federal Service for Health Care Oversight). Also within this period, manufacturers will have to release a number of new products that they had kept off the EAEU market given the prospect of new unified EAEU legislation.

In this situation, the transition period (ending on 31 December 2021) does not provide enough time for the procedures required to ensure timely registration of all medical products circulating in EAEU member states. Amendments to EAEU legislation could remedy the situation, but the need for EAEU inter-state approvals will make it difficult to adopt such amendments before the end of the transition period.

Recommendations:

1. The Eurasian Economic Commission should issue a decision that medical products (medical devices and equipment) registered before 1 January 2022 may continue to circulate in the national jurisdictions where they were registered until their registration certificate and/or shelf life expires and that registration certificates may be modified without any time restriction.

2.2. The need to lower regulatory barriers for modern medical goods used for laboratory diagnostics.

2.2.1. Problem:

Medical goods used for laboratory diagnostics (in vitro medical goods) play an essential role in health care, including in identifying illnesses early, monitoring their development and prescribing the correct treatment. This means the products for laboratory diagnostics, especially reagents, have a relatively short life cycle and are very sensitive to the regulatory environment. The ability of domestic health care to offer the most advanced and effective solutions depends to a large degree on whether the system of market access allows for timely, risk-oriented decision making.

In the Russian system of regulating medical products, all declared parameters of a product must be verified and an expert agency under the regulatory body must assess the supporting information, including when changes are made in a product and product information. This approach has its advantages, but could also result in lengthy waits and high costs to launch new products on the market – a factor that is especially critical for goods such as in vitro medical products.

The current procedure for launching new products, as it has been shaped by national regulation, means that the Russian health care system receives new products after a considerable delay or that such products are regarded by manufacturers as having no prospects on the Russian market. A good example is consumables for lab analyses (test strips, reagents, etc.), which make up 60%-70% of the content of in vitro products: they have a short life cycle (around five years on average), and information must be regularly updated. In practice, the registration of in vitro products in Russia, including testing and preparation, can take two years or more. A number of factors contribute to this problem, including:

- High financial and labor costs for testing that tend to grow over time, a lack of specialized laboratories, an increasing number of excessive and groundless requests along with the growing cost of services;

- The long waiting time for tests (over four months for toxicological and technical tests);

- The lack of direct, recordable communication with experts of the Federal Service for Health Care Oversight, the degree of dependence on the discretion of experts, limited ability to modify documents (twice within a fixed period, regardless of the substance of the request and the specifics of the product), the growing number of excessive and groundless requests, requiring more and more products to be provided for testing,

disagreement between the positions of expert institutions – all of this pushes up labor costs at the registration stage. Two expert organizations under the Federal Service for Health Care Oversight and even two experts in the same organization may take different positions. (For example, one expert organization believes that a thermometer contained in a device requires certification as a measuring instrument – entailing substantial costs for additional tests, further complicated by the lack of qualified laboratories – while another organization does not.);

- Health care specialists lack expedited access to breakthrough products. Despite certain exceptions to accelerate the market entry of in vitro products used to fight COVID-19 (see Government Decree No. 430 of 3 April 2020), the current system does not allow the "conditional release" of high-priority products – a procedure involving testing at the post-registration stage, when goods are already in circulation (if there is an international quality certificate). Current practice also shows that considerably more time is required to register fundamentally new products, and this further delays the launch of innovative products on the Russian market.

As a result of the current procedure for registering changes, updated in vitro products are either launched after a substantial delay or don't appear at all. Another requirement for in vitro products is that product data must be updated on a regular basis (at least once every six months on average). In practice, however, it can take 1.5–2 years or more to amend registration documents and release an updated product on the Russian market (by which time the information may already be out of date). This is due to the following:

- A complete expert examination and testing are required for many changes. Almost any change that will be reflected in documents in the registration file requires a complete expert examination and often testing. Experts frequently ask for information and documents that cannot be requested for such changes under Decree No. 1416 of 27 December 2012;

- A modified product cannot be circulated until the changes are registered. A notification-based procedure, including subsequent "conditional registration," is not envisaged for such changes;

- No changes can be made in "old" files Changes cannot be made in an incomplete file that was created when the regulator had a different approach to file content (before 2013), etc., even when a product has been on the market for 5-10 years or more without any evidence of danger to life and health or of inaccurate findings.

As a result, by analogy with initial registration, manufacturers may decide that it is not feasible to launch certain updated products on the Russian market. The inability to launch a product with new characteristics/information before the changes are registered means that if a product cannot be manufactured for a specific market in its previous form, the Russian health care community and patients may be deprived of access to products that are already registered.

Recommendations:

1. The registration process should be modified:

- To allow for accelerated/conditional registration and a special procedure for in vitro products intended to satisfy "unmet medical needs," by analogy with the changes in drug registration rules now under discussion at the level of the EAEU (draft amendments to Decision No. 78 of the Council of the Eurasian Economic Commission of 3 November 2016, version of 23 April 2021): "On the Rules for the Registration and Expert Examination of Medicines for Human Use");

- The Rules for the State Registration of Medical Products (approved by Decree No. 1416 of the Russian Government of 27 December 2012 "On Approval of the Rules for the State Registration of Medical Products") should include a group of changes not involving the composition or qualities of a product (e.g., changes in instructions based on processed safety monitoring data, etc.), and there should be a notification-based procedure or other streamlined procedure for such changes (e.g., assessment by a test laboratory without the need to import products) or a notification-based procedure for minor changes. The wording should be agreed with a task force created to improve the regulation of medical products for in vitro diagnostics;

- A task force should be created to improve the regulation of medical products for in vitro diagnostics that would involve representatives of regulatory agencies, business and the health care community in developing urgent measures to ease the transition period and changes in documentation due to changing regulatory procedures in the European Union12 and in making other revisions proposed by industry and the

[12] Regulation (EU) 2017/746 – the In Vitro Diagnostic Regulation – makes a number of changes in the regulatory environment affecting the circulation of products for *in vitro* diagnostics in the European Union (EU). This will require a number of changes in the information accompanying these products (packaging/marking and documentation for users) and in some cases (depending on the type of product) will entail changes to be reflected in the registration file. The EU previously published a factsheet for non-member states

health care community in supranational legislation, including by creating a separate body of regulation by analogy with the In Vitro Diagnostic Regulation;

2. The operation of test laboratories and expert organizations should be optimized by:

- Allowing for direct, but recordable and public interaction with an expert organization and making it possible to establish an individual period for the modification of materials, depending on the specific information required;

- Taking measures, including benefits and preferences, to increase the number of laboratories and facilitate the establishment of a coordinating body (possibly a self-regulatory organization) to resolve the problems that have accumulated on the market of testing services;

- Introducing mechanisms to ensure that experts of the Federal Service for Health Care Oversight and expert organizations follow the same approaches, including the practice of publishing information on the service's website concerning new or modified conceptual approaches that experts take to systemic problems with the registration of health care products and/or the creation of a registration file for health care products applicable to future periods;

- Introducing a simplified procedure for accrediting laboratories that are health care facilities and licensing them to conduct testing/research.

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

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 result in deteriorating quality of life, permanent disability or premature mortality of Russian citizens.

Modern medicine offers innovative drug therapy and forms of treatment, including at the level of genes (gene therapy), cells (cellular therapy) and tissues (tissue engineering), that open up dramatically new opportunities for patients and the health care system and transform the lives of patients with serious diseases, enabling them to live active lives and avoid serious disability. By including innovative drugs in state drug supply programs, the government is investing in quality of life and longevity.

The Russian government is working to develop new approaches to ensure that its citizens have access to needed drug therapy. The Circle of Kindness Foundation, established to help children with serious life-threatening and chronic diseases, is now providing thousands of children with the latest life-saving therapy.

However, the availability of innovative therapy is still unsatisfactory. Only a quarter of the innovative drugs approved by the European Medical Agency (EMA) in the last three years have appeared on the market.13

The chief problem is that the current procedure for introducing drugs into the supply system in Russia is focused primarily on the cost of drugs rather than on their clinical efficacy and influence on quality of life and longevity.

For example, the criterion "no adverse effect on the budget during the first year and the three-year planning period" is applied to drugs proposed for inclusion in the list of high-cost drugs (Government Decree No. 871 of 28 August 2014) (the "HCN Program"). This criterion is appropriate for drugs in the anatomical therapeutic group, but is an insurmountable barrier for breakthrough, first-in-class drugs that are the only (first) option in pathogenetic treatment.

As a result, budget funds are used ineffectively to purchase outdated drugs that are generally lower in cost and inconvenient in terms of dosage form, delivery and use, adversely affecting patients' qualify of life and adherence to treatment. Failure to lower the levels of mortality and disability means that Russia's national development goals for the period to 2030 and the targets of the National Health Care Project remain out of reach.

The inability to take a differentiated approach to the assessment and purchasing of innovative drugs is also an insurmountable obstacle for innovative contract models (risk sharing, long-term contracts, etc.) that are designed to optimize government costs and ensure quick access to drugs essential in treating severe, formerly incurable, diseases. This raises doubt as to whether such drugs can be launched on the Russian market.

(https://ec.europa.eu/docsroom/documents/33863/attachments/2/translations/au/renditions/native), but it does not cover all the implications for consumers in the system regulating the circulation of IVD products in the EAEU.

13 IQVIA, EFPIA, "Study on the Availability of Innovative Therapy in 30 European Countries, Including Russia, in 2016-18."

In accordance with Federal Law No. 44-FZ of 5 April 2013, drugs are purchased mainly by electronic auction at prices reduced from an initial (maximum) price. Prices can be minimized in an auction only if there are several participants offering a drug with the same international non-proprietary name (INN), and this method is most suitable for the procurement of generic drugs and biosimilars. An innovative drug has a unique INN, and competitive bidding thus does not bring down the price, but entails temporary organizational costs for the client. The Working Group welcomes measures aimed at listing pharmaceuticals procured by brand name as set out in government decrees No. 965 of 30 June 2020 "On Amendments to the Rules for Establishing the List of Medical Drugs Procured by Brand Name and on the Use of Pharmaceuticals with Specific Brand Names" and No. 1164 of 3 August 2020 "On Amendments to Decree No. 1289 of the Government of the Russian Federation of 30 November 2015" and calls for expanding the list of diseases to which this approach applies, provided there are sufficient medical grounds.

On 28 October 2020, pursuant to FIAC's 34th session, the prime minister called for an analysis of successful foreign experience in introducing innovative treatments into medical practice and the health care system and asked for proposals to improve the national regulatory base (No. MM-P13-1368528 of October 2020).

In many countries, criteria involving the degree of innovation (therapeutic value) have been developed and used to confirm the therapeutic value of innovative drugs. Such criteria serve as a basis for accelerating the entry of such drugs into the health care system and for adding them to the lists of drugs made available to the public on a preferential basis.

There is a proven global approach to procuring innovative drugs, designed to give patients reliable access 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, where there is still a high level of unmet needs. This approach is based on the ability to conclude various agreements with manufacturers via direct negotiations, which helps meet health care needs by ensuring the best treatment, increases the availability of state-of-the-art medicines for patients and optimizes the state's financial, organizational and time costs, while also providing greater predictability for manufacturers of innovative drugs, including in terms of quantity and timing.

Such a long-term approach to planning supplies of drugs protected by patent should also include competitive electronic auctions involving such forms of procurement as contracts providing for risk-sharing and cost-sharing, which will not only increase the availability of costly therapy for patients but also reduce government expenditures for medicines. In view of the quantities and timing of supplies as well as additional risk-sharing liabilities for the supplier if treatment proves ineffective, a reduction in prices would seem economically justified where pharmaceuticals are purchased with funds from the federal or regional budget or from compulsory medical insurance funds. This is important in view of the need to hold down expenses and pay for costly treatment.

Thus a differentiated price-setting mechanism should be introduced to improve the way lists of pharmaceuticals are drawn up. In some cases, under current restrictions and conditions concerning influence on the budget, manufacturers are prepared to reduce prices in Russia below the minimum for reference countries, but are forced to weigh such decisions against the risks of price erosion and significant financial losses in foreign markets.

Such a differentiated approach may include setting the maximum manufacturer's price under current rules when including a drug in the List of Vital and Essential Drugs ("VED List") and a separate maximum manufacturer's price when including a drug in the High-Cost Nosologies Program, the latter being a price that is not public or included in the State Register of Maximum Manufacturer's Prices, but is the maximum for an organization setting prices for supplies under this program. One way of implementing this mechanism is for the listing rules to state that a drug may be removed from the list of high-cost drugs in the course of a regular/extraordinary review if the manufacturer fails to comply with the declared price.

The considerable advantages of innovative drug therapy mean that basic regulatory changes should be made to promote improvements in legislation.

Recommendations:

1. Define the concept of "innovative drug" in Federal Law No. 61-FZ of 12 April 2010 "On the Circulation of Pharmaceuticals."

2. Set criteria for classifying drugs as innovative based on their therapeutic value via an expert examination procedure.

3. Develop and implement a differentiated approach to the inclusion of drugs classified as "innovative" in lists of medicines for human use based on their therapeutic value, including their long-term effect on quality of life and life expectancy by amending Government Decree No. 871 of 22 August 2014 "On Approval of the Rules for Forming Lists of Medicines for Human Use and the Minimum Assortment of Pharmaceuticals

Required for Medical Treatment." Ensure that the criterion of adverse impact on the budget of the High-Cost Nosologies Program does not apply to this category of drugs.

4. Develop special pricing mechanisms for state drug procurement programs that allow a special price to be registered for state procurement based on the manufacturer's offer, regardless of the maximum manufacturer's prices for drugs in the list of vital and essential drugs

5. Amend Federal Law No. 44-FZ of 5 April 2013 "On the Contract System for the Procurement of Goods" to introduce separate procedures involving specialized contract models for the procurement of drugs, including those protected by patent

6. Introduce a flexible mechanism of budget planning for government programs based on the assessment of medical technologies as well as the real needs of patients included in the unified register of patients entitled to subsidies and using digital data-processing technologies.

7. In fulfillment of the prime minister's instruction based on FIAC's 34th Session in Russia and for the purpose of considering and refining the above recommendations made by the Working Group on Health Care and Pharmaceutical Industry Development, FIAC proposes to sponsor a discussion using the resources of the Ministry for Economic Development and invite all concerned ministries, agencies and working group members to discuss the working group's proposals for studying global best practices and formulating recommendations to improve national laws and regulations in order to make innovative drugs available to patients (Letter No. Ks-1801-21-os of FIAC of 18 January 2021).

8. At the level of the federal government, adopt a comprehensive initiative to ensure and improve access to innovative drugs and technologies for the advanced planning of health care system needs, including the definition of innovative health care technologies, development and approval of a procedure for assessing the value of drugs for the health care system and/or for granting, confirming and revoking innovative drug status, differentiated approaches to registration, drug supply, pricing and procurement, and incentives for the development and manufacture of innovative drugs.

Issue 4. Russia's integration into the global system of pharmaceutical research and development.

4.1. Problem:

The COVID-19 pandemic has highlighted the urgent need for modern, well-organized and well-equipped research centers to develop promising new drugs. Russian science, despite its conspicuous achievements, remains largely academic and detached from the real needs of today's world.

This has much to do with the fact that Russian research centers are weakly integrated in the global systems of applied research and international cooperation on cutting-edge medical research.

The global pandemic has demonstrated the need for new, global approaches to research and for open, flexible platforms for the development of new drugs.

The best-positioned countries today are those that came to an early understanding of the opportunities provided by global cooperation and created attractive conditions for international research centers by integrating in the global network of pharmaceutical research. Countries worth mentioning in this regard are China, Israel and South Korea.

Notable advantages of such integration are broader financial possibilities, access to the latest international research methods and materials, and timely exchange of international experience with an extensive pool of colleagues, thus speeding up the development process.

Unfortunately, Russian programs to support the pharmaceutical industry have focused on rapid localization and the production of generics, while neglecting to support domestic drug development. The coronavirus crisis has shown how important it is to support medical and pharmaceutical research and establish international-level scientific centers integrated in the global research network and capable, as needed, of putting innovative research into practice in a short period of time.

This makes it essential to improve the regulatory environment and research standards, increase scientific cooperation, adapt research centers to GLP (Good Laboratory Practice) and ensure ready access to modern, high-demand laboratory materials by means of integration in systems based on digital technologies.

Recommendations:

1. To support the products of Russian R&D on international markets, the regulatory environment for research must be improved and harmonized with accepted international standards, and international GLP should be adopted.

2. Open platforms should be created, and Russian scientists should be given access to innovative international laboratory infrastructure.

3. Projects for international scientific cooperation in the pharmaceutical sector should be supported, and preferences should be given to international companies involved in transferring technology to Russian partners and in doing research in Russia.

4. Support for scientific developments to be used in drug treatment and health care should be included in the Pharma-2030 Program and programs for the development of health care.

5. In today's conditions, with the emergence of new and dangerous illnesses that have pandemic potential (COVID-19), laws and regulations should support investments in scientific and technological developments. Above all, a transparent regulatory environment must be created for the development of applied scientific research in the field of pharmaceuticals and health care, including harmonization with accepted international standards.

The institutional structure of executive bodies currently includes no legally coherent system for monitoring, regulating and stimulating R&D, and no single federal body is responsible for these activities.

Russia also lacks national roadmaps for promoting R&D (both generally and in specific sectors, including pharmaceuticals), while such documents are being adopted and implemented around the world. In 2013, for example, the World Health Organization presented its report "Priority Medicines for Europe and the World," which formed the basis of Horizon 2020, one of the EU's most successful programs for stimulating and funding research.

5.1. This task can be accomplished by: Regulating the activities of the concerned federal agencies, granting them authority in areas involved in stimulating R&D (within these agencies' scope of authority), allocating responsibilities for monitoring target fulfillment; formulating a special agency regulatory and legal base; granting the appropriate authority (special regulator authority) to the executive body responsible for scientific developments in the pharmaceutical sector.

In order to form an effective mechanism for regulating the development of pharmaceuticals, the appropriate powers must be given to at least two agencies: the Ministry for Economic Development, so that it can expand incentives for private (including foreign) investments, and the Ministry of Health Care, as the executive body responsible for regulating health care relations.

In this connection, legal provisions on domestic and foreign investments must be extended to cover investments in R&D (the responsibility of the Ministry for Economic Development), and the Ministry of Health Care must be granted additional powers to regulate R&D in the area of health care and pharmaceuticals.

5.2. To deal more effectively with issues involved in setting up comprehensive programs for the development of pharmaceuticals, biopharmaceuticals and biotechnologies, an interdepartmental task force should be created under the auspices of an executive body such as the Ministry of Health Care, including representatives of other concerned ministries and agencies – above all, the Ministry for Economic Development, the Ministry of Education and Science and the Ministry of Finance as well as key national medical research centers, development institutes and other research centers and members of the business community engaged in applied medical research and interested in high-tech research on innovative drugs in key therapeutic areas. The main function of such a task force would be to coordinate the efforts of players on the market of medical and pharmaceutical research, including the international coordination of R&D regulation, the preparation of draft laws and regulations and the formulation and adoption of medical and pharmaceutical research standards harmonized with international standards.

5.3. As regards the institutional regulation of R&D, it would be advisable to extend (clarify) the scope of authority of the Ministry of Education and Science (by amending the statute on the ministry accordingly). Currently, under the Statue on the Ministry of Education and Science (clause 4.3.1.), the ministry, within its scope of authority, coordinates fundamental scientific research conducted with federal budget funds. This responsibility should be extended to include R&D that is not state-funded – not in the sense of direct regulation, but of creating a transparent regulatory environment for the development of applied research (the Law on Science), including in the area of pharmaceuticals and health care.

The Ministry of Education and Science can thus be given overall responsibility (in the Law on Science) for stimulating and regulating R&D, including coordination of Russian and international research groups, integration of Russian R&D in the global system and harmonization of research done in Russia with international standards to promote the products of Russian R&D on foreign markets, for creating open platforms and for ensuring that Russian scientists have access to innovative international laboratory infrastructure. Amendments are required to include these instruments in the Statue on the Ministry of Education and Science and in ministry regulations.

5.4. Federal executive bodies already involved (often indirectly and insufficiently) in the process of pharma R&D need to be more active. For one thing, the Pharma-2030 Program (a continuation of Pharma-2020), initiated by the Ministry of Industry and Trade, has not yet been approved, and publicly available versions of the program lack a section on pharma R&D. Such a section (on the scope of authority of the Ministry of Industry and Trade and programs and projects overseen by the ministry) should be included in the text of the program.

5.5. Russian government regulations in effect until 2020 concerning the strategy for development of biotechnologies in the Russian Federation should be updated or replaced with new regulations to account for new developments on the biopharmaceutical front Government Regulation No. 337-r of 28 February 2018 "On Approval of the Plan of Measures (Roadmap) 'Development of Biotechnologies and Genetic Engineering' for 2018-20" and "VP-P8-2322, Comprehensive Program for the Development of Biotechnologies in the Russian Federation to 2020" (approved by the Government of the Russian Federation on 24 April 2012, No. 1853p-P8). These programs require additional provisions to stimulate scientific research, integration in the international system of applied pharma research, harmonization of R&D with international standards, regulation of projects for international scientific cooperation in the pharmaceutical sector, and preferences for international companies involved in transferring technologies to Russian partners and in conducting scientific research in Russia.

6. Since pharma R&D requires substantial financial resources, it is essential to put effective mechanisms in place for raising private investments in this sector.

Provisions on sources of financing for R&D, including in the pharma sector, are currently found in a number of legislative acts and need updating:

6.1. The Law on Science (No. 127-FZ of 23 August 1996 "On Science and State Scientific and Technical Policy") currently treats state capital as the main source of R&D financing (Article 15.3 of the Law on Science: "The main source of financing for fundamental and exploratory scientific research is the federal budget as well as funds for the support of science, technology and innovation."

In the current situation, this approach clearly requires fundamental changes, including the regulation of issues concerning the use of new sources of financing for R&D (other than the government) and the attraction of private capital.

The Law on Science could serve as the basis for special legislation (a framework) regulating the use of private capital for scientific research (including in the pharma sector). This would require updated terms and concepts, new provisions regulating relations between researchers/developers and protecting their interests, and tools to enable further integration of R&D in production processes. These issues are essentially absent in the current version of the law.

The Law on Science should also be amended to give more flexibility to a scientific organization's status (as a legal entity or public association of scientific workers whose core activities are scientific and/or scientific-technological) and allow the scientific and research divisions of major pharma companies to have such status – an important benefit.

6.2. There is currently no special regulatory framework for private (including foreign) investments in R&D. The specific characteristics of pharma R&D (high costs, lengthy research) must clearly be taken into account in legislation on investments and foreign investments.

Thus, in the law on foreign investments, the current period of seven years indicated in the grandfather clause for foreign investors in the pharma sector should be lengthened in view of the duration of research.

Co-financing mechanisms should be expanded. Under the Pharma-2020 Program, state co-financing is allowed if there is 25% to 50% funding by a private investor. This will clearly require special acts of the Ministry for Economic Development and changes in the law on foreign investments and related proposals from the Ministry for Economic Development for the Pharma-2030 Program.

Co-financing projects can also be promoted by allowing for public-private partnerships. The relevant law – Federal Law No. 224-FZ of 13 July 2015 "On Public-Private Partnership, Municipal-Private Partnership in the Russian Federation and Amendments to Certain Legislative Acts of the Russian Federation" (most recent version) – does not envisage such arrangements for pharma R&D. It would thus be advisable to adopt a special law, by analogy with the American Federal Technology Transfer Act of 1986 (Public Law 99-502), that would regulate R&D and enable long-term public-private collaboration.

6.3. Under the Tax Code, tax benefits (VAT under Article 145.1.1 of the Tax Code; profits tax under Article 246.1.1; assets tax under Article 381, clauses 19, 20, 27 and 28; land tax under Article 395, part 1; and insurance payments to off-budget funds under Article 427, clauses 1, 2 and 9) are currently provided only to participants in the Skolkovo Program (Federal Law No. 244-FZ of 28 September 2010 "On Skolkovo

Innovation Center") and to innovative science and technology centers (Federal Law No. 216-FZ of 29 July 2017 "On Innovative Science and Technology Centers and on Amendments to Certain Legislative Acts of the Russian Federation").

The Law on Science should extend tax benefits beyond existing high-tech clusters to all operators of R&D projects that meet certain requirements (to be indicated in the Law on Science with special reference to pharma R&D).

6.4. For purposes of translating fundamental research into practical health care and raising private (including foreign) capital for Russian R&D in the sector of pharmaceuticals, biopharmaceuticals and biotechnologies, an effective organizational system must be established for technology transfers to strengthen cooperation between small and medium-sized businesses and academic centers, including universities research centers.

7. The protection of intellectual property rights and measures to establish such protection is another central issue involved in regulation to stimulate pharma R&D.

The key legislative changes here should be amendments (additions) to the Law on Foreign Investments to protect intellectual property rights in connection with R&D investments as well as changes in acts regulating patent law.

To encourage private, including foreign, investments in Russian projects in the field of pharmaceuticals, biopharmaceuticals and biotechnologies, measures must be adopted to ensure that Russian developers receive documents protecting their intellectual property on key foreign markets (the EU, USA, China and Japan).

Issue 5. Effective regulation of the circulation of pharmaceuticals to accelerate the market entry of novel drugs and ensure consistency with international standards in order to stimulate the competencies and export potential of the Russian pharma industry and science.

5.1. Problem:

Under the Agreement on Unified Principles and Rules for the Circulation of Medicinal Products in the EAEU, the circulation of pharmaceuticals is regulated in accordance with the Commission's decisions, which are based on international standards (Article 3).

Since the time of the agreement's adoption by the Eurasian Economic Commission, in cooperation with authorized bodies of member states and representatives of the business community, a substantial number of regulatory acts have been adopted, covering the processes of development, production, distribution, quality control, pharmaceutical oversight and other aspects in the life cycle of pharmaceuticals. Comprehensive changes were also made to adapt proper pharmaceutical practices and registration and production requirements used by international organizations such as the WHO, ICH and PIC/S, leading countries in the field of pharmaceutical regulation, including the EU and the US (federal legislation) as well as other international norms. A single high bar was thus set for requirements with respect to the quality, effectiveness and safety of medicinal products circulating in the EAEU, and all pharmaceuticals will have to meet these requirements in full by the start of 2026.

Note that what is involved here is not simply the establishment of a unified regulatory space and unified procedures in the EAEU, but the adaptation of pharma regulatory practices themselves. In addition to the development of legal regulation, the adoption of best global practices opens up a range of opportunities for putting domestically produced drugs into international circulation and giving patients better and faster access to newly developed medicines.

In terms of the effective functioning of the pharmaceutical business, any unification of procedures in different countries will make it simpler to do business on those markets. The pharmaceutical business thus has a strong interest in the successful and timely functioning of all regulatory mechanisms that underlie the common market of pharmaceuticals.

The Agreement on the Eurasian Economic Union envisages a common market from 1 January 2016, but the Agreement's implementation was delayed due to formalities involved in the accession of one union member, Armenia, and the need to ratify the protocol on Armenia's access to the agreement. As a result, all decisions taken by the Commission entered into force only on 6 May 2017. This is the reason some issues concerning the common market which are especially critical for the transition to mandatory registration in accordance with Eurasian rules from 1 January 2021 and thus require special attention from the FIAC working group.

These issues include:

1. Pharmaceutical inspections to verify compliance with proper pharmaceutical practices, especially in regard to GCP rules.

2. Requirements for full or partial (in terms of the testers) clinical trials in the EAEU.

3. Registration orphan of drugs.

4. Modern approaches to accelerating the market launch of medicinal products – accelerated and conditional registration, etc. – as well as simplified registration for medicines previously registered in the EU and the US.

The commission is working on several of these issues in cooperation with member states, and FIAC support can help expedite the process of developing and adopting a solution.

Issues 1 and 2.

1. Under the agreement (Article 4), member states form a common market of medicinal products complying with proper pharmaceutical practices in accordance with the principles in Article 30 of the Agreement on the EAEU of 29 May 2014. Clinical trials in member states complied with GCP rules and the requirements for drug trials approved by the commission. The production of medicinal products in the EAEU also complies with EAEU GMP rules.

As of December 2020, Decision No. 83 of the Council of the Eurasian Economic Commission of 3 November 2016 “On Approval of the Rules for Pharmaceutical Inspections” sets rules for inspections to verify manufacturers’ compliance with GMP requirements. Procedures for pharmaceutical inspections to verify compliance with other pharmaceutical practices have not yet been developed, despite the direct reference to such procedures in Decision No. 78 of the Council of the Eurasian Economic Commission of 3 November 2016 “On the Rules for the Registration and Expert Examination of Medicines for Human Use.” There is thus an immediate need to initiate and speed up the process of drafting the regulatory acts required for pharmaceutical inspections.

The readiness of EAEU pharmaceutical inspectors to inspect clinical trials is another issue requiring attention. Under clause 36 of Decision No. 78, an authorized body, as part of an expert examination, may require an unscheduled inspection of a clinical center if trials were conducted wholly or partially outside the EAEU. An unscheduled inspection may be conducted during the registration procedure or within three years after registration. This measure is an alternative to local clinical trials.

2. The requirement in EAEU law that clinical trials be done in member states was new for all member states except Russia, where this had been a legal requirement since 2010. The requirement that Russian centers be involved in international clinical trials was positioned as support for the local market of clinical trials. However, statistical data collected by the Association of Clinical Trials Organizations make it clear that the effect was the opposite of that expected. 313 international multi-center trials were conducted in 2019, while 348 were done in 2009. 35 local clinical trials involving international sponsors in were done 2019 and 32 in 2009. As a result of this requirement, fewer new pharmaceutical molecules were released on the Russian market than in other developed economies.

Since it was impossible in practice to involve enough patients in trials of orphan diseases in 2015, Russian law was amended to allow data from foreign clinical trials to be used for orphan drugs, which is an additional indication that there is no real clinical basis for this requirement. Decision No. 78 also exempted orphan drugs from this requirement under EAEU law.

The reduced number of international clinical trials is also an indicator that the number of registered new pharmaceutical molecules has dropped as a result of this requirement. The latest medicinal products currently enter the domestic market much later than they do in the EU and the US, and this affects the target medicines in particular. The fact that medicines registered before 2010 continue to circulate indicates that this requirement has no real scientific or ethical basis. Regulators should not, however, be deprived of the right to require that clinical trials involve patients from the population of the EAEU if this is scientifically justified.

In view of what has been said, it would be highly beneficial in the medium term to make clinical trials involving patients in the EAEU optional (risk oriented), leaving this at the discretion of the regulatory body based on scientific grounds. Regulatory authorities must also be prepared to inspect clinical trials in order to give patients in the EAEU equal access to modern drug therapy if local clinical trials have not been done.

It is thus important to support the current initiative of the Republic of Armenia, which has proposed that the EAEU task force under the Eurasian Economic Commission’s Expert Committee develop a simplified

registration procedure for drugs previously registered in the US and centrally registered in the EU without lowering the requirements for the quality, safety and effectiveness of the registered medicines.

3. The Russian health care system reacted promptly and effectively to the challenges of the pandemic, including measures to accelerate the registration of needed medicines, and these measures were extended to include 2021. The Russian government decided that it could rely on the professional judgment of other international regulators and eliminate a number of requirements, thus substantially accelerating regulatory procedures. As a result, the government adopted Decree No. 441 of 3 April 2020 "On the Circulation of Medicines for Human Use When There is a Threat of an Emergency, When Such an Emergency Occurs and during the Recovery Period and for Purposes of Organizing Medical Assistance for the Victims of Emergency Situations, to Prevent Such Emergencies and to Prevent and Treat Illnesses That Put Others at Risk and Injuries Sustained Due to Harmful Chemical and Biological Factors and Radiation."

This approach is consistent with the statement made on 27 November 202014 by the International Coalition of Medicines Regulatory Authorities (Russia, represented by Roszdravnadzor, is a member) concerning the need for greater regulatory reliance between global regulatory agencies in order to conserve internal resources, allocate them effectively to combat the novel coronavirus infection and give patients prompt access to medication.

This concept is also being promoted at the level of the World Health Organization, which recently presented15 a draft document on the practice of regulatory trust for discussion.

The fight against the COVID-19 pandemic continues, but we can already think about how to use this experience to make health care more resilient in the face of future crises, focusing especially on innovative, safe and effective approaches to treatment.

The working group proposes to use the experience gained in implementing Government Decree No. 441, to apply the principle of regulatory trust to the results of expert examinations, inspections and other regulatory procedures conducted by the regulatory authorities of other countries and to treat this as a routine regulatory practice in EAEU law.

Issue 3.

Despite the fact that orphan drugs are currently exempted from local clinical trials, the registration of orphan drugs under EAEU law remains an unresolved issue, since even the definition of an orphan drug involves a reference to national provisions, which vary from country to country. This makes it impossible to register drugs at the level of the EAEU, which is contrary to the idea of an EAEU common market.

According to Russian law, orphan status may be granted only as part of state registration under Federal Law No. 61-FZ "On the Circulation of Pharmaceuticals," whereas, effective 1 January 2021, all drug registration matters are regulated by EAEU law (Decision No. 78 of the Council of the Eurasian Economic Commission of 3 November 2016 "On the Rules for the Registration and Expert Examination of Medicines for Human Use"). Orphan status is thus impossible to obtain at the present time.

One advantage of a common market is the ability to release such drugs on national markets that are individually too small to support the circulation of many products. Although orphan status is linked to drug supply, a consensus cannot be reached on the definition of orphan drugs, even when an illness has spread throughout the EAEU.

In addition, separate registration procedures for orphan drugs, such as the accelerated expert examination procedure in Russia, are not yet envisaged at the level of the EAEU. The registration of orphan drugs in the EAEU thus requires specialized regulation.

Issue 4.

Modern approaches to accelerate the market launch of medicines – conditional and exceptional registration – should be adopted.

Internationally, these procedures are being used with increasing frequency. In the US, of 48 new drugs registered in 2019, 29 (60%)16 were registered under special registration procedures. In the EU,17 of 30 new drugs, 15 (50%) were centrally registered under special market access procedures.

The procedure now indicated in Chapter VII of Decision No. 78 is not one of these, but rather involves additional requirements under the standard registration procedure. A separate registration mechanism must

[14] http://www.icmra.info/drupal/strategicinitatives/reliance/statement
[15] https://www.who.int/medicines/areas/quality_safety/quality_assurance/QAS20_851_Rev_1_Good_Reliance_Practices.pdf?ua=1
[16] https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/new-drug-therapy-approvals-2019#noveldrugs
[17] https://www.ema.europa.eu/en/documents/report/human-medicines-highlights-2019_en.pdf

thus be developed for innovative and vital drugs to provide for greater involvement by the regulatory authorities at the development stages and generally accelerate the market entry of medicines.

A task force of the Eurasian Economic Commission's Expert Committee is currently discussing draft amendments to Decision No. 78 of the Council of the Eurasian Economic Commission of 3 November 2016 "On the Rules for the Registration and Expert Examination of Medicines for Human Use." These amendments, drafted by the Scientific Center for the Expert Examination of Medical Products under the Ministry of Health based on EU law, provide for such new registration procedures. In addition, Regulation No. 2871-r of Prime Minister Mikhail Mishustin of 5 November 2020 approved a roadmap for systemic changes in laws and regulations on business activity, "Transforming the Business Climate: New Forms of High-Tech Business," which charges the Ministry of Health, the Ministry of Industry and Trade and the Ministry for Economic Development, in cooperation with the Russian Venture Company and the Neuronet Working Group, with amending, by June 2021, the Rules for the Registration and Expert Examination of Medicines for Human Use, approved by Decision No. 78 of the Council of the Eurasian Economic Commission of 3 November 2016, in order to improve the drug registration system and establish an accelerated drug registration procedure, including registration based on the findings of the second phase of clinical trials, including c post-registration measures (conditional registration).

The FIAC working group should be involved in discussing the drafts. Its position should be agreed, and comments should be submitted to the Ministry for Economic Development for consideration at sessions of the task force of the Eurasian Economic Commission's Expert Committee.

Recommendations:

1. Rules for pharmaceutical inspections to verify compliance with proper drug circulation practices (GLP, GCP, GDP, GVP) should be formulated and adopted by a decision of the Council of the Eurasian Economic Commission.

2. A unified registration procedure for orphan drugs should be adopted in the framework of Decision No. 78 of the Council of the Eurasian Economic Commission of 3 November 2016 "On the Rules for the Registration and Expert Examination of Medicines for Human Use."

3. Modern approaches to drug registration – conditional and exceptional registration – should be introduced at the level of the EAEU to accelerate the market entry of medicines.

4. The principle of regulatory reliance should be introduced in EAEU law and applied to regulatory procedures (registration, clinical trials, pharmaceutical inspections) in countries with strict regulatory authorities as defined by the World Health Organization.

Issue 6. Creation of a favorable environment for the treatment of patients with rare diseases.

6.1. Problem:

In recent years, Russia has taken important steps to give patients with rare diseases better access to treatment by approving a research program for genetic technologies, creating a federal register of patients with life-threatening acute and chronic progressive orphan diseases, establishing the Health Care Committee of the State Duma and the Expert Council on Rare (Orphan) Diseases, starting the transition of funding for orphan diseases from the regional to the federal level (the so-called "federalization program") and introducing progressive taxation to provide additional funding for the treatment of children with life-threatening and chronic diseases, including progressive rare (orphan) diseases.

So that patients can be more effectively supplied with medicines, attention should be given to the organizational aspects of health care, above all to the harmonization of all measures for the financial support of drug supplies. Various programs and sources are currently responsible for the supply of medicines for patients with variously classified rare (orphan) diseases. Criteria and procedures for making decisions to include specific nosologies in drug procurement programs have not yet been developed. As a result, patients do not have equal access to medicines. The federalization program begun in в 2019-20, which proved effective in improving access and optimizing government expenditures, has not been developed further.

Other organizational aspects of health care for patients with rare diseases must also be developed: timely diagnostics, rehabilitation, regular monitoring, consultations and other forms of medical and social assistance and support. Global practice shows that a favorable infrastructure for the treatment of patients with rare diseases makes therapy more effective, lowers the risks of disability and increases life expectancy.

An integrated system built around patients will enhance the effectiveness of all state support measures, making this market segment more attractive as an investment for both international and Russian manufacturers and optimizing government expenditures, including for the procurement of high-cost medicines.

Recommendations:

1. A federal project to ensure medical assistance for patients with rare diseases should be developed and implemented in the framework of the Health Care priority national project, which calls for the harmonization of all government support measures – financial, organizational, legal, methodological – in order to create a unified system of medical assistance for patients with rare diseases.

2. A separate department of the Ministry of Health should be established to oversee medical assistance for patients with rare (orphan) diseases.

3. A task force should be created under the Ministry of Health to establish a direct dialog between concerned government structures, patient organizations, the scientific community, and developers and manufacturers of products for the treatment and diagnosis of rare diseases in order to develop solutions and, if necessary, see that legislative amendments are passed to ensure that patients with rare diseases have access to the latest medicines and methods of treatment and diagnosis.

4. A precise and transparent procedure and criteria should be formulated and adopted for including rare diseases in the list of life-threatening and chronic progressive rare (orphan) diseases that shorten life expectancy or cause disability so that patients can readily receive the latest and most appropriate drug therapy in a timely manner and patients with various rare diseases can have equal access to vital forms of therapy.

5. Funding for the procurement of all medicines to treat patients with life-threatening and chronic progressive rare (orphan) diseases should be transferred to the federal level.

6. Mass screening programs (neonatal and selective) for hereditary metabolic diseases should be developed.

7. Conditions should be created at federal and regional levels for the development of support diagnostics for patients with rare diseases, including the use of the latest diagnostic test systems for rare oncological diseases based on next-generation sequencing (NGS).

8. The registration of diagnostic panels should be simplified based on clinical trials done in European countries, the US, etc. Detailed recommendations for diagnostic panels and lists of drugs should be prepared.

9. Conditions should be created to make individual rehabilitation programs available at the early diagnosis stage and throughout the course of therapy.

10. A supporting patronage service should be set up at federal and regional levels to provide medical assistance to patients with limited mobility and ensure that all patients have equal access to treatment, regardless of how far they are from regional centers.

11. A unified coordinating service should be established to provide psychological, social and information support to patients with rare diseases and their families.

12. Foreign manufacturers and developers of products for the treatment and diagnostics of rare diseases should be involved in transferring international experience with patient support programs in order to enhance the health of Russian patients.

ISSUES BEING MONITORED:

Issue 7. 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.

7.1. 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 medicines for human 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 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 measures 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 EEU 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 EEU of 29 March 2019 provides for the introduction of identification signs unified in the EEU. Mandatory requirements for manufacturers and importers of pharmaceuticals in the Russian Federation in respect of products, which circulation is regulated by EEU's legal acts and which may freely circulate on the EEU 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 8. Streamlined drug supply system for Russian citizens.

8.1. 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 Medicines for Human 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 drug supply 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.

Issue 9. Possible legislative amendments that would introduce compulsory licensing.

9.1. 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 rightsholder 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 rightsholder'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 rightsholder'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.

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

- conversion to common shares at an objective pre-specified trigger point or

- 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.

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.

[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").

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 was raised at the FIAC Plenary session on 17 October 2016.

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 (КС-2811-16-ол от 28.11.2016 and КС-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 и 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 and termination of 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 sub-ledger 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.

Or

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.

2021 Status:

At the 2020 FIAC Executive Committee meeting, the working group for developing the banking sector and financial markets brought up an issue that it was necessary to revise certain rules of taxation applicable to the Russian depositories performing tax agent functions when paying income on Russian issuers' securities. On the Minister's initiative, an Interdepartmental Working Group for Property Taxation of Organizations and Investor Activities within the territory of the Russian Federation was established, with both the Ministry of Finance and the Federal Tax Service as participants.

In the fourth quarter of 2020, the Federal Tax Service and the FIAC worked together successfully to develop a unified confirmation form for the actual right to income. Using this form will eliminate some of the ambiguity in applying the tax rules and establish a single standard in the securities market. However, using a single form of confirmation without revising the foreign investors' liability can adversely affect the market.

In our opinion, the next step in successfully resolving this issue is to review certain legal provisions regarding investors' liability in connection with the application of withholding tax to payments on securities. We believe that it is important to share responsibility between depositories and foreign investors. Currently, the responsibility for applying the correct tax rate with a view to the information provided by the investor rests entirely with the depositary. The FIAC working group proposes to consider the possibility of introducing a requirement for mandatory security of foreign investors' tax liabilities to the tax authority or tax agent in the form of a surety or a bank guarantee.

For the FIAC working group, the way to resolving this issue lies through an active dialogue with participation of representatives from the Ministry of Economic Development, the Federal Tax Service, the Ministry of Finance, and representatives from the FIAC working group in order to develop joint decisions regarding Russian depositories performing tax agent functions. It is proposed to actively use the format of the interdepartmental working group brought forward by the Ministry of Economic Development.

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 quite 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.

Status 2020:

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.

2021 Status:

During 2021, various banking associations actively pursued this issue, for instance, the financial technology working group of the Association of Banks of Russia (ASROS) arranged for meetings of the expert community members at the site of the Financial Market Committee of the Russian State Duma with the participation of the Ministry of Digital Development, the Ministry of Industry and Trade, the Bank of Russia, and the FSB. Foreign bank subsidiaries actively participate in these discussions and support the consolidated position of the banking community on this issue. In March 2021, the FIAC working group sent official petitions and proposals to the Ministry of Digital Development, the Central Bank of the Russian

Federation, and the Ministry of Economic Development and Trade, and it welcomes the agencies' readiness to continue dialogue with the banking community regarding this issue.

Following the discussions at the ASROS working group meeting and numerous requests and consultations with the responsible federal executive bodies, the Bank of Russia has become an active participant in drafting the legislation provisions regarding critical information infrastructure (CII) in relation to financial organizations.

However, the following vital issues remain unresolved for banks with foreign participation, as it is not possible for them to use their in-house software or any software purchased from Russian developers.

There are two reasons for that:

1. requirements for software to be included in the register (exclusive rights to the software must belong to a Russian organization without predominant foreign participation), and

2. requirements for software upgrading and warranty maintenance (to be performed by "Russian organizations registered as legal entities in accordance with the legislation of the Russian Federation, which are residents of the Russian Federation", while it is not very clear what the word 'resident' means in the context of that regulation).

In July 2021, important agreements were reached within the framework of the dialogue between the working group for financial organizations transiting to domestic software and equipment under the State Duma Committee on the Financial Market and the Ministry of Digital Development regarding:

- a smooth transition from foreign to domestic software (the banks' transition plans are to be approved by January 1, 2023 and spell out the deadlines for license expiration or amortization. If such deadlines coincide with January 1, 2023, the banks will have to immediately substitute such foreign-made software and equipment with domestic products, while if they fall on a later date, it is possible to make a later transit);

- adding the Bank of Russia to the import substitution procedure as the core financial sector regulator;

- apply these requirements only to significant critical information infrastructure (CII) facilities. For other CII facilities, these provisions will be on advisory basis.

On August 18, 2021, a video conference was held organized by the Ministry of Economic Development with the participation of representatives from the FIAC working group, the Ministry of Digital Development, the Bank of Russia, the Ministry of Economic Development, the Federal Security Service, and the Ministry of Industry and Trade. Representatives of the Ministry of Digital Development confirmed that the agreements reached will be reflected in the Draft Government Resolution, as well as in additional documents, such as Software Requirements for CII Facilities and the Procedure for Transition to Preferential Use of Russian Software.

The FIAC working group welcomes the progress achieved; however, the questions remain open regarding the criteria of significance for CII facilities and the foreign bank subsidiaries using their in-house software and software purchased from Russian developers as domestic software instead of designating such software as foreign-made.

7. Natural Resources and the Environment

Environmental and other issues

Issue 1. 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 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. Amend the definition of "wastewater," i.e. to replace the wording "runoff from a drainage area" with "runoff from a contaminated industrial area." The legislation would allow 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
- Specify in law criteria for categorizing "industrial/non-industrial" sites
- Specify in laws/regulations surface water drainage areas/sites that do not require discharge permits
- Legislate for the reuse treated surface water and its discharge to land/drainage areas

Issue 2. 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, treat, recover, neutralize or place hazard class I-IV waste at a waste neutralization site and/or a site used for hazard class I-IV waste, if another individual entrepreneur or another legal entity, possessing a valid license, uses the site to neutralize and/or place hazard class I-IV waste. Interpretations of this provision, however, differ, leading to a confusion of 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, the placement of waste). Consequently, the 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:
- "2. An individual entrepreneur or legal entity may not conduct activities related to the collection, transportation, treatment, recovery, neutralization and placement of hazard class I-IV waste at a waste neutralization site and/or a hazard class I-IV waste placement site, if another individual entrepreneur or another legal entity, possessing a valid license, uses the site to neutralize or place hazard class I-IV waste, except as specified in Article 9.3."

- Add Article 9.3 to Federal Law No. 89-FZ of 24 June 1998 “On Production and Consumption Waste” reading as follows:

“3. An individual entrepreneur or legal entity that neutralizes and/or places hazard class I-IV waste at a specific hazard class I-IV waste neutralization and/or placement site, may engage other individual entrepreneurs or legal entities possessing a valid license to collect, transport, treat, recover, neutralize and place waste at these sites.

The licensed individual entrepreneur or legal entity engaged by other individual entrepreneurs and legal entities to collect, transport, treat, recover, neutralize and place waste at their specific hazard class I-IV waste neutralization and/or placement sites is liable for any breaches of license requirements and for any damage that it may cause to the rights, legal interests, life or health of citizens, the environment, cultural heritage sites (historical and cultural monuments) of the peoples of the Russian Federation, defense and security of the state.”

- Federal Law No. 99-FZ of 4 May 2011 “On the Licensing of Certain Types of Activity”:

Some provisions governing the licensing of specific types of activity may allow licensors to engage other licensees having a license for this type of activity to deliver work and services subject to licensing. If that is the case, the licensor who engages other licensees to deliver work and services subject to licensing is liable for any breaches by such licensees of license requirements, as well as for any damage that it may cause to the rights, legal interests, life or health of citizens, the environment, cultural heritage sites (historical and cultural monuments) of the peoples of the Russian Federation, defense and security of the state.

Issue 3. Amend rules for the implementation of EPR schemes.

In an effort to implement the Concept for Improving the Institution of Extended Producer and Importer Responsibility (hereinafter, the “EPR Concept”) approved by the Russian Government on 28 December 2020, the Ministry of Natural Resources and Environment has been drafting a federal law titled “On Amendments to the Federal Law ‘On Production and Consumption Waste’ and Article 8 of the Federal Law ‘On the Fundamental Principles of State Regulation of Trade in the Russian Federation’” (hereinafter, the bill).

The FIAC Working Group agrees that the EPR mechanism needs improvements to create an effective system to recycle waste and put secondary material resources to economic use as part of transition to a circular economy, as well as with the purpose of mitigating adverse environmental impacts.

However, any EPR mechanism improvements should build on achievements, while ineffective or lacking elements of the system need balanced solutions. Ill-considered regulatory measures should not be adopted.

FIAC member companies believe that the bill runs counter to the government-approved EPR Concept because of the following conceptual gaps that need to be addressed:

- The bill would not set key performance indicators and would not require anyone to account for achieving (failure to achieve) the environmental goals set by the President, including for proper waste sorting and recovery.
- It would impose an unjustified financial burden by introducing a double environmental fee for packaging, which may cover 200% of packaging placed on the market.
- Instead of encouraging businesses to properly recover resources from waste, it deprives them of the opportunity to pool their efforts aimed at developing the waste collection and recovery infrastructure by forcing EPR entities to choose environmental fees as the main way to settle their EPR obligations and by creating non-transparent conditions for environmental fee spending.

Recommendations:

Although the current version of the bill proposes a number of effective measures to improve the EPR mechanism, many points have yet to be updated:

1. The lack of those responsible for achieving waste sorting and recovery goals, and those accountable for failure to do so.

The EPR mechanism’s goal is to reduce waste dumped at landfill sites by 50% by 2030 and increase the volume of treated waste and recovered materials. To achieve that goal, it is necessary to introduce source separation and special collection schemes because without it would be impossible to segregate packaging from solid waste (packaging accounts for about 40% of solid waste) and send it for recycling.

At present, no one is responsible for source separation in the county and the bill does not make any difference in this respect:

- It does not set out waste sorting targets for Russian constituent entities, municipalities and regional operators;
- It does not offer households any incentives to sort waste;
- Regional operators are interested in collecting as much solid waste as possible (the more they collect, the more they charge) and are not interested in collecting source-separated refuse.

Important to:

- Introduce key performance indicators requiring governors, municipalities and regional operators to establish source-separation infrastructure;
- Create economic incentives for households sorting waste;
- Hold someone (the environment ministry and/or PPK REO) accountable for establishing source-separation infrastructure;
- Introduce separation, treatment and recycling targets for goods categories aligned with EPR goals.

2. Recovery limit and double environmental fee.

The bill would provide for individual responsibility and set a 100% packaging recovery target that is a priori unfeasible. In addition, the bill (Article 24.5.7) provides that if an entity fails to achieve its recovery target, it must multiply the environmental fee by twice the difference between the recovery target and the recovered volume. The bill as it stands means that entities trying to achieve the 100% EPR packaging recovery target on their own may end up paying a fee for nearly 200% of the packaging marketed.

In Germany, EPR entities finance only the achievement of recovery targets set at various levels by type of waste by producer responsibility organizations. Expenses on achieving the targets (not equal to 100% not in a singe country) are calculated in proportion to the amount of packaging marketed (a fee per ton), which creates an impression that businesses are responsible for 100% recovery, but they are not. Russia applies the same principle, but it applies recovery targets to 100% of packaging or goods placed on the market.

The difference between the recovery target and actual volume recovered should not be multiplied by 2, or the multiplier should be used in a way that ensures that the final fee does not cover more than 100%. We also propose that the packaging recovery target should be raised gradually, not instantly.

3. A ban on the sale of goods not reported to the Unified State Waste Accounting Information System.

The bill would require manufacturers to file reports to the Unified State Waste Accounting Information System and “a register of goods and packaging” before placing goods on the market. The clause contravenes the EAEU Agreement, the EAEU (CU) Technical Regulation, which lack that requirement.

The bill does not specify how information will be collected in “the register of goods and packaging,” what information will be collected, what measures will be taken to avoid the duplication of information in the registers that might be involved in interdepartmental document interchange. The current version of the bill would require all manufacturers and importers of all goods and goods categories placed on the market in any packaging to file reports on their products to the register or face a ban on the sale of their products. Therefore, the bill gives the regulator unlimited authority to impose a direct ban on the movement on any goods in the Russian market.

Manufacturers and retailers warned earlier that the proposed measure might give rise to significant risks of supply chain disruptions. However, no specific explanations were presented during bill discussions as to how the proposed provisions would be applied in practice.

It is necessary to specify what data must be reported to the register, delete the discretionary provisions calling for a ban on the sale of goods, remove the requirement for market placers and the owners of aggregators to report goods they are marketing under agency agreements to the Unified State Waste Accounting Information System. The bill should carry a fine, not a sales ban as punishment.

4. Removal of incentives to use recycled packaging materials.

A clause that provides for the application of a discount factor to a fee paid by obliged companies that use packaging containing recycled materials has been removed from the bill. The Concept directly calls for incentives to increase recycled materials in goods production and return packaging waste in circulation. EPR entities should have economic incentives to buy packaging with a greater content of recycled materials for goods production.

It is necessary to keep the effective clause concerning the application of a discount factor as an incentive for manufacturers and importers to increase the use of recycled materials in goods and packaging.

5. Status of professional producer responsibility associations.

The wording of Article 24.2.8 of the bill concerning EPR associations is not in compliance with the EPR Concept (p.8), which provides that EPR associations are established “for the purpose of ensuring that recovery targets are met independently.”

It is necessary to bring the provision on associations into full compliance with the EPR Concept.

The FIAC Working Group for Natural Resources and the Environment believes that it is necessary to improve bill-drafting transparency and involve representatives of FIAC member companies in the process so that they could contribute their views based on earlier 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.

The bill drafters should work toward a consensus that takes into account the opinion of FIAC member companies.

Issue 4. Henkel’s proposals on measures to expand the use of recycled materials as part of EPR system improvement.

To improve the EPR system, the company initially proposes for discussion the following possible measures to increase the use of recycled materials:

1. Basic option: “deducting” recycled materials from the total volume to be recovered.

To ensure the uniform application (given the underdeveloped recovery infrastructure) of Article 24.2.14 of the Federal Law “On Production and Consumption of Waste,” which allows for the use of a discount factor calculated as the difference between one and the share of recycled materials used for packaging production, it is necessary to revoke the ban on the application of the discount factor by manufacturers and importers who pay the environmental fee.

Rules currently in force

Only companies that recover resources from waste on their own are allowed to deduct. Entities that pay the environmental fee are not allowed to deduct.

Article 24.2 of Federal Law No. 89-FZ of 24 June 1998 “On Production and Consumption Waste”:

- 14. If packaging to be recovered is produced from recycled materials, a discount factor, calculated as the difference between one and the share of recycled materials used for packaging production, is applied to the recovery target.
- 15. Clauses 13 and 14 of the article do not apply to goods manufacturers and importers who pay the environmental fee under Article 24.5 of the federal law.

Technically, we suggest that clause 14 should not be mentioned in clause 15, so that those who pay the environmental fee can apply the discount factor.

The Russian Ministry of Natural Resources confirmed that the environmental fee payers are not eligible to apply the discount factor in its statement of 19 May 2017 titled “On Important Questions Regarding the Fulfillment of Extended Producer Responsibility (hereinafter, “EPR) of Manufacturers and Importers”

- If packaging to be recovered is produced from recycled materials, a discount factor, calculated as the difference between one and the share of recycled materials used for packaging production, is applied to the recycling target.
- Companies apply the discount factor if they recover waste from goods on their own (Article 24.2.15 of Law No. 89-FZ, the clause concerning the application of the discount factor does not apply to goods manufacturers and importers who pay the environmental fee).

2. Alternative option: a reduction in the fee payable for waste to be recovered based on the share of recycled materials.

The introduction of material bonuses to reduce the environmental fee in return for certain content of recycled materials:

The approach has been used internationally: in France, Citeo, an EPR system operator, applies a bonus-malus system to calculate rates for plastic packaging with bonus discounts available for the integration of recycled consumer, industrial or commercial packaging in new PET, polyethylene (PE) and polystyrene (PS) packaging19.

Rationale:

The concept for improving extended producer responsibility for manufacturers and importers of goods and packaging, approved by Viktoria Abramchenko, Deputy Prime Minister of Russia, on 28 December 2020, describes the primary purpose of EPR system improvements as follows: "establishing an effective state regulation model aimed at maximizing the return of secondary material resources to economic circulation and minimizing amounts of buried consumer waste." It calls for maximizing the use of recycled materials and creating competitive incentives for it.

The Concept is expected to "increase the amount of recycled materials used in the production of goods and reduce the amount of raw materials."

However, the Concept does not outline enough positive measures to encourage manufacturers to use recycled materials in production of packaging and goods covered by EPR.

In particular, the proposal that companies should take an "obligation to use packaging made using a certain proportion of recycled materials" may have a negative impact on output and production costs, and eventually affect consumers, if the proportion is high and no economic incentives are available. If the mandatory proportion is low, it will have a limited effect in terms of encouraging the use of recycled materials.

The proposal that favorable state procurement terms should be offered for the purchase of goods, including packaging, produced using recycled materials, will have a limited effect on the market as a whole considering private buyers' dominance on consumer markets.

The company therefore considers it appropriate to suggest that participants in discussions with the business community and those involved in work on the "road map" and subsequent changes to legislation as part of Concept implementation, recommend the proposed additional economic measures to support the use of recycled materials, which can create sufficient incentives for expanded use by manufacturers and for EPR system reform in the area.

Issue 5. Introducing regulatory incentives to increase the use of renewable resources in the production of goods packaging in the framework of the EPR mechanism.

The EPR Concept calls for incentives to increase the use of renewable materials in the production of various types of packaging for consumer goods, including food. For PET and glass food packaging, changes are to be introduced to limits set out in sanitary regulations and the CU TR.

The technology used to produce combined cardboard-based packaging limits the use of recycled materials because paperboards may lose both consumer appeal and protective properties.

Recycled materials make combined cardboard-based packaging less rigid and less resistant to damage during transportation. In addition, paperboards from recycled materials are not good for aseptic packaging.

Aseptic packaging is used for ultra-sterile foods, helping reduce food waste, electricity consumption for refrigeration and the environmental footprint of goods across the distribution chain. Aseptic-packaged food can be stored for a year without additional cooling.

Packaging may lose its aseptic properties if it includes paperboards made using recyclable materials.

Recommendations:

As an alternative to mandatory/recommended use of recycled materials in combined food packaging that includes paperboard, we suggest introducing incentives as part of the EPR mechanism to increase the use of:

1. Renewable materials from sustainable sources (FSC-certified paper);
2. Polymers from vegetable oil.

19 The 2021 rate for recycling household packaging. The guide: https://bo.citeo.com/sites/default/files/2020-11/20201008-Citeo_Guide_Tarifs_2020_GUIDE-UK.pdf ; The 2021 rate for recycling household packaging. The rate list: https://bo.citeo.com/sites/default/files/2021-02/20210127-Citeo_Rate%20List_Tarif_2021%20anglais.pdf

The incentives will expand Russia's renewable material sourcing options and encourage the production of new polymers from renewable raw materials.

Issue 6. Inclusion of cement plants as energy recovery 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 the negative environmental impact, including CO2 emissions, and 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 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 recovery 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:

- Add the following sentence to the definition of "recovery": "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 recovery);"
- Add energy recovery to the list of regulated activities;
- Add energy recovery tariffs to the list of regulated tariffs.

Given their wording, these provisions should apply to energy recovered at cement plants from leftovers from municipal solid waste segregation. However, a clarification is needed.

Recommendations:

1. Consider cement plants as eligible EPR entities involved in the recovery of waste and energy recovery from municipal solid waste;

2. Recommend that constituent entities of the federation include cement plants in local waste treatment schemes as energy recovery facilities and that cement plants be engaged to treat leftovers from municipal solid waste segregation, instead of dumping solid waste at landfill sites;

3. Include incentives for energy recovery investment projects involving cement plants in programs to establish the Comprehensive Municipal Solid Waste Management System and subsidize part of their costs;

4. Develop and implement a set of measures to improve municipal solid waste sorting. Outline measures to support the upgrade and construction of facilities equipped to prepare municipal solid waste for further energy recovery at cement plants.

Waste treatment legal framework updates

1. Amend the definition of "recovery of waste" in the federal law "On Production and Consumption Waste" to fully use the cement plants' potential for the recovery of waste within the EPR system and the recovery of energy from municipal solid waste.

2. Amend the Permitted Land Use Classifier to enable cement plants to combine their core business (Code 6.0 in the Permitted Land Use Classifier) with waste management (Code 12.2. Special Activity), for instance by adding a new type of permitted activity to the Classifier or a new subtype of permitted use, 6.13. Production Activity Combined with Waste Management.

3. Update Pricing Basics in the Area of Municipal Solid Waste Management and Rules for Setting Tariffs in the Area of Municipal Solid Waste Management approved by Russian Government Decree No. 484 of 30 May 2016, taking into account waste-to-energy conversion at cement plants.

4. Amend Municipal Solid Waste Management Rules approved by Government Decree No. 1156 of 12 November 2016 to allow regional operators to sign contracts with cement plants that have appropriate

waste management licenses and are included in the local waste treatment scheme of a constituent entity of the Russian Federation, for the recovery of municipal solid waste left after sorting.

5. Amend the draft order of the Russian Ministry of Natural Resources and Environment "On Approval of Requirements for Management of Hazard Class I-V Groups of Heterogeneous Waste," taking into account provisions of ITS 6-2015. Information and Technical Guide to Best Available Technologies. Production of Cement to specify appropriate lubricant oil and tire waste treatment methods.

6. Draft a separate bill of amendments to the federal law "On Expert Environmental Examinations" (hereinafter, No.174-FZ) to:

- Remove technologies included in the database of waste treatment technologies and listed in BAT reference guides from the list of facilities whose engineering and design documents are subject to a federal-level state environmental expert review (Article 11 No. 174-FZ)

- Remove equipment analogous to that already operated in Russia from the list of equipment whose engineering and design documents are subject to a federal-level state environmental expert review (Article 11 No. 174-FZ). Specify the agency authorized to determine analogous equipment, as well as criteria, procedures and documents required to confirm it

- Rewrite the definitions of new equipment and new technology in No. 174-FZ

These changes would help avoid misinterpretations of laws, excessive obligations and expenses for entrepreneurs and organizations investing in waste recovery projects, without undermining the existing measures to mitigate the negative impact of economic and other activity on the environment.

Issue 7. 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 8. Categorization of facilities with a negative environmental impact.

The current version of Russian criteria, which are mainly based on the same principals as Directive 2010/75/EC of the European Parliament and of the Council of 24 November 2020 on industrial emissions (integrated pollution prevention and control), contains an error resulting from incorrect translation from English: the Russian version defines an activity as "crude oil and/or natural gas extraction, including natural gas processing," whereas the Directive defines that Category I activity as "Refining of mineral oil and gas." There is a significant difference between a properly organized oil production facility and an oil refinery in

terms of environmental impact and its mechanism. A production facility (an oil rig, the treatment of hydrocarbons before transportation and intra-field transportation) is making a much smaller impact on the environment than an oil and gas refining facility.

EU legislation does not categorize crude oil and/or natural gas extraction, including natural gas processing, as activities especially dangerous for the environment and these activities are not listed in Annex I to the Directive.

Therefore, criteria for classifying facilities with a negative environmental impact in the first category should take into account the current edition of the EU Directive, and crude oil and/or natural gas extraction and treatment facilities should be included in Category II, and a respective clause should be added to paragraph 2 of GD No. 2398.

The same applies to most industrial incinerators used at hazard class III-V waste treatment facilities, because hazard class III waste includes oil and fuel filters, rags, oil waste, etc., which are incinerated.

Any facility incinerating hazard class III waste (for instance, fuel filters) in a stationary installation would be placed in Category I. If filters are incinerated in a mobile installation, the facility would be placed in Category II. Stationary installations have more effective emission cleaning systems than the mobile ones.

European legislation categorizes incinerators with a capacity in excess of 10 tons per day as hazardous facilities with a negative environmental impact, while Russian legislation places any hazard class III waste incinerator in this category.

Waste placement sites are used as a rule for the placement of various classes of waste. For instance, waste fluids injected into deep isolated rock formations at licensed sites include hazard class III-V waste, with 99% being hazard class IV waste. Since the current version of the GD does not specify hazard classes to which the 500-ton-per-year threshold applies, any waste placement site with a capacity in excess of 500 tons per year would be placed in Category I if it receives a small amount of hazard class III waste and regardless of what small amounts of hazard class III waste it receives.

The fact that burial sites for industrial and household waste in hazard classes IV and V are placed in Category I, without taking into account the method of burial, means that, for example, sites where domestic wastewater is injected into deep isolated formations will be assigned to Category I, while discharges of the same wastewater into a body of water will be placed in Category III.

Recommendations:

Amend Government Decree No. 2398 “On the Approval of Criteria for Assigning Entities to Categories I, II, II or IV Based on Their Negative Environmental Impact” to:

- Remove oil and gas extraction facilities from Category I of facilities with a negative environmental impact. Place such facilities in Category II.
- Remove hazard class I-III waste recovery and neutralization facilities using thermal treatment equipment and/or installations (except for mobile ones) and hazard class I and/or II waste placement facilities with a capacity of less than 10 tons per day from Category I of facilities with a negative environmental impact. Place such facilities in Category II.
- Place the burial of liquid, pulpy and liquefied waste in collector layers, deep isolated formations of licensed fields in Category II of facilities with a negative environmental impact.

Issue 9. Amend Order No. 154 of the Ministry of Natural Resources 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 10. 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.

Issue 11. Procedure to obtain comprehensive permits.

The approved procedure to obtain CEP (including recent changes) is too long, cumbersome and difficult to follow in practice. It would take four to eight months (if one is required to re-apply) to obtain a CEP under the proposed procedure.

If the first CEP application (including amendments) is rejected, the facility remains without permits for four months (the consideration period for the second application), or the constructed facility's commissioning is postponed by the same term, which is fraught with financial losses and lost profits.

The procedure of CEP issuance by local Rosprirodnadzor departments, originally designed as a one-stop-shop process, actually involves several federal executive bodies and/or their local branches, such as the Ministry of Natural Resources, Ministry of Industry and Trade, Rospotrebnadzor, Rosvodresursy, Federal Agency for Fishery (FAF) or its local branch, and executive authorities of Russian constituent entities. FAF and Rospotrebnadzor apply own methods to rate the negative environmental impact from the viewpoint of people's health and fish protection, and own requirements for the composition of materials, which are different from the current RPN requirements. The above-mentioned six approvals that must be obtained as part of the CEP issuance procedure take too long and are excessive and overlapping, or impossible to complete.

For instance, the proposed CEP issuance procedure would give rise to a conflict between environmental and sanitary regulations that will affect natural resource users, who would not be able to obtain required environmental permits. We also note that the proposed amendment, which would require users to obtain approvals not only for maximum allowed emissions but also for discharges, is a new requirement to be added to the current law to impose additional obligations on businesses. Rospotrebnadzor departments do not have appropriate regulations. Therefore, obtaining approval from Rospotrebnadzor departments for CEP paperwork is an excessive requirement that business may not be able to meet in a number of instances.

Therefore, there is a clear duplication of approvals to be obtained from executive authorities as part of the CEP application process — executive authorities receive paperwork for approval from Rosprirodnadzor via the State Industry Information System — and approvals obtained by the user from the same authorities as part of the state environmental expert review procedure, which must be completed before submitting a CEP application to Rosprirodnadzor.

Proposal:

Remove subparagraph b) of paragraph 10 of the Rules for the Consideration of Applications for Comprehensive Environmental Permits, the Issuance, Re-issuance, Review and Revocation of Comprehensive Environmental Permits and Amendments to Permits, approved by Government Decree No. 143 of 13 February 2019, and make corresponding changes to Article 31.1.3 of the Federal Law "On Environmental Protection":

1. CEP applicants should obtain approval from the local Rospotrebnadzor department for the CEP package that includes the following documents:

a. The application form prepared based on established requirements;

b. Information on a state environmental expert review of design and engineering documents with details of the agency that performed it;

c. Approvals from the Ministry of Industry and Trade for technical specifications of facilities with a negative environmental impact, if these specifications were not part of the design and engineering package approved by the state expert commission.

2. The proposed CEP procedure can be completed, the period for obtaining approvals from local Rosprirodnadzor departments would be limited to 30 days by avoiding approval duplication involving various executive authorities.

Issue 12. 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

Federal Law No. 116-FZ of 5 May 2014, "On Amendments to Certain Legislative Acts of the Russian Federation" (hereinafter, "Law No. 116-FZ"), 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. Under Law No. 116-FZ 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 the federal law.

To close the loophole in the law, the Russian Ministry for Economic Development drafted two bills concerning the employment of workers temporarily assigned by an employer that is not a private employment agency, to other legal entities under staff leasing agreements (FZ "On an Amendment to Chapter 53.1 of the Labor Code of the Russian Federation Concerning the Regulation of the Labor of Employees Temporarily Assigned by Employers Under Staff Leasing Agreements" and FZ "On an Amendment 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 an Amendment to Chapter 53.1 of the Labor Code of the Russian Federation Concerning the Regulation of the Labor of Employees Temporarily Assigned by Employers Under Staff Leasing Agreements'"). This law has not yet been adopted, and the delay has created a range of risks for foreign investors operating in Russia.

At the same time, the Federation Council's Budget and Financial Markets Committee has been discussing amendments to current legislation to prohibit legal entities that are not private employment agencies, from using staff leasing agreements. The sooner adoption of the law governing employment under staff leasing agreements by legal entities that are not private employment agencies is essential for major Russian and foreign investors in the Russian economy who need to continue applying staff leasing agreements for doing business in Russia.

Recommendations:

Accelerate the adoption of the bills drafted by the Ministry for Economic Development and designed to govern the work of employees temporarily provided by an employer that is not a private employment agency to other legal entities under staff leasing agreements.

Issue 13. Foreign companies' access to government services: Problems that foreign companies encounter in obtaining permits because they lack a registration number in the Unified State Register of Legal Entities.

Foreign companies operating in Russia through properly registered branches have been struggling to obtain permits because of the lack of a registration number (OGRN) in the Unified State Register of Legal Entities.

Any public services are available only to individuals, including individual entrepreneurs, and legal entities registered in the Unified State Register of Legal Entities in accordance with Federal Law No. 129-FZ of 8 August 2001 "On the State Registration of Legal Entities and Individual Entrepreneurs." Foreign applicants are not eligible.

Under Federal Law No. 160-FZ of 9 July 1999, "On Foreign Investment in the Russian Federation" (Articles 2, 4, 21, 22) and Part I of the Russian Civil Code, foreign investors are entitled to do business in Russia through both the establishment of fully owned or co-owned entities or the accreditation of branches of foreign entities in Russia.

In response to multiple appeals to the Ministry for Economic Development, including from FIAC, the Ministry for Economic Development has made certain steps to address the licensing issue, resulting in the adoption of the federal law "On Amendments to the Federal Law 'On the Licensing of Certain Types of Activity'" that allows foreign legal entities to indicate their accreditation number (in the State Register of Accredited Branches and Representative Offices of Foreign Legal Entities (RAFP)) in applications for licenses instead of an OGRN.

However, this issue as it relates to other types of permits, not licensing, has not yet been resolved.

The issue requires an urgent solution in view of the planned transfer of the primary state electronic permit issuance function to federal executive authorities.

To apply for an electronic state service, an applicant must be registered in the federal Unified Identification and Authentication System (UIAS). However, foreign legal entities operating in Russia through their

accredited branches cannot register in the UIAS because they are not registered in the Unified State Register of Legal Entities (do not have an OGRN). Legislation does not allow applicants for state and municipal services to provide their accreditation number (in the State Register of Accredited Branches and Representative Offices of Foreign Legal Entities) as the legal entity's data identifier when registering in the UIAS.

The Ministry for Economic Development held a joint conference with the Ministry of Communications and the FTS on 20 May 2019 to resolve the issue. Officials at that conference recommended that the FTS and the Ministry of Communications consider making RAFP data applicable to the UIAS and

that the Ministry of Communications "upgrade the UIAS and make appropriate changes to the Regulation Concerning the Federal State Information System 'Unified Identification and Authentication System in the IT Infrastructure Supporting the Interoperability of Information Systems Used to Provide Electronic State and Municipal Services,' approved by Order No. 107 of the Russian Ministry of Communication of 13 April 2012, and to other bylaws to enable accredited branches and offices of foreign entities to file applications via the Unified Portal of State and Municipal Services (Functions)."

The Russian FTS has done its job already to make RAFP data applicable in the Unified System of Interdepartmental Electronic Communication. Under Government Resolution No. 2178 of 27 September 2019, RAFP data has been stored in the interdepartmental electronic communication system since 1 July 2020. But neither has the UIAS been upgraded, nor Oder No. 107 of the Ministry of Communication of 13 April 2012 has been amended.

After a meeting of the FIAC Executive Committee held in May 2021, the Ministry of Digital Development released a comment that it was technically impossible to modify the UIAS "at the moment" to enable the registration of branches of foreign companies with the UIAS. Work is under way to finalize regulations that would make such modification possible.

If the problem is not solved, foreign investors operating in Russia through their accredited branches will not be able to obtain a single permit or license. To obtain electronic permits, companies would have to spend hundreds of thousands of US dollars a year on engaging contractors registered in the UIAS.

Recommendations:

- Amend the Federal Law "On the Licensing of Certain Types of Activity" to allow foreign entities to enter a branch accreditation number instead of an OGRN in applications for licenses.
- Make corresponding changes to other laws and departmental acts governing the provision of state permit issuance services.
- Make it technically possible to use RAFP entries as an identifier in the UIAS.
- Amend the Regulation Concerning the Federal State Information System "Unified Identification and Authentication System in the IT Infrastructure Supporting the Interoperability of Information Systems Used to Provide Electronic State and Municipal Services," approved by Order No. 107 of the Russian Ministry of Communication of 13 April 2012 and other bylaws.

Subsoil use issues

Issue 1. 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 1.1. Mechanism of dividing, splitting off and combining subsoil sites.

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.

Combining is also of great importance for efficient subsurface site management, faster preparation of new sites for operation, complete geological reporting and for making subsoil use a more attractive business for investors. In particular, pooling subsoil sites is essential for accelerating the process of putting new tracts to use and consolidating mining companies’ mineral reserves. Some reservoirs can be divided into several parts and leased out under several licenses (one reservoir is located on several mineral sites). License holders take stock of reserves, plan development and subsequent movements in inventories separately, which takes additional time and resources. A mechanism for pooling subsoil sites owned by one and the same license holder would considerably reduce time needed to put such sites into operation.

Recommendations:

Conceptual proposals

1. Allow the use of all available options to divide and split off subsoil 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 listed 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/split off 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: "... 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 subtitle of the provision 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 provision: "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 1.2. 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 1.3. 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 1.4. Classification of fields of federal significance.

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

- Easy-to-find fields are running out;
- Production shifts 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”.

Issue 1.5. Improving auction procedures for subsoil use projects.

The Ministry of Natural Resources has submitted to the Russian Government draft Federal Law No. 288750-7, “On Amending the Law of the Russian Federation ‘On Subsoil Use’ and Declaring Void Individual Provisions of Legal Acts of the Russian Federation Clarifying the Issues of Subsoil Use and Use of Uniform Terminology.”

The bill proposes a number of important initiatives for subsoil users aimed at optimizing licensing procedures and reducing administrative barriers:

- Electronic auctions for subsoil use licenses (competitive procedures to award subsoil use licenses will be abolished);
- The only bidder at an auction may be awarded the subsoil use license if the previous auction was invalidated because only one bidder had submitted a bid;
- The second-highest bidder may be awarded the subsoil use license if the auction winner fails to pay the reminder of a one-time payment pledged for subsoil use;
- Creating a register of entities that fail to pay the reminder of a one-time payment pledged for subsoil use in order to prevent them from participating in subsequent auctions for subsoil licenses (a register of bad-faith auction participants);
- Obliging bidders to make a one-time payment for subsoil use before they receive the subsoil use license;
- Arranging bylaws concerning subsoil use licensing into a system.

Draft Federal Law No. 288750-7 provides that the only bidder at an auction may be awarded the subsoil use license if the previous auction was invalidated because no bids had been received or only one bidder had submitted a bid. The provision is to be introduced to make sure than an auction will not be invalidated if the auctioned subsoil site is of interest to only one entity for various reasons (difficult geological and geographic conditions for development, the lack of transport infrastructure, a long distance from markets and other conditions driving up costs).

Some companies that participate in auctions for subsoil use licenses on a regular basis and pledge small amounts of one-time payments, fail to pay the pledged amount after license issuance. By doing so, they seek to foil auctions for licenses to use subsoil sites and prevent good-faith entities interested in the legal development of subsoil sites from using the subsoil sites.

Recommendations:

Draft Federal Law No. 288750-7 and the Russian Government's amendments to it address the problem of bad-faith subsoil users' participation in auctions and reduce time that good-faith subsoil users spend on obtaining licenses for subsoil sites.

The above proposals have been discussed by experts for a long time and are a logical step to develop the legal framework for subsoil use.

In view of what has been said, the bill is recommended to be treated as a high priority, and should be considered and adopted as soon as possible to make auction procedures more transparent and subsoil use a more attractive area for investors.

Issue 2. Licensing exports of geological information.

The geological information licensing requirement was introduced in Russia by Government Decree No.540 of 23 August 1992 "On Measures to Regulate Exports of Geological Information on Subsoil" in absolutely different economic and technological circumstances. At the time, information was inseparable from the medium and could be viewed as goods (together with the medium). The provisions were "mechanically" included in regulations of the Eurasian Economic Union (EAEU) on its establishment.

However, based on an analysis of the term "information" as defined in Article 2 of Federal Law No. 149-FZ of 27 July 2006 "On Information, Information Technology and the Protection of Information," it clear that in accordance with effective legislation information is not regarded as goods. This is confirmed by the lack of a code for information in the Unified Goods Classifier for Foreign Economic Activities.

Nevertheless, regulations applicable to goods are still applied to information with foreign investors experiencing serious difficulties as a result.

The licensing of exports of geological information that is not a state secret makes it extremely difficult to implement joint exploration and development projects involving Russian companies in Russia. For information to be processed at foreign data processing centers, a company must obtain a license.

Foreign investors currently have trouble obtaining such licenses, often resulting in project delays, postponed investment decisions and the suspension of work for an extended period.

Government Decree No.540 of 23 August 1992 "On Measures to Regulate Exports of Geological Information on Subsoil" has been annulled as part of the "regulatory guillotine" mechanism, but that decree was not the only regulation concerning the matter. Information on subsurface fuel, energy and mineral reserves by district and deposit remains on the List of Goods Whose Import to, or Export from, the Customs Territory of the Eurasian Economic Community Requires Authorization (clause 2.23), approved by the Eurasian Economic Commission's Decision No. 30 of 21 April 2015.

Recommendations:

To lower administrative barriers, it is necessary to delete geological information from the List, leaving only samples of rock, ore, sludge, flora and fauna fossils, core, rock section, fluid and gases, and other material media of primary geological information. It is necessary to amend the title and text of clause 2.23 of the export regulation (Appendix No. 18 to the Eurasian Economic Commission's Decision No. 30 of 21 April 2015) to replace "Information on subsurface fuel, energy and mineral reserves by district and deposit" with "Samples of rock, ore, sludge, flora and fauna fossils, core, rock section, fluid and gases, and other material media of primary geological information."

The proposal should be submitted to the EAEU Board by a member of the Union, namely on behalf of Russia. Consequently, foreign investors ask the Russian Government to consider repealing the mandatory licensing requirement for geological information export, including with assistance from the Russian Ministry of Industry and Trade, and the Russian Ministry for Economic Development, and initiate the adoption of a decision to that effect by the Board of the Eurasian Economic Commission.