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1. ISSUES AND RECOMMENDATIONS OF FIAC WORKING GROUPS

Foreign Investment Advisory Council

1. Digital Economy and Innovative Technologies

TOPIC 1. Digital economy

(in the light of participation of FIAC member companies in the Digital Economy of the Russian Federation program approved by Directive of the Prime Minister of the Russian Federation No. 1632-r of 28 July 2017).

Issue 1.1. Implementation of Directive of the Prime Minister of the Russian Federation (cl. 12) on the List of Directives of the Prime Minister of the Russian Federation No. DM-P13-7063 of 23 October 2017 regarding the identification of mechanisms for cooperation between Autonomous Non-Governmental Organization – Analytical Center under the Government of the Russian Federation, Autonomous Non-Governmental Organization – Digital Economy, and foreign companies in the implementation of the Digital Economy of the Russian Federation program.

Following FIAC's Plenary Session, including the report of Jean-Pascal Tricoire, Chief Executive Officer of Schneider Electric, France, on the role of leading innovation companies in creating an ecosystem to promote the growth and development of digital economies across Europe and Asia, the Prime Minister directed the Ministry of Digital Development, Communications and Mass Media (the "Ministry of Communications") to draw up proposals on mechanisms for cooperation with foreign companies in implementing the Digital Economy of the Russian Federation program, as agreed with Digital Economy Autonomous Non-Governmental Organization (ANO Digital Economy) and the Analytical Center under the Government of the Russian Federation.

This issue was raised by the Schneider Electric SE CEO to identify the best way of cooperation and integration of the world's top technology companies into the Management System for the Digital Economy of the Russian Federation Program, newly established by Directive of the Government of the Russian Federation No. 1030 of 28 August 2017. FIAC member companies that expressed their strong interest in participating in the program to confirm it repeatedly in 2017-18 include ABB AG, Samsung, Schneider Electric SE and Siemens AG.

On 15 November 2017, the Ministry of Communications was requested in writing to make FIAC member companies part of the project management office (PMO) and task forces set up under the Digital Economy program. No reply has been received as of 20 August 2018.

As of 23 November 2107, the deadline set in the instruction, the Ministry communicated its official position to the Government of the Russian Federation:

"To ensure cooperation with foreign companies in implementing the Digital Economy of the Russian Federation Program (the "Program"), it is advisable to establish a single platform for sharing experiences between leading foreign and domestic companies with competencies in digital economy, and to engage professionals from the Foreign Investment Advisory Council (FIAC). The objective of the Council is to assist the Russian Federation in creating and developing an enabling environment for investment based on global best practice and the experience of multinational companies operating in the Russian Federation.

Further, to acquire and retain relevant competencies and increase the number of jobs in the Russian Federation, it is recommended to localize foreign technology and production in the Russian Federation and to involve foreign companies in the Program in accordance with the Russian Federation Government's Decree No. 719 of 17 July 2015, On the Criteria for Classifying Industrial Products as Having no Equivalents Produced in the Russian Federation.

In addition to the above, it is necessary to explore ways to develop a systematic approach to promoting domestic products and brands into international markets using best business practice and state aid mechanisms, primarily, for small and medium-sized businesses.

It is necessary to study the possibilities to localize the production of foreign high-tech products contributing to the development of digital economy in the territory of the Russian Federation. This can be achieved by

using various tools, including a framework of legal and economic mechanisms to reduce interest rates on loans for upgrading and/or developing new production capacities that create or use cross-cutting technologies in the real sectors of the Russian economy.

It is necessary to consider inviting foreign companies that create or adopt internationally competitive cross-cutting technologies to locate their production facilities in Russia on preferential terms, including tax credits.”

On 2 March 2018, a meeting was held with the Public Administration Department of the Ministry of Economic Development to get an update on their position and explore solutions for establishing acceptable mechanisms of cooperation with foreign companies in implementing the Program. No progress has been achieved as of 27 August 2018.

On 6 March 2018, FIAC sent a letter to Oleg V. Fomichev asking him to support the inclusion of Alexander V. Ivlev, Coordinator of FIAC’s foreign members, in the Program’s Project Management Office and the ANO Digital Economy task forces. The response was received on 23 August 2018 (Letter No. 329 addressed to Mr. Shipov).

Recommendations:

To enable efficient cooperation with foreign companies in implementing the Program, the Project Management Office and the ANO Digital Economy task forces should consider accumulating time-tested knowledge, solutions and FIAC member global best practices under FIAC to further transfer them to the Russian Government in the form of consultations and recommendations for the purpose of finding the best solutions supporting the performance of public administration functions.

As for day-to day communications, these should be organized at the level of the ANO Digital Economy task forces and joint centers of competence established in collaboration with the FIAC Working Group on Digital Economy and Emerging Technologies (as represented by ABB AG, Samsung, Schneider Electric SE and Siemens AG) and focused on priority areas of Russia’s Ministry of Communications, with the engagement of experts in all events and the possibility of official exchange of information.

In the light of the above and taking into consideration the proposal sent by ANO Digital Economy to the Ministry of Economic Development on 23 August 2018, as well as acting on the instructions of the Prime Minister of the Russian Federation to establish cooperation between FIAC and the Russian Government under the Digital Economy of the Russian Federation program, we recommend that the Ministry of Economic Development:

1. Support the proposal to include Alexander V. Ivlev, a coordinator on behalf of FIAC’s foreign stakeholders, as a permanent member of the ANO Digital Economy’s Task Force (formed on 31 January 2018) and the Center of Competence dealing with regulatory matters.

2. In response to the cooperation offer of 23 August 2018, ANO Digital Technology should approve the engagement of the FIAC Working Group on Digital Economy and Emerging Technologies (notably, representatives of ABB AG, Samsung, Schneider Electric SE and Siemens AG) in the work of special task forces of ANO Digital Economy’s Center of Competence dealing with the regulation of integration processes, building digital trust, Big Data, cyber physical systems, intellectual property, special regulatory regimes, standardization and labor law.

TOPIC 2. Implementation or support of cutting-edge solutions (primarily government information monitoring systems) including Big Data marking, collection, processing and deployment systems

Issue 2.1. Building a regulatory framework governing data processing by information system operators (ISO), including those holding the status of the Fiscal Data Operator (FDO), which collect, process and transfer data, as well as data commercialization and the liabilities of ISOs and FDOs for non-compliance.

1. Currently, Russian operators of information systems (Platon, Mercury, State Industry Information System, online terminals, etc.), including those holding the status of Fiscal Data Operators, collect and process vast amounts of data, including commercially confidential information, about manufacturers and service providers, including retailers. Being anonymous, Big Data has big potential for commercial applications and is of great interest to many companies that want to use it for market analysis and high-quality marketing research across industries. However, the lack of an adequate legal framework for data processing by entities that collect, process and transfer it, including operators, which are mostly private companies, administrators or system owners represented by competent supervisory authorities, for purposes other than the management of state information systems makes this process legally impossible and gives rise to high risk of data misuse.

Recommendations:

Russia's Ministry of Communications should set up a working group comprising FIAC members to put the issue on the agenda of the Digital Economy program and draw up proposals for creating a robust regulatory framework.

2. The situation is aggravated by the fact that data collection parameters are often inconsistent and chaotic, set by competent government agencies on a case-by-case basis depending on the statement of work or based on electronic traceability catalogs of retail chains, which gives rise to the proliferation and duplication of master data generation principles across companies and is expected to add difficulty to the aggregation of all data stored in a variety of information systems for the purposes of the Uniform National Marking and Traceability System.

Recommendations:

Russia's Ministry of Industry and Trade and Russia's Ministry of Finance should support the proposal for drawing up a Uniform National Catalog of Goods and appointing an operator in charge, and take into account FIAC's proposals when developing master data generation principles for the catalog for the purpose of harmonizing numerous catalogs in place for their subsequent integration into the Uniform National Marking and Traceability System.

General recommendation for both issues:

Direct ANO Digital Economy to include Alexander Ivlev, Coordinator of FIAC's foreign members, in the Program's Project Management Office to ensure participation in decision-making on delivering and developing digital economy.

Topic 3. Digital HR Document Management

Reducing the administrative burden on business by switching to digital HR document management, expanding the use of electronic digital signature and improving related state regulation.

Issue 3.1. Expanding the use of digital signature.

The Russian Government has implemented, and plans to implement, a number of measures to transition to digital HR document management. This move is applauded by businesses regardless of their size and industry.

In particular, the Russian Labor Code now operates the 'remote worker' concept (Article 312.1) and allows the use of an enhanced digital signature for exchanging electronic documents with the employer (applications, internal regulations, copies of documents, etc.).

At this point, however, transition to the electronic document management that involves all employees is not possible, as the use of digital signature is restricted to remote workers only. This makes it impossible to switch standalone divisions in different cities to a remote-work style, giving rise to considerable costs associated with document delivery and high risks that documents will be either lost en route or never sent back by an employee. When performing HR document management functions for their office-based staff, large companies have to create numerous paper documents, each of which must be physically signed and then safely stored. This affects business performance, as companies have to invest in maintaining obsolete paper-based processes.

Given that digital signature is now legally permitted for remote workers, it would be reasonable to extend it to all other employees, whether or not they work on a remote basis. While the initiative to expand the scope of digital signature is currently underway, it has certain limitations as to the use of electronic document management tools in HR processes.

Following inputs from the Human Capital and Productivity Task Force of the Expert Council on Business Climate Transformation under Russia's Ministry of Economic Development, a number of measures were included in the Council's Q1 2019 action plan to promote electronic HR document management. Some of them are listed below:

1. Extending the use of digital signature to all employees (not only remote workers), provided that the employee consents to electronic document management, for the following purposes:

- signing employment agreements, including any addenda thereto;
- documenting business travel, including the issuance of relevant orders;
- documenting vacation, including the issuance of relevant orders;

- procedures relating to employee acknowledgment of internal policies.
- 2. Introducing electronic employment record books
- 3. Introducing electronic T-2 cards.

Issue 3.2. Introducing electronic employee record books and T-2 cards.

In addition to the above, it also is essential to revamp the obsolete processes of documenting an employee's work history and length of service ('employment record book') and maintaining primary records on employment and payroll (T-2 card) by switching from hard copies to their electronic counterparts.

These documents are currently completed manually and must be stored in a secure location in compliance with high requirements for safekeeping, which leads to additional administrative burden on business. Note however, that unlike their electronic counterparts, paper documents can neither guarantee a high degree of data protection and safety, nor provide an acceptable speed of access to information or make it suitable for further processing.

Pursuant to the law on electronic employment record book, drafted by Russia's Ministry of Labor, transition to the new system is scheduled for 1 January 2020 and employers will be obliged to maintain both electronic and paper versions of the employment record book until 1 January 2027. Rather than reducing the burden on business, this law, if adopted, will effectively result in a double burden for many years to come, while the abolishment of T-2 cards is currently not on the agenda for various reasons.

Recommendations:

In view of the above, we ask the Ministry of Economic Development to support the efforts of the FIAC Working Group on Digital Economy and Emerging Technologies and give the following recommendations to concerned federal executive bodies (Russia's Ministry of Labor and Ministry of Communications):

1. Amend the Russian Tax Code to expand the scope of electronic document management and digital signature to all employees (regardless of the remote nature of work) as well as to all types of primary personnel and payroll accounting documents, including, but not limited to:

- signing employment agreements, including any addenda thereto;
- documenting business travel, including the issuance of relevant orders;
- documenting vacation, including the issuance of relevant orders;
- procedures relating to employee acknowledgment of internal policies.

2. Adopt a Federal Law determining the type of digital signature to be used for the purposes of HR record management.

3. Reduce the transition period for maintaining both paper and electronic versions of the employment record book to three (3) years.

4. Abolish the requirement for maintaining T-2 cards alongside the adoption of electronic employment record book. Incorporate critical sections of T-2 card, such as military registration status, in the electronic employment record book, and switch to the electronic exchange of this data between employers and relevant ministries and government agencies.

TOPIC 4. Creating conditions for the development of engineering competencies and innovation centers (including research and engineering centers and centers for technology transfer and enablement)

Issue 4.1. Need for building and rolling out a model of education consortia between Russia's leading universities to develop engineering competencies for the technology sector.

Today, we face a shortage of qualified engineers, especially those with world-class cutting-edge expertise and foreign language knowledge. This can adversely affect the investment attractiveness of projects involving modern production, engineering and research.

Any attempts to drive the innovative development of the Russian regions against the backdrop of digital economy trends that have increasingly pronounced effects, a shift in the technological and economic paradigm and the need to integrate into the local, national and global competitive environment are challenged by the center-focused geographical footprint of the higher education system. Only a limited number of leading Russian universities, located in the cities of Moscow and St. Petersburg and the Tomsk and Moscow regions, supply highly skilled specialists for the technology sector. At the same time, the science and technology capabilities of regional economies remain poor, as local universities are slow to

progress and improve education quality for students studying competencies that are in high demand on the labor market.

With scarce local capabilities to provide an adequate supply of talent, any attempts to build and grow high-tech industries (including engineering), markets and production facilities in the Russian regions remain hampered by the following:

poor quality of education due to the shortage of qualified academic staff with requisite competencies that meet modern requirements, including world-class expertise in certain disciplines and training areas;

a very limited number of government-sponsored student places in required technical disciplines; there is a need to significantly increase the number of government-sponsored student places in selected regions to empower competency centers for certain industries;

a small number of academic staff taken on secondment from other universities: local universities only occasionally resort to 'expensive' highly skilled resources from Moscow, St. Petersburg and the Tomsk and Moscow regions; special professional and financial incentives could spread the practice, but more needs to be done to address talent shortages across regions.

Unfortunately, the efforts of the Ministry of Education and Science over the past decade to support regional universities through increased public funding and various mechanisms, such as competitive bidding and other target measures, have not come to fruition. Russia's top universities continue to move up quickly in national, international and global rankings, while regional universities remain low in the league tables, with one of the reasons being the absence of required modern competencies, equipment and resources. Regional universities can no longer develop in isolation without close collaboration with top Russian and global competence centers and rely only on increased funding from public sources.

Given a widening gap between Russia's leading universities and their regional peers, which are gradually pushed to the periphery, there is a need to establish a legal framework shaping the forms of inter-university collaboration and joint initiatives supported by the government. This spans almost all areas of the university's performance, from education quality, research outcomes and internalization to academic productivity and teaching quality.

The most acceptable approach would be to establish and develop multi-university education consortia between Russia's leading universities and their regional peers, which will tap into the expertise of foreign universities and work closely with global competence centers.

Multi-university education consortia, which can be organized as an association, partnership, etc., are designed to serve as a collaborative platform for training highly skilled [ICT and engineering] workforce by drawing on new education programs and techniques and creating conditions to build and expand professional networks to empower intellectual capabilities.

Education consortia, focused on promoting various forms of collaboration, will have the following key objectives:

Establish and implement higher education programs (including network-based curricula) aimed at training highly skilled ICT and engineering workforce

Develop new education techniques and create a conducive environment to build and expand professional networks empowering academic staff both intellectually and professionally

Facilitate the use of resources for developing ICT and engineering education programs, including international programs and projects

Team up with domestic and foreign partners and international institutions in developing ICT and engineering education programs

These education consortia, acting on their goals and objectives, will contribute to creating conditions for training highly skilled professionals at regional universities on a par with leading domestic and international universities in terms of competencies and academic excellence. This is an essential prerequisite for creating world-class technology clusters in selected regions on the basis of local technology and engineering centers.

Note, however, that the existing administrative and regulatory environment, coupled with the current system of public funding of higher education, are not conducive to the establishment and development of multi-university consortia. Since this practice is not present in Russia, the legal framework currently in place does not outline or commit any financing mechanisms to support such associations. These mechanisms could include grants of the Ministry of Education and Science awarded on a competitive basis to, for instance, the leading university of the consortium, but it is not clear in this case how such funds should be distributed among participating universities. There is neither clarity around post-grant financing sources for education programs. Thus, a decision is needed to determine a financing framework for education consortia.

Key impediments to inter-university collaboration in the form of consortium include the following:

No mechanisms have been legally established to finance education consortia that will run education programs.

No steps have been taken to promote multi-university consortia and make them attractive to leading local players (primarily) and their foreign counterparts.

It is necessary to design mechanisms allowing various stakeholders to participate in supporting multi-university consortia (R&D, internship and apprenticeship programs, collaboration in graduation projects, equipment supplies, etc.).

Recommendations:

1. The Ministry of Education and Science, Ministry of Economic Development, Ministry of Industry and Trade, Ministry of Digital Development, Communications and Mass Media of the Russian Federation, in cooperation with the business community (industrial product manufacturers – FIAC members), should consider creating multi-university education consortia and determine their location in order to build world-class technology clusters.

2. The Ministry of Finance should develop a set of measures to promote the establishment of multi-university education consortia.

3. The Ministry of Finance should consider improving relevant tax regulations and providing tax incentives to companies which contribute to the educational system, including those that organize teaching courses, supply laboratory equipment, run R&D projects, etc. (an example is to allow deducting the cost of equipment from the income tax base).

4. In the course of implementing innovative development programs, FIAC member companies should continue with their efforts to share expertise, provide competent advice and collaborate with Russian scientific and research institutes as well as higher education establishments. Leading universities should cooperate with industry players to arrange science and technology competitions in these players' innovation areas and award grants to winners for the development of technological solutions.

5. Further efforts are needed, including from the Ministry of Education and Science of the Russian Federation, to improve recommendations on teaching interdisciplinary skills. The priority here is to further develop centers of excellence and competence centers of science and technology, and enhance the potential for implementing complex science and technology projects requiring input from various stakeholders as well as interdisciplinary and intersectoral collaboration.

Note on issue 4.1:

Further elaboration of the proposed initiatives may be critical to make interactions more efficient and improve cooperation between FIAC member companies and higher education institutions in driving innovation development.

FIAC's Innovation Development Working Group (ID WG) contributed to the measures taken to improve the system of managing talent for high-tech and knowledge-intensive industries, for example, helped to organize the National Championship for Cross-Industry High-Tech Professional Employees under the WorldSkills method (together with the WorldSkills Russia Agency for the Development of Professional Communities and Workforce).

The ID WG undertook substantial efforts to provide advisory and expert support and boost cooperation of FIAC member companies with Russian scientific institutions and higher education establishments, including the participation in events hosted by the Higher School of Economics, collaboration with the Far Eastern Federal University under innovative development programs. FIAC experts visited leading technical universities, technoparks and innovation hubs in a number of regions, such as the Tomsk, Ulyanovsk, Krasnodar and Kaliningrad regions.

FIAC members also established ongoing relationships with Immanuel Kant Baltic Federal University, Kaliningrad, one of the fastest-growing Russian universities and participant in the 5-100 Project, aimed at improving the competitive position of Russian universities among the world's leading research and education centers (Decree No. 211 of the Russian Government of 16 March 2013).

TOPIC 5. Accelerated and simplified implementation of advanced technologies, products, components and ingredients

Issue 5.1 Development and implementation of special statuses of a “Russian innovative enterprise” and “Russian innovative product”, criteria to grant them, and the related benefits. Outdated regulations and lack of the mechanism for their timely amendment as an impediment to the implementation of the Strategy of Russia’s Research and Technology Development.

The old regulations contradict the logic of the fast implementation of digital solutions, prevent the introduction of new digital products and technologies, for such products can be replaced within a few months. There is economic rationale for certifying mass-market digital devices, whereas certification of unique engineering products that can be used for commercial purposes is often economically unjustified. In such circumstances, the choice of digital solutions existing in the Russian market is limited, and delays arise in the supply and implementation, where implementation is necessary.

Despite the technical regulation reform, outdated or excessively strict norms balancing on the brink of total control are still in effect. They are not in line with modern approaches to safety protection and represent a serious obstacle on the path to innovation.

For example, CU Technical Regulation No. 021/2011, On Food Safety, sets identical requirements for both finished food products and food ingredients not intended for consumption. The norm is excessively tough; as a result, it seriously restricts deep wheat processing and makes such production methods less attractive. It should be noted that no other countries but the Russian Federation and EurAsEc member states apply such restrictions. We believe that excessive administrative regulations may significantly impair the implementation of the Strategy for the Development of Russia’s Food and Processing Industry for the Period up to 2020 insofar as it relates to increasing the share of premium protein products in the course of processing grain amylaceous materials. A significant point here is that the existing procedure for amending technical regulations is extremely bureaucratized and virtually precludes prompt response to innovations, which will only widen the technological gap in the long run.

In addition, there is no mechanism to assess and enforce changes in industry regulations that would allow access to modern technologies and their smooth implementation, which stands in the way of technology advancement. The new technological paradigm is largely dependent on cross-border disruptive innovations. However, the impact that such disruptive forward-looking innovations might have on GDP and government spending is far less significant than the potential effect of implementing technologies that are successfully used and proved effective in countries other than Russia. This is in reference to the most profitable type of innovations for which the fundamental and applied research works have already finished, the technology has been successfully tested in standard operating conditions, and its significant economic efficiency has been proved. Our country has already embarked on this course. The recently approved mechanism for determining best available technologies (BAT), customized for industry specifics, has already formed a basis for more efficient and viable control, as well as for the prevention of any adverse environmental effects.

For example, the technologies of cement concrete road construction and soil stabilization with road binders are hardly used in the Russian road construction sector. That said, cement concrete roads are by no means preferable, as they are cheaper to construct and require less maintenance throughout the entire service life (29 years). Their cost is comparable to that of asphalt roads, with operating costs twice as low. There is a range of other advantages, including, but not limited to, enhanced transport safety, potential for reducing lighting costs, lower fuel consumption.

The modern technological paradigm is surely promising in terms of boosting the Russian GDP and cutting state budget costs merely by ensuring the creation of a favorable regulatory framework, which would support the implementation of economically justified technologies and products that proved efficient in other countries and the simplification of procedures to introduce new products to the Russian market.

Recommendations:

1. Review the relevant technical regulations and standards of the Customs Union in order to identify excessive requirements that hinder the implementation of new products
2. Consider the possibility of access to the global component database that would help to introduce best available technologies at reasonable cost and create a competitive domestic product.
3. Analyze the balance between the required degree of localization, cost and potential to use innovative solutions for small-scale products.
4. Pursue a consistent policy of stimulating the localization of high-tech industrial products (including small-scale products) in Russia focusing on stable and reasonable production costs of finished products.

Issue 5.2. Participation of FIAC members in the activities of the National Technological Initiative markets (NTI Markets) working groups (EnergyNet, HealthNet, AutoNet and others).

Innovation advancement is designated as one of the priorities of Russia's long-term development. Its priority status was underlined in the Presidential Address to the Russian Federal Assembly of 1 December 2016 and in the Strategy of Russia's Research and Technology Development, whereas certain tasks aimed at stimulating innovation advancement are already being addressed under the National Technological Initiative (NTI), which is targeted at delivering sustainable solutions for identifying key technologies in the key global development areas.

FIAC member companies have a wealth of scientific, technological and engineering experience. They are world leaders in their segments and could use their research and technical expertise to determine how competitive the proposed technological solutions are in the global context and to resolve other related matters. FIAC member companies have their own research, innovation and technology centers in Russia that work with Russian partners. The competences of FIAC member companies could help to perform a comprehensive comparative analysis of proposed solutions in order to draw a clear picture of the existing industrial markets and global research programs, to compare Russia's strategies and those pursued by the industry leaders (including in the related sectors), thus enabling to determine areas for investments and to develop those industries in the new technological paradigm.

Technical experts of FIAC member companies were engaged in the work of the existing advisory councils on innovation development, including the National Technological Initiative (NTI). FIAC's Innovation Development Working Group (ID WG), being part of the team of experts helping to design and implement road maps (under the open government doctrine), has been actively discussing, evaluating and making recommendations on NTI plans.

Members of the ID WG were actively engaged in the work of the Strategic Council for Investment in New Industries chaired by Denis Manturov, the Russian Minister of Industry and Trade.

The ID WG also contributed to the Development of Innovation Clusters – Top Global Investment Destinations, a priority project implemented by the Russian Ministry of Economic Development, and helped to assess draft applications from regional innovative clusters wishing to participate in the project.

The ID WG was extensively involved in the preparation of an amended version of the long-term Strategy of Russia's Innovative Development, presenting its proposals to amend the Strategy. The ID WG experts were directly engaged in the activities of a number of focus groups designated to prepare and elaborate the Building High-Tech Industries and the Target Future of Russia: Research and Technology Aspects, forecasts of Russia's research and technology development. The ID WG participated in discussions with key experts (Skoltech, Higher School of Economics) to find out their views on prospects of implementing innovations in the cutting-edge production technologies sphere. Experts of FIAC technological companies also helped to conduct foresight studies (Research and Technology Foresight, Higher School of Economics).

FIAC members have a lot more to offer in terms of NTI development, as many decisions are currently made without regard to international best practice. Considering the proliferation of technologies which are claimed to be innovative, there is a risk that technologies that have already been proved, tested and used in other countries will be positioned as novel in Russia, since they are not yet present on the domestic market and are therefore unknown either to Russian regulators or the research community. In the absence of appropriate benchmarks, this may lead to unnecessary efforts to redesign technologies that a priori lack innovation potential, or, even worse, funds will be spent to deliver technologies unknown to the Russian market, but already rejected by global leaders at the testing stage.

Recommendations:

Based on the above, we recommend that the Ministry of Economic Development:

1. Consider more extensive and active participation of FIAC experts in the activities of the National Technological Initiative (NTI), integration into the Inter-departmental Working Group on the Development and Implementation of the NTI, as well as the coordination of its participation in the development of a framework for the NTI's cooperation with foreign partners.

2. Assess the potential for FIAC experts to be fully engaged in the activities of designated task forces and competent bodies under the Russian Government, for example, those of the Working Group on the Promotion of Green Transport and Related Infrastructure headed by Maxim Akimov, Deputy Prime Minister of the Russian Federation.

Issue 5.3. Necessity to promote construction of cement concrete road surfaces and bases using innovative technologies in order to improve useful lives of road dressings and cut down on repair and maintenance expenses during the life cycle of roads.

One of the key tasks set in the May decree of the Russian President is the development of safe high-quality roads using new technologies and materials, and conclusion of life-cycle contracts. The improvement of useful lives of road dressings and surfacing in the face of larger traffic loads and their effects is a primary concern for the road industry. According to Government Decree No. 658 of 30 May 2017, mandatory road overhaul periods must be extended to 24 years for major repairs and 12 years for regular repairs.

The task is multifaceted; however, progress has been made in one area only, which is the improvement of the quality of asphalt concrete surfacing. Measures have been taken to enhance the quality of road bitumen (using polymer-bitumen binders), thicken constructive layers, amend filler requirements, and improve quality control methods. International experience has shown that it is impossible to improve useful lives of road dressings and surfaces and reduce operation costs without a full-scale implementation of modern technologies to pave rigid bases of road dressings with concrete and cement concrete surfaces.

Russia built a number of highways with cement concrete surfacing in the 1970s, including the Moscow-Volgograd, Omsk-Novosibirsk, Yekaterinburg-Chelyabinsk, Yekaterinburg-Serov, Moscow Ring Road-Serpukhov-Tula, Moscow Ring Road-Kashira highways, a highway bypassing Kolomna, etc. The total length of concrete roads exceeded 10,000 km.

Starting in 1980, the construction of roads with cement concrete surfaces slowed almost to a standstill. There was a sharp drop in the number of roads designed to be built with cement concrete surfacing. Research works were put on hold, with regulatory documents unchanged for over 30 years. Production of machines and mechanisms for placing and consolidating cement concrete mixtures was suspended. A slump in domestic production of concrete surfaces has forced major specialist contractors to wind down their operations. This created a misleading stereotype that cement concrete roads are far more expensive to build than asphalt concrete roads and that they cannot be constructed to the required standard or repaired properly due to the absence of requisite technologies.

As a result, 99% of roads in Russia have asphalt concrete surfacing, as opposed to Europe and the US where cement concrete highways account for 13–50% and 60% of total road network, respectively. The People's Republic of China has been focused on constructing cement concrete roads (at least 50% of all highways), as well as Japan and Australia. Kazakhstan and Belarus have accumulated particularly extensive experience in building roads with cement concrete surfacing.

A halt in cement concrete surfacing production was caused by a number of factors, including low construction quality, loose technical controls, lack of high-quality concretes (with no state standards for road cement, for instance), using concrete of low quality classes, lack of effective plastifying and air-entraining concrete agents and sealant materials for expansion joints.

Modern global practices rely on the use of new technologies designed and implemented to produce cement concrete surfacing, which involve full-scale mechanization and automation of key processes for placing and consolidating concrete mixtures, concrete surface finishing, concrete curing and expansion joints installment. One-pass slip-form paving machines perform the whole range of road paving works. Contractors have bridged the deficit in high-quality cements using a new generation of extra strong and durable concretes, which have proved to be easily maintainable.

Economic estimates and international practice suggest that the cost to build road dressings with cement concrete surfacing is almost comparable to that of dressings with asphalt concrete layers. The useful lives of cement concrete roads, however, are twice as long, with maintenance costs substantially lower. Taking into account the entire life-cycle costs, cement concrete surfacing is 40-50% cheaper than asphalt concrete pavements. One of the ways to significantly reduce costs when constructing and renovating roads is to use local road building materials stabilized with hydraulic binders. Given the emphasis on enhancing road safety, it should also be noted that cement concrete surfaces are characterized by higher coefficients of friction. Hence, the braking distance on such surfaces under certain conditions is shorter. In addition, such surfaces reflect more light and make concrete roads nearly 30% lighter than other roads, given the same source of light. Plus, harder surfacing allows cutting down on fuel and, therefore, mitigating the environmental impact.

It is worth emphasizing that the importance of building roads with cement concrete surfacing was underlined in the Strategy for the Development of the Construction Materials Industry till 2020 and Further to 2030 adopted by Order No. 868-r of the Russian Government of 10 May 2016. Pursuant to the Strategy, the share of commissioned roads with cement concrete surfacing in the total number of roads built in Russia is set to rise gradually. The Strategy implementation plan approved by Order No. 630 of the Russian Government of 6 April 2017 included provisions on the delivery of pilot projects for the construction of cement concrete surface roads in a number of climatic zones of the Russian Federation, including with the help of composite

building materials, in order to assess the potential for their wider usage in the future. So far, though, those provisions have been neglected.

We believe it important to revise the approaches to road construction and start applying efficient advanced technologies involving the use of cement concrete. Decisions concerning the choice of road surfacing should only be based on the results of economic calculations.

Recommendations:

1. The Ministry of Transport of the Russian Federation should design a set of measures to promote wider use of rigid bases of road dressings and cement concrete surfaces in the process of road construction and renovation. Steps should be taken to oversee compliance with the provisions of Order No. 868-r of the Russian Government of 10 May 2016 and Order No. 630 of the Russian Government of 6 April 2017 concerning the construction of cement concrete road surfaces.

2. The Ministry of Transport of the Russian Federation should design and submit the draft government decree on construction of cement concrete road surfaces to the Government of the Russian Federation. Measures should be planned to increase the share of roads with cement concrete surfacing, which should amount to 40% of the total number of newly built roads by 2024.

3. The Ministry of Transport of the Russian Federation, the Federal Road Agency and the Russian Highways State Company (Avtodor) should design a set of documents and technical regulations to ensure high-quality construction of rigid bases of road dressings and cement concrete road surfacing. The Book of Typical for rigid road dressings should be drawn up.

4. The Ministry of Transport of the Russian Federation should draft an order on making mandatory economic comparisons of rigid and flexible road dressing structures as part of road designing.

2. Localization and Regional Development

Issue 1. Availability of equipment for enterprises in the food and food-processing industry.

The Russian Ministry of Industry and Trade is preparing a draft Strategy for Machine Production for the Food and Food-Processing Industry to 2030 (hereinafter, the “Draft Strategy”).

The Draft Strategy sets ambitious goals for increasing the share of Russian-built equipment for food enterprises on the domestic market, including a threefold increase in sales of domestic equipment for the Russian food and food-processing industry by 2030 (as compared with 2016). By 2030, the share of Russian companies on the domestic market is expected to reach 62%, and exports are to grow even more dramatically – to 3.7 times the level of 2016.

The Draft Strategy includes both incentives (subsidies for R&D and the production of equipment prototypes, partial reimbursement of costs for producing pilot batches, etc.) as well as disincentives. As an example of the latter, import duties are to be raised for foreign-produced equipment (Step 12 in the Draft Strategy Implementation Plan).

Such a step is of serious concern to business and is ill-advised for a number of reasons, including some set forth in the Draft Strategy itself:

- The production of equipment for the food industry is not a core business for many Russian manufacturers, which are thus not as ready or able to meet the needs of consumers (enterprises in the food industry) as are foreign companies that specialize in producing such equipment;
- The market of food industry equipment has been in flux for several decades; training, manufacturing processes and services have been refined and adapted for work with foreign manufacturers, and long-term contracts have been signed. All this means that foreign equipment cannot be rapidly replaced with foreign equivalents;
- The use of foreign equipment makes it easier to draw on foreign experience and shortens the time required to launch new products, which is an important factor for the development of the consumer market;
- The share of imported equipment is high (up to 99% in some sectors). Niches where domestic manufacturers can do the job (e.g. the production of food containers) have already been filled by Russian suppliers. The necessary conditions for rapidly increasing the share of Russian equipment are thus lacking;
- On a global scale, food production is growing steadily and is highly competitive. In this situation it is important for the industry to be more competitive (to lower production costs in Russia) and not to hinder its development.

In view of these trends, higher import duties will serve to increase government revenues, but also raise food manufacturers' costs, thus running counter to the purposes of the Draft Strategy. We can see evidence of this in the fact that ruble devaluation has not resulted in foreign equipment being replaced by Russian equivalents.

Discussions at a variety of industry forums have made it clear that a wide range of sectors are unprepared for higher duties: manufacturers of confectionery goods, soft drinks, meat products, bread, milk, etc.

It should be noted that proposals to raise import duties may proceed while the Strategy is still going through the approval process, and efforts along these lines must therefore be proactive.

Recommendations:

The Working Group recommends that the Ministry of Industry and Trade:

- consider the opinion of the Ministry of Agriculture and industry associations in putting the Draft Strategy into practice;
- take measures to promote success in those niches where Russian-made machines are in demand, including a plan to support expansion into foreign markets;
- in collaboration with industry experts, set priorities for developing machine production for the food and food-processing industries and prepare a realistic road map of measures to be taken in this direction.

Issue 2. Excessive requirements for the localization of production in Russia.

In recent years, Russia has set its sights on localization and import substitution. In the area of manufacturing, this policy is regulated by Decree No. 719 of the Russian Government of 17 July 2015 “On

the Verification of the Manufacture of Products in the Russian Federation,” where manufacturing processes that must be carried out in Russia are listed for the following industries:

- machine tools
- automobiles
- special machine engineering
- photonics and lighting technology
- power engineering
- heavy engineering
- medical products and pharmaceuticals
- radioelectronic equipment
- construction materials
- furniture and wood-processing
- railway engineering
- fittings
- chemicals used for the extraction of commercial minerals
- equipment for the preparation, storage and processing of hydrocarbons
- compressor and refrigeration equipment
- light industry
- shipbuilding
- pump equipment
- drilling rigs
- equipment for the food industry
- paints and varnishes
- measuring devices

This document is still very much a work in progress and has been updated 13 times since the middle of 2015, mainly to add to the list of industries affected and tougher localization requirements.

Based on our own experience (automobiles and special machine engineering), we can say that some of the requirements are clearly excessive and fail to take into account:

1. The size of the Russian market by segment and the corresponding volumes of production (a differentiated approach must be taken to the regulation of car and truck manufacturing, for example, because of the radically different business models involved).

An example is the requirement that engines be produced in Russia. With annual sales of a few hundred vehicles, it does not make economic sense to localize engine production (which is justified when yearly production runs to tens of thousands of engines) or to adapt vehicles to domestic engines (which, in addition to technical and logistical difficulties, will inevitably result in reputation losses). Failure to comply with the requirements of Decree No. 719 effectively puts Russian-made and imported equipment on the same level, making local production ineffective and giving an advantage to direct importers. Thus measures designed to strengthen Russia’s “technological sovereignty” in fact clear out the market for Russian manufacturers, eliminating competition and perpetuating Russia’s technological lag in this industry.

2. Russia already has excess production capacity in a number of areas – for example, the Kamaz-910 (R6) and YMZ-770 projects for domestic production of 11-13 liter engines (380-540 hp).

3. Global technology trends (scaling back investments in traditional technologies to focus on breakthrough technologies – for example, electrical, connected and autonomous vehicles in the auto industry). Government Decree No. 719 essentially requires that 20th-century technology be localized in Russia in order for a product to be classified as domestic-made.

Another questionable requirement is that a Russian legal entity have intellectual property rights to a number of high-tech components – for example, to software for electronic control units and telematic systems. 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 unlikely that separate versions of such software will be developed for the Russian market or that intellectual property rights will be transferred 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.

These issues are regularly raised by the management of Volvo Group Russia in meetings with the heads of government executive bodies, including Deputy Prime Minister Dmitry Kozak and Minister of Industry and Trade Denis Manturov.

Recommendations:

There are two constructive options (which may also be used in combination) for resolving this situation:

1. Promote the localization of innovative products by supporting traditional products. Our industry (automobiles and special machine engineering) will be revolutionized in the next 5-10 years by the transition from internal combustion engines to electric drive and by automated control. In our opinion, Russia would benefit from not requiring further localization of traditional products whose days are numbered, but rather promoting the localization of innovative products. On the other hand, the percentage of innovative products sold during these 5-10 years will be quite low, traditional products will be the core of business, and substantial investments will be required in order to develop the market and create a stable demand for new technology. We thus think it would be best for traditional products to be regarded as Russian even if they don't fully meet localization criteria, provided that the manufacturer undertakes to localize the innovative products destined to replace them.

2. Graduated levels of localization requirements, depending on volume of output. Economies of scale play an important part in reducing costs, i.e. per-unit production costs rise or fall markedly when certain output thresholds are crossed. It thus becomes cost-effective to localize certain components only when specific volumes of production are reached. It seems unfair, then, to set the same localization requirements for companies whose production capacity and potential markets in Russia may differ dramatically in size.

Issue 3. Support for Russian producers and processors of agricultural products needed by leading food manufacturers. Increasing the export potential of Russian agricultural products.

Foreign companies are ready to increase the involvement of Russian producers in their procurement system, thus improving their level of localization, lowering costs and making their output more competitive on the market. The food industry in particular offers strong potential for the development of primary agro-processing. This involves such products as dried vegetables (cut up), dried vegetables/herbs, powdered milk, milk fat, dry whey, raw materials for juice products (apple puree and apple juice concentrate), malt and other products.

Cooperation with Russian suppliers may, however, be hindered by certain problems. One of the key issues is lack of international certification or only formal compliance with the requirements.

In 2017, in furtherance of the proposals of the Foreign Investment Advisory Council (FIAC) localization working group, a training project was implemented for Russian food raw material and product manufacturers.

The purpose of the pilot project was to share best practice with entrepreneurial groups seeking to develop their business, including, in particular, working with international corporations. The training took the form of two-day workshops on GFSI (Global Food Safety Initiative) certification. A GFSI certificate will be an advantage, or, sometimes, even a requirement that international corporations impose on prospective suppliers. The project was implemented in 5 regions: Voronezh and Lipetsk regions, the Republic of Tatarstan, Krasnodar and Stavropol regions.

The pilot project itself was delivered in October-December 2017, but was preceded by preparatory work started in June 2017, including a workshop on 13 September 2017 where the supplier development issue was discussed by a wide range of stakeholders, including the Ministry of Economic Development, regional SME support agencies, SME Corporation, FIAC member companies and their Russian suppliers, training providers, certification auditors, etc.

In 2018, in order to involve a wider range of entrepreneurs across the country, the Ministry for Economic Development proposed another scheme for implementing the project: training courses to be made freely available on the Business Environment portal. As of today, the Control Union company has confirmed that it would participate in the pilot program.

Working group members have been offered the opportunity to take part in determining the course topics, which will not be limited to GFSI or the food industry.

Issue 4. Enhancement of state measures to support the processing of goods for domestic consumption (jointly with FIAC's Working Group for Improvement of Customs Law).

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 EEU 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 the rates for raw and other materials exceeding those for the 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 EEU 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 (Article 264 of the Customs Code of the Customs Union). 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. Even so, Chapter 36 of the Customs Code of the Customs Union sets clear, unambiguous and exhaustive requirements for foreign trade operators to ensure proper use of the procedures 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 EEU 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 36 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 that prevent 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 following should be noted in connection with the identification of foreign goods in processed products. Under Article 242 of the Customs Code of the Customs Union, 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 indicated in 1)-4) are unacceptable because the raw materials used: 1) do not or cannot have definite identifiers (chemical raw materials, food raw materials, small components and spare parts). 2) disappear during manufacture (evaporation, chemical transformation). 3) are difficult to isolate and identify due to the specifics of the final product (food products, sophisticated equipment). Under Article 265 of the Customs Code of the Customs Union, 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 Russia, the list is established by Article 265 of Federal Law No. 311-FZ of 27 November 2010 "On Customs Regulation in the Russian Federation" and by Decree No. 565 of the Russian Government of 12 July 2011 (the "Decree"). The list is limited to about 50 goods that are clearly intended for specific production efforts. As a result, the procedure of processing for domestic consumption is not used in practice, and this holds back the development potential of domestic high-tech production with high added value as well as new investment in such production. It is important to note that the customs procedure 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 for goods 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 Russian Ministry of Finance should revise the draft Federal Law "On Customs Regulation" to allow the use of the FIFO method, whereby foreign goods in processed products are identified on the assumption that foreign goods imported earlier are processed first, unless the declarer proves otherwise.

3. The Russian Ministry of Finance should draft a legal act setting requirements for the corporate accounting systems of entities applying customs processing procedures and for reports aligned with accounting (tax) or internal accounting systems that serve as evidence of using foreign goods to manufacture certain amounts of processed products during a certain period.

4. The Russian Federal Customs Service, in cooperation with concerned federal executive bodies, should set methodological guidelines with detailed instructions for customs officials, tailored for the accounting policies of companies operating in different industries.

Issue 4.1 Increasing localization and boosting exports of Russian baby foods (jointly with the Working Group for Improvement of Customs Law).

The adopted Food Security Doctrine involves a long-term program for replacing a long list of foreign-made food products with products made in Russia. In recent years, import substitution as it affects finished food products has become an important issue and a priority for Russian economic development.

Clearly, the stage of sustainable production of agricultural raw materials and primary processed products must be reached before products with high added value are localized. A key role in this process is played by state programs of support for agribusiness in the form of soft loans, subsidies, etc. In addition to direct financial instruments, other state support measures may serve to stimulate localization and exports in a number of industries.

One promising area for the localization of production in Russia is the baby food market. Efforts have recently been made to create conditions for more thoroughgoing localization of adapted and partially adapted baby formulas and beverages. Some 80% of baby formulas and breast-milk substitutes are currently imported from the EU and the US, and only around 5% are made from processed raw milk originating in the EEU. The problem is that the raw material base is insufficiently developed. Raw materials meeting strict quality requirements as well as microbiological and toxicological safety requirements are used for these products – the so-called milk base. Some sixty percent of children in Russia up to one year of age need products in this category, but the main factor hindering their localization is the severe shortage of raw materials of the required level of quality and safety.

Baby food manufacturers have nevertheless begun major projects to localize the production of both finished baby food and the raw materials used to produce it.

In early summer of 2018, for example, it was announced that a plant would be launched to produce a range of Pharmalact baby foods in Noginsk, and Nestle began construction of a baby formula plant. Another initiative – a joint project of Danone Nutricia and Meleuz Milk Canning Plant – will ensure annual production of 12,000 tons of milk base, so that in 2020, 78% (and eventually 100%) of the company's products sold in Russia will be made from Russian raw materials.

These projects should supply 70% of the market of finished baby formulas with locally made products and the raw materials used to make them, create an additional market for Russian agricultural products (dried milk), and lay the groundwork for increasing exports of Russian-made baby food. This task – to enhance

the investment appeal of baby food manufacturing projects – is currently being worked on by the Ministry of Agriculture.

At the same time, investors' efforts to localize production are hindered by an imbalance between the rates of import duties for finished products and the raw materials used to make them – something that has been repeatedly noted by member companies of FIAC's working groups for localization and customs regulation. Thus, the EEU's Unified Customs Tariff imposes a 5% import duty on finished goods (baby formula), but an 11% duty on raw materials (milk base). This imbalance violates the principle of tariff escalation and does not encourage the substitution of imported finished products. This is why production volumes have fallen steadily in the last few years: at Danone Nutricia, output has dropped over 30% in 2014-17, and this decline will continue if current conditions persist, since it is more cost-effective to import finished products. The levels of local processing must be maintained and increased, however, if domestic raw materials are to be used to full capacity upon completion of the joint project.

Production volumes may be kept from falling further by developing the customs procedure of processing for internal consumption, and this is the reason for including milk base used in making baby food in the list of goods that qualify for this procedure (Decree No. 565 of the Russian Government of 12 July 2011).

This issue was discussed and, under Section V, clause 1, of Minutes No. 4 of a Meeting of the Subcommittee for Customs Tariff and Non-Tariff Regulation and Foreign Trade Protective Measures of the Government Commission for Economic Development and Integration of 31 July 2017 (approved by the First Deputy Prime Minister of the Russian Federation), it was decided that the list of goods that may be processed for internal consumption should be expanded to include products used in baby food that are in commodity group 1901 90 990 0 of the EEU's Goods Classifier for Foreign Economic Activities. As of now, however, this commodity group has not been added to the list, and the Ministry for Economic Development has exhausted the administrative resources at its disposal for resolving this issue.

Recommendations:

The Ministry for Economic Development, jointly with the Ministry of Agriculture and the Federal Customs Service, should see that milk base for breast-milk substitutes in commodity group 1901 90 990 0 of the EEU's Goods Classifier for Foreign Economic Activity is included in the list of goods that may be processed for internal consumption, approved by Decree No. 565 of the Government of the Russian Federation of 12 July 2011 for a period of three years.

The Ministry of Agriculture, jointly with industry unions, should prepare a road map for modernizing the milk-processing industry based on up-to-date principles of quality control and safety, tracking of raw materials and cost effectiveness.

Issue 5. Providing high-quality locally produced meat-and-bone meal to pet food production companies.

The production of pet food is a dynamically growing industry, and investments in domestic pet food production have topped USD 3 billion in the last 20 years. FIAC member companies have already built seven plants in Russia. Annual turnover on the pet food market is over RUB 170, and over 20,000 people are employed in production and distribution. In addition, substantial quantities of finished pet food are exported to CIS countries and beyond (more than 30 countries).

High-protein meat-and-bone meal is an essential ingredient in pet food. FIAC member companies have always given priority to the localization of raw materials, including meat-and-bone meal.

Today over 70% of raw materials used in the industry are purchased in Russia, but a number of problems, including the quality of meat-and-bone meal and legislative regulation of its use in Russia, prevent local producers from purchasing more. Certain types of meat-and-bone meal, such as rabbit, duck, turkey, salmon and bone meals, are not produced in Russia or are only manufactured in small volumes, forcing producers to import raw materials from third countries.

Limits on imports of meat-and-bone meal from some countries are being discussed, and in May 2017 the Ministry of Agriculture set up a task force to monitor the meat-and-bone meal market, develop a road map for import substitution and coordinate cooperation between consumers and meat-and-bone meal producers in order to boost manufacturing in Russia. The work done in 2017 has helped to improve the situation and ensure high-quality meat-and-bone meal supplies to the industry (projected through the end of 2018), but there is still an overall deficit of 24.4%, or 24,500 tons.

We believe that the ministry task force should continue its efforts until manufacturers can be fully supplied with locally produced raw materials. Limitations could create serious problems, including a shortage of raw materials for all Russian producers of finished pet food in 2018, a drop in production to 300,000 tons (over RUB 30 billion rubles in monetary terms), and a RUB 3 billion reduction in tax revenues for budgets at various levels. If Russian pet food manufacturers have to curtail production, they will lose share on the EEU

and CIS markets, and pet food will have to be imported. In this case, it will take a long time for Russia to recover its export positions.

Given the circumstances, we have drafted proposals for a road map to develop the Russian market of meat-and-bone meal used in cat and dog foods (Appendix 1). The proposals focus on measures to facilitate the transition to locally produced raw materials by 2020 (potentially compensating for an expected shortfall in supplies from third countries).

Recommendations:

The plan of action (road map) to localize high-quality meat-and-bone meal by 2020 should be supported and approved by an order of the Russian Ministry of Agriculture.

Annex 1. Draft road map to develop the Russian market of meat-and-bone meal for cat and dog food

I. General description

The purpose of the road map to develop the Russian market of meat-and-bone meal for cat and dog food is to promote the transparent localization of meat-and-bone meal for pet food production, ensure the quality of localized raw materials and boost exports of Russian-made products. The measures set out in the road map are aimed at optimizing government regulation and standardizing the requirements for manufactured products.

The road map will be implemented in 2017-20 in tandem with the Development Strategy for the Food and Food-Processing Industry of the Russian Federation for the Period to 2020, approved by Government Regulation No. 559-r of 17 April 2012, and the charter of the Agricultural Exports priority project, approved by the Presidential Council for Strategic Development and Priority Projects (Minutes No. 11 of 30 November 2016). The goals of the road map can be achieved by:

1. drafting and amending EEU technical guidelines and federal standards;
2. boosting the production capacity of high-quality meat-and-bone meal manufacturers by promoting competition on the market;
3. expanding exports of finished goods.

The following benchmarks have been selected to evaluate progress made on the road map:

Benchmarks:

	Indicator	Base value	Period, year		
			2018	2019	2020
1	Supply of poultry byproduct meal	40%*	60%	80%	100%
2	Supply of pork meat-and-bone meal	89%*	95%	100%	
3	Supply of meat-and-bone meal from other raw materials	38%*	40%	50%	60%
4	Exports of finished pet foods, USD million (TN VED Group 2309 10)	81.4**	85	90	100

* for 2017

** for 2016

II. Measures to be taken

	Measure	Name of document	Expected results	Timeframe	Responsible
1.	Improvement in the quality of domestic meat-and-bone meal				
1.1.	Formulation and introduction of amendments to regulatory acts to regulate the quality and safety of meat-and-bone meal	State standard	Amend GOST 17536-82 State Standard of the USSR "Feed meal of animal origin. Technical specifications." Standard technical specifications for the production of high-quality meat-and-bone meal		Ministry of Agriculture Federal Agency for Technical Regulation and Metrology (Rosstandart) Meat Industry Institute
1.2.	Prohibition of intra-species feeding to create a market of byproducts and meat-and-bone meal	Technical Regulations	Adoption of Technical Regulations on Feed and Feed Additives		Ministry of Agriculture Ministry of Industry and Trade Ministry for Economic Development
1.3.	Improvement of quality control systems at Russian meat-processing enterprises that process waste and produce meat-and-bone meal	Agency regulatory act	Guide to best available technologies: "Animal slaughter at meat processing and packing plants and the byproducts of livestock farming"		Ministry of Agriculture Federal Agency for Technical Regulation and Metrology (Rosstandart)
2.	Increase in the production capacity of Russian enterprises producing high-quality meat-and-bone meal				
2.1.	Program to inform agribusinesses of the requirements for high-quality meat-and-bone meal	Agency regulatory act	Information program		Ministry of Agriculture
2.2.	Program of subsidies for investment projects to expand production of high-quality meat-and-bone meal	Agency regulatory act	Subsidy program		Ministry of Agriculture

2.3.	Program to accelerate the production of fish meal as well as rabbit, duck, turkey and sheep meal in Russia.	Agency regulatory act	Development program		Ministry of Agriculture
3.	Monitoring of the import substitution of meat-and-bone meal	Report to the Government	Report to the Government	annually	Ministry of Agriculture

Issues being monitored:

Issue 1. Harmonizing Russian and EU technical compliance procedures for chemical and other products in order to increase the export potential of goods produced in Russia.

One of Russia's key economic tasks is to increase exports of non-resource and high-tech goods and make them more competitive abroad.

One essential step towards this goal would be to eliminate technical barriers that limit the volume of trade between Russia, EU member states and other countries. One such barrier to industrial growth in Russia is the lack of unified standards of technical compliance for a number of goods accounting for a sizable share of Russia's trade with EU member states.

Harmonization of the Russian and European technical regulation systems, including mutual recognition of lab tests and the elimination of any need for repeat tests of goods produced in the EU and Russia, will give each country greater access to the others' markets. This would have a very positive influence on the development of Russian industry and exports of Russian-made goods as well as on the Russian economy as a whole.

The importance of harmonizing Russian and EU technical compliance procedures is a topic of discussion in the business community as well as at the highest level of government. Following his participation in the 2016 Sochi International Investment Forum, Prime Minister Dmitry Medvedev instructed that this issue be studied by the Ministry for Economic Development and the Federal Accreditation Service.

The great majority of companies investing in the Russian economy are convinced that there is strong potential for further localization in Russia and for exporting Russian products to other countries.

We welcome any initiatives to lower barriers limiting growth in the volume of trade between our countries and are ready to propose a number of measures that we think would have a positive influence on the development of Russia's industrial and export potential:

1. Inclusion of representatives of the business community as permanent members in EEC working groups that are drafting regulatory documents on technical regulation and sanitary measures.

2. A review of the requirements of EEU technical regulations in view of international best practices and the goal of harmonization with the EU, with input from the business community, including the following Customs Union Technical Regulations: 009/2011 "On the Safety of Perfumes and Cosmetics" (toxicity parameters, appendices, definitions), 005/2011 "On Packaging Safety" (labeling requirements), and "On the Safety of Chemical Products" (common register of chemical substances in the EU).

3. Harmonization of approaches to determining the hazard classes of products by more closely aligning Russian (in the long term, Eurasian) and European law (on the basis of the CLP – Classification, Labeling and Packaging Regulation No. 1272/2008).

In 2013 Russia adopted the Intergovernmental Standards for the Classification and Labeling of Chemicals, based on UN recommendations. In furtherance of the GHS, the EU has adopted and implemented the new CLP Regulation No. EU/1272/2008 on the Classification, Labeling and Packaging of Substances and Mixtures.

Work on the standards must be continued to bring them into line with the CLP Regulation.

4. Introduction and recognition of alternative testing methods in Russia (at the level of the EEU): methods of calculation and of using biological models; harmonization of safety requirements and testing methods to ensure a uniform approach to evaluating products' compliance with safety requirements. Introduction of agreements on the bilateral recognition of test protocols.

In Russia the classification of chemicals, including household chemicals, based on calculation methods is not currently recognized on the legislative level. This means that products of a known composition are tested several times for no reason. Administrative barriers arise.

Toxicological safety parameters for perfumes and cosmetics in the EEU are currently regulated by two standards: GOST 33506-2015 and GOST 32893-2014. These standards include alternative methods: luminous bacteria tests, tests using the chorioallantoic membrane from chicken embryos and a method based on mobile cell cultures.

What is proposed is to supplement these standards or develop new ones that include a number of other tests recognized and successfully used in the EU and characterized by higher degrees of correlation:

- OECD TG 435 (2006), OECD TG 431 (2004), OECD TG 430 (2004), OECD TG 435 (2006)
- OECD TG 439 (2010), OECD Guidance 2012b, OECD TG 442 c, OECD TG 442 d
- OECD TG 437 (2013), OECD TG 438 (2013), OECD TG 460 (2012), OECD TG 492

5. Further development of current methods and the introduction of new methods of in vitro toxicology testing recognized by the international scientific community and their harmonization with EU rules (in the long run, at the level of the EEU) from a legal and practical standpoint; Ensuring that testing can be done without the use of laboratory animals (initially at the applicant's discretion), drawing on the long-term experience of such testing in the EU. Spreading these methods among testing centers, facilitating their implementation (with equipment and training) and providing accreditation to use them.

In Russia only two alternative methods are currently used to evaluate household chemicals (the express method of toxicological and hygienic evaluation of cleaning agents using the luminous bacteria test and the express method of evaluating the toxicity of cleaning agents using bovine semen).

These are local methods not used in Europe. To be recognized internationally they must be validated in Europe, or else tried and recognized European methods must be introduced.

Toxicological safety parameters for perfumes and cosmetics in the EEU are currently regulated by two standards: GOST 33506-2015 and GOST 32893-2014. These standards allow alternative testing methods to be used only for a number of quarantinable products. Other products, including hair dyes, must be tested using laboratory animals.

The proposal involves applying the alternative methods already in use to other categories of quarantinable goods. Such a practice already exists and has been successfully used to the extent of introducing GOST33506-2015 in 2017.

6. Elimination of administrative and technical barriers to the evaluation of product safety by increasing the number of state-recognized independent testing centers.

7. Elimination of administrative barriers so that documents can be adopted and amended more rapidly in the framework of the EEC. Legislation of time limits for preparing and adopting EEC regulatory acts and liability for failing to meet such time limits (e.g. in some cases it may take nearly five years to amend technical regulations); Introduction of a simplified procedure for amending the appendices to technical regulations in connection with new information on the safety of chemical compounds.

8. Official use in Russia of European chemical databases to eliminate the need for additional testing in Russia.

9. Introduction of the institution of independent attested experts for purposes of arbitrating disputed issues (interpreting contradictory findings from various testing centers). Consideration of the issue with input from the business community.

3. Improvement of Tax and Customs Law and Administration

Improvement of Tax Law

In 2017 and 2018, the working group for the improvement of tax law was focused on the following issues.

Issue1. Property tax.

Following the amendments to Federal Law No. 401-FZ “On Amending Part One and Part Two of the Tax Code of the Russian Federation and Certain Legislative Acts of the Russian Federation” of 30 November 2016, the procedure for tax exemptions with respect to property tax has been changed. Since 1 January 2018, the tax exemptions provided for in clause 24 and clause 25 of Article 381 of the Tax Code of the Russian Federation shall be applied in the territory of the constituent entity of the Russian Federation in case the respective law of the constituent entity of the Russian Federation has been adopted.

As part of the previous reform, it was decided to not impose taxes on movable property, to encourage the production asset renovation, which has been actually provided since 1 January 2014.

Despite that, since 1 January 2017, a new article has been introduced in the Tax Code – Article 381.1, which has brought back the property tax for movable property starting 1 January 2018. The only condition provided for by Article 381.1 of the Tax Code of the Russian Federation to retain the existing movable property tax exemption is the adoption of the “respective law of the constituent entity of the Russian Federation”.

Very few regions have validated this tax exemption at a regional level. Given wide Russian geography and extremely tight deadlines for regional law approval, this means that starting the new year, the business is to lose a considerable share of income, which is presently being streamlined to improve production capacities.

Recommendations:

The tax law working group supports the draft amendment on cancellation of tax imposed on business-owned movable property since 2018, which has been prepared by the Ministry of Economic Development of the Russian Federation for introduction in the Tax Code.

Status

As a result of the joint work of the Ministry of Economy of Russia, the Ministry of Finance of Russia and the working group, movable property will be excluded from the property tax base starting 1 January 2019.

Issue 2. Centralized cost allocation for multinational corporations.

In 2017, the consultations were carried out in respect of allowing expenses transferred under a cost allocation agreement from a foreign company to a related Russian legal entity, to be treated as costs for profits tax purposes. This will enhance Russia's investment appeal, improve its investment climate and contribute to higher tax revenues due to the emergence of a large number of subdivisions of major foreign companies in Russia.

Recommendations:

The working group drafted amendments to the Russian Tax Code.

Issue 3. Trend towards tightening tax control over transactions performed by Russian subsidiaries of international companies.

Recent amendments to the Russian tax legislation are a big step forward as they have introduced a number of new concepts and institutions, including rules on controlled foreign companies, tax residency rules for legal entities and the concept of a beneficial owner, as well as transformed the national transfer pricing rules and more. In addition, there are extensive opportunities for Russian subdivisions of foreign companies to drive their inorganic growth strategies through acquiring novel or upgraded plants that have innovative capabilities. As multinational corporations with subdivisions in Russia have grown bigger in scale and more complex, Russian assets are increasingly viewed as an essential component of a global supply chain.

However, the tax authorities tend to believe that transactions are entered into primarily for the purposes of reducing the tax burden. It is a common practice for the tax authorities to assess additional taxes after challenging the economic substance of transactions. In certain cases, the tax authorities make such decisions relying on approaches that are not stipulated in the Russian tax legislation but are only recommended by the OECD or other regulators. This gives rise to tax risks that cannot be taken into account by investors and have an adverse effect on the investment environment.

Recommendations:

Develop a special regulatory act containing simple and clear rules for carrying out the business activities associated with integration processes across different areas (including, but not limited to, sales and distribution, logistics and supplies, human resources, outsourcing and corporate actions) with a focus on the economic inexpediency rules.

Issue 4. Need for stable legislation and predictable rules of changing the tax burden on foreign investors in Russia, including excises.

We are currently witnessing attempts to increase the tax burden on business, including a higher excise tax on brewery production and its subcategories, as a means of boosting state revenues. One example is the ongoing discussion of a possible increase in the excise rate for beer-based beverages to RUB 32 per liter of finished product (the current rate is RUB 20) as well as a rise in the rate for beer by 30%.

An increase in excise tax on brewery production and its subcategories would inevitably deal a blow at scrupulous manufacturers and would create more favorable conditions for the “shadow” production of excisable goods, invariably putting transparent legal businesses that always pay taxes at a disadvantage. The excise system suffers from sharp and significant increases in rates and requires long-term planning.

Because of unpredictable regulation and the disproportionate growth of the excise rate only the brewery industry lost 61,000 jobs (another 1.51% of unemployed population), with GDP decreasing by RUB 59 bln or 0.09 pp. Moreover, the State is losing billions in excise revenues and production output is decreasing.

Recommendations:

Do not support proposals to increase the tax burden, including an increase in the excise tax rate for brewery production and its subcategories. Keep the excise tax rates for brewery production in 2018 and 2020 at the 2016 level in order to improve and stabilize the development trends of the brewery industry and boost tax revenues while addressing the public health concerns.

Issue5. Fiscal Regulation of Electronic Nicotine Delivery Systems.

Today, the Russian market of innovative nicotine delivery products is peculiar for its absolute segmentation, no large-scale players, and poor development following the uncustomary nature of the product.

Previously, the Tax Code provided for the following nicotine liquid excises: RUR 10 per 1 ml in 2017; RUR 11 per 1 ml in 2018; and RUR 12 per 1 ml in 2019. We suppose that the excise rate exceeding RUR 5 per 1 ml (about 10% of the cigarette pack excise duty) will hurt considerably the still-unsettled legal ENDS market, force it to get illegal and prevent new players keen on absolute transparency to enter the market. Consequently, the above rate will hamper not only the excise collection, but also the market development overall.

The excise duty rates provided for by the Tax Code are at absolute variance with the world’s best practices of excise regulations in this segment. For example, in the European countries where the consumer purchasing power is mostly equivalent to that in Russia (Hungary, Romania, Serbia, Latvia etc.), the average nicotine liquid excise duty is about 5% of the cigarette pack excise. Meanwhile, Italy and Portugal having an inadequately high nicotine liquid excise (exceeding 10% of the cigarette pack excise) suffered a legal market crash, illegal market growth and consumer use of self-made nicotine liquids.

It arises out of the Tax Code that the excise duty is solely imposed on liquids for disposable ENDS. This results in certain problems. First, disposable ENDS are actually subject to double taxation: they are already excised as a separate excise category (ENDS), and in addition the nicotine liquid inside is excised too. Second, there arises a legal gap, which allows that the nicotine liquids for non-disposable ENDS, which are sold separately, are not subject to excise, and unfair and less responsible market players may well benefit from this gap to evade from taxation.

Recommendations:

To decrease the excise rates per 1 ml nicotine liquid to 5-10% of the cigarette pack excise, and to further increase them pro rata the increase of the cigarette excise. To amend the definitions of ENDS and ENDS liquid for the purpose of extending the excise regulations to all types of ENDS liquids.

Improvement of Customs Law

Issue 1. Categorization of foreign trade operators.

As part of the Federal Customs Service's priority project "Comprehensive Measures to Promote International Cooperation and Exports" (in the area of "International Cooperation and Exports"), the Procedure for Automated Categorization of the Risk Level of Foreign Trade Operators was amended to provide for automatic categorization of foreign trade operators engaged in exports. This procedure establishes criteria for placing foreign trade operators in high, medium and low risk categories.

The Order of the Federal Customs Service of Russia of 1 December 2016, as amended by Order No. 1247 of the Federal Customs Service of 31 July 2017, is posted on the service's official website (www.ved.customs.ru) in the section "Categorization of Foreign Trade Operators."

The Federal Customs Service also adopted several departmental acts regulating the categorization of exporters and manufacturers as low-risk companies:

1. Order No. 732 of the Federal Customs Service of Russia of 11 April 2016 "On Approval of the Procedure to Be Followed by Customs Officials Collecting and Analyzing Information to Determine the Risk Category of Entities Engaged in Manufacturing"

2. Order No. 731 of the Federal Customs Service of Russia of 11 April 2016 "Approval of the Procedure to Be Followed by Customs Officials Collecting and Analyzing Information on the Risk Category of Entities Exporting Goods That They Have Produced Entirely or Processed Sufficiently So That Export Duties Do Not Apply."

The predictability of foreign trade operations is a key factor for FIAC member companies that are manufacturers.

Some FIAC members, however, are subject to measures intended for high-risk companies. Applications and materials required under Orders No. 731 and 732 also involve a substantial administrative burden, and it can take over 90 days to consider, analyze and prepare conclusions on the possibility of low-risk categorization.

Recommendations:

We recommend that the Federal Customs Service consider the issue that companies be informed of their risk category, including via their personal accounts, as well as of potential violations that could entail a change in risk category.

Issue 2. Improvement of the institution of AEO in the EEU.

Issue 2.1. Development of the institution of AEO in the EEU.

The development of customs cooperation with the trading partner countries is vital to solving the tasks of developing the international cooperation, increasing non-resource exports and improving the efficiency of domestic enterprises that use raw and other materials and equipment imported from third countries.

In recent years, owing to the attention of the Government of the Russian Federation, the Federal Customs Service, and the Eurasian Economic Commission, the international program of the authorized economic operator (AEO) is actively developing in Russia, based on the recommendations and standards of the World Customs Organization (WCO.) The foreign trade operators that have been granted the status of an authorized economic operator are allowed a special simplified procedure for customs administration.

The AEO program is a worldwide trend that allows customs services to separate bona fide foreign trade operators from those who perform operations in a generally established manner. As a result, the AEO program makes it possible to create the international trade environment, which is safe for businesses and transparent for the customs authorities.

In addition, the institution of AEO stimulates the development of exports, since this status demonstrates that its holder is compliant with the world standards of WCO.

According to the latest WCO information, AEO programs are being developed in 94 countries, including all the largest global economies within the G20.

For example, according to the WCO information, 19,001 businesses are registered as AEO in EU, 3,475 in China, 11,605 in USA, 664 in Japan.

One of the AEO program development areas is the conclusion of agreements on mutual recognition of AEO programs (AEO AMR) with third countries. Now, 57 AEO AMR are being concluded globally and 39 AEO AMR pending development.

The key objective of these agreements is to make safe supply chains between AEO, which allows to significantly reduce the number of control measures of the customs authorities and ensure a high degree of transparency of foreign trade operations. From the perspective of export development, this will allow to create additional benefits for domestic exporters in foreign markets, as it demonstrates their compliance with the international business standards. Import operations within a secure supply chain are becoming more transparent and less risky for customs administration, which results in reduced workload of the customs authorities.

Thus, the institution of AEO keeps on developing globally and has become demanded by businesses and customs authorities as a tool intended to increase the transparency and efficiency of international trade.

At the same time, a number of factors exist currently in the Russian Federation that impede a full-scale AEO institution development preventing it from reaching the world level.

The existing institution of categorization allows assigning a low risk to not only AEOs, but also other organizations with observance of fewer requirements. As a result, getting the status of an authorized economic operator becomes not as attractive. This situation is inconsistent with the WCO Framework of Standards to Secure and Facilitate Global Trade and conflicts with the international practice.

In the customs services of foreign countries (for example, the FRG, the Republic of Korea, China and others), there are separate divisions for the development of the AEO institution. Such divisions cooperate at all levels with the organizations granted or seeking to be granted the AEO status and effectively implement the concept of partnership between the government and the business.

The Customs Code of the Eurasian Economic Union (EEU Customs Code) has considerably extended the list of requirements for AEO and the list of simplified procedures provided to AEO. In addition, the EEU Customs Code introduces a number of advantages for AEO, which have not yet been reflected in the national legislation and law enforcement practice. For example, those are the provisions on the priority of customs operations, the organization of separate lanes at road checkpoints, the automatic assignment of a low risk, the dedication of divisions and officials to cooperate with AEO. Also, there are other simplified procedures in the international practice to be reasonably considered for inclusion in the legislation of the Russian Federation and the EEU. It is required to study the possibility of introducing additional requirements for AEO, which would comply with the applicable WCO Framework of Standards.

In this respect, we consider it efficient to develop a list of measures for AEO development.

Recommendations:

1. The Ministry for Economic Development of the Russian Federation (M.S. Oreshkin), the Federal Customs Service of Russia (V.I. Bulavin), together with the concerned federal executive bodies and business associations, should prepare proposals on measures to develop the institution of an authorized economic operator (AEO) in the Russian Federation and increase the number of AEOs up to the level of the world's largest economies, and should submit them to the Government of the Russian Federation until 1 February 2019;

2. The Ministry for Economic Development of the Russian Federation (M.S. Oreshkin), the Ministry of Agriculture of Russia (D.N. Patrushev), the Federal Service for Veterinary and Phytosanitary Oversight of Russia (Rosselkhoznadzor) (S.A. Dankvert), the Russian Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing of Russia (Rospotrebnadzor) (A.Yu. Popova) should prepare proposals on assigning a low risk to the AEO status holder organizations, and should submit them to the Government of the Russian Federation until 1 February 2019.

Issue 2.2. The option of bundling obligations when the special simplified procedure of “release prior to declaration” is used.

Today authorized economic operators (AEO) make wide use of the special simplified procedure of release prior to customs declaration in order to simplify imports and reduce the time required for goods to be released into free circulation.

In the case of release prior to declaration, a customs official releases goods into free circulation when a commitment to submit a goods declaration (the “commitment”) in the standard form has been accepted and registered and the required documents and information have been provided. Then, by the tenth (or fifteenth under the EEU Customs Code) of the following month, the AEO submits a goods declaration covering goods in a single lot to be released on the basis of several commitments made in the previous reporting period.

Clause 2 of the Instruction on Completing a Goods Declaration, approved by Decision No. 257 of the Customs Union Commission of 20 May 2010 (the "Instruction"), states that a single goods declaration should provide information on goods in a single lot (unless otherwise stated by the Instruction) under the same customs procedure. For the purposes of this Instruction, a single lot of goods imported into the customs territory of the EEU includes:

1. goods shipped by the same shipper to the same recipient in the customs territory in fulfillment of commitments under a single document verifying a foreign trade operation
2. goods that, within the time limits stipulated in Article 185 of the Code, are presented to the same customs authority in the place where they enter the customs territory, or where they are delivered if the customs procedure of customs transit is used, and
3. goods released within the time limits set for the submission of a goods declaration.

Thus, based on the provisions of the Instruction, a single goods declaration may be used to declare all goods released in the previous period as part of a single lot based on several commitments in accordance with Article 197 of the Customs Code of the Customs Union. This practice is used by AEOs, including those engaged exclusively in trade, and is popular, since it greatly simplifies customs clearance and reduces administrative requirements for both customs authorities and operators that submit one or more declarations in a month for import shipments forming part of a single lot. For purposes of calculating import duties and taxes, use is made of custom duty, tax and currency rates established under the laws of the Customs Union member country and in effect as of the date on which the customs declaration is registered.

At the same time, Article 120.14 of the EEU Customs Code states that customs duty, tax and currency rates apply as of the date on which the customs authority registers an application for the release of goods prior to declaration (the "application".) Note that the form of applications for release prior to declaration does not include sections for the calculation of customs payments.

Article 52.3 of the EEU Customs Code states that information on the calculation of customs duties and taxes should be given in the goods declaration, customs credit slip or another customs document that is specified by the Commission or in Article 52.4 of the EEU Customs Code. It is important to note that none of these customs documents is legally tied to the procedure of release prior to declaration, and information on the calculation of customs payments can thus only be declared in the goods declaration.

According to the Instruction, when a goods declaration is completed, section 23 should indicate the exchange rate of the foreign currency whose code is entered in section 22 against the currency of the EEU member country in which the goods declaration will be submitted, as established by this country's central (national) bank on the date when the goods declaration is registered.

There is thus a legal conflict regarding how the exchange rate of foreign currency should be indicated for purposes of calculating customs payments when the procedure of release prior to declaration is used. This conflict not only interferes with AEOs' practice of using a single declaration to declare goods in a single lot that are released on the basis of several commitments/applications on different days, but also makes it impossible to use the procedure of release prior to declaration as established in current law.

The Board of the Eurasian Economic Commission has prepared draft amendments to the Instruction allowing the above conflict and allowing combining the commitments issued on different dates within a single customs declaration.

Recommendations:

1. The Ministry for Economic Development of the Russian Federation, the Russian Ministry of Finance, the Federal Customs Service of Russia, when formulating Russia's opinion on the draft amendments to the Instruction on Completing a Goods Declaration, approved by Decision No. 257 of the Customs Union Commission of 20 May 2010, should support the possibility of combining goods within a single customs declaration released prior to declaration under the commitments on different dates with different foreign exchange rates.

Issue 2.3. Storage of AEOs' goods with other AEOs.

For foreign trade operators, special simplified procedures allowing goods to be stored in an AEO's buildings and areas is a key advantage in doing business.

In Russian and internationally, however, the practice of using external warehouses under storage agreements, i.e. warehouses belonging to affiliates and third parties, including AEOs, has become more complicated. Foreign trade operators seek to make their operations more effective by using warehouses for several companies, engaging professional warehouse operators and doing more to ensure the safety of stored goods. In the event of such storage, the title to goods is not transferred to a third party and remains with the foreign trade operator, i.e. the importer.

Article 437.3 of the EEU Customs Code envisages simplified procedures for AEOs with a type-two certificate, including temporary storage of an AEO's goods in the AEO's buildings, structures (parts of structures) and/or open areas (parts of open areas.)

Article 439.3 of the EEU Customs Code indicates that, along with goods in temporary storage, other goods may be stored in an AEO's buildings, structures (parts of structures) and/or open areas (parts of open areas) as prescribed by member countries' laws on customs regulation.

Article 388 of the Draft Federal Law "On Customs Regulation" permits other goods owned by an AEO to be stored in the AEO's buildings, structures and areas.

Recommendations:

1. We request clarification of how this provision applies to situations in which goods of one AEO are stored in the buildings, structures and areas of other AEOs.

Issue 2.4. Issues of remote access to the information kept in the accounting systems of AEOs.

In accordance with clause 1.7 of Article 433 of the Customs Code of the Eurasian Economic Union, one of the mandatory conditions for the inclusion of a legal entity in the register of authorized economic operators, with the issuance of a type-one certificate, is "the available goods accounting system that meets the requirements established by the customs regulations of the member countries, which makes it possible to compare the information provided to the customs authorities during the customs operations, with the information on business operations performed, and provides the customs authorities with the access (including the remote one) to such information."

The form and procedure for providing remote access to the information kept in the accounting system are not established by customs law. However, FIAC member companies interested in being included in the register of authorized economic operators faced the requirements of the customs authorities, including during on-site customs inspections, of remote access to be provided directly to the accounting systems and information systems, rather than to information alone.

Currently, to process the data related, among other, to the import and export operation management, FIAC member companies use in most cases global corporate-wide automated systems based on SAP hardware-software solution (SAP G-ERP.) Often, the server capacities are located in the data centers outside the Russian Federation.

As part of implementation of the information security requirement to protect critical corporate information systems, companies use special organizational, software and technical protection tools, including restrictions on access, identification and authentication of users when accessing such systems.

Direct access to G-ERP systems is solely possible from the corporate network of a certain company and only from corporate computers linked to the account of a particular employee. Provision of external access (from the premises other than the office, from external computers etc.) seems technically impossible.

In this regard, for the purpose of authorization, we suggest to consider the method of providing remote access as a so-called "data mart" system, as well as other methods that provide access to information kept in the accounting system with no direct connection to the internal corporate information systems.

Remote access of authorized customs officers can be ensured through user authentication with individual logins and passwords using a web interface that automatically provides access, via a secure communication channel, to the required information retrieved directly from the SAP G-ERP accounting system about the customs and business operations in respect of the goods that have passed customs clearance to the extent of the company's use of the AEO status.

We recommend considering a possibility to make recommendations for the foreign trade operators concerned about using the AEO status and for the customs authorities on standard ways of providing remote access to the information kept in the AEO accounting systems in addition to direct remote access to the accounting systems and a list of the information, for which the remote access is provided.

Issue 2.5. Requirements to the reporting provided by AEO.

The draft order provided for public discussion (<http://regulation.gov.ru/projects/List/AdvancedSearch#departments=38&npa=80575>) and approving the AEO report format contains information about all business transactions related to the movement of AEO goods, in particular - acceptance, storage, release to production and sale.

Many data are provided in excess, since, as a condition for inclusion in the register of authorized economic operators, Art. 433 of EEU Customs Code defines the provision of remote access to AEO information

systems for the customs authorities. Given that, such duplicated information is an excessive burden on the business.

For example, the information on customs operations with goods is already available in the databases of the customs authorities, and the information on business operations related to the sale of goods can be obtained independently by the customs authority from the Federal Tax Service.

At the same time, the EEU regulations and the national legislation impose the requirements on AEO, including with respect to the accounting system, which should comply with Federal Law No. 402-FZ "On Accounting" of 6 December 2011, and also with the tax laws of the Russian Federation, according to which the Goods Declaration number and the goods index number in the Goods Declaration are presented in the accounting systems only at the initial acceptance.

The form of the report provided for in Appendix No. 2 is not most preferable for the enterprises engaged in continuous production, when the movement of raw and other materials occurs daily and continuously, the system accounting is done by production lot and does not have any pass-through link to the Goods Declaration numbers and the goods index numbers in the Goods Declarations.

Thus, the proposed format of the report (in particular, Appendix No. 2, which additionally includes the information on storage, movement and sale of goods) introduces additional requirements for the AEO accounting system and thereby creates additional administrative barriers and entails the emergence of additional financial costs associated with providing for and operating the AEO accounting system.

Recommendations:

The Federal Customs Service of Russia should improve the draft order by removing the information – provided by AEO through remote access, – which is contained in the databases of other federal executive authorities, as well as the information not related to the simplified procedures applied by AEO, from the list of the information annually provided by AEO.

Issue 3. Enhancement of state measures to support the processing of goods for domestic consumption (jointly with FIAC's localization working group).

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 EEU 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 the rates for raw and other materials exceeding those for the 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 EEU 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 (Article 264 of the Customs Code of the Customs Union.) 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. Even so, Chapter 36 of the Customs Code of the Customs Union sets clear, unambiguous and exhaustive requirements for foreign trade operators to ensure proper use of the procedures 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 EEU 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 36 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 keeping 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 following should be noted in connection with the identification of foreign goods in processed products. Under Article 242 of the Customs Code of the Customs Union, 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 operational processes:

1. do not or cannot have definite identifiers (chemical raw materials, food raw materials, small components and spare parts)

2. disappear during manufacture (evaporation, chemical transformation)

3. are difficult to isolate and identify due to the specifics of the final product (food products, sophisticated equipment.)

Under Article 265 of the Customs Code of the Customs Union, 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 Russia, the list is established by Article 265 of Federal Law No. 311-FZ of 27 November 2010 "On Customs Regulation in the Russian Federation" and by Decree No. 565 of the Russian Government of 12 July 2011 (the "Decree".) The list is limited to about 50 goods that are clearly intended for specific production efforts. As a result, the procedure of processing for domestic consumption is not used in practice, and this holds back the development potential of domestic high-tech production with high added value as well as new investment in such production. It is important to note that the customs procedure 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 for goods 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.

Issue 3.1. Classification of raw materials used in baby food.

The procedure of processing for internal consumption is of interest to Russian manufacturers and promotes the policy of localization in Russia. The baby food industry is one of those concerned, because the required

raw materials are not produced in Russia, and customs duties for those materials are higher than for finished products.

Minutes No. 4 of the Meeting of the Subcommittee for Customs Tariff and Non-Tariff Regulation and Foreign Trade Protective Measures of the Government Commission for Economic Development and Integration of 31 July 2017, recommend that the list of goods that may be processed for internal consumption, as approved by Decree No. 565 of the Russian Government of 12 July 2011, be expanded to include products used in baby food in commodity group 1901 90 990 0 of the EEU's Goods Classifier for Foreign Economic Activities. The Russian Ministry of Agriculture and Federal Customs Service should be charged with clarifying the names of these goods and preparing a draft decree of the Russian Government.

Based on materials provided by concerned companies, the Ministry of Agriculture has sent a request to the Federal Customs Service (10 November 2017, No. 57923).

Recommendations:

1. We request that the Federal Customs Service clarify whether the information provided by concerned companies is sufficient.

Issue 4. Improvement of tax mechanisms for processed products when the procedure of processing in the customs territory is used.

Pursuant to the effective Tax Code of the Russian Federation, tax is levied at a tax rate of 0% with respect to the sale of: goods which have been exported under the export customs procedure; goods which qualify for processing under the free customs zone customs procedure; work (services) involving the processing of goods placed under the customs procedure. At the same time, Article 249 of the Customs Code of the Customs Union states that the customs procedure of processing in the customs territory is completed by placing goods under the customs procedure of re-export. According to the tax legislation of the Russian Federation with regard to products processed in the customs territory, the VAT rate of 0% is not applied with respect to the sale of processed products where the entity purchases raw materials from abroad and exports goods manufactured from such materials under sale and purchase agreements. The VAT rate on such operations is 18(10)%, which results in higher prices for goods manufactured in Russia and so makes them less competitive in foreign markets. Therefore, we believe it expedient to amend Articles 164 and 165 of the Tax Code.

Recommendations:

1. The Ministry for Economic Development, in cooperation with concerned federal executive bodies, should draft amendments to the Russian Tax Code to provide for the 0% VAT rate with regard to the products processed in the customs territory, which are placed under the re-export customs procedure upon sale.

2. The Russian Ministry of Finance should issue a clarification of the procedure for verifying a zero rate of VAT when the mechanism of equivalent compensation is used.

Status (11 December 2017): Federal Law No. 350-FZ on the revision of the Russian Tax Code was adopted.

Issue 5. Simplification of the confirmation procedure for a zero rate of VAT on exports to foreign countries, including EEU 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. Exporters are required to submit hard-copy documents marked by the customs authorities when exporting goods outside the Customs Union. This takes up to a month and makes heavy demands on human resources. Although Federal Law No. 452 of 29 December 2014 amended Article 165 of the Russian Tax Code to permit shipping documents, customs declarations and other documents to be submitted in the form of registers, including electronically, hard copies marked by the customs authorities may still be requested under Article 165.15. We thus request that further amendments to the Tax Code be drafted to rule out the possibility that such documents will be requested during an inspection. There are still difficulties with exports to Customs Union countries. Under Appendix No. 18, Part II, clause 3.3, to the EEU 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.

Recommendations:

To resolve these problems and simplify export procedures, the Working Group for Improvement of Customs Law proposes the following steps:

1. Draft additional amendments to the Russian Tax Code to eliminate the requirement that documents be marked during inspection.
2. Draft amendments to Appendix No. 18 to the Agreement on the Formation of the EEU 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
3. Organize electronic communication between the tax authorities of Customs Union countries. Eliminate the requirement that payment of VAT in Customs Union countries be verified and that copies of shipping documents bearing the seals of counterparties in Customs Union countries be provided.

Issue 6. Establishment of a procedure for issuing health certificates for goods exported from the EEU and improvement of the procedure for issuing free-sale certificates.

According to the effective Russian legislation, health certificates are not required for exported food products that are not subject to veterinary and phytosanitary control (oversight). Such products include, but are not limited to, oil-and-fat products of vegetable origin, confectionery, processed vegetable products, juice products, baby food, pasta, coffee, tea (packaged for retail sale), and fruit and berry ice cream (from groups 09, 15 and 17-21 of the TN VED.)

However, according to exporters, many countries demand that imported goods have health certificates issued by an authorized organization of the exporting country and verifying that products are safe and in compliance with regulatory requirements – generally those of the exporting country.

The form of the required document is similar to the standard form approved by guidelines CAC/GL 38-2001 of the Codex Alimentarius.

It should be noted that veterinary and phytosanitary certificates are required for exported goods subject to veterinary and phytosanitary control (oversight.) These certificates are similar to health certificates and are prepared according to the standard form approved by the guidelines CAC/GL 38-2001 of Codex Alimentarius. The lists of controlled products that require veterinary and phytosanitary certificates are approved by 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 and Decision No. 318 of the Customs Union Commission "On Ensuring Plant Quarantine in the Eurasian Economic Union" of 18 June 2010.

Thus, health certificates are not required for a wide range of exported food products not subject to control.

To avoid the risks of not meeting export targets for domestic agricultural products due to technical and other requirements of foreign countries, we suggest expanding the powers of the Russian Export Center to issue health certificates for exported food products that are not subject to veterinary and phytosanitary control (oversight), using the standard form approved by guidelines CAC/GL 38-2001 of the Codex Alimentarius.

Recommendations:

1. The Ministry for Economic Development, in cooperation with concerned federal executive bodies, should consider authorizing the Russian Export Center or a federal executive body to issue health certificates.

Issue 7. Imports of samples.

When importing samples of products subject to control and products subject to compliance assessment and verification, foreign trade operators encounter problems in obtaining permits and having shippers listed among those permitted to import to Russia. The time involved in obtaining permits for samples is often similar to that involved in obtaining permits for finished products. Foreign trade operators wishing to import samples, including for production purposes (to determine whether such materials can be used in production), thus incur additional time and administrative costs. The most serious problems affect imported samples of controlled products subject to veterinary and phytosanitary control and compliance assessment (verification.) In the first quarter of 2016, the Ministry of Industry and Trade drafted amendments to Decision No. 294 of the Customs Union Commission of 25 December 2012 that would eliminate the need for documents on compliance assessment (verification) when products are imported for the sole use of the declarer.

Recommendations:

1. Submit the agreed draft amendments to Decision No. 294 to the Eurasian Economic Commission.

2. Add the following phrase to Note * (* Both the TN VED code and the name of goods should be taken into account in using this list) in the Unified List of Goods (Appendix No. 1 to Decision No. 317 of the Customs Union Commission): This list does not include samples of controlled goods imported into (exported from) the Common Customs Territory of the Customs Union individually (no more than 5 items under a single classification code of the Customs Union's Goods Classifier for Foreign Economic Activity) or in limited amounts (no more than 20 kg of commodities whose weight (net) is measured in kilograms according to the generally accepted rules of retail trade) for one of the below purposes, provided that the purpose of importation is indicated in the shipping documents and that the recipient of the goods gives a written undertaking to use them as intended and not to alienate them in the Customs Union.

3. Add the following phrase to Chapter VI of Decision No. 317 of the Customs Union Commission:

"For the import or transit of the following controlled goods, or when such goods are transported within the Customs Union from the territory of one Party to that of another Party, there is no need during transport for veterinary supporting documents from officials of the Parties' authorized bodies or competent bodies of the exporting countries or for such documents to accompany the goods, nor is there any need for registration by the Parties' authorized bodies or for exporting companies to be entered in the Register of Organizations and Entities Engaged in the Manufacturing, Processing and/or Storage of Controlled Goods Imported into the Customs Territory of the Customs Union, provided that the epizootic situation is favorable in the country of the exporting company (manufacturer of the controlled goods) and the exporting country – i.e. product samples for:

1. Research and development;
2. Laboratory and analytical research;
3. Testing and comparison;
4. Establishing internal controls (in accordance with GOST ISO 17025);
5. State registration, certification or declaration of compliance;
6. Calibration and adjustment of instruments;
- 7 Validation and refining of methods;
8. Market research and samples not intended to be sold in the customs territory of the Customs Union".

4. Extend the scope of Chapter VII of Decision No. 318 of the Customs Union Commission to cover the entire list of products subject to quarantine and imported as samples, i.e.:

- Samples do not need to be accompanied by phytosanitary documents (phytosanitary certificate, import quarantine permit.) A phytosanitary quarantine control certificate may be made out after samples are visually examined by a quarantine inspector, which must not result in a violation of packaging integrity or a reduction in the value or quantity of samples;

- Packaging may be nonstandard and unsealed;

- Samples must not exceed 20 kilograms/20 liters/50 pieces;

- Samples may not be sold/distributed/commercially used in the Customs Union;

- Samples are not required to bear the manufacturer's name (only the name of the shipper and the country of dispatch);

- The name of a sample may be encoded on the label, including digitally (the shipper, the recipient, content and purposes may be indicated in accompanying documents);

- If additional laboratory research/testing is required to assess the phytosanitary condition of imported samples, the goods may be released at the request of the recipient/importer, without the right to use/sell them, and stored in a place specified by the recipient until a report on the phytosanitary condition of the imported goods is received.

Add the following phrase to Note * (* Both the TN VED code and the name of goods should be taken into account in using this list) in the List of Goods Subject to Quarantine (Appendix No. 1 to Decision No. 318 of the Customs Union Commission):

This list does not include samples of controlled goods imported into (exported from) the Common Customs Territory of the Customs Union individually (no more than 50 items under a single classification code of the Customs Union's Goods Classifier for Foreign Economic Activity) or in limited amounts (no more than 20 kg

of commodities whose weight (net) is measured in kilograms according to the generally accepted rules of retail trade) for one of the below purposes, provided that the purpose of importation is indicated in the shipping documents and that the recipient of the goods gives a written undertaking to use them as intended and not to alienate them in the Customs Union.

Add clause 9.5. to Chapter IX or clause 7.3. to Chapter VII of Decision No. 318 of the Customs Union Commission as follows: 9.5. (or 7.3.) For the import or transit of the following quarantine goods presenting a high phytosanitary risk, or when such goods are transported within the Customs Union from the territory of one Party to that of another Party, import quarantine permits and phytosanitary certificates are not required during the period of transport for purposes of quarantine phytosanitary control (oversight), provided that the phytosanitary situation is favorable in the country of the exporting company (manufacturer of the controlled goods) and the exporting country, as well as their samples for:

1. Research and development;
2. Laboratory and analytical research;
3. Testing and comparison;
4. Establishing internal controls (according to GOST R ISO 17025);
5. State registration, certification or declaration of compliance;
6. Calibration and adjustment of instruments;
7. Validation and refining of methods;
8. Market research and samples not intended to be sold in the customs territory of the Customs Union.

Issue 8. Adjustment of the amount of customs duties.

As part of development of the regulations that implement the provisions of the Federal Law “On Customs Regulation in the Russian Federation” (the “Draft”) the discussion takes place with regard to the amounts of the customs clearance fees that differ from those currently in effect in Russia. The discussion takes place with regard to raising the upper limit on customs clearance fees from the current RUB 30,000 to RUB 60,000.

We should point out that, in addition to the additional financial burden on importers of valuable lots of goods, this provision is contrary to Russia’s commitments to the World Trade Organization (the “WTO”) as stated in clause 382 of the Report of the Task Force for Russia’s Accession to the World Trade Organization (the “Report”). According to the Report, the Russian Federation assumed the following obligations with respect to the amounts of customs duties:

- the government is to modify the system of customs clearance fees so that the maximum amount of such fees in the Special Drawing Rights does not exceed the equivalent of RUB 30,000 on the date of accession
- The government is to set lower fixed rates of customs clearance fees for electronic declaration and other simplified filing methods in order to ensure compliance with the WTO Agreement – in particular, Article VIII of GATT-94

Note that Russia’s commitments in terms of the amounts of customs fees are in the national currency and not tied to the rates of foreign currencies. The WTO may thus view an increase in the upper limit of customs fees as a violation of Russia’s commitments.

For foreign trade operators, an increase in customs fees will entail unreasonable additional expenses, thus pushing up the cost of products manufactured in Russia from imported raw and other materials and resulting in higher prices for end consumers.

We propose that the maximum amount of customs fees be kept at the current level of RUB 30,000.

Issue 9. 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 EEU 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.

Under Regulation No. 1125-r of the Russian Government of 29 June 2012 “On Approval of the Plan of Measures (Roadmap) ‘Enhancement of Customs Administration,’” the Federal Customs Service of the Russian Federation (the “Federal Customs Service”) and the Federal Service for Veterinary and Phytosanitary Oversight were charged with reducing the time that goods are kept in seaports to forty-eight hours by 2017 (except for goods stored at the initiative of foreign trade operators.)

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, has launched a pilot project, as part of the risk-oriented approach, to reduce the number of containers of controlled products that should 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 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 the 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 the 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 through 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 10. Problem with application of a joint clarification of the Federal Customs Service and the Federal Service for Accreditation (RusAccreditation) regarding the issue of the import of samples for compliance assessment (verification).

In the Clarification of the Federal Customs Service and the Federal Service for Accreditation (RusAccreditation) dated 29 December 2017 with regard to the procedure for the customs operations related to the imports of goods into the Russian Federation as samples, explanations are given regarding the procedure for completing the goods declaration or other document accepted by the customs authorities as a customs declaration in accordance with the EEU Customs Code, and regarding the specifics of storage of and accounting for the documents by the certification authorities and test laboratories that research samples for acceptance (registration) of the conformity declaration. There are still issues where the approach to how to observe these recommendations is not fully clear.

Currently, several ways of importing the controlled products for research and testing are actively used.

1. Supplies of controlled products through express carriers. The above samples in the quantity required for the tests are mostly provided by the supplier for free and are subject to simplified customs clearance procedures with the submission of the Express Cargo Register as a document replacing the Goods Declaration.

Question: How should the recommendations on completing the goods declaration (specifics of completing sections 31, 37, 44) be implemented when goods are released using the Express Cargo Registers to the extent that sections 31, 37, 44 are missing in such Registers?

Proposal:

To advise the express carrier companies on the need to specify the required information, including with the ability to make separate registers for the samples imported for compliance assessment (Register 061 – Samples for Compliance Assessment Works.)

In the field of the Register where the descriptive part of the goods can be provided, to provide the information about the purpose of the import of goods, under code 01999, the details of the documents (of the contract with the certification authority, of the letter from the test laboratory (center), of the pro forma invoice for the goods.)

In future, to be able to use the above information, including separate “Registers 061” to set up automatic processes for reconciling the information on the facts of import of samples and the certificates and compliance declarations issued in relation to such samples. This will make the customs procedure easier for the foreign trade operators in terms of imports of samples and will prevent from re-submission of documents and information to the customs authorities.

2. Supplies of controlled products in automobile compartments and containers when the cargoes are delivered by road and by sea, which are packed separately from other goods (the main commercial supply) supplied in the same vehicles.

The above samples in the quantity required for the tests are provided by the supplier for free and sent to the buyer together with the regular supply of other goods. In case of customs registration, the Application is submitted for the controlled goods as the document accepted by the customs authorities as the goods declaration.

Question: How should the recommendations on completing the goods declaration (specifics of completing sections 31, 37, 44) be implemented when goods are released using the Application to the extent that sections 31, 37, 44 are missing in such Applications?

Proposal:

In the section "Information on goods" or other applicable section of the Application, to indicate the necessary information in sequence:

Samples for compliance assessment (research and testing) works

Code of specific aspects of movements “061”

code 01999, the details of documents (of the contract with the certification authority, of the letter from the test laboratory (center), of the pro forma invoice for the goods).

3. Supplies of controlled products as part of the imported raw materials for manufacturing, with subsequent selection of samples for compliance assessment.

Question: How should the recommendations on completing the goods declaration (specifics of completing sections 31, 37, 44) be implemented when the controlled products are released as part of the raw materials for manufacturing supplied with no separate packing and separate place (in bulk, barrels, tanks etc.)?

Proposal:

To distinguish the samples, which are supplied as part of the raw materials for manufacturing, as a separate commodity (Commodity No. 2) when completing the goods declaration and to indicate all the necessary information in the applicable sections 31, 37, 44. In the Goods Declaration section, to indicate the number of places as “part of place.” To select the samples at the recipient`s warehouse with the preparation of the Sample Selection Act.

Recommendations:

1. We recommend clarifying the algorithm of actions of foreign trade operators in the above situations to ensure the observance of the laws related to compliance assessment and imports of the controlled goods to the Russian Federation.

2. To introduce changes to the joint letter of the Federal Customs Service and RusAccreditation following the proposals of the working group.

Issue 11. Issues of application of transportation cost deductions in customs value estimation.

At present, companies tend to receive many requests from the customs authorities to support their applications for the deduction of the costs of transportation of goods in the territory of the Customs Union from the customs value of goods and to provide documentary evidence of such deduction, 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), and, as a result, face extensive customs value adjustments.

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

According to clause 2.2 of Article 40 of the EEU Customs Code, the customs value of the imported goods should not include the cost of transportation of the imported goods in the customs territory of the Union from the place of arrival of such goods to the customs territory of the Union, provided that those costs are separated from the price, which is actually paid or payable, are declared by the declarer and are supported with the appropriate documents.

The list of documents confirming the declared customs value of goods is given in Appendix No. 1 to the Procedure for Declaration of the Customs Value of Goods, as approved by Decision No. 376 of the Customs Union Commission of 20 September 2010 "On the Procedures for Declaration, Control and Adjustment of 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 declaration of the customs value of goods, while the procedure for control of the customs value of goods, as well as the procedure for adjustment of the customs value of goods are determined by Decision No. 42 of the Board of the Eurasian Economic Commission of 27 March 2018 "On Specifics of Customs Control of the Customs Value of Goods Imported to the Customs Territory of the Eurasian Economic Union".

According to Decision No. 376 of the Customs Union Commission of 20 September 2010, for the amount of deduction from the customs value of the declared goods to be accepted by the customs authority, three basic conditions should be observed:

- expenses for the delivery of goods within the EEU territory are separated from the price actually paid or payable, i.e. the amount of transportation costs is presented in the invoice in a separate line;
- amount of such expenses is declared by a declarer in the declaration of customs value;
- information about the amount of expenses for the delivery of goods within the EEU territory is supported with the appropriate documents.

At the same time, according to 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 customs value structure:

- contract of goods transportation (freight forwarding agreement, if concluded), loading, unloading or reloading; invoice for transportation, loading, unloading or reloading of goods; bank documents (if the invoice is paid);
- or documents (information) related to transportation tariffs;
- or accounting documents where the cost of transportation is reported (should the goods be transported by the declarer's vehicles.)

As per wording, the listed documents should not be submitted simultaneously for the purpose of confirming the customs value, and the declarer, subject to the above list, can provide any of the documents available.

According to para. 9 of Resolution No. 18 of the Plenum of the Supreme Court of the Russian Federation of 12 May 2016 "On Certain Issues of Application of Customs Law by Courts" (the "Resolution"), the customs value of the imported goods should be calculated following the principles provided for by the Agreement in terms of application of Article VII GATT 1994 and should be based on the criteria compatible with commercial practice.

Given that, the obligation to provide the documents – when required by the customs authority, – which confirm the structure of the declared customs value, may be imposed on the declarer solely regarding those documents that the declarer has or should have by virtue of law or business practice.

In particular, a declarer is not obliged to have and may not have the documents confirming the fact of concluding the contract of goods transportation (freight forwarding agreement), loading, unloading or reloading; invoice for transportation, loading, unloading or reloading of goods; bank documents (if the invoice is 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.)

Para. 7 of the Resolution establishes that the declarer may submit to the customs authority the evidence of the transaction, on which basis the goods were purchased, in any form not contradicting the law, including in the form of a commercial invoice, as well as the documents (information) related to transportation tariffs in the form of an information letter from the seller of goods.

In this regard, we consider it reasonable to make clarifications for the customs authorities and foreign trade operators with the list of sufficient documents required to confirm the structure of the customs value of the declared goods and to support the applications for the deduction of the costs of transportation of goods in the territory of the Customs Union from the customs value of goods and to provide documentary evidence of such deduction, 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 the concerned business associations, should make clarifications on the list of sufficient documents required to confirm the structure of the customs value of the declared goods and to support the applications for the deduction of the costs of transportation of goods in the territory of the Customs Union from the customs value of goods and to provide documentary evidence of such deduction, 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.)

Issue 12. Problems involved in using certificates (declarations) received in Belarus and Kazakhstan for electronic declaration.

Today many companies – above all importers of household appliances and electronics – are having trouble clearing goods through customs when declarations or certificates of compliance (the “authorization documents”) are issued by accredited bodies of Belarus and Kazakhstan.

Since mid March 2017, companies have been unable to clear such goods through customs, since declarations referring to authorization documents issued in Belarus do not pass checks involving document “masks” established by the Federal Customs Service. No changes in the open data passport “Document number masks used in declaring information in section 44 of Goods Declarations and Customs Declarations” have been published on the official website of the Federal Customs Service (www.customs.ru) since 31 December 2016.

It should be emphasized that authorization documents were obtained in a country other than the country of the importer's registration because, after the Technical Regulation “On the Safety of Low-Voltage Equipment” was added to the List of Standards, Russia no longer had an accredited certification body.

We should also point out that some importers currently engage in foreign trade as authorized economic operators and use a simplified procedure that allows goods to be released before a customs declaration is submitted under Article 197 of the Customs Code of the Customs Union. This simplification allows goods to be released before a goods declaration has been prepared. Importers may thus have goods that have been released into free circulation, but have not been declared due to a lack of technical capability. The importers provide a written commitment to submit a customs declaration and other required documents and information by the tenth of the month following the month in which the goods are released and include information on the goods' intended use and the customs procedure used. Since these importers cannot meet their commitments, there is a risk that their certificates of registration as authorized economic operators will be suspended.

Recommendations:

In view of what has been said, we ask the Federal Customs Service to clarify the following:

- How can importers clear goods through customs when the authorization documents were issued by the accredited bodies of Belarus or Kazakhstan?
- If such goods cannot be cleared through customs, how can the importer meet its commitments to submit a customs declaration and other required documents and information by the tenth of the month following the month, in which the goods are released, in view of the time it takes to obtain new authorization documents in Russia?

Issue 13. On the submission of statistical forms.

Clause 1 of Decree No. 1329 of the Russian Government of 7 December 2015 “On the Maintenance of Statistics on Mutual Trade between the Russian Federation and Member Countries of the Eurasian Economic Union” (the “Decree”) states that the Federal Customs Service is the authorized body responsible for maintaining statistics on trade between Russia and EEU member countries.

Clause 5 of the Decree requires that statistical forms be submitted to the Russian customs authorities by a Russian entity that concludes a transaction or on whose behalf (at whose behest) a transaction is concluded, where goods are imported into Russia from EEU member countries or exported from Russia to EEU member countries or, in the absence of such a transaction, by a Russian entity that, when goods are received (in the case of imports) or shipped (in the case of exports), is entitled to own, use and/or dispose of such goods.

Under clause 7.1.18 of Decision No. 525 of the Customs Union Commission of 28 January 2011 “On a Unified Methodology for Maintaining Customs Statistics on Foreign Trade and Statistics on Mutual Trade between Customs Union Member Countries” (the “Decision”), Customs Statistics on Foreign Trade and Statistics on Mutual Trade between Customs Union Member Countries must include goods sent by international post or courier service, including transactions concluded by electronic means (electronic trade.)

The current regulatory legal acts of the Russian Federation and the EEU thus require that statistical forms be prepared for goods sold by a Russian tax resident via the Internet (an online store) to legal entities and individuals registered in other EEU member countries.

Clause 3.2 of the Decision states that information in documents provided by foreign trade operators to authorized bodies of Customs Union member countries in the course of mutual trade makes up the initial data used in preparing statistics on mutual trade Under the national legislation of EEC member countries (clause 2 of Decree No. 1329 of the Russian Government of 7 December 2015, Order No. 278 of the Chairman of the Statistics Committee of the Ministry of National Economy of the Republic of Kazakhstan of 29 November 2016 and Decree No. 2 of the State Customs Committee of the Republic of Belarus of 26 January 2012), individuals are required to submit statistical forms only if they are registered as individual entrepreneurs.

Thus, if a private individual registered in another EEU member country places an order via a Russian online store, information on this transaction will not be included in the receiving country’s national system of foreign trade customs statistics.

Clause 6 of the Decree states that a statistical form is completed for the reporting month for several shipments (receipts) of goods shipped (received) on the same terms under a single contract (agreement) (if any) or separately for each shipment (receipt) of goods. At the same time, the current version of the Statistical Declaration online service requires that the following purchaser information be entered in a statistical form for goods exported from Russia (section 2):

- full name of individual
- city, town, locality
- street address

The Federal Customs Service’s Statistical Declaration online service thus requires a foreign trade operator to prepare a separate statistical form for each order placed with an online store for goods sent to private individuals who are EEC residents. Since customers may place several thousand orders during a reporting period, a foreign trade operator must prepare and register thousands of statistical forms, placing an excessive administrative burden on both the operator and Russian customs officials responsible for checking the information.

It should also be kept in mind that, since 29 January 2017, administrative liability has applied under Article 19.7.13 of the Administrative Offenses Code if a statistical form on the movement of goods is not submitted to the customs authority, is submitted late or is submitted with inaccurate information. For such an offense, legal entities are charged an administrative fine of from RUB 20,000 to RUB 50,000. For a repeat offense, the fine is from RUB 50,000 to RUB 100,000.

In view of what has been said, the current procedure for using the Statistical Declaration online service to submit statistical forms for goods sold via online stores to private individuals registered in other EEC member countries is inefficient and exposes business to excessive financial risks.

Article 11 of Federal Law No. 311-FZ of 27 November 2010 “On Customs Regulation in the Russian Federation” states that the customs authorities operate on the following principles:

- customs authorities, in exercising their powers, should not impose excessive and unreasonable costs on foreign trade operators

- customs control should be improved, and modern information technologies and progressive customs administration methods should be adopted.

Recommendations:

In view of the provisions of Order No. 892 of the Federal Customs Service of Russia of 4 May 2016 “On Approval of the Regulation on the Customs Statistics and Analysis Department,” we request that you:

1. Under clause 40 of Order No. 892 of the Federal Customs Service of Russia of 4 May 2016, initiate the process of amending Decree No. 1329 of the Russian Government of 7 December 2015 to eliminate the requirement that foreign trade operators submit statistical forms for goods sold via online stores to private individuals who are not registered as entrepreneurs and are acquiring goods for their own needs, unrelated to any entrepreneurial activities on their part.

2. Confirm that, until Decree No. 1329 of the Russian Government of 7 December 2015 is amended, based on clause 6 of this Decree, one statistical form may be submitted in a reporting period for goods sold via an online store to individuals who are residents of EEU member countries, taking into account the following:

- a separate statistical form is submitted for all goods sold in the reporting period to private individuals who are residents of each EEU country

- the following purchaser information must be entered in section 2 of the statistical form:

- full name of individual → “private individuals”

- city, town, locality → put a dash

- street address → put a dash

- the details of a consolidated invoice containing information on all orders placed in the reporting period should be entered in section 10 of the statistical form, or else “Other” should be indicated in the “document name” section, and the numbers of orders placed in the reporting period should be listed.

4. The Development of Consumer Market and Technical Regulation

Issue 1. Fundamental principles of state regulation of trade.

Summary

The amendments to the Law "On Trade" effective from 15 July 2016 have brought about radical restructuring of the entire system of relations between suppliers and retailers. The legislation 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, that 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 (several thousand 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. These inspections, to ensure that suppliers and retailers complied with the amended law, found no major violations. The process of self-regulation that in 2014-2015 partially enabled market participants to find helpful solutions and restrain price growth proved non-performing. Only gradually, as new business practices developed under the amended Law, were market players able to resume the dialog on self-regulation. There have been early successes: self-regulation helped market players effectively address the problem of bakery product returns. Now the dialog between retailers and suppliers is focused on adapting the code of good practices to the new regulatory environment.

Since the Law was amended, however, the retail situation has not yet regained equilibrium. Market players (suppliers and retailers) are increasingly dissatisfied with the business climate created by the amended Law "On Trade." We observe a trend towards politically-driven and non-expertise-based solutions on how to further "improve" the Law. A draft law totally prohibiting food returns has passed its first reading in the State Duma. In addition, other topics are now being publicly discussed, such as the regulation of markups, prices, direct imports, in-house production and own trademarks, the introduction of shelf quotas for local manufacturers and the limitation of contractual penalties, 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.

WG's position on this 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 will inevitably be perceived as a retreat by the Russian leadership from market principles.

Recommendations:

1. Do an impact assessment to analyze the actual market impact of the amended Law (as compared with the Law's officially stated objectives). Based on the findings of the impact assessment, consider whether the amendments made to the Law in 2016 should be retained or not.

2. Ensure that additional legislative restrictions on free contractual relations between consumer market players are not initiated or introduced before the impact assessment procedure is completed.

3. At the federal level, formulate a 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.

Issue 2. Legal and technical readiness for electronic veterinary certification and impact on commodity supply chains.

Summary

Electronic veterinary certification ("EVC") came into effect on 1 July 2018. As a significant proportion of finished (processed) food products was removed from the scope of EVC before that date, the burden on the system declined dramatically, preventing significant system failures in processing electronic supporting veterinary documents (eSVD), which was especially important when implementing the system on a massive

scale. However, the performance of the EVC system remains unstable: a lot of issues have to be resolved manually, which creates various problems for business community.

The main problem with the EVC system is that it is permission-based. In the absence of a formal, structured standard setting out clear requirements to transmitted data, it is impossible to fully automate the already re-engineered operational processes for ordering, accepting and transporting goods further to all market participants at each stage of the supply chain. This causes system integration failures to most members of the supply chain – suppliers, major distributors and retail chains. Before the previous certificate is canceled and a new one is issued, no further movement of goods is possible, including return of rejected goods.

According to retailers, currently, 20 to 30% of veterinary documents accompanying products of animal origin are to a greater or lesser extent in breach of veterinary legislation, resulting in that deliveries to retail outlets get suspended for one day or more until the irregularities are removed. Another 10-15% of veterinary documents are presented in a form that does not result in suspension of deliveries, but does require certain additional efforts from retailers to input the information into their accounting systems.

Further, according to the available information, since 1 July 2018, in some constituent entities of the Russian Federation there have been cases of inconsistent interpretation of veterinary legislation by the veterinary authorities issuing eSVDs.

Additional tension arises from the fact that the Russian Ministry of Agriculture has not yet come up with amendments to the veterinary rules for issuing supporting veterinary documents and the Procedure for issuing electronic supporting veterinary documents approved by Order No. 589 of the Russian Ministry of Agriculture of 27 December 2016, as well as from the authorized federal authority's unclear stance on some disputed matters of veterinary legislation. The General Prosecutor's Office has received several enquiries from stakeholders on this matter. In this context, quick explanations on the EVC system are required from the Ministry of Agriculture, as well as amendments to the departmental regulations on EVCs. Concerns are also being raised over the fact that federal legislation placing a moratorium on administrative liability for failure to comply with statutory requirements for the execution of eSVDs has still not been passed into law.

If the proposed measures are not made law, entrepreneurs transporting goods under non-conforming eSVDs may face charges under part 2 article 10.8 of the Administrative Offenses Code "Transportation of agricultural animals and(or) agricultural products not accompanied by veterinary documents, except for personal use" that imposes fines on legal entities ranging from kRUB300 to kRUB500.

The fact that a substantial proportion of enterprises in traditional retail segments (non-chain stores, food markets, etc.) are not ready to transition to EVCs remains completely unaddressed. We estimate from polling our business partners that no more than 20% of businesses in this segment are ready to work with eSVDs.

Furthermore, the EVC system's functionality does not support the logistics and other operating procedures that are currently present on the market, e.g., issuing eSVDs for product sets, or multimodal transportation, or moving goods among the EEU countries and to Kaliningrad Region.

Of special concern are the inconsistencies remaining between product classifications in the Argus system that is responsible for international transportation and the Mercury system that supports further movement of imported goods across the country. This leads to the need for significant manual efforts to perform regular reclassification "stock takes" of incoming goods.

Legal issues to be clarified

- Currently, paragraph 2 in Appendix 1 to Order No. 589 does not require that a separate eSVD be issued for each consignment. An official clarification is required on the eSVD issuance procedure to state that an eSVD may (or may not) be issued for a group of goods.

- Currently, Order 589 does not provide a procedure for reporting information about laboratory tests on raw materials or products. Clarification is required on how the information about laboratory tests has to be reported in eSVDs, including the specific fields where the information should be contained, and on the procedure for ordering laboratory tests where it is not provided in the terms of shipment set out in the Regionalization Rules, including the regulatory documents that form the basis for ordering tests.

- Currently, Order No. 589 does not prescribe a procedure for switching to hard copies in case of an EVC system failure. There are no criteria for considering the system to be out of order, no procedure for notifying entities, no clear acknowledgment that, if SVDs are issued in hard copy, this will not affect the distribution of powers among the authorized in-house specialists, certified specialists and government veterinarians approved by the Ministry of Agriculture's Orders No. 646 and 647. Also, it is not determined if a hard copy VSD should be a protected form, or a simple stamp will suffice.

- Some constituent entities of Russia require that an eSVD must state the number and date of issue of the export permit for controlled products, and that an import permit must be obtained for such products specifying the manufacturer and the export region, in spite of the fact that the transportation terms for agricultural products are established by the Decision on assigning a contagious animal disease status to the regions of Russia depending on the epizootic situation in the region. Clarification is required that there is no need to obtain an export/import permit for controlled animal products if an eSVD is in place.

- Some constituent entities of Russia require that shopping centers issue production eSVDs for self-produced products, despite the fact that shopping centers produce ready-to-cook meat and fish products based on company standards or technical specifications and from raw materials that have undergone comprehensive veterinary hygiene evaluation (or produced from raw materials that have undergone veterinary hygiene evaluation) and are supplied to the shopping center with a complete set of documents confirming the quality and safety of the products. Self-produced food products are sold in the shopping center to end users (for personal use) and are not intended for further transportation. Clarification is required that there is no need for shopping centers to issue production SVDs for self-produced products if the products are sold to end users.

- Laws and regulations governing eSVDs do not address the procedure for conducting veterinary hygiene evaluation (VHE) of raw milk supplied to milk processing plants for industrial processing, and are silent on whether a statement of veterinary hygiene evaluation should be included in an eSVD. Compliance with the requirement for veterinary hygiene evaluation is hindered by lack of a regulatory framework, namely, veterinary rules for conducting veterinary hygiene evaluation. For eSVD purposes, official clarification is required on the VHE procedure for raw milk.

Recommendations:

1. Pass the amendments to the Administrative Offenses Code of the Russian Federation (i.4 of Minutes No. АД-П11-86np of the meeting of 18 September 2017 hosted by Deputy Prime Minister Arkady Dvorkovich) placing a moratorium on liability for failure to comply with statutory requirements for the execution of eSVDs;

2. Expedite the passing of amendments to Order No. 589 of the Ministry of Agriculture of 27 December 2016 to remove the numerous legal uncertainties surrounding the eSVD procedure, including the multimodal transportation problem and the procedure for switching to hard copy in case of a system failure. Develop and adopt an administrative procedure for working with hard copy documents;

3. Based on the list of questions raised by the business community, prepare and publish official guidance on how to interpret applicable legislation governing the execution of eSVDs;

4. Develop and implement in the EVC system functions to support the existing operations, for example, add the so-called product sets, i.e., goods comprised of more than one product item.

5. Synchronize the product classifiers in Argus/Mercury SVH and Mercury HS to enable automated acceptance of incoming products.

Issue 3. The impact of multiple product tracking and accounting systems on consumer market.

Summary

In the recent years, various governmental agencies in Russia have implemented electronic systems that use additional marking to monitor and record the movement of goods within the consumer market (tracking systems). This refers to the EGAIS (Unified State Automated Information System – from 1 July 2018, alcoholic sales are recorded on an item-by-item basis), to placing RFID marks on fur products, to Mercury electronic certification system (also applies from 1 July 2018), and to online cash register equipment. A federal law has been enacted (No. 229463-7) that authorizes the Government to establish a list of marked products and imposes the requirement to print item identification numbers on cash register receipts. Also, at the instruction of Prime Minister Dmitry Medvedev (i. 3 of Minutes No. DM-P10-67pr of 10 November 2017), a Concept is currently under development for the creation of a unified Russian marking and tracking system by 2024. Resolutions No. 791-p and 792-p of the Russian Government of 28 April 2018 approved an operating model for the system of identification marking of goods in the Russian Federation, and a list of selected goods subject to mandatory identification marking.

In the current year (2018), pilot identification marking projects have been or planned to be launched for tobacco products, jewelry, pharmaceuticals and footwear. Currently, various proposals are being debated to expand the existing list to cover foodstuffs.

In parallel with individual country efforts, work to implement product tracking systems is also being conducted at the EEC level. At the end of 2017, an interstate agreement “On marking goods with means of

identification in the Eurasian Economic Union” was distributed to EEU member countries for ratification, which is now underway.

The regulator regards the product tracking system as a key instrument of state oversight policy in the fight against counterfeit products. While generally supporting efforts to combat counterfeit products, the FIAC working group member companies note that implementing these systems has already caused significant costs to market participants (equipment purchases, development/customization of IT solutions, training for own staff and partners). The lack of a uniform standard for such systems (a uniform list of goods, a shared IT platform, marking standards, product tracking principles etc.) has seriously diluted the effect of implementing them and increased the burden on market players, especially on small and medium businesses and retailers. We can therefore confidently predict a significant increase in the cost of consumer goods (including essentials) for end consumers, since companies will have to include some or all of these costs in the final cost of goods.

Of special concern is the risk of lack of common product tracking standards at the EEU level, which may cause the common economic space of the Union to disintegrate and nullify the successes achieved in ensuring the free movement of goods as one of the four inalienable freedoms of the common economic space.

In this connection, the companies insist that there should be a common and unique product tracking system for all EEU member countries. We believe it is essential that the Government and business community develop and submit proposals to improve digital data exchange between business and government on statutory accounts, declaration, certification and other statutory compliance matters by creating a uniform information service (a “one stop shop”), in order to:

1. streamline data exchange between corporate and government IT systems (both existing and planned) based on standard units of measurement via single sign-on;
2. reduce the number of data transmissions between corporate and government IT systems;
3. improve the quality and relevance of information exchanged;
4. minimize the costs to business and government of integrating, gathering and storing data as part of implementing new IT systems;
5. improve data exchange between IT systems within government;
6. ensure a free service providing aggregate market data to help companies improve their business-planning processes.

Recommendations:

1. In cooperation with good-faith manufacturers and their industry unions, develop criteria for deciding whether to apply tracking systems to particular product categories.

The key criteria include, without limitation:

- the percentage of counterfeit and/or contraband products exceeds a certain threshold (based on comprehensive quantitative studies),
 - the cost of the product compared with costs to purchase and install additional equipment,
 - how market players (including small and medium businesses) and the investment climate will be affected by the introduction of marking for each category and group of goods.
2. Consider inviting open discussion with expert community to assess, in particular, the regulatory impact, appropriateness of introducing product tracking systems for a particular product segment, and submit the initiative for approval by resolution of the Government.
 3. Consider introducing a mandatory requirement to agree in advance with market players (manufacturers, wholesalers, retailers) trading in each category of goods on the type and format of means of identification.
 4. Harmonize the approaches to product tracking in existing national information systems and those under development; eliminate overlapping functions and, where possible, ensure that all such systems are integrated on a single IT platform.
 5. Align the requirements of national tracking systems with global practices, to avoid the tracking mechanism turning into another administrative barrier to international trade, including the EEU market.
 6. Describe the proposed system in detail:

- rights, obligations, the business model of the system's commercial operator (along with key provisions of draft regulatory acts)
- the private operator's interaction with the market (prohibition and approval functions, and prevention of the operator's function from being monopolized);
- interaction with government agencies (prohibition and approval functions);
- whether or not work with the system involves additional commercial intermediaries;
- preservation of the confidentiality of information constituting a commercial secret.

7. Before a full-scale tracking system is launched, a uniform product description and classification framework must be developed, approved and tested, to ensure traceability. Using the classifier must not cause additional costs to market players.

8. Develop a roadmap with precise deadlines for the phased introduction of tracking for each planned category of goods, carry out pilot projects with a sufficient transition period during which fines are not charged, and avoid parallel introduction of marking in several categories in order to minimize the burden on business.

9. Formulate a procedure for imported goods released into free circulation in the EEU following customs clearance, and for sales of goods on retail markets.

Issue 4. Draft national strategy for the promotion of a healthy lifestyle, including product marking initiatives and passport of the "Building a Healthy Lifestyle" priority project, and potential impact on companies in the consumer sector.

Summary

Russia currently has several state projects under way to promote a healthy lifestyle, and these projects overlap to a large extent and are sometimes at odds with one another.

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 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.

At the same time, FIAC working group member companies feel called upon to point out a number of terminological and technical problems in draft documents.

The Ministry of Health has drafted a government order approving the Strategy for the Promotion of a Healthy Lifestyle and the Prevention and Control of Noncommunicable Diseases until 2025 (the "Strategy"). The Strategy's goal is to create an integrated prevention-oriented environment with optimal conditions for leading a healthy lifestyle and fully realizing human potential.

From a formal point of view, the Strategy development process is not transparent and with minimum involvement of market players affected by the proposed regulation; it is impossible to obtain an up-to-date version of the draft Strategy, making it much harder to hold a constructive discussion. In addition, a number of requirements of Federal Law No. 172-FZ of 28 June 2014 "On Strategic Planning in the Russian Federation" have been overlooked. Such an approach not only complicates any assessment of the Strategy's financial impact, it also threatens to disrupt the unitary and interconnected legal space of Russian strategic documents.

From the point of view of terminology, FIAC working group member companies oppose the use of the term "healthy product" or "healthy diet" and believe that the division of food products into good/healthy and bad/unhealthy is unjustified. Such an approach will not further the Strategy's stated goals and will have very negative socioeconomic and political repercussions, including for the country's food security, that have not been assessed or taken into account by the document's authors. This opinion was once again voiced in public hearings held in January 2018 in the Russian Civic Chamber.

In international practice, the most reliable option is a "balanced diet" containing all the essential components, vitamins and micronutrients, rather than a "diet that excludes particular products."

Any references to specific types of products as "discretionary" or as not in line with a comprehensive approach to the promotion of a healthy lifestyle, enhanced food value and balanced meals should be removed. The Strategy also lacks internal terminological consistency, using such terms as "healthy diet," "products for a healthy diet," "healthy food products," "products with a high content of ...," "harmful products" and "products with an excessive content of ..." Of these, "healthy diet" is the only term defined.

The Strategy also contains a number of provisions designed to limit marketing and toughen the technical requirements for marking and ingredients (including by amending EEU technical regulations) as well as fiscal measures that are either impracticable on a national level or are excessive and require additional substantiation.

It should be noted that advertising is not designed to change an individual's choice from one product to another. I.e., advertising does not make one forgo fruits in favor of chocolate, but merely raises awareness of new products and helps promote specific brands. That being said, the OVERWHELMING majority of brands and manufacturers that can afford large-scale advertising campaigns are good-faith manufacturers producing safe, high-quality and useful products meeting all applicable standards and specifications. If advertising were removed, this would cause some customers migrate from high-quality brand name products to "no name" alternatives of unknown quality. That is to say that a ban on advertising would not lead to reduced consumption of particular categories of products, but would almost certainly cause deterioration in the diets of people in Russia – especially, children.

The family and family well-being, objectively, play the key role in forming balanced eating habits. A WHO study found a positive correlation between higher family income and developing healthy habits, such as consumption of fruits and physical activity. The same is true for family meals, i.e., having regular meals together (breakfast, dinner). Family meals are an opportunity to set a good example to children, and to support them psychologically; also, regular breakfasts help prevent impulse eating of high-calorie foods. A comprehensive review of nutrition problems among children and adolescents shows that material well-being and healthy relationships within family are the key factors. The root of the childhood obesity problem lies not in commercials but, in the first place, in the child's work and rest schedule and ways of how this rest time is spent, so greater focus needs to be placed on promoting active games and sports among children.

Inasmuch as the Strategy may have a decisive influence on the development of the food manufacturing and retail, FIAC working group member companies are convinced that work on the Strategy must include an open public discussion of the draft, involving representatives of the scientific and business community as well as concerned social organizations and representatives of federal executive bodies.

The second document for the promotion of a healthy lifestyle is the passport of the priority project "Building a Healthy Lifestyle," approved by the Presidium of the President's Council for Strategic Development and Priority Projects (Minutes No. 8 of 26 July 2017). The project addresses such important topics as the marking of food products, the program of grants for NGOs and employer responsibility for the health of employees, which will make it an important influence (including administrative and financial) on state policy in many areas, including economic and agricultural policy.

FIAC member companies feel compelled to point out a number of problems in the document. First, we urge that the term "balanced diet" be used, since "healthy diet" divides all products into "healthy" and "unhealthy," which is inappropriate. The summary plan's time frame is unrealistic and in need of correction. The document's poor financial elaboration should also be noted. All of this makes it doubtful that the project can be successfully realized.

The approved idea of a communication campaign involving manufacturers to promote a healthy lifestyle deserves special attention. This is a pilot project for the marking of goods based on certain criteria and advisories on a healthy lifestyle. FIAC member companies oppose such an approach as discriminatory and incompatible with the principles of a balanced diet. The Ministry of Health has not yet offered any scientific basis for the nutrient profiles underlying the proposed pilot project or for its chosen list of products, leaving the justification of these criteria open to debate.

The proposed criteria conflict with, for example, the criteria of optimal and excessive nutrient content, developed by the Federal Consumer Rights and Welfare Service, jointly with the Nutrition and Biotechnology Federal Research Center, in fulfillment of clause 53 of the Implementation Plan for the Strategy to improve the quality of food products in the Russian Federation to 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.

It is thus clear 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.

Recommendations:

1. Request that the Government charge the Ministry of Health with forming a permanent interdepartmental working group on the harmonization of documents concerning the promotion of a healthy lifestyle, the prevention of noncommunicable diseases and the enhancement of food quality with other

program documents (e.g. the Strategy for Increasing the Quality of Food Products in the Russian Federation to 2030) and with EEU law. The working group should include representatives of concerned executive bodies, including the Ministry for Economic Development, the Ministry of Industry and Trade, the Ministry of Agriculture, the Federal Antimonopoly Service, the Federal Consumer Rights and Welfare Service, etc., as well as members of business associations and the scientific and expert community. Adopt an inclusive decision-making procedure for work with this working group. For an effective dialog, ensure that adopted decisions are implemented in further work with the document, and require that decisions be endorsed by a co-chair(s) from the business community, responsible executive bodies and members of the scientific community.

2. Recommend that the Ministry of Health do a regulatory impact assessment of the draft Healthy Lifestyle Project, keeping in mind that the draft contains provisions, including prohibitions and restrictions affecting production, marketing and the circulation of food products in some categories, that are not envisaged by current Russian law and other regulatory acts. (The Federal Antimonopoly Service, the Ministry for Economic Development and the Ministry of Agriculture pointed to unjustified restrictions and prohibitions in their negative opinions as part of the interdepartmental approval process.)

3. Recommend that the Ministry of Health refine the draft Healthy Lifestyle Strategy to emphasize a balanced diet and exercise, responsible consumption and self-regulation and reduce the disproportionate number of restrictions, prohibitions and fiscal measures applied to some food categories.

4. Recommend that the Ministry of Health include provisions in the Healthy Lifestyle Strategy based on food manufacturers' current self-regulatory practices in the areas of production, advertising and sales to promote a healthy lifestyle among consumers and eliminate measures that would involve an additional fiscal and regulatory burden.

5. Eliminate any references in the documents to specific types of products as "discretionary" or as not in line with an integrated approach to promoting a healthy lifestyle, enhanced food value and balanced meals.

6. Consider including recommendations in the Strategy on limiting the promotion of breast-milk substitutes in accordance with the WHO International Code of Marketing.

Issue 5. Technical Regulation of the Eurasian Economic Union "On Safety of Chemical Products" and its impact on companies in the consumer and chemical sectors.

Summary

The Council of the Eurasian Economic Commission (decision No. 19 of 03.03.2017) adopted EEU Technical Regulation "On safety of chemical products". The technical regulation sets out unified and compulsory requirements for chemical products placed on the market across the EEU customs territory, as well as the procedures and forms of conformity assessment, identification guidelines, terminology and labeling requirements. The regulation tasks the Eurasian Economic Commission and governments of EEU member states with developing and approving a procedure to create and maintain the EEU register of chemical substances and mixtures and a notification procedure for new chemical substances, and make sure that they come into force by 1 December 2018. If these conditions are met, technical regulation "On safety of chemical products" will become effective from 2 June 2021. Appendices to technical regulation contain, among other things:

- List of chemical products exempt from the regulation;
- Maximum tolerance of hazardous substances in chemical products;
- Chemical safety report structure;
- Maximum permissible content of restricted chemical substances in chemicals;
- State registration application form for chemicals.

According to preliminary assessment, the enactment of the technical regulation will give rise to the following probable risks:

- The notification procedure for chemicals can take up to 1.5 years to complete.
- No confidentiality commitments are made regarding mixture compositions.
- Substantial funds and resources will need to be spent on product validation.
- While there is no laboratory infrastructure in Russia to support testing, foreign protocols are not accepted.

In March this year, we submitted a letter to Denis Manturov, the RF Minister of Industry and Trade, with comments and suggestions on Draft Decisions “On the approval of the procedure for creating and maintaining a register of chemical substances and mixtures of the Eurasian Economic Union”, “Notification procedure for new substances” and EEU Technical Regulations “On safety of chemical products” and “On transitional provisions in EEU TR “On safety of chemical products”. The document put forward by the Eurasian Economic Council for public discussion reflects to a varying extent many of the comments proposed by the working group.

Recommendations:

1. Determine if companies are interested in being involved in updating standards to ensure compliance with the technical regulation;
2. Monitor public discussion (papers “On the approval of the procedure for creating and maintaining a register of chemical substances and mixtures of the Eurasian Economic Union”, “Notification procedure for new substances”, EEU TR “On safety of chemical products”, “On transitional provisions in EEU TR “On safety of chemical products”);
3. Monitor the content of the EEU register of chemical substances and mixtures.

Issue 6. Impact of recent amendments to the Federal Law “On road traffic safety” on corporate cars: likely problems and how to solve them.

Summary

Amendments to Federal Law No. 196-FZ of 10 December 1995 “On road traffic safety” (“Road Safety Law”) are scheduled to come into effect in December 2018.

The amended article 20 of the Road Safety Law imposes stricter road safety requirements (mandatory basic and advanced training for drivers; leaving vehicles in designated parking areas after a ride or shift; daily pre-departure and pre-shift vehicle maintenance checks; daily pre-shift medical checks on drivers, etc.) that will apply to organizations transporting people (other than the driver) and (or) goods in vehicles without entering into an agreement (in-house transportation).

This wording effectively imposes stricter road safety requirements on personnel (sales representatives, managers, CEOs, etc.) of organizations that manage vehicle fleets but are not engaged in freight or passenger transport business.

This creates significant risks for the entire corporate (passenger car) transport segment nationwide. Compliance with the new requirements in FZ No. 398 will require fundamental changes in technical and administrative regulations and corporate by-laws. Companies are often unable to ensure sufficient parking space, and daily medical checks and car checks will place a substantial time burden.

Since these requirements are not practically achievable for many companies that use passenger cars (no less than 1.5 mln cars, by FIAC’s estimate) to ensure mobility of their staff (managers, sales representatives, medical workers, service engineers, etc.) without offering passenger or cargo transportation services, this will force companies to seek other ways of keeping staff mobile. This, in turn, will lead to a decline in corporate car purchases, which may result in a national economic downturn with the associated reduction in car output and job cuts in the automotive and related industries (auto component manufacturing, oil refining, tire manufacturing, vehicle insurance, car repair services, etc.)

Currently, the overwhelming majority of large Russian and international companies have internal safe driving policies in place to effectively help improve road safety and reduce road accidents involving corporate cars. For instance, telematics and satellite monitoring facilities are used to help control speed and aggressive driving by staff, or limit nighttime driving.

For this reason, we believe that extending the requirements of article 20.2 of the Road Safety Law (with amendments taking effect from 20 December 2018) to corporate passenger cars would be excessive and unreasonable for the purposes of the Road Safety Law.

Recommendations:

1. Request the Government to task the Ministry of Transport with drafting and initiating amendments to Federal Law of 10 December 1995 No. 196-FZ “On Road Traffic Safety” to take corporate cars not used for freight or passenger transportation out of scope of art. 20 of the Federal Law.

5. Health Care and Pharmaceutical Industry Development

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

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

Problem

Today there are companies that systematically launch generics (including biosimilars) with a breach of existing patents on reference (brand-name) pharmaceuticals. Generics manufactured illegally using registered inventions become state-procured items.

In 2017, the governmental authorities entered into certain procurement contracts for generics registered when the patent protection for reference pharmaceuticals was still in effect. Recently, the number of such contracts increased significantly. Since early 2018, more than 16 constituent entities of the Russian Federation entered into over 35 procurement contracts for generics that violate the patent holders' rights.

Such practice results from existing legislative gaps. According to Federal Law 61-FZ "On the Circulation of Pharmaceuticals", state registration of generics or biosimilars is allowed during the period when the patent on the reference (brand-name) pharmaceuticals are effective. If the respective pharmaceuticals are included in the List of Vital and Essential Drugs ("VED List"), unscrupulous manufacturers may register maximum manufacturer's price and offer the pharmaceuticals for state or municipal procurement.

According to the existing law, the State Register of Pharmaceuticals (the "SRP") does not prevent public circulation of generics if the patent for reference pharmaceuticals is still in effect. Therefore, contracting authorities and consumers are misled and believe that simultaneous existence of reference and generic pharmaceuticals on the market is appropriate.

As a result of actions taken by unscrupulous members of the market, patent holders have to protect their rights in the course of lengthy litigations, which sometimes require participation of the state or municipal contracting authorities, as well as federal and regional authorities as parties of those litigations. Today, as many as seven international pharmaceutical companies are involved in litigations with just one generic manufacturer (Nativa). There are particular concerns that an approach taken by Nativa may be adopted by other market participants.

The need to improve law enforcement practice relating to exclusive rights to invented pharmaceuticals was also stated in Instructions for the Russian Government, including Instruction No. DM-P13-7063 of Russian Prime Minister Dmitry Medvedev pursuant to the 31st Session of the Foreign Investment Advisory Council in Russia (FIAC) of 23 October 2017 (clause 6) and certain instructions of Deputy Prime Minister of the Russian Federation Arkady Dvorkovich issued in 2017 and 2018.

However, the problem remains unsolved. To optimize working on this issue, the FIAC's Health Care and Pharmaceuticals Working Group offers the following steps:

- Create an inter-departmental working group on IP rights in circulation of pharmaceuticals that include representatives of the Russian Ministry of Health, the Russian Ministry of Industry and Trade, the Russian Ministry of Economic Development, the Federal Service for Intellectual Property, the Russian Federal Antimonopoly Service and pharmaceutical manufacturers.
- Consider recommendations of the FIAC's Working Group and make the respective decision through amending existing legislation to prevent violation of the patent holders' rights and to prevent public circulation of pharmaceuticals manufactured with a breach of existing patents.

Recommendations:

1. Pharmaceuticals registered in the period when the respective patent is effective may be put into public circulations only with the consent of the patent holder or upon the patent expiry. Information of the existing patents and the dates of putting the pharmaceuticals into public circulation can be found in the state register of pharmaceuticals for medical use.

2. State registration of declared maximum manufacturer's price for the pharmaceuticals in the period when the respective patent is effective is allowed only with the consent of the patent holder or upon the patent expiry.

3. To ensure fulfillment of clause 37 of Federal Law 61-FZ "On the Circulation of Pharmaceuticals" of 12 April 2010 by making information about all applications for state registration of pharmaceuticals publicly available at the web-site of the Russian Ministry of Health.

4. To align Russian legislation with legal acts of the Eurasian Economic Commission in terms of indicating information about the protection of IP rights for pharmaceuticals by patents effective in EEU member states and the applicant's confirmation that rights of third parties protected by the patent or transferred under a license were not breached due to registration of a new pharmaceutical.

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

Upon accession to the WTO and in accordance with clause 1295 of the Working Group's Report on Russia's Accession to the WTO, the Russian Federation committed itself to prevent subsequent registration of products in the scope of the data exclusivity provisions of Article 39 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) within six years after those products were initially registered. An exception to the above is that a party may register subsequent products if it provides its own data about the products that meet the same criteria as the data provided upon the initial registration.

Exclusive nature of data is understood as non-usage of information about the findings of pre-clinical and clinical studies of reference (brand-name) pharmaceutical for the registration of generics (biosimilars).

This provision was met by clause 18 of Federal Law 61-FZ prior to its amendments by Federal Law 429-FZ of 22 December 2014, which resulted in a significant decrease of previously agreed six-year term of the data exclusivity.

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 pharmaceutical in the Russian Federation.

It is remarkable that in this respect biopharmaceuticals are less protected than other pharmaceuticals, although the former are more innovative and require investments in a larger number of pre-clinical and clinical studies.

According to Federal Law 61-FZ "On Circulation of Pharmaceuticals" (paragraph 1u of Part 1 of Article 33), the state register of pharmaceuticals contains information about the period for putting a drug into public circulation. Currently, such information includes registration confirmation period (five years) or "no definite term". We suggest adding one more line to the state register of pharmaceuticals to present information in respect of the period of bringing the generic or biosimilar on circulation in respect of the reference pharmaceutical exclusivity period.

Recommendations:

1. Amend Part 18 of Article 18 of Federal Law FZ-61 "On Circulation of Pharmaceuticals", i.e. to prohibit usage of information about pre-clinical studies of pharmaceuticals and clinical trials of pharmaceuticals presented by the applicant for the purposes of state registration without its consent during six years since the date of state registration for the purpose of state registration of pharmaceuticals.

2. Provide that the state register of pharmaceuticals includes the information about the period of exclusivity of findings of pre-clinical and clinical studies.

3. Provide that the state registration procedure includes the assessment of exclusivity status of the findings of pre-clinical and clinical studies.

4. Amend regulatory documents of the Russian Ministry of Health – in particular, the Administrative Regulation on the State Service of State Registration of Pharmaceuticals for Medical Use – to ensure proper legal protection of the findings of pre-clinical and clinical studies within six years after a reference drug is initially registered. Require that data exclusivity status be reviewed when generics/biosimilars are registered, and, therefore, disallow the state registration if data exclusivity period is in effect.

1.3. Possible legislative amendments that would introduce compulsory licensing.

1.3.1. Problem

Proper protection of intellectual property rights is fundamental to the successful development of an innovation-based economy and to long-term investment. There is a direct correlation between the intellectual property protection index and the venture capital & private equity country attractiveness index. Therefore, initiatives to amend existing legislation in terms of compulsory licensing, including draft law concerning compulsory licensing for export production of pharmaceuticals prepared by the Russian Ministry of Education and Science do cause significant worries among manufacturers of reference drugs.

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 confirm its quality, safety and efficiency.

The proposed amendments may result in deterioration of investment attractiveness of the Russia's innovations market thus decreasing the patent activity in the Russian Federation and negatively affecting the Russian research and development, as well as significantly restricting the patients' access to the most recent developments in most R&D and innovative industries, including health care.

Recommendations:

In order to consider future development of the Russian science and innovative industry, attract further investments to the non-resource sector of the economy, as well as to maintain balance of rights and legitimate interests of the society and of the right holders, to keep existing exclusive procedure of restricting rights of patent holders in terms of compulsory licensing, the FIAC Health Care and Pharmaceuticals Working Group in Russia asks the following:

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

2.1. Simplified registration procedure under the new EEU rules for medical products that are already locally registered and in circulation in EEU member states, and extension of the transition period for local registration systems until 31 December 2025.

2.1.1. Problem

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

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

Therefore, to circulate in the EEU after 2021, all medical products currently circulating on the EEU market in accordance with local rules are subject to the comprehensive registration procedure in accordance with the new EEU Rules for Registration and Examination of Safety, Quality and Effectiveness of Medical Products by 31 December 2021. The new registration rules do not provide for any exceptions or simplified registration procedures for the medical products already registered and successfully circulating on local markets of EEU member states.

Second-level documents on medical products circulation, including the Rules for Registration and Examination of Safety, Quality and Effectiveness of Medical Products approved by Decision No. 46 of the Council of the Eurasian Economic Commission of 12 February 2016 (hereinafter, the "Rules"), have already entered into force. However, it should be emphasized that, in all objectivity, the new medical products registration mechanism is not working and unlikely to do so until 2018, in the best-case scenario. In reality, the transition period within which producers will have to re-register all their medical products in accordance with the new Rules is reduced to four years.

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

In the meantime, only in the Russian Federation there are currently about 32,000 registered medical products, which will have to be re-registered by 31 December 2021 under the new Rules. We believe the number of registered medical products circulating in other EEU member states is also impressive. In addition, given the prospect of the new unified EEU legislation, producers have kept a number of medical products from releasing to local markets, which means they will also have to release the new products to the EEU market within the determined period.

In this context, the logical conclusion is that the determined transition period (ending on 31 December 2021) is reasonably not enough to perform all the necessary procedures to ensure timely registration of all medical products circulating in EEU member states. Amendments to the effective EEU legislation could remedy the

situation, but another obstacle is the existing challenges of EEU inter-state approvals, which will complicate adopting the required amendments within the remaining time before the end of the transition period.

It should also be noted that even the simplified re-registration procedure for locally registered medical products will not help – the remaining transition period up to the end of 2021 will not be enough from a technical point of view to re-register all medical products currently circulating in the EEU market.

Therefore, apart from the proposed simplified registration/re-registration procedure for locally registered medical products, it is necessary to extend the transition period for the medical products registered in accordance with the EEU member state legislation to circulate in the territory of this state. It should be extended at least to 31 December 2025, plus, both the Agreement on Common Principles and Rules for Circulation of Medical Products (Medical Devices and Equipment) within the Eurasian Economic Union of 23 December 2014 and Decision No. 46 of the Council of the Eurasian Economic Commission “On Rules for Registration and Examination of Safety, Quality and Effectiveness of Medical Products” of 12 February 2016 should be amended.

Recommendations:

I. Extend the transition period for the medical products registered in accordance with the EEU member state legislation to circulate in the territory of this state to 31 December 2025 and make the corresponding amendments to the Agreement on Common Principles and Rules for Circulation of Medical Products (Medical Devices and Equipment) within the Eurasian Economic Union of 23 December 2014 and Decision No. 46 of the Council of the Eurasian Economic Commission “On Rules for Registration and Examination of Safety, Quality and Effectiveness of Medical Products” of 12 February 2016.

II. Consider introducing a special simplified registration/re-registration procedure for medical products locally registered and circulating in EEU member states, and make the corresponding amendments to the Rules for Registration and Examination of Safety, Quality and Effectiveness of Medical Products approved by Decision No. 46 of the Council of the Eurasian Economic Commission of 12 February 2016. The proposed mechanism is as follows:

1. A simplified registration (re-registration) procedure should apply to all medical products that have passed the procedures prescribed by law for verifying the compliance with the local requirements of EEU member states and are in circulation on the market of at least one EEU member state at the time of re-registration.

2. Technical tests, tests to assess biological activity and tests of medical products to approve the means of measurement are not required.

3. Clinical (clinical-lab) testing is not required either. Instead of tests, registration files include clinical data on the use of a medical product in EEU member states (opinions from clinics in at least one EEU country) as well as other clinical data (where available), verification that the medical product has not been withdrawn from the EEU market at the time of re-registration, publications in scientific literature on the product’s use in EEU countries (where available) and marketing information.

4. An inspection report is submitted if the manufacturer was previously inspected for this category of medical products.

If no such inspection has been done, an inspection report on compliance with the requirements for quality management systems in the EEU is not required for re-registration. To register medical products, it is enough to provide documents verifying that the quality management system complies with ISO13485 and similar national and interstate standards.

An inspection of compliance with the requirements for quality management systems in the EEU must then be done within three (3) years after re-registration.

5. A positive report on re-registered medical products by experts in the reference country does not have to be additionally recognized in countries where the re-registered products have already been locally registered and circulated successfully, as verified by clinical data and materials in the registration file as well as in the expert report. A medical product’s registration certificate applies to such countries when the product is registered in the reference country.

To register (re-register) the locally registered medical products, the following documents should be submitted to the authorized body of the reference country:

1. Application for re-registration in the EEU reference country + countries of recognition (at the applicant’s discretion) along with the documents indicated in clauses 2-16 and 20-29 of Appendix No. 4 to the Rules for Registration and Examination of Safety, Quality and Effectiveness of Medical Products.

2. Copies of documents, valid at the time of application, verifying registration in EEU member states.

3. Clinical data (clinical opinions on the medical product's circulation in at least one EEU country) + verification that the product has not been withdrawn from the EEU market at the time of re-registration + publications in scientific literature on the product's use in various countries (where available).

4. Marketing information (history of circulation on the EEU market).

5. Registration fee receipt + examination report + act of acceptance of the expert report.

Summary of the procedure:

1. The applicant submits an application for re-registration of a medical product along with the required documents and registration fee.

2. Within three business days, the registration authority checks the credentials of the person who submitted the application. If the credentials are properly documented, the registration authority forwards the documents to an expert organization for examination.

If the credentials are not properly documented, the registration authority returns the application and all attached documents to the applicant for correction.

When the faults have been corrected, the applicant may re-apply without paying an additional registration fee for the given medical product.

3. The expert organization performs an examination of the registration file within 30 calendar days after receiving the documents from the registration authority.

If the registration authority finds problems with the documents (required information not available), the applicant is notified that such problems should be corrected, with the examination suspended. When the problems have been corrected, the examination is resumed.

When the examination has been completed, the expert issues an opinion as to whether the product should continue to circulate in EEU member states (indicating valid reasons if the opinion is negative) and sends its opinion to the registration authority.

4. The countries of recognition, in which the medical product has not been previously registered, have ten business days to submit any objections to the expert opinion. Differences are settled as prescribed in the Rules of Registration. If no objections are submitted within this period, the expert report is regarded as having been accepted by all countries of recognition indicated in the application.

5. When the expert report has been prepared and accepted, the registration authority issues a new registration certificate or a decision not to issue such a certificate, giving valid reasons in the latter case.

2.2. Regulation of alcohol-containing medical products (Federal Law No. 278-FZ "On Amendments to the Federal Law 'On State Regulation of the Production and Turnover of Ethanol and Alcoholic and Alcohol-Containing Products and on Restricted Consumption (Drinking) of Alcoholic Products' and Certain Legislative Acts of the Russian Federation" of 29 July 2017).

2.2.1 Problem

Certain provisions of Federal Law No. 278-FZ of 29 July 2017 "On Amendments to the Federal Law 'On State Regulation of the Production and Turnover of Ethanol and Alcoholic and Alcohol-Containing Products and on Restricted Consumption (Drinking) of Alcoholic Products' and Certain Legislative Acts of the Russian Federation" relating to the circulation of alcohol-containing medical products will become effective on 1 January 2018.

In particular, with a view to prevent medical products containing alcohol from being used as a surrogate for alcoholic products, Federal Law No. 278-FZ applies not only to production of alcohol-containing medical products but also to all other aspects of their circulation, including purchases, supply, storage and (or) transportation.

The list of alcohol-containing medical products has been extended; starting 1 January, the Federal Law applies to all medical products in liquid form that contain ethyl alcohol (ethanol) as a pharmaceutical ingredient in any concentration, whereas medical products with under 0.5% of alcohol were outside the scope of the earlier regulations.

In addition, the Government of the Russian Federation is entitled to make lists of alcohol-containing medical products that are outside the scope of this Federal Law (clause 4 of Article 1) in terms of their production, preparation and (or) turnover. The Government decides on whether a medical product should be included in the list based on the volume of its container (packaging) and (or) its value and (or) functional purpose.

According to the State Register of Medical Products and Organizations (Individual Entrepreneurs) that Manufacture and Prepare Medical Products, the following types of medical products containing ethyl alcohol

in liquid form have been duly registered and are in circulation in the Russian Federation: reagents for lab tests and in-vitro diagnostics, dental bonding agents and primers for fillings and braces (in 6- to 8-milliliter containers).

It should be noted that these alcohol-containing medical products have a form that does not allow pure alcohol to be obtained/extracted from them and are sold at a price substantially (in some cases, dozens of times) higher than the retail prices of vodka and other products with an alcohol content of over 28% per 0.5 liters of the finished product, as established by Order No. 58n of the Russian Ministry of Finance of 11 May 2016. This makes their use as surrogate alcohol very doubtful. Moreover, such alcohol-containing medical products as reagents for lab tests, and dental bonding agents and primers are not intended for retail sale and are sold exclusively to professional users (medical institutions and health care workers) via a distribution network that rules out the possibility of their being used as surrogate alcohol.

In the period from 2012 through 2016, the Law regulated all aspects of the circulation of alcohol-containing medical products: production, turnover, purchases (including imports), storage and supply (including exports). All entities that circulated such medical products had to comply with licensing and declaration requirements and record all transactions in the Unified State Automated Information System. Such heavy regulation nonetheless failed to prevent cases of mass poisoning in Irkutsk in December 2016, when 75 died after drinking methanol-based surrogate alcohol. On the contrary, tighter regulation forced a number of importers and manufacturers out of the market, leading to the illicit turnover of unlicensed medical products containing alcohol. One of the most effective ways of preventing such tragic consequences of surrogate alcohol consumption would be, as stated in Instruction No. AKh-P11-7pr of Deputy Prime Minister Alexander Khloponin of 7 February 2017, to require manufacturers of non-food alcohol-containing products (including medical products) to inspect raw materials (alcohol) received to determine the methanol content of each shipment.

It is important to note that (by contrast with medical pharmaceuticals, perfumes and cosmetics, windshield washer fluids, household chemicals and alcohol-containing food flavorings), there have been no known cases in the Russian Federation in which alcohol-containing medical products have been used as alcohol surrogates, let alone cases resulting in injury or death.

Additional recording and declaration requirements introduced by Federal Law No. 278-FZ for alcohol-containing medical products create undesirable administrative barriers for small and medium-sized businesses engaged in the circulation of alcohol-containing medical products, which, in its turn, will substantially drive up prices for such products. Challenges faced by small and medium-sized businesses when connecting to the Unified State Automated Information System also imply that imported alcohol-containing medical products which lack equivalents produced in Russia and the EEU may be restricted for a long period, or disappear from circulation altogether.

On top of everything else, with the entry into force of the Agreement on Common Principles and Rules for Circulation of Medical Products (Medical Devices and Equipment) within the Eurasian Economic Union, the proposed regulation could provoke an undesirable increase in the flow of unregistered, poor-quality and counterfeit alcohol-containing medical products from EEU member states where there are no restrictions on the turnover of such goods.

Recommendations:

- The Government of the Russian Federation should instruct the Ministry of Health of the Russian Federation and the Ministry of Industry and Trade of the Russian Federation to design the procedure for making lists of alcohol-containing medical products that are outside the scope of Federal Law No. 171-FZ in terms of their production, preparation and (or) turnover and approve those lists; the instruction should be executed by 1 January 2019.

2.3. Decriminalization of the circulation of medical products that cannot endanger life and health (amendments to Article 38 of Federal Law No. 323-FZ “On Principles of Public Health Care in the Russian Federation” of 21 November 2011 and Article 6.33 of the Code of the Russian Federation on Administrative Offenses).

2.3.1. Problem

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

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

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

Recommendations:

1. Amend the existing term of 'a poor-quality medical product' in Article 38.13 of Federal Law No. 323-FZ "On Principles of Public Health Care in the Russian Federation" of 21 November 2011 so that it indicates the potential danger of using the product: «13. A poor-quality medical product is a product that is non-compliant with the requirements of the regulatory, technical and (or) operational documentation of the producer (preparer) or, in the absence of the above, the requirements of other regulatory documentation, and that may endanger life or health.»

2. Amend Article 6.33 of the Code of the Russian Federation on Administrative Offenses so that it includes a provision on liability for untimely amendments to the registration file for the medical product.

2.4. Regulation of prices for implantable medical products (Government Decree No. 1517 "On State Regulation of Prices for Medical Products Included in the List of Medical Products Implanted in the Human Body under the State Program of Guaranteed Free Medical Treatment for the Public" of 30 December 2015).

2.4.1 Problem

Government Decree No. 1517 "On State Regulation of Prices for Medical Products Included in the List of Medical Products Implanted in the Human Body under the State Program of Guaranteed Free Medical Treatment for the Public" of 30 December 2015 (hereinafter, "Decree No. 1517") envisages a mechanism for determining weighted average prices and for subsequent state and municipal purchases of medical products in the List of Medical Products Implanted in the Human Body under the State Program of Guaranteed Free Medical Treatment for the Public, approved by Government Regulation No. 2762-r of 29 December 2014 (hereinafter, the "List").

The implementation of Decree No. 1517 in its current form is very likely to create a situation in which whole groups of medical products will become unavailable for purchase in the state guarantee program. Above all, this would affect high-tech and often quite costly medical products. As a result, the treatment of certain diseases could be greatly complicated by the need to obtain the essential medical products. This has to do with the following key features of the Decree:

- Average prices will be determined by type of implantable medical product (hereinafter, "IMP") in the List, each given one weighted average maximum purchase price.
- Purchases of IMPs by health care facilities for use in medical treatment under the state guarantee program will be possible only for medical products included in the List.
- Limiting the maximum price of certain types of medical products to the average weighted price will make the latest medical products unaffordable for state purchasers. Such a limitation will also prevent new, high-tech medical products from entering the market.

In the Working Group's opinion, virtually every current group of medical products requires greater detail (a breakdown) based on the following criteria:

- Functionally distinct IMPs that are not analogs or mutually interchangeable and that have various areas of application are combined in a single type. This combination and the related price averaging inevitably rules out the most costly and frequently the most innovative medical products without guaranteeing the availability of analogs and functional substitutes.

- IMPs supplied in packages standardized variously by weight, number of linear meters, etc., are not differentiated in terms of quantity to determine the average price. Packages of differing amounts of a single substance are combined in a single type.

The current List is thus insufficient in terms of the number and detail of listed types and requires substantial revision before it is used for state price regulation. Otherwise, medical treatment under the state guarantee program may be seriously complicated.

Recommendations:

1. The Working Group recommends revising Government Decree No. 1517 of 30 December 2015 to ensure that implantable medical products are available to the public under the state guarantee program.
2. Where the existing mechanism cannot be optimized, the Working Group suggests investigating alternative mechanisms, including the existing industry schemes.

Issue 3. Localization and access to innovative technologies.

3.1. Terms of access of pharmaceuticals when purchased for state and municipal needs (initiatives to amend Government Decree No. 1289 “On Restrictions on and Terms of Access of Vital and Essential Drugs Originating in Foreign States When Purchased for State and Municipal Needs”).

3.1.1. Problem

The members of FIAC’s Health Care and Pharmaceuticals Working Group are concerned about amendments to Government Decree No. 1289 “On Restrictions on and Terms of Access of Vital and Essential Drugs Originating in Foreign States When Purchased for State and Municipal Needs” and introduce a “three-tier system of preferences” that would to introduce a three-step regime of preferences to pharmaceuticals produced from pharmaceutical substances originating in EEU countries.

The decree has already created a system of preferences for pharmaceuticals produced in EEU member states. There is a rule, for example, excluding imported drugs from an auction in which two or more pharmaceuticals produced in EEU countries are involved. Since 1 January 2019, if the application was rejected due to access restrictions to the purchases and at least one application contains an offer to supply pharmaceuticals completely produced in the EEU (including synthesis of active ingredient molecules of a pharmaceutical substance), and information about such pharmaceutical substances are included in registration files of such pharmaceuticals, the terms of access to procurement contracts stipulated by Order No. 155 of the Ministry for Economic Development of 25 March 2014 apply to these pharmaceuticals. Therefore, applicants, who submitted such applications enjoy a 15% preference for the contract price. Such amendments would seriously hinder the efforts of foreign investors who follow the principle of global cooperation to maintain affordable prices for their products. This initiative could also result in monopolization of the market of pharmaceutical substances for a number of international non-proprietary names and in higher prices for pharmaceuticals produced from these substances.

All too often such practices increase the state’s health care expenditures due to weaker competition between manufacturers. A more effective way of encouraging the localization of pharmaceutical production would be to offer long-term state contracts guaranteeing stable demand for manufacturers, fixed prices for the state.

Production of biotechnological pharmaceuticals, namely, polycompotent vaccines is a lengthy and complicated process. Long-term contracts with pharmaceutical manufacturers could contribute to more efficient planning of production and supply and, therefore, simplify the patients’ access to the treatment.

Long-term planning of the drug supplies should be based on the treatment cycle rather than on the annual plan of purchases of drugs from the VEDs. Multiple criteria analysis will help to forecast economic costs for certain categories of patients for whom such treatment is live-saving.

Furthermore, long-term planning to the pharmaceuticals procurement, including biotechnological ones, should include alternative forms of procurement (other than e-auctions), such as risk-sharing contracts and cost-sharing contracts, which not only make innovative treatment more affordable for the patients, but also will lead to lower budget costs for the pharmaceuticals supply. Decrease of prices considering scales and timing of supplies, as well as additional supplier’s liabilities related to risk sharing if the treatment does not prove to be positive, seem to be economically feasible for procurements of pharmaceuticals using the federal or regional budget or the one of the compulsory medical insurance, which has sense in the context of moderation of expenses and the need to recover costly treatment.

Recommendations:

1. Analyze the linkage between federal decisions on pharmaceutical import substitution (including the introduction of preferences in the state procurement system) and trends in state expenditures resulting from changes in the cost of products in this category.

2. Amend and improve legal regulation of alternative forms of the pharmaceuticals procurement, such as long-term contracts between the state and manufacturers of pharmaceuticals, risk-sharing contracts and cost-sharing contracts, including those related to reference and biotechnological pharmaceuticals, as well as procurement of reference pharmaceuticals under the patent protection without e-auctions.

3. Work over budgeting and allocating funds for the pharmaceuticals procurement based on long-term planning principle and, if necessary, introduce respective amendments to internal documents, laws and regulations.

3.2. Special investment contracts.

3.2.1. Problem

In order to implement the policy aimed at setting up production of competitive industrial goods in the Russian Federation, Federal Law No. 488-FZ "On Industrial Policy in the Russian Federation" was adopted on 31 December 2014, and Article 16 thereof provides for a special investment contract (SPIC) as an instrument to support investors.

Among other things, the purpose of this instrument is "to encourage investments in the establishment and modernization of production through providing investors with industry benefits and preferences and ensuring stable business environment." However, currently, proposals to improve SPIC instrument (by creating new SPIC 2.0 format) are being discussed.

Therefore, the Working Group believes that it is essential to preserve all regulatory environment for the entities, which have already entered into SPIC (including keeping existing terms unchanged when making amendments to SPIC) and to prevent automatical transition to SPIC 2.0.

We suggest considering the possibility to improve the existing measures and develop additional ones to encourage investors, which take into account the specifics of the pharmaceutical industry and production of medical products, as well as the needs of the Russian health care system. Besides, the Working Group believes that the measures should be focused on the demand development. These support measures will ensure the effectiveness of SPICs as an instrument for improvement of the investment climate and greater access to modern innovative pharmaceuticals and medical products for Russian patients.

In this regard, we suggest considering the possibility to improve the existing mechanisms to encourage investors, which take into account the specifics of the pharmaceutical industry and production of medical products, as well as the needs of the Russian health care system. In order to accomplish the task of increasing export of manufactured goods set by the President of the Russian Federation (Decree No. 204 of 7 May 2018), it is necessary to implement additional measures to support localization and creating guaranteed demand, which among others will create favorable environment for development of the high-tech products' export potential. Such additional measures may include the following: providing subsidies for or applying 0% rate import (for raw and other materials) and export customs duties (including subsidies for validation batches, transportation and logistic costs), and other measures.

Recommendations:

Prepare additional incentives to the investors that are aimed at existence of guaranteed demand and development of high-tech export of localized pharmaceutical products, considering, among other things, subsidies for or applying 0% rate import (for raw and other materials) and export customs duties.

Issue 4. Timely implementation of efficient and operating system to monitor the movements of pharmaceuticals.

4.1. Problem

Member companies of FIAC's Working Group support efforts of the Government of the Russian Federation in creation and implementation of efficient and operating system to monitor the movements of pharmaceuticals for medical use that is in line with safety requirements and development of health care and pharmaceutical industries. Most member companies initially participate in the experiment to mark medications with control (identification) marks, are actively involved in discussion and development of the basic principles of such a track, and trace (T&T) system. Considering analysis of accumulated experience of creating similar systems in other countries, the Russian Ministry of Health has developed and approved Methodological Recommendations¹ for an Experiment in Applying Control (Identification) Marks and

¹ Methodological Recommendations for an Experiment in Applying Control (Identification) Marks and Monitoring the Circulation of Certain Kinds of Pharmaceuticals for Human Use in Circulation in the Russian Federation, approved by the Russian Ministry of Health on 28 February 2017.

Monitoring the Circulation of Certain Kinds of Pharmaceuticals for Human Use in Circulation in the Russian Federation, approved by the Decree No. 62 of the Russian Ministry of Health².

The reasons for the experiment support included not only the fact that the companies were interested in control over the circulation and analysis of the respective data in real time, but also global trends in pharmaceutical tracking systems.

During the most recent 1.5 years, the companies purchased and implemented equipment and IT solutions for Russian and foreign production sites to be ready to comply with legislative requirements. Besides, they amended package design and registration files of pharmaceuticals and perform respective procedures to comply regulatory, technological and logistics processes and procedures with existing methodological recommendations for an experiment in applying control (identification) marks. Alignment of all internal processes to the requirements of projected Russian system of the goods marking did not cause significant difficulties, and the costs were economically feasible as the experiment's framework was in line with the international approaches to organize similar systems. Consistent requirements not only simplified financial issues, but also required fewer efforts from the manufacturers to meet deadlines for introduction of the making system.

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 January 2020³.

It is assumed that in accordance with the current version of methodological recommendations⁴, characteristics of means of identification will be drastically amended due to introduction of cryptographic protection and centralized generation of cryptographic protection codes. Therefore, all insights and completed investments (costing up to EUR 1 million per one production line) that took place in the course of the current experiment will become irrelevant. There is no cryptographic protection requirement in most of the international goods tracking systems. Where it used to be applied (e.g. in China), the authorities discontinued using them due to insufficient reasonableness of use, excessive complexity, high costs and low efficiency. According to the generally accepted international practice, global standards of monitoring of pharmaceuticals' movements are in line with all requirements of governmental authorities and do not require additional measures of cryptographic protection.

Since 13 October 2016, the Russian Federation as represented by the Federal Health Care Oversight Service is a member of International Coalition of Medicines Regulatory Authorities (ICMRA), which ensures comprehensive representation of Russian interests in considering relevant issues concerning circulation of pharmaceuticals in the international arena. ICMRA believes that it is important to implement T&T systems to monitor movements of pharmaceuticals, including ones used to protect integrity of commodity supply chain, to ensure prompt information exchange between the regulators of member state to prevent circulation of counterfeit products, to improve operation of pharmacovigilance bodies and to develop cooperation under MEDICRIME Convention. On 25 October 2017, ICMRA adopted Recommendations on Alignment of Existing and Planned Track and Trace (T&T) Systems to Allow for Interoperability as a strategic initiative to ensure integrity of the pharmaceutical supply chain⁵. Namely, ICMRA believes that it is necessary to align technical characteristics of the T&T system, including standardizing information of bar codes at the packages and application of international goods identifier in accordance with the ISO.

At this stage, failure to implement international standards restrains the development of the Russian pharmaceutical industry and limits its operation by one product market only, which contradicts strategical goals of development the export potential of the Russian pharmaceutical industry.

Due to the reporting requirements, a T&T system to monitor movements of pharmaceuticals implemented in the Russian Federation is the most ambitious and the most complicated system of this type ever existed. No country has existing or planned system of such complexity. Adding cryptographic protection requirement makes the project more complicated for implementation and does not help to better protect the pharmaceuticals from falsification and makes production and other business processes of the companies more complicated without any objective benefits for the end consumer and for the state.

Using means of cryptographic protection will lead to necessity to supplement an additional symbols to the means of identification (DataMatrix bar code), which, in its turn, will require larger secondary packages,

² Government Resolution No. 62 "On an Experiment in Applying Control (Identification) Marks and Monitoring the Circulation of Certain Kinds of Pharmaceuticals for Human Use" dated 24 January 2017

³ 2. Clause 2 of Article 2 of Federal Law No. 425-FZ "On Amendments to the Federal Law 'On Circulation of Pharmaceuticals'" of 28 December 2017

⁴ Dated 23 April 2018

⁵ <http://www.icmra.info/drupal/sites/default/files/2018-01/ICMRA%20T%26T%20Recommendations.pdf>

higher transportation costs due to larger dispatch boxes, stricter requirements to density and quality of printing. All these will require pharmaceuticals manufacturers to acquire new or upgrade existing equipment and software. As a result of testing of planned changes, the manufacturers faced with higher level of scrapping, which is unacceptable for an up-to-date production facility.

According to our estimates, average additional cost of upgrading completed high-speed package lines at one production site will require at least EUR 100-300 thousand of additional investments per one production line. According to the estimate, the total number of packaging lines operating in Russia approximate 3,000, therefore, the respective additional investments will total EUR 300-900 million.

Please note that implementing of marking system is very important in the context of EEU. 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).

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 should be in line 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: adoption of common rules in the field of circulation of pharmaceuticals and harmonization of member state legislation in the field of control (supervision) in the field of circulation pharmaceuticals.

The EEU has already prepared unified requirements to the goods marking at supranational level. E.g., legal registration of marking fur products was made in accordance with requirements of EEU by adopting in 2015-16 Special Treatment "On the Realization of a Pilot Project to Apply Control (Identification) Marks to Goods Categorized as "Articles of Clothing, Clothing Accessories and Other Goods of Natural Fur" 6. In order to implement this project, the Russian Government adopted Decree No. 7877.

To align new legislative acts of the Russian Federation with the norms of international treaties where the Russian Federation participates, as well as to ensure free circulation of pharmaceuticals on the common market of the EEU, it is appropriate to use legal regulation algorithm that provides for unification and agreement of requirements towards marking of pharmaceuticals among the member states on the EEU level. Therefore, T&T system that is based on the goods description under GS1 RUS system and a system for generating serial numbers by the manufacturers will be in line with manufacturers of all EEU member states and will not lead to isolation of commodity markets.

The Working Group analyzed if the member states are ready to introduce amendments of all previously made changes in accordance with possible new requirements. The analysis indicated that in the current circumstances possibility of the member states to meet the determined marking implementation deadlines remain extremely low. The primary concern is whether it is practical to develop a local solution, actually meaning that the Russian pharmaceutical market will be isolated from the international markets and absence of benefits of the proposed amendments against those already accepted during the experiment and technical difficulties in practical implementation. The member states held working sessions with representatives of newly appointed system operator⁸ at the Russia-based production sites of the member states, however they found no solutions for production and IT issues for implementing those changes. As the health care system has a large social importance, we believe that the selection of appropriate solution should be made in favor of a proved efficient approaches accepted by the international T&T system practice.

Recommendations:

1. Ensure preserving technical solutions that have been already tested and implemented in the course of the experiment and aligned with requirements of international standards describing characteristics, structure and format of means of identification, as well as to the respective marking procedures in order to integrate Russian pharmaceutical industry into the global trade turnover system and maintain industrial cooperation focused on expanding the pharmaceutical industry's export potential.

⁶ The experiment period was extended to 31 December 2018 (Minutes of extending the term of Special Treatment "On the Realization of a Pilot Project to Apply Control (Identification) Marks to Goods Categorized as 'Articles of Clothing, Clothing Accessories and Other Goods of Natural Fur' of 8 September 2015" (signed in Moscow on 23 November 2016).

⁷ Decree of the Russian Government No. 787 of 11 August 2016 "On the Realization of a Pilot Project to Apply Control (Identification) Marks to Goods Categorized as 'Articles of Clothing, Clothing Accessories and Other Goods of Natural Fur' and on the Annulment of Decree No 235 of the Government of the Russian Federation of 24 March 2016".

⁸ Decree of the Russian Government No. 1018 of 28 August 2018.

2. Together with the Eurasian Economic Commission agree the consistent mandatory requirements in respect of marking pharmaceutical 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: adoption of common rules in the field of circulation of pharmaceuticals and harmonization of member states' legislation in the field of control (supervision) in the field of circulation pharmaceuticals. This step should take place prior to approval of the final version of requirements to the T&T system for pharmaceuticals.

3. In order to prepare aligned decisions on the product marking both in Russia and on the common market of pharmaceuticals at the Eurasian Economic Union, create a separate working group consisting of representatives of the Russian authorities and representatives of the pharmaceutical industry on the basis of an authorized federal-level body, and also to create a working group consisting of authorized bodies of EEU member states and representatives of the pharmaceutical industry on the basis of the Eurasian Economic Commission.

4. Postpone mandatory application of special means of identification to the packaging of pharmaceuticals and entering pharmaceutical information in the T&T system for pharmaceuticals for medical use till 1 January 2025.

5. Consider timely amendments to the transitional provisions of Federal Law No. 425-FZ "On Amending the Federal Law 'On the Circulation of Pharmaceuticals'" dated 28 December 2017 that include permission to distribute and sell after 1 January 2020 the high-quality pharmaceuticals put in circulation prior to 2020 without means of identification until they expire.

6. Financial Institutions and Capital Markets

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

Recommendations: improvement of legislation (adoption of laws/amendments to laws):

- "On Unilateral Accounts Closure"
- "On criteria for financial institutions to enable the access to state funds and strategic companies, and bank guarantees for tax / custom authorities for the purpose of ensuring tax/custom payments"
- "On accounting policy of a lending institution in respect of placement of deposits under the general agreement" (time deposits).

Issue 1. Collateral legislation.

The Russian Ministry for Economic Development, in close collaboration with the European Bank for Reconstruction and Development, is working to reform collateral legislation in accordance with clause 66 of the Anti-Crisis Plan. The reform is intended to address the most serious problems encountered by market participants in using collateral. An increase in the market participants' confidence in the reliability and effectiveness of collateral as a form of security should result in greater financing on more favorable terms and so make it possible to satisfy the economy's demand for capital in a more timely and adequate manner.

In the context of an extensive reform of civil legislation, the Presidential Council for Codification and Improvement of Civil Legislation drafted a revised Civil Code, which addresses, among other things, provisions on collateral (Chapter 23, paragraph 3).

It should be noted that the collateral provisions of the draft Civil Code, if adopted in their current form, would not allow Russia to fully meet its goals in reforming collateral legislation. It is therefore very important to ensure that the key areas of this reform are reflected in the Civil Code.

Advantages: The draft Civil Code (prepared for its second reading in the State Duma) is more advanced than current legislation with respect to the following:

- confirms the legitimacy and possibility of levying charges in relation to syndicated loans;
- recognizes the legitimacy of pledging bank accounts;
- envisages the registration of collateral and recognizes the validity of collateral in relation to third parties from the date of its registration. These provisions are supplemented by a recently adopted law under which the Federal Chamber of Notaries is to develop a unified register of notifications of pledges of immovable property and ensure its functioning; this is a revolutionary development in Russia.

Disadvantages: a more flexible and effective approach to pledge transactions is not introduced in the draft, e.g.,

- there are still many restrictions affecting extra-judicial claims;
- pledges of bank accounts will not be as flexible as in many other markets;
- transaction costs may remain high due to excessive requirements.

Critically important: the draft contains problematic provisions relating to:

- Description of assets that may be pledged: the parties must be allowed to describe pledged items as they deem appropriate for their transaction, provided that such a description allows them to identify a pledged item at the time of enforcement. That will expand the range of assets pledged by borrowers and will ensure lenders' confidence in the reliability of pledges offered to them (e.g., lessen the risk that a transaction will be declared "non-existent" on formal grounds that a pledge is described inadequately; currently, such a risk is quite high for lenders) and will also reduce transaction costs involved in secured financing (e.g., when a pledged item is changed, amendments to the pledge agreement need not be made if such a change is covered by the initial general description).

- Obligation to notarize an extra-judicial claim agreement in relation to pledged immovable property, regardless of who the pledger is. Such a requirement may be needed to protect individual pledgers, since individuals are usually in a more vulnerable position and would be better protected if they consulted a notary. But there would seem to be no reason for similarly protecting legal entities that pledge their immovable property; besides, such an obligation would substantially increase the transaction costs. There are also provisions in the draft which actually oblige the parties to notarize all pledge agreements so as to have the option of making an extra-judicial claim, but this also increases transaction costs and negatively affects Russia's economic development in the long term.

- Obligation to notify a debtor about a pledge of the right of claim against him within five days after entering into a collateral agreement. In the contemporary financial world, it is quite common to pledge rights of claim. The debtor should be notified of such a pledge voluntarily, since there may be various reasons for the parties to consider it inexpedient to notify the debtor immediately. Such notifications also result in additional transaction costs. It is also important to allow the pledge holder to send notification himself without relying on the pledger, because relations with the pledger may worsen by the time such a notification is required by the pledge holder, and the pledger will not then cooperate with the pledge holder.

Recommendations 2013:

According to FIAC, the above-mentioned shortcomings should be rectified in the pledge provisions to be considered in the second reading by the State Duma. The European Bank for Reconstruction and Development (EBRD) is ready to provide the text of the corrections which should be made.

In cooperating with FIAC, the EBRD is willing to provide full technical assistance to the Ministry of Justice and the Federal Chamber of Notaries in developing a unified register of notifications of pledges of immovable property so that the system will meet today's market requirements.

Status 2013: the issue is resolved. The application of amendments should be monitored and additional recommendations should be introduced.

On 6 December 2013, amendments to the Civil Code concerning collateral were published and submitted to the Duma for the second reading. The working group proposed many of those amendments. The amendments concerned the free description of collateral, explicit registration rules, the priority of collateral, and the absence of the need to notify the debtor of the collateral rights. However, there are proposals which were made but not taken into account. The changes are scheduled to come into force on 1 July 2014.

- The requirements for a collateral agreement were sufficiently eased, and the parties could (were flexible enough) to determine the key parameters of the agreement (description of the collateral and the securing commitments) at their discretion; in this respect, account was taken of the interests of debtors, who may be less versed in financial issues. A favorable effect of these new provisions will largely depend on their interpretation by the courts;

- The introduction of the concept of collateral manager, who represents a group of lenders, and the recognition of agreements between lenders on the priority of their collaterals can be regarded as important achievements in Russian law. However, certain issues are not regulated quite clearly; therefore, the market may be wary of the new concepts until there is clarity.

- The new collateral register will be the most noticeable aspect of reform for the market players. It will provide clarity and certainty, which are so needed. Hopefully, the register (e.g. the registration process) will prove to be effective and economical.

- The recognition in the Civil Code of the general principle of determining the priority of lenders relating to the time of registration of collaterals is a very important change which, together with the transparent registration system, should make the lenders far more confident. However, there could be certain problems when the same asset serves as collateral several times.

- The reform has substantially consolidated the approaches to pledging claim rights and filing a charge against them. It also became legal to use bank accounts as security; they were used as such earlier, but it was not clear whether that had legal force, and the instruments were weak.

- As regards the claim to collateral, the reform seems to be more modest, although certain positive clarifications were made. Additional work may be required, especially after the new provisions are tested in practice.

Status: 2015:

The reform of the Russian pledge legislation, which has been discussed and called for, for so long, was aimed to reflect both the most serious problems encountered by market participants in using pledge to secure obligations - in terms of existing legislation and its application by Russian commercial courts, as well as best international practices. In December 2013, new provisions amending the Russian Civil Code and some other laws were adopted to enhance secured lending framework. Most of the changes became effective on 1 July 2014. The provisions bring significant benefits to the legal framework and expectation is that the benefits will be felt by market players. However, close examination has also revealed a number of issues, which would be very beneficial to address in subsequent amendments.

Recommendations:

1. The concept of a pledge manager introduced in the Civil Code has a special significance for syndicated lending. The Civil Code provides that the pledge manager acts in the name of creditors who appointed him and not in his own name. Therefore, it is possible that the parties will interpret this provision as requiring the lenders and not the pledge manager to appear in the registers as pledgeholders (the register of notices of pledges, shareholders' registers, immovable register, etc.). It means, in turn, that upon assignment of the debt of one of the lenders in the syndicate the new lender will need to appear in the registers – hence the need to amend the registration record. In other words, loan transfers, which are quite common in syndicated lending, would entail the need for updating records about the pledgeholder in all the registers where the pledge securing the loan is registered. This would be quite cumbersome and against the spirit of providing the concept of pledge manager in the first place.

This concern could be eliminated by changing a number of Russian laws (Law on Notariate, Mortgage Law, Securities Market Law, etc.) and sub-laws. It is necessary to expressly provide that it is the pledge manager who will appear in a register where the relevant pledge is recorded (register of notices of movable property, register of rights to immovable property, shareholders' registers, etc.) and not the lenders in whose interests he acts.

2. It is also necessary to expressly confirm that the pledge manager will be able to fulfil his functions even in case of the pledgor's bankruptcy. Therefore, it is necessary to amend the Bankruptcy Law to specify, that it is the pledge manager who is to exercise rights and duties of secured creditors in the interests of which he acts in the course of the pledgor's bankruptcy proceedings.

3. In addition, the progressive changes introducing a pledge manager concept may be impaired by certain provisions, as described further. The current Civil Code wording may be interpreted as allowing the termination of a pledge management at the initiative of one of lenders who appointed the pledge manager. In other words, one lender could defeat the will of all the others within the syndicate. If this interpretation prevails in practice, syndicated lenders may feel that appointing a pledge manager is too fraught with uncertainty to be worthwhile.

Further, it is not clear whether the powers of the pledge manager remain after assignment of claims by one of the lenders or whether these powers need to be further confirmed by entering into some additional agreement. If the practice settles so that some additional actions are required to ensure that the new lender can enjoy the "service" of the pledge manager, it would add unreliability to the instrument.

These concerns could be eliminated by amendments to the Civil Code. However, even without changing the Civil Code, the risk of the above interpretations could be mitigated if a Supreme Court clarifying opinion is issued to confirm that (1) the pledge management agreement cannot be terminated at the initiative of one of the creditors, it can be terminated only upon the decision of all the creditors (with such decision being adopted as per the procedures described in a pledge management agreement), and that (2) the loan transfer results in the automatic change of the relevant party in the agreement on management of pledge (i.e. the new lender becomes a party to the agreement without the need for undertaking some additional actions). These clarifications would greatly enhance the market participants' trust to the concept of the pledge manager.

4. The concept of agreements on changing priorities of pledges introduced in the Civil Code is also very important for multi-lender lending deals. To strengthen this concept, it would be highly desirable to expressly recognize its effectiveness in case of bankruptcy of the pledgor. Therefore, it is necessary to amend the Bankruptcy Law and expressly provide that the priority for the satisfaction of pledgeholders' claims is to be determined with due regard to the agreements on changing priorities of pledges, if any. It would be also very useful to confirm that this concept is applicable to mortgages as well (the issue could be addressed by a Supreme Court clarifying opinion).

Overall, further legislative changes and court clarifications as described above would contribute to the correct application of the relevant Civil Code novelties on pledges and, respectively, to the achievement of the goals for which they were conceived.

Issue 2. Banking reform and the banking sector's development strategy – CBR's reports.

Bank regulation has sustained drastic changes in 2017. To change banking standards in Russia so as to align them with the preliminary findings of our evaluation, we have had to prepare more than 20 normative acts. Some of them are amended regulations, some have been designed from scratch.

Implementation of normative ratio N25 regarding the maximum exposure to the bank's related party or a group of the bank's related parties from January 1, 2017 becomes the headliner regulatory event. The normative ratio rollout is expected to be lenient and sustainable for the banks. The bank's related companies are granted a two-year grace period before they are added to reporting for this ratio. In 2017,

they will be weighed at 20 per cent, while in 2018 the weight will increase to a ratio of 50 per cent. Subsequently, they will be weighed at a ratio of 100 per cent, as all other related borrowers. This amendment to Regulations No. 139 was adopted in November and is in the process of registration at the Ministry of Justice. Another two ordinances were released at the same time.

Ordinance No. 4203 “On the Signs of Potential Interconnectedness between a Person (Persons) and a Credit Institution” stipulates for a range of characteristics, which the regulatory body, the Bank of Russia’s banking supervision committee, will use to substantiate their assertions regarding interconnectedness of companies or individuals with the bank for the purpose of applying N25 ratio. Together with amendment to Regulation No. 139, this document is being registered by the Ministry of Justice. And the third document is a procedure of the Bank of Russia’s banking supervision committee to recognize a person as a related party of a credit institution or part of a group of related parties of a credit institution based on the substantiated assertion, sending requests to credit institutions and considering their applications.

Amendments were also made to Ordinance No. 2005-U, namely, to Ordinance No. 4187-U that introduces preapproval of decisions to assign PU-4 indicator by territorial units of the Bank of Russia and the supervision departments. PU-4 means an indicator used to evaluate the bank risk management system with a value equal to or exceeding the 2.35-point limit. This decision must be confirmed by the banking supervision department. There are also a number of changes that enable prompter reaction to issues in banking activity in case of non-compliance with the statutory ratios. Those were exactly the changes in methods in Ordinance No. 2005-U. That ordinance is being registered by the Ministry of Justice; it will be enacted in 10 days from the moment it is published.

Ordinance No. 4204 was published to amend Ordinance No. 3081-U regarding disclosure of business information by credit institutions. The amendment sets out to require the banks to disclose a wide range of details on transactions with non-residents, in particular, remaining balances of correspondent accounts, amounts raised from non-residents, investments into securities of non-residents, assets encumbered by foreign-based counterparties, including those available as collateral for operations with the Bank of Russia. It is also with the Ministry of Justice; it will be enacted in 10 days after it is published, and it will be applied for the first time in respect of earnings reports for the first quarter of the next year.

Methodological Recommendations No. 40-MR were also among the released documents, it is intended to determine participants of a banking group and contains clarifications for a number of questions: how to form a banking group, for example, what is considered to be a subsidiary, an associated company, a jointly controlled entity; how to determine the primary type of activity of the banking group participants, the consolidation perimeters and calculate the potential indicators.

An important change was made by releasing an amendment to the new version of Ordinance No. 2332-U on reporting forms, specifically, the procedure for compiling Form 127 “Interest Rate Risk Details”. The so-called interest rate shock amount and scale were lowered. Instead of the interest rate change by 400 bps in either direction, this amendment provides for 200 bps fluctuations, as envisaged in the document of the Basel Committee on Banking Supervision. Those changes will be enacted on January 1, 2017. They will make evaluating interest rate exposure for the banks more loyal, more favorable. The document is also being registered by the Ministry of Justice.

Amendments to Regulation No. 283 that introduces a number of material new developments in calculating provisions for potential losses for various types of assets came into force on October 1 in all respects, except for the requirements to provisioning for accrued interest, which will be applied starting from February 1. This was done deliberately in order to give the banks time to prepare.

Another amendment to Instruction No. 139 was adopted in September and has already been published and enacted. It introduces of a reduced preferential rate of 20 per cent compared to the previously used general ratio of 100 per cent for claims against banks denominated and funded in rubles, which are guaranteed by AHML (Russia’s Agency for Housing Mortgage Lending), as well as AHML securities denominated and funded by the bank in rubles.

At the moment, the Basel Committee on Banking Supervision is reviewing the validity of this ratio at our request. In the case of a nonpositive decision, if we are told that this preferential rate is ungrounded then we will consider returning to the old 100 per cent ratio that was applied before the amendment.

Amendment to Regulation 254-P was specifically adopted as a separate document, also on its course to be registered by the Ministry of Justice. It increases the collateral sale period from 180 days to 270 days, thus enabling the bank to take the collateral into account for a longer period of time when making provisions and, consequently, reduce the provisions if the collateral is adequate.

A huge draft of amendments to Regulation No. 254 covering a multitude of issues was moved to 2017. The changes to the collateral sale periods were the only thing that was sped up.

Other changes included stricter provisioning for loans for working capital and an entire range of other issues, which are intended to bring together the reserve requirements for banks operating with the valuation of assets, in particular the amounts for the banks that fall within the framework for reorganization in Ordinance No. 3707-U. The discussions are very active; we have received lots of comments and feedback that are currently processed and reviewed. On December 12, a new draft version of amendments to Regulation No. 254-P will be published.

Adoption and enactment of amendment to Regulation No. 395 regarding the procedure for calculating the bank capital, namely, removing direct and indirect investments from the capital, was also moved to early 2017.

Issue 3. Taxation.

3.1. Problem of FATCA in Russia and its application models.

The Foreign Account Tax Compliance Act (FATCA) (<http://www.cticompliance.com/assets/pdf/FinalFATCAText.pdf>) was enacted by the United States Congress in 2010. The Act is designed to make significant changes in the current tax treatment of payments made by US residents through foreign financial institutions.

The mechanism for applying FATCA requires that Russian financial institutions enter into a special agreement with the U.S. Internal Revenue Service (IRS); keep track of any accounts opened by U.S. taxpayers with Russian financial institutions and report these to the IRS; withhold 30 percent of the revenues from sources in the United States, including revenues earned by entities that fail to disclose the information required under FATCA or by non-participating foreign financial institutions, and remit the amount to the IRS.

The Association of Russian Banks (ARB) and National Payment Council Non-Profit Partnership (NPC) have repeatedly asked the Russian Government, the Ministry of Finance, the Federal Tax Service, the Ministry of Foreign Affairs, the Federal Financial Markets Service, the Federal Financial Monitoring Service and the Bank of Russia to consider the conclusion of a special intergovernmental agreement between the Russian Federation and the United States on the procedure for implementing FATCA.

In addition, to expedite the decision-making process on a model for implementing FATCA in Russia, NPC assessed Russian banks' costs in the first year after the adoption of FATCA in Russia. The findings were presented to Presidential Aide Elvira S. Nabiullina, the Bank of Russia and the Russian Ministry of Finance.

Unfortunately, no official information detailing the status of the negotiation process between the concerned state agencies of the Russian Federation and the United States and the selected mechanism for implementing FATCA in Russia has been released so far.

Since no information is available on the Russian Federation's official position and the effective date of FATCA is approaching, a number of financial institutions controlled by a foreign parent have to consider entering into agreements directly with the IRS, since under FATCA an international banking group may be considered compliant only if all its members comply with FATCA.

It should be also noted that Russian credit institutions that have correspondent banking relationships with European and U.S. partners are already getting questions from their foreign partners on how the new regime works in Russia, since a foreign correspondent bank may withhold 30 percent of all payments made to a correspondent account of a non-participating Russian credit institution held with such bank or may suspend or close such correspondent account.

The position of the Russian Ministry of Finance is that any agreements between Russian banks and the U.S. IRS and any related disclosure of information constituting a bank secret will be regarded as a violation of Russian law (see the enclosed Letters No. 03-08-07 of 24 April 2012 and No. 03-08-05 of 20 August 2012).

At the same time, Russian financial institutions are seriously concerned about the possibility of partial withholding of payments made to them through the United States, should the Russian Federation decline to participate in FATCA.

Many countries are already actively negotiating with the United States to conclude bilateral agreements whereby any transfer of information under FATCA is made centrally through local government bodies, with the possible exchange of similar information in some cases by the United States (among countries planning to do this are Germany, France, the UK, Italy, Spain and the Netherlands). Switzerland and Japan intend to take a different approach to the information exchange with the United States under FATCA: local banks will provide information directly to the IRS along with an ad hoc exchange of information between the state agencies of these countries.

In view of what has been said and in order to avoid negative implications for Russian credit institutions, the Association of Russian Banks (ARB), the non-profit partnership National Payment Council (NPC) and the Association of European Businesses (AEB) strongly recommend that the Russian Ministry of Finance and the Bank of Russia inform credit institutions of the official position on the means of implementing FATCA.

On 10 February 2014, FIAC addressed official inquiry No. KS-1002-ib to the Bank of Russia, the Ministry of Finance and the Ministry for Economic Development, offering assistance in carrying out the following initiatives:

Providing information and recommendations in ensuring the inclusion of Russia in the list of countries which are regarded by the U.S. side as countries which entered into an information exchange agreement with the United States (taking account of the fact that less than three months remain until 25 April 2014);

Working out legislative acts and bylaws which would allow Russian financial institutions to apply the provisions of the Agreement in Russia.

In its reply No. 41-2-3-3/564 dated 11 March 2014, the Bank of Russia said:

If an agreement on the implementation of FATCA is entered into by Russia and the United States, the Russian financial institutions will not be obliged to register on the website of the US Tax Service within the same time limits as those set for the financial institutions of the countries which did not enter into such agreements.

Pursuant to §1.1471-3 (d)(4)(iv) of FATCA concerning payments made prior to 1 January 2015, US tax agents are not obliged to check the Global Intermediary Identification Number (GIIN) of the payees if the financial institution which is receiving payment reports to the US tax agent that it belongs to a country which signed an inter-governmental agreement on the implementation of FATCA.

Status 2014-2015:

A. Requirements for Russian players on the financial market in connection with provisions of Law # 173-FZ dated June 28, 2014

At the present time, no intergovernmental agreement exists which could be instrumental in regulating the application of FATCA requirements. Russian banks, including Russian subsidiaries of foreign-based banks, have the opportunity to individually register with the IRS (USA tax authorities), and, under certain conditions, provide information to the IRS. In this case, the information provision format and obtaining consent of Russian competent authorities has not been developed so far.

FIAC recommendations:

Persistence of the situation calls for a quickest possible additional comparative analysis of provisions of Federal Law # 173-FZ dated June 28, 2014, as well as FATCA requirements, so as to amend Law # 173-FZ accordingly, with a view to removing inconsistencies and providing opportunities for Russian banks to abide by law.

The FIAC working group sent recommendations to amend the Federal Law #173-FZ "On Specifics in Conducting Financial Transactions with Foreign Nationals and Legal Entities, on Amendments to the Russian Administrative Offences Code and Invalidation of Certain Provisions of Russian Legislative Acts" dated June 28, 2014 to the Bank of Russia to be considered on March 20, 2015.

List of proposals:

1. The Law #173-FZ prevents Russian financial organizations from fully complying with the FATCA requirements, as law of the Russian Federation do not provide for an opportunity of direct debit of the 30-percent fine from the payment amounts intended for the clients as prescribed by the FATCA. The Russian financial institutions will have to impose that obligation on their payment counterparties. Moreover, the law does not stipulate for any mechanism that a bank may use to provide information regarding payment to the withholding agent (and to identify that agent) in order to subsequently disclose the client information to the U.S. tax authorities.

Proposal:

It is proposed to clarify Article 2, Part 1 of the Law #173 in order to include the following entities in the scope of the Law #173-FZ:

- a) foreign taxpayers (individuals and legal entities);
- b) financial organizations not registered with the IRS, i.e. non-compliant financial organizations under the FATCA (both Russian and foreign organizations);

c) organizations that failed to provide or provided incomplete set of documents to identify them but gave a waiver for disclosure of their information, i.e. "recalcitrant accounts";

d) individual clients with foreign taxpayer indicators who failed to provide a complete set of documents to identify them but gave a waiver for disclosure of their information, i.e. "recalcitrant accounts".

2. Pursuant to Articles 2 (Article 2, Part 7) and 4 (Article 4, Part 1) of the Law #173-FZ, in case of a reasonable assumption that the client falls into the foreign taxpayer category confirmed by documents, and if that client fails to provide the requested documents or a waiver (refusal to provide waiver) allowing disclosure of their information to a foreign tax authority, a financial market organization may decide to refuse signing a bank account (deposit) agreement with the client, refuse performance of operations for that client and/or, to the extent provided by the Law, to terminate a financial services agreement in their sole discretion by notifying the client about such a decision no later than on the day following that decision date.

It appears that a financial market organization will not have an opportunity to confirm their assumption with documents in cases when the client refuses to provide information regarding presence/absence of foreign taxpayer criteria.

Proposal:

- to clarify the relevant articles order to enable financial market organizations to refuse service to foreign taxpayer and Russian Federation resident clients who refuse to provide information regarding presence/absence of foreign taxpayer criteria or criteria for any person regulated by a foreign law on foreign account taxation or a waiver allowing disclosure of information. In respect of organizations that are not registered with the IRS, assumption may only be verified by monitoring the IRS website.

3. Pursuant to the Law #173-FZ, a financial organization may terminate an agreement with a foreign taxpayer client only if they refuse to disclose their information, provide a waiver allowing disclosure etc. If the client provides all the necessary information and waives the financial organization may not refuse service to them.

Proposal:

- to reinstate a provision in the Law #173-FZ that was previously part of Article 2 of the Federal Law #112-FZ dated May 5, 2014, namely, to provide for unconditional right of financial organizations to terminate/not enter into an agreement with any individual or legal entity that is a foreign taxpayer if the state of their tax residency demands the Russian financial organizations to enter into special agreement to control presence of accounts of taxpayers from that foreign state.

B. Obligatory disclosure by foreign-based players on the financial market of information on Russian corporate and individual accounts.

The provisions of Article 6 of the Law are purely declarative and failing to provide for detailed understanding of requirements applying to foreign-based players on the financial market. Among the numerous unclear questions are:

- what entity is behind the definition of " foreign-based players on the financial market" for the purposes of the Law;

- what criteria underlie the list of individuals and entities whose accounts are earmarked for monitoring;

- what accounts categories are subject to the requirements;

- what kind of information on such accounts should be provided;

- what supervisory authority is to receive and in what format it is to receive information regarding clients' accounts;

- what punitive measures are imposed under the Russian Federation law for non-compliance.

The tiresome experience of introduction of the USA FATCA provisions, in conjunction with elaborate designing and flexibility of introduction of the requirements in question, make European banking institutions concerned about the situation, caused by insufficient awareness in respect of provisions of Art. 6 of the Law, as well as the difficulties in the practical implementation thereof.

On 30 March 2015 CBR sent an official reply on FIAC's working group request from 18 February 2015.

There was also a draft of amendments to Law #173-FZ published that changed the criteria (it is not the final document). At the moment, this draft is discussed by the market participants. It was planned to finalize the

discussions before the end of June. This draft may work out many issues, for example, regarding the identification.

A draft order of the Federal Tax Service on the reporting procedure for foreign financial institutions in respect of accounts of Russian citizens and organizations that was published on the website of the Government of Russia for publishing draft legislation (June 2015). This is what we call the Russian FATCA. It is the first additional information for the past 11 months. The point of the project is that the FNS provides a sufficiently detailed list of those foreign financial institutions that are required to submit information on accounts of Russian citizens and organizations; it must be done before September 30. This is a very wide range of institutions. Separately, the annex to the order mentions types of accounts, for which you need to do reporting, and it is also a wide-ranging list.

Recommendations:

The situation calls for elaboration on the requirements and attitude of RF governmental authorities in respect of the application of Article 6 of Law # 173-FZ in so far as they relate to disclosure of information on Russian Federation citizens' accounts (deposits) with foreign-based players on the financial market.

Status 2016:

Federal Law No. 173-FZ On Conducting Financial Operations with Foreign Citizens and Legal Entities, Amendments to the Administrative Offenses Code of the Russian Federation, and Invalidation of Certain Legislative Acts of the Russian Federation ("Law No. 173-FZ", effective date: June 30, 2014) stipulate the duty of foreign financial institutions to submit to Russian tax authorities reports on accounts opened with such institutions by citizens of the Russian Federation or by legal entities directly or indirectly controlled by citizens of the Russian Federation.

Foreign financial institutions are to submit such reports annually on or before September 30 of the year following the year during which such accounts were opened, using a form still to be developed and communicated to the stakeholders.

On December 7, 2015, there was published, on the official legal information internet portal pravo.gov.ru, Order of the Federal Taxation Service No. MMV-7-14/501@ dated November 9, 2015, On Approval of Forms to Be Used by Foreign Financial Market Institutions Situated Outside of the Russian Federation to Disclose the Details of Accounts (Deposits) Opened with Such Institutions by Citizens of the Russian Federation or Legal Entities Directly or Indirectly Controlled by Citizens of the Russian Federation (the "Order"). According to the Order, foreign financial institutions must furnish the Russian tax authorities with information about foreign accounts of citizens of the Russian Federation or legal entities directly or indirectly controlled by citizens of the Russian Federation. The Order took legal effect on December 18, 2015.

Problem:

Russia has undertaken to engage in exchange of information in accordance with the Common Reporting Standard, or CRS, adopted within the framework of the Organization for Economic Cooperation and Development (OECD). However, emergence of the Order testifies to the fact that our government bodies seek to gain access to a proprietary "source" of information regardless of the CRS procedure, inter alia, on a unilateral basis, which, in our opinion, is difficult to accomplish, and will have pronounced adverse effect on business environment, foreign investments, and investment appeal of Russia as a member of international business relations.

We believe that it is difficult to implement such information disclosure within the assigned limited time for the following reasons:

- absence of an electronic / internet portal and an automated disclosure system;
- need to design a paper form in the Russian language for each account;
- tight disclosure implementation deadline;
- violation of local banking and other laws resulting from disclosure pursuant to the Order, and absence of relevant legal instruments, such as intergovernmental bank information exchange treaties;
- absence of clarifications or recommendations regarding the required disclosure (only the form has been published to date).

In our opinion, concurrent CRS reporting and Order reporting represents unreasonable duplication of efforts which is labor-intensive and costly both to the business community and the government bodies of the Russian Federation.

Recommendations 2016:

- expediency and necessity of disclosure according to the Order using the existing form, taking into consideration implementation of CRS tax information exchange standards; and

- possibility of suspension of Article 6 of the Federal Law, taking into consideration implementation of CRS tax information exchange standards.

The above issue is critical for foreign financial institutions, inter alia, for the purposes of implementation of international best practices in the area of tax information exchange, and any discussions and meetings facilitating exchange of opinions on that matter will be greeted by all Foreign Investments Advisory Council members seeking to resolve the issues raised in this document.

On 15 April 2016 FIAC working group on Financial Institutions and Capital Markets sent repeated request on Minister of Economic Development Alexey Ulyukaev.

On 25 May 2016 Dmitry Volvach, Federal Tax Service, Standards and International Cooperation Division, took part in the FIAC banking working group meeting and informed that within the implementation of §6 of 173-FZ special forms in Russian and English have been issued. At this moment it's not clear how many companies will provide their reporting, because there are no penalties for non-providing information. That's why Federal Tax Service suggest to wait and observe how this reporting will function and if there will be a real need of online portal for this reporting. After implementing CRS in Russia there might be no need in §6 of 173-FZ and the FTS will support the deactivation of this §6.

Issue 4. Problems of amending Currency legislation.

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 5. Standard loan agreement for small and medium-sized enterprises.

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 6. Conversion.

6.1. 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-P9 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.

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 to 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:

⁹ "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").

- 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 licence.

- 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.

EBRD will be happy to discuss these and other related issues with the responsible authorities.

Issue 7. Banking secrecy regulation.

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

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 comply 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 2015:

In February 2015 FIAC working group sent a request on Bank of Russia regarding the implementation of the Law for banking sector. On 3 March 2015 a meeting took place with Artem Sychev, Deputy Head of the Bank of Russia's Chief Directorate of Information Security and Protection. It was decided that banking community will provide with list of practical questions that will be forwarded to Roskomnadzor for further execution.

Roskomnadzor organized a meeting for foreign associations operating in Russia. AEB provided list of 54 questions regarding implementation of 242-FZ.

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 9. 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 10. Unilaterally Accounts Closure.

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

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

Current status as of September 2017:

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

Issue 11. Access to state funds and strategic companies for foreign (non-state) financial institutions.

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

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

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

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

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

In October 2015 Association of European Business sent an official letter to First Deputy Prime-Minister I. Shuvalov regarding the intention of the Government to forbid state-owned companies to keep their liquid funds in foreign banks. On 19 November 2015 in its response to the query initiated by the AEB and banking community the Financial Policy Department of the Ministry of Finance said that requirements applicable to credit institutions where business companies strategically important for the defense industry complex and national security of the Russian Federation and companies directly or indirectly controlled by the state may keep their accounts are stipulated by Federal Law dated July 21, 2014, No. 213-FZ. Pursuant to part 3 of Article 2 of Federal Law 213-FZ, the Central Bank publishes on its web site a list of credit institutions which meet the requirements set forth in Federal Law 213-FZ. The list includes subsidiary credit institutions of foreign banks. The Federal Law does not envisage any restrictions on the financial operations with foreign banks.

Status 2016:

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

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

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

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

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

Recommendations:

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

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

2017 Status:

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

Issue 11.1. Banking tax and custom guarantees.

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.

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 12. Power of attorney register (changes to 332 FZ).

The FIAC pursues activities to improve business environment for entrepreneurship, trade and attracting investments to the Russian Federation.

The banks with foreign capital participating in the FIAC came up with a question about how to apply the following provision of Russian legislation.

Federal Law #332-FZ dated July 3, 2016 "On Amending Articles 188 and 189 of Part One of the Civil Code of the Russian Federation and the Basic Principles of Notary Activities in the Russian Federation" (the "Federal Law") provides that the notary enters information on revocation of a power of attorney certified by a notary into the electronic notarial register maintained in accordance with the procedure established by the legislation on notary activities. That information is made available to general public by the Federal Notarial Chamber through the Internet information and telecommunications network

What is more, if third parties were not previously informed of the power of attorney revocation, they are deemed to be informed of the power of attorney revocation certified by notary on the next day after the relevant information is entered into the notarial register.

These provisions of the Federal Law come into effect from January 1, 2017.

It is also stipulated in the Federal Law that the Federal Notarial Chamber should enable confirmation of the contents of any document certified by a notary using the infrastructure for information and technological

interaction of information systems used to provide government and municipal services and to perform government and municipal functions in the electronic form, in respect of powers of attorney certified by a notary from January 1, 2017.

As of the date of this letter, the Federal Notarial Chamber provided an option to review the canceled powers of attorney via the website (<http://reestr-dover.ru/>) by manually entering the following data in respect of each power of attorney:

- notarial certification date of the power of attorney;
- number of the power of attorney in the register.

Unfortunately, it is impossible to use this review method for the revoked powers of attorney certified by a notary via the website (<http://reestr-dover.ru/>) either in banking or in any other sphere of business with an extensive customer and counterparty base who use powers of attorney certified by a notary in order to grant authority to control accounts and perform other banking transactions and operations. The number of such powers of attorney certified by a notary may run into thousands. The banks have no actual possibility to review such power of attorney manually, as described above.

In our opinion, the objective set forth in the Federal Law — that is, to enable information and technological interaction of information systems used to provide government and municipal services — has not been achieved in full. For instance, notification of revoked letters of authority through the Kommersant website is supported by the information system for interaction with interested companies (including banks) by sending them automatic notifications.

Specifically, credit institutions face a high risk of transacting or trading with an unauthorized person, whose notarized power of attorney has been revoked, since any lender running a huge amount of operations on a daily basis cannot review revoked powers of attorney certified by a notary every day manually as suggested by the Federal Notarial Chamber.

In our opinion, the absence of an electronic platform for interacting with the Federal Notarial Chamber in order to automatically obtain information from the register of revoked notarized powers of attorney brings a significant risk of deterioration in business environment, possible abuse by unscrupulous parties, which would result in legal and operations risks and financial losses.

Recommendations:

1. to consider whether it is possible to develop a single electronic platform to automatically review any revoked powers of attorney certified by a notary (by way of example, the service provided by Kommersant in respect of letters of authority);

2. to postpone enactment of the final paragraph of Article 1, Clause 2, subclause b) of the Federal Law until the single electronic platform is introduced to enable automatic review of revoked powers of attorney certified by a notary.

This issue is essential for the financial market organizations, including foreign institutions. Participants of the FIAC working group for developing the Russian banking sector and capital markets would welcome any forms of discussion and exchange of opinions, as well as live meetings to discuss the questions raised by this request.

The FIAC working group sent an official request on Minec and Ministry of Justice on 12 December 2016 and received formal feedback from the Ministry of Justice in January 2017.

Issue 13. 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 14. Changes in the legislation on information security: Implementation by banks with foreign participation in 2018 of the Financial System Information Security Outsourcing Standard.

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:

2. 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?

3. 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:

4. 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.

7. Natural Resources and the Environment

I. Subsoil use and other issues

Issue 1. Amending laws and regulations with a view to improving the investment climate in the subsoil use sector (Russian Federation Laws No. 2395-I of 21 February 1992, On Subsoil Use; No. 57-FZ of 29 April 2008, On Foreign Investment Procedure in Businesses of Strategic Significance for National Defense and State Security).

1.1. Exploration and production.

Foreign investors may participate in the development of continental shelf areas of federal significance only as minority partners of companies controlled by the Russian Federation. As for other subsoil areas of federal significance, the development thereof by foreign companies shall be by special permits only issued on a case-by-case basis. In practice, such permits will apparently be granted exclusively to Russian joint ventures with foreign companies established in compliance with the Russian law. Generally, such practice is used 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 for the development of Russian mineral resources, however, a number of specific provisions of the applicable Russian laws effectively hamper such collaboration.

By way of general business practice, international oil and gas companies act as both investors and operators of oil and gas development projects. To date, major oil and gas projects are executed mostly by “special-purpose vehicles” established by project partners for the only purpose of carrying out a given project. Such a company would normally be a new legal entity.

Hence, the provisions of the Law, On Subsoil Use, stipulating that the subsoil user of a continental shelf area of federal significance must have prior five-year experience of such development in the Russian Federation makes it impossible to implement such projects through a special-purpose vehicle because a newly registered joint venture set up by government-controlled Russian companies with foreign investors would be a new legal entity established for a specific purpose of implementing a given project, and so, by definition it cannot have the experience required by law. A possible solution could be to count continental shelf development experience of such joint venture founders and/or their subsidiaries. Notably, offshore development experience in Russia could be counted as well as the relevant expertise gained by the member-companies elsewhere in the world. Also, the law may stipulate that the operator has the legal status of a subsoil user. It is important for investors that a “special-purpose vehicle” established by project partners can become an operator and a subsoil user (license holder) at the same time.

Recommendations:

Amend the Law, On Subsoil Use, in order to allow counting years of continental shelf development experience of the founders of a legal entity engaged in such development in the Russian Federation or subsidiaries thereof gained both in and outside Russia against the five-year continental shelf development experience in the Russian Federation presently required from such legal entity.

Amend the Law, On Subsoil Use, in order to clarify what the development of a subsoil area on the continental shelf involves and specify what types of subsoil use or operations on the Russian continental shelf will be considered relevant in evaluating earlier experience.

Amend the Law, On Subsoil Use, in order to define the concept and legal status of the operator as a subsoil user.

1.2. Geological exploration.

An option to terminate the subsoil use right held by legal entities with foreign ownership or foreign investors in the event of a discovery of federal significance made thereby is a big disincentive to foreign investors in geological exploration in Russia.

The recovery of costs incurred in exploration and appraisal of discoveries would not work because the cost recovery amount would not cover the costs incurred in other projects in the event of failure to make a new discovery (for instance, dry wells). Oil and gas and ore mining companies invest in exploration of multiple subsoil areas that may be located in different regions and even in different countries, and by far not all of them happen to contain commercial mineral reserves. Major companies conduct large investment programs involving multiple subsoil areas. This investment is risky from purely geological standpoint; additional risks related to potential termination of the subsoil use right make the overall risk prohibitively high. Moreover, international oil and gas and ore mining companies invest in exploration projects precisely because they expect to participate in subsequent development of new discoveries.

While Federal Law No. 57-FZ of 29 April 2009, On Foreign Investment Procedure in Businesses of Strategic Significance for National Defense and State Security defines the term “Foreign Investor,” the Law, On Subsoil Use, has no clear definition of 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.” The former Law defines the term “control” and specifies appropriate criteria therefor, while the latter contains no definition of “participation” and no defining criteria. So, the term may even be interpreted as ownership of a single share of stock, because neither the law nor the regulations thereunder set any limits for what should qualify for “participation” (as opposed to Federal Law No. 57-FZ of 29 April 2009).

Recommendations:

Add a provision to the Law, On Subsoil Use, excluding an option to deny subsoil users (including those with foreign ownership) controlled by the Russian Government either directly or through companies controlled thereby the right to develop a discovered field of federal significance or terminate such right on the grounds of 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 Foreign Investment Procedure in Businesses of Strategic Significance for National Defense and State Security.

Add a provision to the Law, On Subsoil Use, stipulating that prior to announcing a competitive tender or auction for the right to subsoil exploration, including exploration under a combined license, the Government of the Russian Federation or an authorized body thereof shall conduct a survey and make a representation of the presence (or absence) of a threat to national defense and state security in the event the subsoil user is a company with foreign ownership and the exploration conducted thereby results in a discovery meeting the criteria stipulated by the Law, On Subsoil Use, Part 3, Article 2.1. Such a representation by the Russian Government or an authorized body thereof shall be published as part of an official announcement of a subsoil use tender or auction. If by the time of such a tender or auction, the Russian Government or an authorized body thereof has concluded that the option described above constitutes no threat to national defense or state security and the representation of such conclusion has been made public as part of the tender or auction announcement, the Russian Government shall not deny the subsoil user with foreign ownership the right to use the subsoil area in question for exploration and production purposes or terminate the use right thereof under a combined license.

There may be other ways of securing foreign investor’s participation in a joint venture to be established for the development of a new discovery.

1.3. Improving evaluation procedure of subsoil use requests for the purpose of geological exploration (filing order).

The Russian Government has presently named efficient replacement of the mineral resource base with the help of private (including foreign) investment its top priority goal. A favorable legal and regulatory framework for granting mineral exploration rights is instrumental for reaching that goal.

Certain steps have been taken to improve subsoil exploration licensing system. Specifically, some amendments were made to the Evaluation Procedure of Subsoil Use Requests for the Purpose of Geological Exploration (excluding subsoil areas of federal significance) (hereinafter, the “Procedure”) (see Order of the Russian Ministry of Natural Resources and the Environment No. 61 of 15 March 2005, as amended 27 January 2014 and Order of the Ministry of Natural Resources and the Environment No. 583 of 10 November 2016).

The said amendments essentially allowed – by way of exception from the general rule – a geological exploration license to be granted to a subsoil user in response to the first favorably evaluated request, without going through a tender or auction as required under the general rule in the event two or more requests have been registered for exploration rights. Such provision is applicable to subsoil areas having no data on prognostic mineral resource in the P1 and P2 categories and not included in the programs or lists of subsoil areas to be granted for use. The exploration rights including exploration and appraisal of mineral fields for subsoil user’s own account (and/or financed thereby by borrowed funds) shall be granted under a simplified procedure without the need to put such subsoil areas on the said lists. The P3 category is known to indicate an extremely low exploration level of a given area. Such resources reflect “...no more than a probability of discovering mineral reserves of one type or another based on favorable geological and paleo-geographic features identified in a given region by medium- and small-scale geological and geophysical surveys, satellite image interpretations, and the results of geophysical and geochemical studies” (see Classification of Solid Mineral Reserves and Probable Resources, Par. 20, approved by Order of the Ministry of Natural Resources and the Environment No. 278 of 11 December 2006). Such resources cannot be defined as containing mineral occurrences, and they are not covered even by such tough regulations as, for instance, those governing the use of subsoil areas of federal significance.

By limiting the types of areas that could be granted for exploration to first requestor to those containing P3 resources only, the lawmakers considerably narrow the applicability of the “filing order,” and accordingly reduce its positive effect on market players contemplating potential investment in geological exploration.

As known from international practice, the attractiveness of geological exploration projects to investors would be the highest in a legal environment allowing for granting the areas containing prognostic resources to the first requestor meeting eligibility criteria without any further restrictions.

Recommendations:

Consider removing the restrictions established in the “filing order” procedure regarding P1 and P2 prognostic resources in respect of those subsoil users who are engaged in exploration activities in the Far Eastern Federal Okrug (FEFO) regions using their own (including, borrowed) funds.

Any first requestor eligible under the Procedure should apparently have the right to the area requested thereby for geological exploration purposes without any additional encumbrances or restrictions (such as the presence or absence of the area in question in a program or list).

The proposed amendments to the Procedure will require no approval, amendment, suspension, or invalidation of other regulations.

1.4. Developing mechanisms of legal regulation of regional geological study operations using the funds provided by subsoil users.

Due to the reduction of the government financing of geological exploration operations, the portfolio of exploration prospects and of the mining targets prepared for commercial development has been diminishing. It is believed that attraction of private funds for geological subsoil exploration at early stages, specifically, for difficult-to-reach areas in the Far East and the Arctic, would accelerate replacement of the mineral resource base.

It is proposed that the mechanism for attracting private financing by subsoil users should be used at the stage preceding that of the “filing mechanism” of granting the right for subsoil resource use for the purpose of geological study.

Draft Federal Law No. 288750-7, On Amending the Law of the Russian Federation On Subsoil Use and Recognizing Individual Provisions of Legal Acts of the Russian Federation Void where Related to Clarifications of the Issues of Subsoil Use and Use of Uniform Terminology, brought before the State Duma of the Russian Federation by Letter of the Russian Government No. 7407p-P9 of 17 October 2017 provides, inter alia, for inclusion in the Russian Law, On Subsoil Use, of a provision for the absence of the requirement to obtain subsoil use licenses for regional geological studies.

This provision may be regarded as permitting subsoil users to perform regional geological study operations at their own expense. At the same time, the Draft Law does not stipulate any specific mechanisms for legal regulation of the above relations.

Recommendations:

Implement an enabling mechanism for granting the right for subsoil users to perform regional geological studies at their own expense, including the following key elements. The target for regional geological study operations is not a subsoil block, but a territory that can be described by specifying the geographic coordinates of the corner points or by other methods (e.g., by tying to a geological feature, a map sheet, etc.). It is proposed that major subsoil user companies would be permitted to perform regional geological study operations using private funds (it is proposed that the existence of certain minimal mineral reserves in the company’s inventory and confirmation of availability of financial, technical and manpower capability of the subsoil user would be the qualifying criterion), as well as exploration companies (“junior companies”) that have experience in geological exploration and access to funding sources. The subsoil users shall perform regional geological study works using private funds based on a permit for regional geological study (this norm needs to be fixed in the Draft Law). The territory granted for regional geological study acquires the status of “offered for granting for use” (the period for which the subsoil block within its boundaries is granted for use shall be limited by the period granted for regional geological study). It is proposed that a single applicant should be granted the use of not more than two or three territories with the maximum total area from 1,000 sq. km to 5,000 sq. km. The objective of the regional geological study using private funds shall be the conferred right of the subsoil user to subsequently obtain, under a simplified filing procedure, subsoil blocks with the identified prospective features for further geological exploration including prospecting for and appraisal of mineral deposits (this norm needs to be fixed in the Draft Law). The subsoil user will be granted the right to have a priority to use the filing procedure to obtain an area of 100 to 500 sq. km for the purpose of further geological exploration.

1.5. Classification of fields of federal significance.

The solid mineral resource base is revealing the following development trends:

- the fund of easy-to-discover fields is being used up;
- fields rich in high-grade and easy-to-concentrate ores are being taken out of service and replaced with fields of poor difficult-to-dress ores;
- exploration works are carried out in remote areas with harsh geological and climatic conditions and less developed infrastructure.

This makes it necessary to encourage subsoil users for prospecting new large fields that will be developed because of their economic attractiveness, which would not only bring real investments into the Russian economy and create jobs in remote regions but also promote introduction of new, more advanced technology in the industry.

However, the existing legislation contains a number of provisions that prevent from increasing investments into exploration and enhancing its efficiency. For instance, when the Federal Law, On Foreign Investment Procedure in Businesses of Strategic Significance for National Defense and State Security, was passed, the Russian law, On Subsoil Use, set criteria for regarding subsoil areas as subsoil areas of federal significance. Currently, subsoil areas of federal significance include subsoil areas containing more than fifty tons of vein gold reserves, more than 500,000 tons of copper reserves; there are certain solid natural resources whose mere showings make subsoil areas regarded as those of federal significance. In view of the above description of the mineral base and a tendency for diminishing of valuable concentration of noble metals in ores, these subsoil areas are not so promising in terms of economic viability of their separate development. The regulatory regime does not encourage companies for discovery or detailed exploration of medium-size and large fields, which has a poor effect on the state of the country's mineral base.

In view of the above, it makes sense to review limitations for sizes of subsoil areas of federal significance so that they are indicative of their real strategic importance and encourage investments into exploration.

Recommendations:

Amend Article 2.1.2 to read as follows: "2) that are located in a constituent of the Russian Federation or in constituents of the Russian Federation and that contain, based on the state balance sheet of natural resource reserves starting from 1 January 2006:

- recoverable oil reserves of 70 million tons or more;
- gas reserves of 50 billion cubic meters or more;
- vein gold reserves of 250 tons or more;
- copper reserves of 7 million tons or more."

1.6. Proposals regarding Federal Law No. 57-FZ of 29 April 2008, On Foreign Investment Procedure in Businesses of Strategic Significance for National Defense and State Security.

Article 4.4 of the said Law says that transactions involving shares (interests) of a strategically important business entity shall not be subject to early approval if prior to carrying out such a transaction the foreign investor or a group of persons have already controlled more than fifty percent of the voting rights carried by voting shares (interests) constituting the charter capital of such an entity and (or) if the foreign investor contemplating such a transaction is controlled by an entity controlling such a legal entity. This provision appears fair and justified.

However, a reservation "except business entities of strategic significance using subsoil areas of federal significance" makes transactions with such business entities' shares unreasonably complicated. This provision may be interpreted in such a manner that a preliminary approval would be required for purchases and sales of shares (interests) within one group of persons that controls more than fifty percent of a Russian company having strategic significance and using subsoil areas of federal significance. It seems unjustified to obtain an approval for transferring shares from one participant of the group to another.

Recommendations:

Exclude the phrase "(except business entities of strategic significance using subsoil areas of federal significance)" from Article 4.4.

The above amendments would help foreign investors assess their risks properly, which would in turn improve the attractiveness of natural resource development projects to investors, specifically Russian energy projects.

Issue 2. Liberalizing exports of geological information.

A necessity for obtaining a license even for export of unrestricted geological data has been a real issue.

The Eurasian Economic Commission's Decision No. 30 of 21 April 2015 approved the List of Goods that Are Subject to Regulatory Approval Procedure for Import to the Customs Territory of the Eurasian Economic Community and (or) Export from the Customs Territory of the Eurasian Economic Community (hereinafter referred to as "the List"). The List title states that it is a list of goods. However, the List includes Clause 2.23, Subsoil Information Grouped by Regions and Fields of Energy and Mineral Resources. The internal logics seems upset here because, based on the analysis of the notion "information" in Article 2 of Federal Law No. 149-FZ of 27 July 2006, On Information, Information Technology and Protection of Information, one can draw a clear conclusion that information is not goods. A review of the Federal Law proves the above conclusion. Pursuant to Article 2.26 of this Law, goods mean "movable property, immovable property including air-, sea crafts, inland waterways vessels, combined navigation (river-sea) vessels, space crafts, as well as electric power and other types of energy, that are commodities of foreign trade activities." It is obvious that information does not fall within this definition, which is supported by the fact that no code for information is provided in the Integrated Commodity Classifier of Foreign Economic Activities.

Licensing of export of geological information that is not state secret makes it extremely difficult to implement joint projects dealing with geological survey and development of subsoil of the Russian Federation and to operate using advanced technical methods. Using state-of-the-art techniques for effecting transactions, for instance, an electronic access to the partner's documents (Electronic Due Diligence Room), results in breach of legislation. For information to be processed in foreign data processing centers, a company has to obtain a license, which often causes suspension of work for quite a long time.

Recommendations:

For effective lowering of administrative barriers, it seems necessary for information that a priori cannot be regarded as state secret pursuant to Clause 67 of the List of Details Regarded as State Secret (approved by Decree of the President of the Russian Federation No. 1203 of 30 November 1995, as amended in Decree of the President of the Russian Federation No. 90 of 11 February 2006), to be taken out of the aforementioned List, i.e. information obtained during joint works engaging foreign states' individuals and legal entities in particular natural resource fields or in their parts.

Issue 3. Drafting, reviewing and endorsing mining plans and schedules (hereinafter, "Mining Plans") by mineral types.

Article 24 of Law No. 2395-1 On Subsoil Use and Russian Government Decree No. 814, On Rules of Drafting, Reviewing and Endorsing Mining Plans and Schedules by Mineral Types (hereinafter, "Decree No. 814") envision the drafting, reviewing, and endorsing Mining Plans. The agency authorized to review and endorse Mining Plans is the Rostekhnadzor (RTN).

Subsoil users, including oil companies, are presently obligated to draft Mining Plans and obtain endorsement thereof. The review and endorsement process takes five months or more. However, in practice hydrocarbon fields are developed in compliance with their field development plans (Tekhschemas), project field development documentation and well programs. It would be fair to say that oil companies draft Mining Plans for the sole purpose of meeting subsoil use regulations and avoiding noncompliance and administrative prescriptions by auditors.

Meanwhile, RTN agencies conduct regular audits of hazardous facilities for compliance with industrial safety regulations and maintain continued oversight if required by applicable law. Also, the government conducts geological oversight, including verification of compliance with field development Tekhschemas, through its Rosprirodnadzor agency (RPN). Hence, considering that subsoil users are required to have several project development documents at a time (supporting field development, development facility construction, and well construction) and are subject to government control by the RTN and RPN agencies, the demand for one more duplicating document appears excessive and creates yet another administrative hurdle. We believe that the Mining Plan is redundant and merely duplicates other documents.

Recommendations:

In view of the above, initiate the process of dropping the requirement for drafting and obtaining endorsement of Mining Plans for hydrocarbon fields as redundant and creating additional administrative barriers.

Amend Article 24.6 of the Law, On Subsoil Use, to read as follows (the addition is shown in blue): "Actions aimed at ensuring compliance with the main operational safety provisions related to subsoil use shall be provided for in Mining Plans subject to endorsement by a government agency authorized to conduct mining oversight. The procedure for drafting, reviewing and endorsing Mining Plans by types of minerals (excluding hydrocarbons) shall be determined by the Russian Government."

Amend the title of Government Decree No. 814, On Rules of Drafting, Reviewing and Endorsing Mining Plans and Schedules by Mineral Types, to read as follows (the addition is shown in blue): “Government Decree No. 814, On Rules of Drafting, Reviewing and Endorsing Mining Plans and Schedules by Mineral Types (Excluding Hydrocarbons).”

Issue 4. The need for a law, On Specific Labor Regulations for Employees Sent by their Employer Other than a Private Employment Agency on Temporary Assignments to Other Legal Entities under Secondment Agreements.

Federal Law No. 116-FZ of 5 May 2014, On Amending Individual Legal Regulations of the Russian Federation (hereinafter, “Law 116-FZ”), effective as of 1 January 2016, prohibits the use of “borrowed employee labor” and imposes restrictions on the use of agreements for temporary assignments of personnel in the Russian Federation.

After the effective date of Law No. 116-FZ, private employment agencies (PEAs) were the only agencies still allowed to make personnel available to other entities under temporary agreements. According to Law No. 116-FZ, entities other than PEAs may, in certain instances, send employees to third-party entities according to the terms and procedures set forth in a federal law. As at this time, approval of the law is still pending.

The Ministry of Economic Development drafted such a special Law, On Specific Labor Regulations for Employees Sent by their Employer Other than a Private Employment Agency on Temporary Assignments to Other Legal Entities under Secondment Agreements, which was endorsed by all interested government bodies, but was denied endorsement by the Government Law Office under the Russian Federation President.

Delays in the adoption of the draft law create a plethora of risks for foreign investors operating in the Russian Federation.

Major investment projects, both internationally and in Russia, are generally carried out by groups of investors in various forms of relationship: joint ventures, consortia, operating agreements, etc. In such arrangements, highly skilled foreign personnel would often be assigned to a partner entity under personnel secondment agreements. The limitation imposed by Law No. 116-FZ on eligibility for secondment agreements of only a small group of entities effectively precludes secondment of highly skilled foreign personnel to and from entities outside the group indicated in Law No. 116-FZ. The law drafted by the Ministry of Economic Development addresses that issue because of a clearer definition of the group of entities participating in secondment agreements. This approach reflects the long-term business practice of using such a tool in Russia by major businesses that existed before the enactment of Law No. 116-FZ.

If the draft law in question is not adopted, companies that have been using that mechanism will have to restructure their relationships within the group or withdraw from certain projects altogether, as well as assume corporate tax risks arising from the impossibility to deduct personnel secondment costs.

Adoption of the draft law is equally important to Russian companies, because it will allow them to keep access to unique foreign technology, skills, expertise and experience in a range of areas, including production and processing of minerals in capital intensive and remote projects, to operate high-tech equipment purchased from foreign manufacturers more effectively and to access new technologies and methods, including for their further localization in the Russian Federation.

Early adoption of the law drafted by the Ministry of Economic Development will remove the existing legal uncertainty and considerably mitigate risks arising on investment projects jointly implemented by Russian and foreign partners.

Recommendations:

Accelerate enactment of the Law On Specific Labor Regulations for Employees Sent by their Employer Other than a Private Employment Agency on Temporary Assignments to Other Legal Entities under Secondment Agreements.

Issue 5. Impossibility for foreign companies to register in the Unified State Register of Legal Entities.

It is impossible for foreign companies that have no registration number in the Unified State Register of Legal Entities to obtain any approvals, permits or licenses required by law.

State bodies that provide public services refuse to issue any approvals, licenses or other permits to foreign companies by making references to the effective laws and regulations of state agencies on the provision of services whereby public services can only be provided upon request of individuals, including individual entrepreneurs, and legal entities registered in the Unified State Register of Legal Entities pursuant to

Federal Law No. 129-FZ of 8 August 2001, On State Registration of Legal Entities and Individual Entrepreneurs.

Without being registered in the Unified State Register of Legal Entities, foreign companies face challenges (are denied a service) when:

- Registering their facilities in the register of facilities producing a negative environmental impact (NEI) – Rosprirodnadzor;
- Applying for the main state expert review of design documents – Glavgosexpertiza;
- Obtaining licenses to conduct activities involving the operation of explosive, flammable and chemically hazardous production facilities in hazard classes I, II and III – Rostekhnadzor;
- Obtaining licenses to conduct activities involving the assembly, maintenance and repairs of fire safety devices in buildings and constructions – Rostekhnadzor;
- Obtaining licenses to engage in handling operations as applied to hazardous cargos on inland water-borne vehicles and at sea ports – Mintrans, Rostransnadzor;
- Obtaining licenses for collection, transportation, processing, disposal, neutralization and placement of wastes of hazard classes I-IV – Rosprirodnadzor;
- Obtaining approvals to construct and reconstruct capital facilities, implement new technological processes and conduct other activities that impact marine living resources and their habitat – Rosrybolovstvo.

The denial to provide the above services appears to contradict federal laws. Pursuant to Federal Law No. 160-FZ of 9 July 1999, On Foreign Investment in the Russian Federation (Articles 2, 4, 21, 22), and the general provisions of Part I of the Russian Civil Code, foreign investors are entitled to conduct entrepreneurial activities on the territory of the Russian Federation through both the creation (establishment) of an entity with full or partial foreign participation and the accreditation of branches of foreign entities in Russia.

Foreign legal entities operating in the Russian Federation in full conformity with Russian laws operate via, inter alia, their branches duly accredited to operate in the Russian Federation and registered in the state register of accredited branches and representative offices of foreign legal entities.

Therefore, regulations of state agencies (administrative regulations) on the provision of public services, namely, on the issue of permits, are not in line with the effective federal legislation.

Proposal

The Russian Ministry for Economic Development should consider the issue, elevate it to the Russian Government and request it to instruct the authorized bodies to amend the regulations of state agencies so as to address the inconsistency relating to the provision of public services to foreign entities and their accredited branches.

II. Proposals to improve laws on environmental protection, environmental expert review and waste treatment.

Certain gaps and inconsistencies have been identified in the course of applying the new laws and regulations, namely, Federal Law No. 219-FZ of 21 July 2014, On Amendments to the Federal Law, On Environmental Protection, and Certain Regulations of the Russian Federation (hereinafter, "Law No. 219"), and Government Decree No. 1029, On Approval of the Criteria to Include Facilities Producing a Negative Environmental Impact in Categories I, II, III and IV (hereinafter, "Decree No. 1029"). Provided below is a list of key issues and proposed measures to resolve them.

1.1. Gaps and inconsistencies in Decree No. 1029 and Federal Law No. 219-FZ of 21 July 2014:

- Decree No. 1029 sets no criteria to determine oil and gas treatment as a type of business activity.
- Proposal – amend Section II of Decree No. 1029 by adding the following type of business activity: oil and gas treatment to transport oil and gas from production sites to points of shipment (delivery).
- Decree No. 1029 sets no criteria to determine natural gas liquefying (for example, an LNG plant) by cooling it to –160°C without changing its chemical properties as a type of business activity. It should be noted that the gas liquefying technology, which is based on changing physical gas parameters, cannot be regarded as a petroleum technology as it does not involve deep chemical conversion of hydrocarbons.

Proposal – amend Section II of Decree No. 1029 by adding the following type of business activity: natural gas liquefying by cooling it to –160oC without changing its chemical properties.

- Facilities designated to neutralize hazard III wastes are included in category I, although no criteria for the amount of waste are set. As a result, entities that have incineration systems for typical wastes, such as wiping materials or sorbent wastes, are included in the first (highest) category. At the same time, facilities, including, for example, “facilities to operate”:
- ✓ radiation sources (except those containing only radionuclide sources of the fourth or fifth radiation hazard category), where the facility houses sources of pollutant radioactive emissions and discharges;
- ✓ storage sites for nuclear materials and radioactive substances, storage sites for radioactive wastes, radioactive waste disposal sites;
- ✓ chemical weapons storage and (or) destruction sites.

are included in category II.

Proposal – set criteria to include facilities in category I by volume of hazard class III wastes to be neutralized using equipment and (or) units with a design capacity of at least 300 kg/h.

- In accordance with the criteria to include facilities in negative environmental impact categories, category III facilities should include all facilities with diesel generators used as emergency power sources (office blocks, hospitals, etc.), and vehicles, which, when in operation, cause emissions of category I and II pollutants (for example, benzo(a)pyrene) into the atmosphere, with potential gross emissions of the pollutants not exceeding several kilograms per year.

Proposal – amend paragraph 6a) of Section IV of Decree No. 1029 by appending the phrase “where the emissions do not contain any hazard class I or II substances” with the words “with a total weight over 0.1 tons per year” (the criterion).

- Federal Law No. 219-FZ of 21 July 2014, On Amendments to the Federal Law, On Environmental Protection, and Certain Regulations of the Russian Federation (hereinafter, “Law No. 219”), contains no provisions on the registration of temporary structures. It can be assumed that temporary structures are not subject to registration and categorization, for they are generally not regarded as capital facilities and do not require any operation permits.

Proposal – the Ministry of Natural Resources and the Environment / Rosprirodnadzor should clarify that temporary structures do not have to be registered or categorized.

In addition, it is worth analyzing the work processes related to the electronic module used to register facilities producing negative environmental impact. There is an issue of data entry when operating the module.

Proposal – address the following inefficiencies of the module: lack of timely technical support (work schedule follows Moscow time only); the requirement for OGRN, which is impossible for foreign entities to meet; limited time to enter a vast volume of data (coordinates and parameters of all sources of emissions and discharges taken separately, including sources producing an insignificant negative environmental impact, stationary and mobile sources. Where there is a variety of sources located at a single facility, all of them may fall within the error margins of the same coordinate). When changing the procedure and introducing new electronic communication systems, a trial period of three to six months should be set to monitor the operations.

II. Federal Law No. 174-FZ of 23 November 1995, On Environmental Expert Review.

Pursuant to Article 18.5 of the Federal Law, “The positive report following the state environmental expert review (SEER) is effective within a term set by the regulator. The positive SEER report becomes void when it expires”.

In practice, these regulations result in additional/duplicating reviews, which are costly and time-consuming, for the following reasons:

- The effective term of the SEER report appears to be redundant, as the text of the report itself indicates the schedules/terms of the projects that are subject to the SEER.

- As a rule, the approved term of the SEER report limits the project term to the construction stage, while documents subject to the SEER also cover the operational stage activities (with the environmental impact to be considered), including such specific activities as oil/gas well drilling, etc. The activities approved by the SEER report go on for years and cover the whole period of the facility's operation, including the time after the SEER report expires.
- The interpretations of the term of the SEER report vary. The term of the report and the related liabilities are not defined clearly.
- There is no mechanism to extend the term of the SEER report.
- No expiry dates are indicated in reports of Glavgosexpertiza.

Proposal – amend/supplement Federal Law No. 174-FZ of 23 November 1995, On Environmental Expert Review.

If the provision on the term of the SEER report is cancelled and the Federal Law is amended to include certain clarifications and provisions on expiring the SEER report term, it will enable entities to efficiently plan their project activities and avoid any costly and time-consuming duplicating expert reviews.

Costs may be cut by:

- RUB 7 million (EIA)
- RUB 400 thousand (repeat SEER)
- Approximately USD 380 thousand (total for the year)

III. Federal Law No. 174-FZ of 23 November 1995, On Environmental Expert Review; Federal Law No. 155-FZ, On Inland Sea Waters, Territorial Sea and Contiguous Zone of the Russian Federation; Federal Law No. 187-FZ, On Continental Shelf.

The SEER procedure for an oil spill contingency plan (OSC Plan) as a separate area under review creates additional administrative barriers when approving OSC Plans, which require natural resource users to invest more effort, time and money, for the following reasons:

- Pursuant to Federal Law No. 174, On Environmental Expert Review, documents to be analyzed during the SEER (OSC Plan) must contain information on the environmental impact assessment (EIA); Government Decree No. 1189, however, does not set the same requirement for OSC Plans.
- The law provides no clear guidance on how to identify those OSC activities that should be subject to an environmental impact assessment. The time frames for emergency preparedness activities are specified in the project documentation. The ambiguity in the existing requirements creates unacceptably high risks for mineral rights holders, as they may fall victim to regulatory arbitrage on the part of SEER panels.
- The EIA requirement for each OSC Plan, introduced for the sole purpose of ensuring formal compliance with Federal Law No. 174-FZ, not only creates another administrative barrier but imposes an additional financial burden on business, affecting project economics. An EIA for an OSC Plan adds no new insights to the findings of the emergency risk assessment performed as part of an SEER or the state expert review conducted by the Glavgosexpertiza for projects involving the construction and rehabilitation of hazardous production facilities.
- Technologies and materials referred to in an OSC Plan have already been subject to an SEER, so there is no other information in an OSC Plan that may qualify for such a review.
- As prescribed by Federal Law No. 7-FZ, On Environmental Protection, an environmental impact assessment shall be performed in respect of any contemplated business or other activities. Current information provided in OSC Plans is intended rather to mitigate or prevent such impact.
- In a SEER report, experts are supposed to make a conclusion on whether the environmental impact of a given activity is acceptable or not. In the case of oil-spill localization and clean-up activities, however, no such conclusion can be made as these activities are originally intended to mitigate and prevent an environmental impact.
- Potential damage caused by emergencies may not be assessed using conventional methods applied to business activities. This makes an environmental impact assessment a methodologically cumbersome exercise and leaves ample room for loose interpretation of perceived adequacy and severity of such damage.

The issue around amending OSC Plans has not been resolved. As it stands now under Federal Law No. 174, an OSC Plan shall be subject to a repeat SEER in case of any changes made thereto. This could result in the majority of OSC plans becoming no longer legitimate and in the need to conduct repeat reviews (e.g., membership changes in the Commission on Emergency Prevention and Response, the replacement of the OSC vessel indicated in the SEER report, etc.). A repeat approval of an OSC Plan prior to its expiry date was previously required only if changes thereto resulted in more efforts and spending on OSC events.

Additional administrative barriers will be eliminated when OSC Plans are exempted from the SEER.

Proposal – exempt OSC Plans from the SEER and amend Federal Law No. 187 and Federal Law No. 155 accordingly.

Develop and formalize a unified approach to OSC Plans preparation and approval for onshore and offshore facilities.

IV. Article 9.2 of Federal Law No. 89-FZ of 24 June 1998 (as amended on 29 July 2018), On Production and Consumption Waste.

An individual entrepreneur or legal entity may not collect, transport, process, dispose of, neutralize or place wastes of hazard classes I to IV at a certain waste neutralization facility and (or) facility used to place hazard classes I to IV wastes, where another individual entrepreneur or another legal entity, possessing a valid license, already conducts activities to neutralize and (or) place wastes of hazard classes I to IV.

Because of the varying interpretations of the requirement, certain terms are confused, for example, “production site” as a place to conduct licensable waste treatment activities, “waste placement facility”, and “waste neutralization facility.”

In particular, the provision above serves as a reason to deny licenses for waste neutralization activities (for example, using incineration units) at a production site, which another company determines as a place to conduct waste placement (injection) activities.

Another example is the replacement of one contractor possessing an effective license to neutralize (for instance, incinerate) wastes at a production site with another who won in the tender but cannot obtain a license to perform works thereunder because the previous contractor's license is valid indefinitely.

Proposals:

1. Elaborate the term “waste neutralization facility” (Article 1 of Federal Law No. 89-FZ) as a specialized capital facility.

2. To prevent unfair restrictive business practices, amend Article 9.2 by adding provisions that allow for two or more licenses to conduct activities at the same waste placement/neutralization facility. Such activities, however, should be conducted by one entity only provided it is entitled to do so under the Russian Civil Code.

3. Cancel provisions that restrict other waste treatment activities at certain facilities used to place and (or) neutralize wastes other than treatment and (or) neutralization, respectively.

4. When obtaining a license to conduct waste treatment activities, namely, to place wastes, specify a particular waste placement facility as a place to conduct such activities (the number from the state register of waste placement facilities is also required).

5. When obtaining a license to conduct waste treatment activities, namely, to neutralize wastes, specify a particular waste neutralization facility as a place to conduct such activities in accordance with the project construction documentation.

6. When obtaining a license to conduct waste treatment activities, namely, to transport wastes, and other such activities using mobile units (including incineration units), indicate the legal address of the license holder as a place to conduct activities.

V. Federal Waste Classification Catalog.

The Federal Waste Classification Catalog (FWCC) now includes over six thousand descriptions of wastes. The list is continuously growing, so the catalog is still not exhaustive.

The procedure to include new types of wastes into the FWCC (including those produced regularly) is time-consuming and requires considerable effort and resources both from the entity and from the state. At the

same time, registration with the FWCC is mandatory to obtain a waste treatment license, set waste placement limits and prepare other documents required by statutory regulations.

It means that wastes that were not entered into the FWCC are regarded as illegal; in addition, entities face additional administrative barriers when launching new technologies and purchasing new waste treatment equipment and have to extend approvals and permits on a recurring basis.

Proposals

7. Apply a simplified hazard-class classification of wastes which is similar to the waste color code (green, amber and red lists) used in Western European countries.

8. Indicate the same hazard classes of wastes in waste treatment licenses and permits, omitting unnecessary details on types of wastes.